



FEDERAL REGISTER

Vol. 89

Thursday,

No. 153

August 8, 2024

Pages 64779–65164

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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Proclamation 10789 of August 2, 2024

The President

National Health Center Week, 2024

By the President of the United States of America

A Proclamation

Federally funded community health centers are a lifeline for over 30 million Americans nationwide—providing affordable access to quality medical, dental, and behavioral health services, which save lives. Community health center sites are especially critical for people in Tribal, rural, and underserved communities because they are often the closest and most convenient sources of care. During National Health Center Week, we recognize the importance of the nearly 1,400 federally funded community health centers that provide critical services to Americans. We express our gratitude to their dedicated staff, who tirelessly devote themselves to the well-being of their patients. And we recommit to ensuring that every American has access to good-quality, affordable health care.

I have seen firsthand just how vital community health centers are to our entire Nation. At the height of the COVID–19 pandemic, we invested \$7.6 billion in our Nation’s health center network so Americans could get the care they needed, no matter their background or zip code. It worked. For example, health centers distributed over 20 million COVID–19 vaccines—2 out of 3 went to people of color, and 2 out of 10 went to rural residents. And every day, health centers have empowered Americans to access the affordable, quality health care services they need—from cancer screenings and maternal health care to telehealth services that reach people where they are.

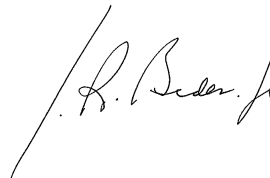
Community health centers play a key role in making sure health care is a right in this country, not a privilege—that is why my Administration is investing in them at a historic rate. My Budget would put the Health Center Program on a pathway to double in size. We have also delivered funding for community health centers to expand critical services, including substance use disorder treatments, behavioral health care, pregnancy-related care, and preventative cancer screenings.

At the same time, my Administration is lowering health care costs so every American has access to the care that they need. We strengthened the Affordable Care Act, and more people in this country have health care coverage under my Administration than ever before. We are also capping total prescription drug costs for seniors on Medicare at \$2,000 per year, even for expensive medications. We slashed the price of insulin to \$35 per month for seniors on Medicare, down from as much as \$400 per month. And we finally beat Big Pharma by giving Medicare the power to negotiate lower drug prices.

During National Health Center Week, we honor all of the health center staff, who sacrifice so much to care for the health and well-being of their communities. We celebrate the impact of health centers across the country, and we recommit to supporting their efforts and their vision—a future where everyone has access to affordable, quality health care.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim the week of August 4 through August 10, 2024, as National Health Center Week.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of August, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-ninth.

A handwritten signature in black ink, appearing to read "Joe Biden", is written over a horizontal line.

[FR Doc. 2024-17775

Filed 8-7-24; 8:45 am]

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Memorandum of August 5, 2024

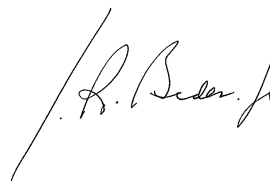
Delegation of Functions and Authorities Under Section 6(a)–(c) of the United States-Taiwan Initiative on 21st-Century Trade First Agreement Implementation Act

Memorandum for the United States Trade Representative

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the United States Trade Representative the functions and authorities vested in the President by section 6(a)–(c) of the United States-Taiwan Initiative on 21st-Century Trade First Agreement Implementation Act (Public Law 118–13), including to make and submit the required certification to the Congress and to consult with, and submit the required report to, the appropriate congressional committees.

The delegation in this memorandum shall apply to any provisions of any future public laws that are the same or substantially the same as those provisions referenced in this memorandum.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 5, 2024

Rules and Regulations

Federal Register

Vol. 89, No. 153

Thursday, August 8, 2024

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS–NOP–24–0024]

National Organic Program: 2025 Sunset Review and Substance Renewals

AGENCY: Agricultural Marketing Service, USDA.

ACTION: 2025 sunset review and substance renewals.

SUMMARY: This document announces the renewal of 47 substances listed on the National List of Allowed and Prohibited Substances within the U.S. Department of Agriculture's organic regulations. This document reflects the outcome of the 2025 sunset review processes and addresses recommendations submitted to the Secretary of Agriculture, through the USDA's Agricultural Marketing Service, by the National Organic Standards Board.

DATES: Applicable June 22, 2025.

FOR FURTHER INFORMATION CONTACT: Jared Clark, National List Manager, Standards Division, National Organic Program, Phone: (202) 720–3252; Email: jared.clark@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On December 21, 2000, the Secretary established the Agricultural Marketing Service's (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80548, December 21, 2000). Within the USDA organic regulations (7 CFR part 205) is the National List of Allowed and Prohibited Substances (or "National List"). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that

may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products.

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. chapter 94), and the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List (7 CFR 205.601, 205.603 and 205.605(b)). Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling be on the National List (§§ 205.605(a) and 205.606).

The OFPA at 7 U.S.C. 6518 authorizes the National Organic Standards Board ("NOSB" or "Board"), operating in accordance with the Federal Advisory Committee Act (section 1 *et seq.*, 5 U.S.C. App. 2), to evaluate substances for organic production and handling and to advise the Secretary on the USDA organic regulations. The OFPA "sunset provision" (7 U.S.C. 6517(e)) requires review of all substances included on the National List within 5 years of their addition to, or renewal on, the list. A list of all National List sunset dates is posted online for public access in the "NOSB Work Agenda" document on the NOP's NOSB web page, <https://www.ams.usda.gov/rules-regulations/organic/nosb>.

As required by the OFPA, during a sunset review, the NOSB considers any new information about a substance's impact on human health and the environment, its necessity, and its consistency with organic production and handling. The NOSB then votes on proposals to remove individual substances from the National List, with a 2/3 majority needed to recommend removal of a substance.

As delegated by the Secretary, AMS evaluates the NOSB's reviews and recommendations for compliance with the National List substance evaluation criteria in the OFPA at 7 U.S.C. 6518(m) and other federal statutes or regulations. AMS also considers public comments submitted in association with the sunset review process, as described in the

notice published on September 16, 2013 (78 FR 56811).

Review of Sunset Substances

AMS published notices in the **Federal Register** announcing the Spring 2023 (88 FR 9426, February 14, 2023) and Fall 2023 (88 FR 37505, June 08, 2023) NOSB meetings and invited public comments on the 2025 sunset review of the substances included in the tables below. AMS also hosted public webinars prior to these NOSB meetings to provide additional opportunities for public comment. At these public meetings, the NOSB reviewed substances scheduled to sunset from the National List and recommended that they either be removed or remain on the National List.

AMS has reviewed and accepted all NOSB sunset review recommendations for substances with sunset dates in 2025. AMS is renewing the listings of these substances until 2030. AMS determined that the substance allowances listed in this notice are still necessary because of the unavailability of organic forms or wholly natural substitutes for the specified uses (7 U.S.C. 6517(c)(1)(A)(ii)). The renewal of these substances will avoid potential disruptions to the organic industry that may otherwise result from removal from the National List. AMS also has determined that the prohibited natural substances listed in this notice should remain prohibited because their use remains inconsistent with organic production (7 U.S.C. 6517(c)(2)(A)(ii)).

Sunset Renewals

This document renews 46 of the 47 substances in this notice for another 5 years past their existing sunset date of June 22, 2025.

One of the forty-seven substances renewed in this notice currently has an existing sunset date of December 7, 2025. This notice renews tamarind seed gum another 4 years and 6–1/2 months past its existing sunset date of December 7, 2025, to establish a new sunset date for this substance that matches the sunset dates of the other substances renewed in this notice.

This document establishes a new sunset date for the following substances as outlined in the header for table 1.

TABLE 1—NATIONAL LIST SUBSTANCES RENEWED UNTIL JUNE 22, 2030

Citation	Substance
7 CFR 205.601 Synthetic substances allowed for use in organic crop production:	
§ 205.601(a)(1)(i)	Ethanol.
§ 205.601(a)(1)(ii)	Isopropanol.
§ 205.601(a)(8)	Sodium carbonate peroxyhydrate (CAS #-15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
§ 205.601(b)(2)(i)	Newspaper or other recycled paper, without glossy or colored inks.
§ 205.601(b)(2)(ii)	Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
§ 205.601(c)	As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.
§ 205.601(e)(2)	Aqueous potassium silicate (CAS #1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
§ 205.601(e)(5)	Elemental sulfur.
§ 205.601(e)(6)	Lime sulfur—including calcium polysulfide.
§ 205.601(i)(1)	Aqueous potassium silicate (CAS #1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
§ 205.601(i)(4)	Hydrated lime.
§ 205.601(i)(6)	Lime sulfur.
§ 205.601(i)(10)	Elemental sulfur.
§ 205.601(j)(2)	Elemental sulfur.
§ 205.601(j)(8)	Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
§ 205.601(j)(11)	Sulfurous acid (CAS #7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.
§ 205.601(k)(1)	Ethylene gas—for regulation of pineapple flowering.
§ 205.601(o)(1)	Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.
7 CFR 205.602 Nonsynthetic substances prohibited for use in organic crop production:	
§ 205.602(e)	Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
7 CFR 205.603 Synthetic substances allowed for use in organic livestock production:	
§ 205.603(a)(1)(i)	Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.
§ 205.603(a)(1)(ii)	Isopropanol—disinfectant only.
§ 205.603(a)(2)	Aspirin—approved for health care use to reduce inflammation.
§ 205.603(a)(4)	Biologics—Vaccines.
§ 205.603(a)(11)	Electrolytes—without antibiotics.
§ 205.603(a)(14)	Glycerin—allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
§ 205.603(a)(25)	Phosphoric acid—allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs.
§ 205.603(b)(6)	Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
§ 205.603(b)(7)	Mineral oil—for topical use and as a lubricant.
7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”:	
§ 205.605(a)(6)	Calcium carbonate.
§ 205.605(a)(12)	Flavors—nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
§ 205.605(a)(13)	Gellan gum (CAS #71010-52-1)—high-acyl form only.
§ 205.605(a)(21)	Oxygen—oil-free grades.
§ 205.605(a)(23)	Potassium chloride.
§ 205.605(b)(3)	Alginates.
§ 205.605(b)(8)	Calcium hydroxide.
§ 205.605(b)(14)	Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.
§ 205.605(b)(16)	Glycerides (mono and di)—for use only in drum drying of food.
§ 205.605(b)(19)	Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
§ 205.605(b)(23)	Phosphoric acid—cleaning of food-contact surfaces and equipment only.
§ 205.605(b)(24)	Potassium carbonate.
§ 205.605(b)(35)	Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.
§ 205.605(b)(37)	Xanthan gum.

TABLE 1—NATIONAL LIST SUBSTANCES RENEWED UNTIL JUNE 22, 2030—Continued

Citation	Substance
7 CFR 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”:	
§ 205.606(g)	Fructooligosaccharides (CAS #308066–66–2).
§ 205.606(j)	Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
§ 205.606(l)	Lecithin—de-oiled.
§ 205.606(r)	Tamarind seed gum.
§ 205.606(s)	Tragacanth gum (CAS #–9000–65–1).

Authority: 7 U.S.C. chapter 94.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–17378 Filed 8–7–24; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2198; Airspace Docket No. 23–AEA–12]

RIN 2120–AA66

Establishment and Amendment of United States Area Navigation (RNAV) Routes; Eastern United States; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on July 5, 2024, that establishes three United States Area Navigation (RNAV) Routes T–434, T–454, and T–458; and amends three United States RNAV Routes T–291, T–314, and T–634 in the eastern United States. This action supports Next Generation Air Transportation System (NextGen) which provides a modern RNAV route structure to improve the

efficiency of the National Airspace System (NAS).

DATES: Effective date 0901 UTC, September 5, 2024. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments. **ADDRESSES:** FAA Order 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (89 FR 55497; July 5, 2024), amending and establishing multiple RNAV T-routes in support of the FAA’s NextGen program. Subsequent to publication, the FAA determined that the PAWLN, NY; SCAAM, PA; NECCK, NJ; NWTN, NJ; and RAHKS, NY route points were inadvertently identified as Fixes, in error. Additionally, the DANZI, NY

route point was inadvertently identified as a waypoint (WP) in error. This rule corrects those errors by changing all references to the PAWLN, SCAAM, NECCK, NWTN, and RAHKS route points as WP; and changing all references to the DANZI route point as a Fix. These are editorial changes only to match the FAA’s aeronautical database information.

Correction to Final Rule

■ Accordingly, pursuant to the authority delegated to me, in Docket No. FAA–2023–2198 as published in the **Federal Register** on July 5, 2024 (89 FR 55497), FR Doc. 2024–14345, is corrected as follows:

- 1. On page 55498, in the second column, under “The Rule” in the paragraph starting with “T–291”, correct “DANZI, NY, WP” to read “DANZI, NY, Fix”.
- 2. On page 55498, in the third column, under “The Rule” in the paragraph starting with “T–434”, correct “SCAAM, PA, Fix and the NECCK, NJ, Fix.” to read “SCAAM, PA, WP and the NECCK, NJ, WP”.
- 3. On page 55498, in the third column, under “The Rule” in the paragraph starting with “T–454”, correct “SCAAM, PA, Fix and the NWTN, NJ, Fix. to read “SCAAM, PA, WP and the NWTN, NJ, WP”.
- 4. On page 55499 correct the table “T–291 Tar River, NC (TYI) to Albany, NY (ALB) [Amended]” to read:

T–291 Tar River, NC (TYI) to Albany, NY (ALB) [Amended]

Tar River, NC (TYI)	VORTAC	(Lat. 35°58′36.21″ N, long. 077°42′13.43″ W)
COUPN, VA	WP	(Lat. 36°42′50.83″ N, long. 077°00′44.04″ W)
Harcum, VA (HCM)	VORTAC	(Lat. 37°26′55.18″ N, long. 076°42′40.87″ W)
COLIN, VA	FIX	(Lat. 38°05′59.23″ N, long. 076°39′50.85″ W)
SHLBK, MD	WP	(Lat. 38°20′16.21″ N, long. 076°26′10.51″ W)
LOUIE, MD	WP	(Lat. 38°36′44.33″ N, long. 076°18′04.37″ W)
GRACO, MD	FIX	(Lat. 38°56′29.81″ N, long. 076°11′59.22″ W)
BAABS, MD	WP	(Lat. 39°22′01.36″ N, long. 076°27′31.21″ W)
VINNY, PA	FIX	(Lat. 39°45′16.64″ N, long. 076°36′30.16″ W)
Harrisburg, PA (HAR)	VORTAC	(Lat. 40°18′08.06″ N, long. 077°04′10.41″ W)
Selinsgrove, PA (SEG)	VOR/DME	(Lat. 40°47′27.09″ N, long. 076°53′02.55″ W)
HYATT, PA	WP	(Lat. 41°01′24.47″ N, long. 076°39′54.34″ W)
MEGSS, PA	FIX	(Lat. 41°11′13.28″ N, long. 076°12′41.02″ W)
LAAYK, PA	FIX	(Lat. 41°28′32.64″ N, long. 075°28′57.31″ W)
DANZI, NY	FIX	(Lat. 42°10′41.86″ N, long. 074°57′24.19″ W)

Albany, NY (ALB)

VORTAC

(Lat. 42°44'50.21" N, long. 073°48'11.46" W)

■ 5. On page 55499 correct the table “T–314 Kingston, NY (IGN) to Kennebunk, ME (ENE) [Amended]” to read:

T–314 Kingston, NY (IGN) to Kennebunk, ME (ENE) [Amended]

Kingston, NY (IGN)	VOR/DME	(Lat. 41°39'55.63" N, long. 073°49'20.06" W)
PAWLN, NY	WP	(Lat. 41°46'11.51" N, long. 073°36'02.64" W)
SASHA, MA	FIX	(Lat. 42°07'58.70" N, long. 073°08'55.39" W)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09'43.05" N, long. 072°42'58.32" W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32'45.32" N, long. 072°03'29.48" W)
Kennebunk, ME (ENE)	VOR/DME	(Lat. 43°25'32.42" N, long. 070°36'48.69" W)

■ 6. On page 55499 correct the table “T–434 SCAAM, PA to NECCK, NJ [New]” to read:

T–434 SCAAM, PA to NECCK, NJ [New]

SCAAM, PA	WP	(Lat. 41°11'37.46" N, long. 077°58'15.20" W)
HYATT, PA	WP	(Lat. 41°01'24.47" N, long. 076°39'54.34" W)
BEERS, PA	FIX	(Lat. 40°52'47.50" N, long. 075°27'37.36" W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34'58.96" N, long. 074°44'30.45" W)
TYKES, NJ	FIX	(Lat. 40°17'22.38" N, long. 074°23'06.13" W)
NECCK, NJ	WP	(Lat. 40°18'41.79" N, long. 074°09'35.79" W)

■ 7. On page 55499 correct the table “T–454 SCAAM, PA to NWTON, NJ [New]” to read:

T–454 SCAAM, PA to NWTON, NJ [New]

SCAAM, PA	WP	(Lat. 41°11'37.46" N, long. 077°58'15.20" W)
FAVUM, PA	FIX	(Lat. 41°15'59.17" N, long. 077°35'42.32" W)
Williamsport, PA (FQM)	VOR/DME	(Lat. 41°20'18.81" N, long. 076°46'29.52" W)
Wilkes-Barre, PA (LVZ)	VORTAC	(Lat. 41°16'22.08" N, long. 075°41'22.08" W)
NWTON, NJ	WP	(Lat. 40°59'45.19" N, long. 074°52'09.21" W)

■ 8. On page 55499 correct the table “T–458 STUBN, NY to Boston, MA (BOS) [New]” to read:

T–458 STUBN, NY to Boston, MA (BOS) [New]

STUBN, NY	WP	(Lat. 42°05'38.58" N, long. 077°01'28.68" W)
Binghamton, NY (CFB)	VOR/DME	(Lat. 42°09'26.97" N, long. 076°08'11.30" W)
DANZI, NY	FIX	(Lat. 42°10'41.86" N, long. 074°57'24.19" W)
Chester, MA (CTR)	VOR/DME	(Lat. 42°17'28.75" N, long. 072°56'57.82" W)
SPENO, MA	FIX	(Lat. 42°16'48.55" N, long. 072°09'14.70" W)
GLYDE, MA	FIX	(Lat. 42°16'03.84" N, long. 071°48'42.76" W)
Boston, MA (BOS)	VOR/DME	(Lat. 42°21'26.82" N, long. 070°59'22.37" W)

■ 9. On page 55500 correct the table “T–634 VIBRU, NY to Sandy Point, RI (SEY) [Amended]” to read:

T–634 VIBRU, NY to Sandy Point, RI (SEY) [Amended]

VIBRU, NY	WP	(Lat. 44°20'21.30" N, long. 076°01'19.96" W)
Watertown, NY (ART)	VORTAC	(Lat. 43°57'07.67" N, long. 076°03'52.66" W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09'37.87" N, long. 076°12'16.41" W)
STODA, NY	FIX	(Lat. 43°07'00.20" N, long. 075°51'21.23" W)
RAHKS, NY	WP	(Lat. 42°27'59.28" N, long. 075°14'21.68" W)
DANZI, NY	FIX	(Lat. 42°10'41.86" N, long. 074°57'24.19" W)
WEETS, NY	FIX	(Lat. 41°51'26.98" N, long. 074°11'51.51" W)
Kingston, NY (IGN)	VOR/DME	(Lat. 41°39'55.63" N, long. 073°49'20.06" W)
CASSH, NY	FIX	(Lat. 41°35'38.16" N, long. 073°42'17.07" W)
Carmel, NY (CMK)	VOR/DME	(Lat. 41°16'48.32" N, long. 073°34'52.78" W)
CREAM, NY	FIX	(Lat. 41°08'55.85" N, long. 072°31'18.32" W)
Sandy Point, RI (SEY)	VOR/DME	(Lat. 41°10'02.77" N, long. 071°34'33.91" W)

Issued in Washington, DC, on August 2, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024-17485 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[SATS No. KY-264-FOR; Docket ID: OSM-2022-0008; S1D1S SS08011000 SX064A000 245S180110; S2D2S SS08011000 SX064A000 24XS501520]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Kentucky regulatory program (hereinafter, the Kentucky program), under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). We are approving Kentucky's revision to its regulations regarding the qualifications of members of the Kentucky Reclamation Guaranty Fund Commission.

DATES: The effective date is September 9, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Castle, Field Office Director, Telephone 859-260-3900, Email: mcastle@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Kentucky Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Statutory and Executive Order Reviews

I. Background on the Kentucky Program

Subject to OSMRE's oversight, section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the

Kentucky program, effective May 18, 1982. You can find background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Kentucky program in the May 18, 1982, **Federal Register** (47 FR 21434). You can also find later actions concerning the Kentucky program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16, and 917.17.

On July 18, 1986, we approved the creation of Kentucky's bond pool commission, which from 1986 to 2013 oversaw Kentucky's initial alternative bonding system known as the voluntary bond pool fund. 51 FR 26002 (July 18, 1986). In May 2012, we concluded that the State regulatory authority was not effectively implementing, administering, enforcing, and maintaining its reclamation bond program, and we initiated the regulatory process to correct the identified regulatory program issues. See 30 CFR part 733. In response to our part 733 letter, Kentucky submitted various amendments. One amendment, which we approved in large part in 2018, repealed the voluntary bond pool fund and replaced it with the Kentucky Reclamation Guaranty Fund. See 83 FR 3948 (Jan. 29, 2018). Those amendments also replaced the bond pool fund commission with the Kentucky Reclamation Guaranty Fund Commission (KRGFC or commission). *Id.* The purpose of the KRGFC is to review membership applications and ratings; notify members of tonnage fees required; revoke or reinstate membership; employ a certified public accountant to audit the bond pool fund; authorize necessary expenditures from the fund; and report the financial status of the fund to the governor annually. The KRGFC provisions also specified the composition of the KRGFC membership and qualifications that those members must meet.

II. Submission of the Amendment

By letter dated April 18, 2022 (Administrative Record No. KY-2008), Kentucky sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). This submission proposes to revise the qualifications for members appointed to the seven-member KRGFC. Currently, the governor appoints three members to the KRGFC that are representatives of the coal industry. The coal industry representatives are permittees that participate in the fund and are selected based on the amount of coal produced and subsequently sold annually. Three tiers were created, based on tons of coal sold, to represent

a large, a medium, and a small operator. One member from each tier was to be selected. The revision would allow the governor to appoint a member from a lower tier when no permittee that participates in the fund meets the production level of an upper tier. Kentucky's submission also removes requirements that are no longer relevant to the operation of the KRGFC and makes minor revisions.

We announced receipt of the proposed amendment in the May 23, 2023, **Federal Register** (88 FR 33016) (Administrative Record KY-2008). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting as neither was requested. The public comment period ended on June 22, 2023. We received two comments from concerned individuals that are addressed below in the PUBLIC COMMENTS section.

III. OSMRE's Findings

We made the following findings concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. The full text of this program amendment is available at www.regulations.gov.

We are approving the following changes to KRS 350.506:

A. Section 1. Kentucky deleted the date by which the Governor was to appoint the first six appointed member of the commission, which was "July 1, 2013."

B. Section 1(a). Kentucky revised this provision to require that the three members of the commission who are representative of the coal industry must be permittees that participate in the fund and to reinforce that they are tiered to represent the size of the operator measured in tons of coal sold.

C. Section 1(a)(3). Kentucky deleted subparagraph (b), which specified that if no operator from the largest tier is available to sit on the commission, a member shall be selected from the middle tier. Kentucky replaced subparagraph (b) with the following coda to subsection (a)(3): "If no permittee that participates in the fund meets the qualifications stated in subparagraph 2 or in subparagraph 3 of this paragraph, then a qualified permittee shall be selected in a lower tier."

D. Section 2(a). Kentucky deleted this provision, which dictated the term of years for the Governor's initial appointments to the commission and

renumbered subsequent paragraphs accordingly.

E. Section 1(5). Kentucky revised this provision to delete the requirement that the commission meet monthly during the first year, leaving in place the requirement that it meet every three months thereafter.

OSMRE Finding: As we noted in our initial approvals of both the voluntary bond pool commission and the KRGFC, no comparable Federal regulations exist addressing the creation or management of alternative bonding programs. Section 509(c) of SMCRA provides for alternative bonding systems stating that “the Secretary may approve as part of a State or Federal program an alternative system that will achieve the objectives and purposes of the bonding program pursuant to this section.” The Federal rules at 30 CFR 800.11(e) provide that OSMRE may approve an alternative bonding system if the system assures that the regulatory authority will have available sufficient money to complete the reclamation plan for any areas in default at any time and provides an economic incentive for the permittee to comply with all reclamation provisions. We find that the proposed changes, which affect minor aspects of commission make-up and governance, some of which are now obsolete, are not inconsistent with section 509(c) of SMCRA or with the Federal regulations at 30 CFR 800.11(e) and are hereby approved.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment and received two. The first was from a private citizen recommending the qualifications of the board members to consist of only scientists studying fossil fuel consumption and its effects. As we discussed above, should a State elect to establish an alternative bonding system, its means of implementing the alternative bonding system is at the State’s discretion so long as it complies with the general requirements of section 509 of SMCRA and 30 CFR 800.11(e). Therefore, the specific qualifications of the KRGFC members are beyond the scope of this rulemaking.

The second public comment was from the Kentucky Resources Council, Inc. (Council). The Council agrees that the proposed revisions to the commission membership qualifications are acceptable in efforts to support changing coal industry demographics. Further, the Council recommends that an annual review of the Kentucky Permanent

Regulatory Program, which would include the assurance of adequate funding in the event of bond forfeiture or permittee bankruptcy, fall under OSMRE’s oversight function. Oversight of Kentucky’s bonding program has always been and will continue to be one of our responsibilities.

Federal Agency Comments

On July 13, 2022, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various agencies with an actual or potential interest in the Kentucky program (Administrative Record KY–2008–1). The Natural Resources Conservation Service sent a “no comment letter”; and we did not receive any comments from other agencies.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*) None of the revisions that Kentucky proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on July 13, 2022, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. KY–2008–1). EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On July 13, 2022, we requested comments on the Kentucky amendments (Administrative Record No. KY–2008–1). We did not receive comments from the SHPO or ACHP.

V. OSMRE’s Decision

Based on the above findings, we are approving KY–264 submitted to us on April 18, 2022 (Administrative Record No. KY–2008). To implement this decision, we are amending the Federal regulations at 30 CFR part 917 that codify decisions concerning the Kentucky program. In accordance with the Administrative Procedure Act (5 U.S.C. 533), this rule will take effect 30 days after the date of publication.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule would not effect a taking of private property or otherwise have taking implications that would result in private property being taken for government use without just compensation under the law. Therefore, a taking implication assessment is not required. This determination is based on an analysis of the Federal regulations that set minimum performance standards for alternative bonding systems.

Executive Orders 12866—Regulatory Planning and Review, 13563—Improving Regulation and Regulatory Review, and 14094—Modernizing Regulatory Review

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance dated October 12, 1993 (OMB Memo M–94–3), the approval of State program amendments are exempted from OMB review under Executive Order 12866, as amended by Executive Order 14094. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by section 3 of Executive Order 12988. The Department determined that this **Federal Register** document meets the criteria of section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency’s legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive Order to the quality of this **Federal Register** document and to changes to the Federal regulations. The review under this Executive Order did not extend to the language of the State regulatory program amendment that Kentucky drafted.

Executive Order 13132—Federalism

This rule has potential Federalism implications as defined under section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to “grant the States the maximum administrative discretion possible” with respect to Federal statutes and regulations administered by the States. Kentucky, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the state level. This rule approves an amendment to the Kentucky program submitted and drafted by the State, and thus is consistent with the direction to provide maximum administrative discretion to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department’s consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on the distribution of power and responsibilities between the Federal Government and Tribes. The basis for this determination is that our decision on the Kentucky program does not include Indian lands as defined by SMCRA or other Tribal lands and it does not affect the regulation of activities on Indian lands or other Tribal lands. Indian lands under SMCRA are regulated independently under the applicable approved Federal Indian program. The Department’s consultation policy also acknowledges that our rules may have Tribal implications where the State proposing the amendment encompasses ancestral lands in areas with minable coal. We are currently working to identify and engage appropriate Tribal stakeholders to devise a constructive approach for consulting on these amendments.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is

(1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not significant energy action under the definition in Executive Order 13211, a Statement of Energy Effects is not required.

National Environmental Policy Act

Consistent with sections 501(a) and 72(d) of SMCRA (30 U.S.C. 1251(a) and 1292(d), respectively) and the U.S. Department of the Interior Departmental Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon the Federal regulations that set minimum performance standards for alternative bonding systems for which an economic analysis was prepared, and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations. The Federal regulations were also promulgated to provide flexibility to ensure the availability of surety bonding to small operators.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business

Regulatory Enforcement Fairness Act. This rule: (a) does not have an annual effect on the economy of \$100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local or Tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based on an analysis of the Federal regulations that set minimum performance standards for alternative bonding systems, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,
*Regional Director, North Atlantic—
Appalachian Region.*

For the reasons set out in the preamble, 30 CFR part 917 is amended as follows:

PART 917—KENTUCKY

■ 1. The authority citation for part 917 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 917.15 is amended by adding a new entry to the table in paragraph (a) in chronological order by “Date of final publication” to read as follows:

§ 917.15 Approval of Kentucky regulatory program amendments

(a) * * *

Original amendment submission date	Date of final publication	Citation/description
April 18, 2022	August 8, 2024	KRS 350.506

[FR Doc. 2024–17333 Filed 8–7–24; 8:45 am]
BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation
and Enforcement

30 CFR Part 938

[SATS No. PA–167–FOR; Docket ID: OSM–
2017–0009; S1D1S SS08011000 SX064A000
234S180110; S2D2S SS08011000
SX064A000 23XS501520]

Pennsylvania Regulatory Program
AGENCY: Office of Surface Mining
Reclamation and Enforcement, Interior.
ACTION: Final rule.

SUMMARY: We, the Office of Surface
Mining Reclamation and Enforcement
(OSMRE), are approving an amendment
to the Pennsylvania regulatory program
under the Surface Mining Control and
Reclamation Act of 1977 (SMCRA or the
Act). The amendment authorizes and
implements a land reclamation financial
guarantee program as a new alternative
bonding option for operators that meet
certain requirements. The amendment
also authorizes and implements a
bioenergy crop bonding program to
provide financial guarantees to reining
operators that grow bioenergy crops as
a postmining land use. Finally, the
amendment standardizes certain terms
and corrects citations in statutory and
regulatory provisions affected by the
addition of a new section to the
Pennsylvania regulatory program or
changed for other reasons.
DATES: This rule is effective September
9, 2024.

FOR FURTHER INFORMATION CONTACT: Mr.
Ben Owens, Acting Field Office
Director, Pittsburgh Field Office, Office
of Surface Mining Reclamation and
Enforcement, 3 Parkway Center,
Pittsburgh, PA 15220, Telephone: (412)
937–2827, Email: bowens@osmre.gov,
Fax: (412) 937–2177.

SUPPLEMENTARY INFORMATION:
I. Background on the Pennsylvania Program
II. Submission of the Amendment
III. OSMRE’s Findings
IV. Summary and Disposition of Comments
V. OSMRE’s Decision
VI. Statutory and Executive Order Reviews

I. Background on the Pennsylvania
Program
Section 503(a) of the Act permits a
State to assume primacy for the
regulation of surface coal mining and
reclamation operations on non-Federal
and non-Indian lands within its borders
by demonstrating that its approved State
program includes, among other things,
State laws and regulations that govern
surface coal mining and reclamation
operations in accordance with the Act
and consistent with the Federal
regulations. See 30 U.S.C. 1253(a)(1)
and (7). On the basis of these criteria,
the Secretary of the Interior
conditionally approved the
Pennsylvania program on July 30, 1982.
You can find background information
on the Pennsylvania program, including
the Secretary’s findings, the disposition
of comments, and conditions of
approval of the Pennsylvania program
in the July 30, 1982, **Federal Register**
(47 FR 33050). You can also find later
actions concerning the Pennsylvania
program and program amendments at 30
CFR 938.11, 938.12, 938.13, 938.15, and
938.16.
II. Submission of the Amendment
By letter dated July 26, 2017
(Administrative Record No. PA 900.00),
the Pennsylvania Department of
Environmental Protection (PADEP) sent
us an amendment to its program under
SMCRA (30 U.S.C. 1201 *et seq.*). The
amendment included the following
proposed changes to the Pennsylvania
Surface Mining Control and
Reclamation Act (PASMCR), 52 P.S.
1396.1–1396.19b, title 25 of the
Pennsylvania Code, and Pennsylvania’s
approved program.
Statutory Changes
Mining Permit and Bioenergy Crop
Bonding, Act 95 of 2012, House Bill 608
Pennsylvania adopted an amendment
to PASMCR (52 P.S. 1396.1–1396.19b),
Act 95, entitled Mining Permit and
Bioenergy Crop Bonding, on July 5,
2012, Public Law 918, No. 95, and
designated it as becoming effective on
September 3, 2012 (pending OSMRE
approval). In addition to standardizing
references to “department” and
“secretary” throughout PASMCR, Act
95 amended section 4(a) to “encourage
and promote” the use of bioenergy crops

for revegetation during reclamation of
remined lands. See 52 P.S.
1396.4(a)(2)(c) (referring to remined
lands as “areas previously disturbed by
mining activities that were not
reclaimed to the standards of this act”).
In addition, the provisions added
section 4.14 to PASMCR, 52 P.S.
1396.4(n), which provides for sum-
certain financial guarantees to
qualifying operators for stage III
reclamation liability at reining sites,
among other things.
Mining Permit, Reclamation Plan, and
Bond and Land Reclamation Financial
Guarantees, Act 157 of 2012, House Bill
1813
Pennsylvania adopted an amendment
to PASMCR (52 P.S. 1396.1–1396.19b),
Act 157, entitled Mining Permit,
Reclamation Plan, and Bond and Land
Reclamation Financial Guarantees, on
October 24, 2012, Public Law 1276, No.
157, and designated it as becoming
effective on December 23, 2012
(pending OSMRE approval). Act 157
amended section 4 of PASMCR and
added section 19.2 (52 P.S. 1396.19b). In
conjunction, these provisions authorize
and direct PADEP to establish a program
to provide “land reclamation financial
guarantees” (LRFGs) to qualified
operators to ensure reclamation of
certain mining lands. An LRFG is a form
of bond or collateral that may be
available to qualified surface coal
mining operators engaged in surface
mining activities. Pennsylvania
provides the financial guarantee to
qualified operators to satisfy, in part, the
required bond obligation.
The LRFG program provides for the
assessment and collection of premiums
from operators for such guarantees in an
amount sufficient to assure the financial
stability of the financial guarantee
program and to cover Pennsylvania’s
cost to administer the program. This
program replaces Pennsylvania’s
Conversion Assistance Program (CAP) of
2001. The CAP was a temporary
program intended to assist existing mine
operations in transitioning to
Pennsylvania’s newly established full
cost bonding requirements. The
statutory provisions address site and
operator eligibility, establish an account
for a new program in the Surface Mining
Conservation and Reclamation Fund
(referred to as the LRFG Account), and

authorize the transfer of funds from the CAP to the LRFG Account. In addition, these provisions authorize PADEP to transfer funds from the LRFG Account into the Remining Financial Assurance Fund, established under 52 P.S. 1396.18, or into the Reclamation Fee Operation and Maintenance Trust Account (hereafter the "Trust Account"), established under 25 Pa. Code 86.17 and 86.187, as well as to allocate interest earned on the account. These provisions also set conditions for management of the account and dissolution of the program.

Regulatory Changes

On April 21, 2015, the Pennsylvania Environmental Quality Board adopted changes to mining regulations in title 25 of the Pennsylvania Code, changes that were designated as becoming effective on August 22, 2015. In particular, the Board adopted sections 86.162b and 86.162c and made various amendments to chapters 77, 86 to 90, and 211. The additional sections in chapter 86 implemented the statutory changes in Act 95 and Act 157. The amendments in chapters 77, 86 to 90, and 211 also corrected citations affected by addition of section 19.2 to PASMCR, corrected additional citations changed for other reasons, and made other non-substantive changes.

We announced receipt of the proposed amendment in the April 3, 2019, **Federal Register** (84 FR 12983). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because one was not requested, and we received no public comments. The public comment period ended on May 3, 2019.

III. OSMRE's Findings

We are approving the amendment to the Pennsylvania regulatory program under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, as described in our findings below. The full text of the amendment is available at www.regulations.gov.

Finding 1: Section 4(d) of PASMCR

Pennsylvania, through Act 157, revised section 4(d) of PASMCR to add LRFGs to the list of available forms of reclamation bond set out in section 4(d). The revised provision requires that LRFGs be consistent with section 19.2 of PASMCR and regulations implementing the LRFG program, which are described in *Finding 2* and *Finding 4*.

OSMRE Finding: We have determined that the change to this section is no less stringent than section 509(a) of SMCRA, 30 U.S.C. 1259(a), which requires that performance bonds be sufficient to assure completion of reclamation, and that it is no less effective than the Federal regulation at 30 CFR 800.11(e), which governs OSMRE approval of alternative bonding systems. The LRFG program as referenced in section 4(d), described at section 19.2 of PASMCR, and implemented by the proposed regulations at 25 Pa. Code 86.162b, is an alternative bonding system. For reasons discussed in *Finding 2* and *Finding 4*, this system meets the requirements of 30 CFR 800.11(e)(1) and (2) that alternative bonding systems assure financial solvency and include a substantial incentive for operators to fulfill their reclamation plans.

Finding 2: Section 19.2 of PASMCR

Pennsylvania, through Act 157, added section 19.2 to PASMCR. See 52 P.S. 1396.19b. Section 19.2 made LRFGs an acceptable form of bond or collateral, available to certain operators for use in combination with surety bonds, as further discussed below. Pennsylvania provides the financial guarantee to qualified operators to satisfy, in part, the required bond obligations. In addition, section 19.2 directed the Environmental Quality Board to promulgate regulations implementing the LRFG program, and the Board did so on April 21, 2015.

As discussed in *Finding 4*, the implementing regulations at 25 Pa. Code 86.162b provide, among other things, that qualifying for an LRFG requires an operator to have possessed a coal mining license in Pennsylvania for at least five years and have a surety bond or letter of acceptance for a surety bond covering at least 50 per cent of the reclamation liability for the site. In addition, the implementing regulations provide for the assessment and collection of premiums from operators for such guarantees in an amount sufficient to assure the financial stability of the program and to cover Pennsylvania's cost to administer it. These premiums are paid on an annual basis and are additional to the one-time, acreage-based reclamation fees that operators pay into the Trust Account upon permit issuance.

This program replaces the CAP, which replaced a predecessor program (alternative bonding system) in 2001, a change that was accompanied by "conversion" of all surface coal mine sites to full-cost bonding. The CAP program was created to serve as a bridge to the new full-cost bonding program. Section 19.2 replaces the CAP through

terms that address site and operator eligibility, establishment of an account for the financial guarantees (specifically, the LRFG Account), transfer of funds from the CAP program to the LRFG Account, and transfer of funds from the LRFG Account into either the Remining Financial Assurance Fund or the Trust Account. In addition, these provisions address allocation of interest earned in the account, conditions for dissolution of the program, and management of the account.

OSMRE Finding: We have determined that the provisions of section 19.2 are no less stringent than section 509(a) of SMCRA, 30 U.S.C. 1259(a), and no less effective than the Federal regulation at 30 CFR 800.11(e). Under section 800.11(e), OSMRE may approve alternative bonding systems if they assure financial solvency and include a substantial economic incentive for operator compliance with reclamation standards. We find that section 19.2 does so.

Pennsylvania's implementing regulations include several provisions intended to assure financial solvency, as discussed below. In addition, subsection 19.2(b)(1) directs Pennsylvania to assess and collect premiums annually from operators who choose to obtain the financial guarantees. This subsection also directs Pennsylvania to establish, by regulation, an annual premium amount sufficient to assure the stability of the fund. Subsection 19.2(b)(3)(i) adds to the overall solvency of the account by transferring funds from the previous financial guarantee program (the CAP), and subsection 19.2(b)(7) authorizes the appropriation of up to \$2 million annually to supplement the program.

Pennsylvania also proposes to limit solvency risk by screening potential financial guarantee recipients according to the provisions in subsection 19.2(c), including site conditions, operator financial stability, operator compliance history, and the availability of coal reserves at the site. Pennsylvania proposes to track and respond to the changing financial outlook of the account through regulations establishing underwriting methods for insuring the account against declared forfeitures, subsection 19.2(d)(2), and by allowing the guarantee program to cease immediately if 25 percent or more of the outstanding bond amounts in the program are declared forfeit, subsection 19.2(e)(1). These measures, along with further limitations described in the amendment's implementing regulations at 25 Pa. Code 86.162b (discussed and approved in *Finding 4* below) and 86.162c (discussed and approved in

Finding 9 below), aid in assuring that Pennsylvania will maintain sufficient funds to complete reclamation activities at any site where the operator forfeits the bond, as required by 30 CFR 800.11(e)(1).

For these reasons, we have determined the LRFG program proposed in section 19.2 is no less stringent than SMCRA and no less effective than the applicable Federal regulations. Accordingly, we are approving section 19.2 of PASMCRA.

*Finding 3: 25 Pa. Code 86.17(e)(2).
Permit and Reclamation Fees*

Pennsylvania revised this subsection of chapter 86 of its administrative code to add additional reporting requirements to the annual fiscal-year report to the legislature on the revenue and expenditures of the Reclamation Fee Operation and Maintenance Trust Account. In addition to items previously required when the Trust Account was originally established under 25 Pa. Code 86.17 and 86.187, information about the need for supplemental funding would now be required in the annual report. The revised subsection also requires PADEP to provide an estimate of the per-acre charge to be assessed in the next calendar year on operators seeking permits. This one-time reclamation fee is paid by operators and credited to the Trust Account. PADEP calculates the per-acre fee based on projected revenues and expenditures for the upcoming year.

OSMRE Finding: We have determined that this change is no less effective than the Federal regulation at 30 CFR 800.11(e)(1). The regulation requires that alternative bonding systems include measures to assure that the regulatory authority will have enough money to complete reclamation at bond forfeiture sites. This regulatory change requires Pennsylvania to add information to the annual program analysis about the funding mechanism of the Trust Account and whether the reclamation fee is expected to be sufficient to cover operation and maintenance costs for the next fiscal year. We agree with Pennsylvania that analysis of long-term operational and maintenance costs at bond-forfeited legacy sites will help determine whether supplemental funding of the Trust Account is needed. The requirement that this additional information be included in the annual report will allow Pennsylvania to respond more effectively to changing conditions and supplement the account, as needed. These enhancements, in conjunction with other provisions in this chapter, satisfy the Federal regulatory requirement for States using alternative bonding systems to maintain

sufficient funds to fulfill reclamation obligations at bond-forfeited sites. Therefore, we are approving the change to 25 Pa. Code 86.17(e)(1).

Finding 4: 25 Pa. Code 86.162b. LRFGs

Pennsylvania added this section to chapter 86 to detail implementation of the LRFG program and a financial account to facilitate administration of these guarantees. The LRFG Account is a financial instrument used to underwrite LRFGs and financially assure qualified operators of their bonding obligations. The LRFG Account also serves to fund bioenergy crop bonding as authorized in section 86.162c (see *Finding 9*) and fund any remaining sum-certain financial guarantees from previous programs such as the CAP. Another use of the LRFG Account is to assure sufficient funds for reclamation liabilities are available should any bond forfeitures occur.

Section 86.162b imposes several limits on Pennsylvania in issuing financial guarantees; it converts existing financial guarantees previously issued by Pennsylvania into LRFGs subject to outlined limits; and it requires Pennsylvania to prepare a report no less frequently than every five years that analyzes the revenue and expenses of the account and evaluates the limits on financial guarantees. Additionally, section 86.162b establishes eligibility requirements for recipients of financial guarantees; requires the operator to pay annual premiums to Pennsylvania of 1.5 percent of the total amount of the financial guarantee; requires additional bonds or financial assurance if a postmining pollutional discharge develops; establishes procedures for bond forfeiture from operators who choose to obtain the financial guarantees; and establishes procedures for discontinuing the financial guarantee program.

OSMRE Finding: We have determined that section 86.162b is no less effective than the Federal regulations at 30 CFR 800.11(e). Subsections (a) through (d) of this section are a straightforward description of the LRFG Account as a mechanism for receiving and distributing funds associated with the financial guarantee program. Subsection (e) describes the uses of the monies in the account, including covering reclamation liabilities when bond forfeiture occurs and underwriting financial guarantees for bioenergy crop bonding under 25 Pa. Code 86.162c. These provisions aid in achieving the objectives of 30 CFR 800.11(e).

Subsection (f) imposes several limits on Pennsylvania in issuing financial guarantees. Pennsylvania may not issue

financial guarantees exceeding 50 percent of the required bond amount for the permit, and it may not issue guarantees to individual operators in excess of 30 percent of the funds in the account. Pennsylvania also may not issue guarantees to any operators when the total amount of outstanding guarantees exceeds the amount of money in the account divided by the historical rate of bond forfeiture plus a safety margin. The total program limit on financial guarantee amounts aids in assuring solvency of the overall fund. The noted 50 percent limit also enhances solvency by ensuring that operators post traditional performance bonds for 50 percent or more of the reclamation liabilities. These traditional performance bonds will provide a significant economic incentive for compliance with the reclamation plan. The program limits and financial incentives all help Pennsylvania in achieving the objectives of 30 CFR 800.11(e)(1) and (2).

Subsection (g) of this section converts existing financial guarantees previously issued by Pennsylvania into LRFGs. The LRFGs are subject to the operator, permit, and program limits described elsewhere in section 86.162b. The new alternative bonding system will be easier for Pennsylvania to manage by consolidating the previous financial guarantees under the LRFG program. Because Pennsylvania will subject these converted financial guarantees to the limits of subsection (f), the LRFG program will help to assure that the objectives of 30 CFR 800.11(e)(1) and (2) are met, for the same reasons described previously.

Subsection (h) of this section directs Pennsylvania to prepare a report no less frequently than every five years to analyze the revenue and expenses of the LRFG Account and evaluate the limits on financial guarantees. This report is independent of the annual Trust Account report previously discussed. Pennsylvania must submit the report to the Mining and Reclamation Advisory Board (tasked with advising Pennsylvania on all matters of surface mining and reclamation) and make the report available to the public. Subsection (h) requires that, if Pennsylvania changes the financial guarantee limits based on the report, it will publish a notice highlighting those changes in the *Pennsylvania Bulletin*. These reports and the analyses they require will strengthen Pennsylvania's capacity to assure the solvency of the alternative bonding system, as required by 30 CFR 800.11(e)(1), by revisiting the various program limits, as well as revenue and expenses, with the input of

both the Mining and Reclamation Advisory Board and the public.

Subsections (i) and (j) of this section authorize Pennsylvania to transfer interest and payments from the LRFG Account to the Trust Account, as described at 25 Pa Code 86.17. No new alternative bonding system sites will come into existence because Pennsylvania has transitioned to full-cost bonding. The interest transfer is intended to transition existing alternative bonding system sites to a full funded status for their long-term treatment obligations. Pennsylvania may only use funds in the Trust Account for treating postmining pollutional discharges at alternative bonding system sites. The transfer of funds from one account to another does not affect the overall solvency of Pennsylvania's alternative bonding system. However, a check and balance on these transfers has been included in subsection (j), whereby PADEP must seek input from the Mining and Reclamation Advisory Board prior to any funds transfer into the Trust Account from the LRFG Account. Together these provisions will aid in achieving the objectives of 30 CFR 800.11(e)(1).

Subsection (k) establishes eligibility requirements for those who choose to obtain the financial guarantees. This subsection requires that operators hold valid coal mining leases, satisfy the requirements of subsections 86.37(a)(8) to 86.37(a)(8)(11) and 86.37(a)(8)(16) (relating to correction of previous violations), have a record of making timely payments on previous financial guarantees, and have not failed to maintain proper bonds within the previous three years. Operators obtaining financial guarantees for the first time must demonstrate experience in mining and reclamation by having coal mining licenses for at least five years. Operators must also submit either a surety bond for the remaining portion of the reclamation liability or a letter of acceptance from a surety company. These eligibility requirements reduce the chances of an operator forfeiting a bond by screening out inexperienced operators or operators with uncorrected violation histories. In doing so, this subsection helps assure solvency of the LRFG Account, furthering the objectives of 30 CFR 800.11(e)(1).

Subsection (l) describes the requirements for applications for financial guarantees, which include descriptions of the environmental and safety hazards of the proposed site, the availability of coal reserves at the site, and any prior denials of surety coverage. These requirements will help Pennsylvania select sound investments

for financial guarantees and help assure the solvency of the LRFG Account, furthering the objectives of 30 CFR 800.11(e)(1).

Subsection (m) requires operators obtaining a financial guarantee to pay annual premiums to Pennsylvania of 1.5 percent of the total amount of the financial guarantee and imposes related requirements and limitations. This subsection authorizes Pennsylvania to use the annual premiums to fund reclamation activities if bond forfeitures occur or to transfer excess funds to the Trust Account. These provisions help assure the solvency of the LRFG Account, as required by 30 CFR 800.11(e)(1).

Subsection (n) authorizes Pennsylvania to adjust the payment percentage rate to assure the financial stability of the LRFG Account, after soliciting advice from the Mining and Reclamation Advisory Board. The annual premiums will supplement the funds in the Account from the transfer of Pennsylvania's previous financial guarantee program and the annual appropriations from the electricity tax. Together these provisions will aid in achieving the objectives of 30 CFR 800.11(e)(1).

Subsection (o) requires Pennsylvania to reduce or release financial guarantees from the previous CAP before other obligations, followed by financial guarantees from the proposed LRFG program, and finally remaining performance bonds from the operator. By holding onto the remaining performance bonds until after releasing guarantees under the LRFG program, Pennsylvania will maintain the substantial economic incentive for the operator to fulfill its reclamation obligations as required in 30 CFR 800.11(e)(2).

Subsection (p) requires that when a postmining pollutional discharge develops, the operator must provide Pennsylvania with a separate bond or financial assurance to cover long-term treatment costs. The requirement for separate bond mechanisms for long-term treatment of pollutional discharges is no less effective than the Federal regulations at 30 CFR 800.40(c)(3), which stipulate that no bond can be fully released until the operator meets all reclamation requirements. By helping to ensure coverage of all reclamation liability, including the often late-arising liability associated with discovery of pollutional discharges, it is also no less stringent than section 509(a) of SMCRA, 30 U.S.C. 1259(a), which requires a bond "sufficient to assure the completion of the reclamation plan if

the work had to be performed by the regulatory authority"

Subsections (q) through (s) establish the procedures for bond forfeiture under the LRFG program. In such cases, Pennsylvania will declare forfeiture of the financial guarantee and the operator's other performance bonds and use the money to complete reclamation of the site. The forfeiture declaration will not discharge the operator's obligation to meet other requirements under the Pennsylvania regulatory program. These procedures are identical to the Federal regulation at 30 CFR 800.50 and are therefore as effective as those regulations.

Subsection (t) provides that Pennsylvania may suspend issuance of financial guarantees when the number of participating permits declared forfeit equals the number of participating permits multiplied by the historical forfeiture rate, plus a margin of safety. This subsection also provides that Pennsylvania may resume the financial guarantee program after evaluating and approving adequate funding levels with advice from the Mining and Reclamation Advisory Board. Subsection (u) provides that Pennsylvania will discontinue issuance of financial guarantees if 25 percent or more of the outstanding bond obligations for LRFGs are declared forfeit under section 86.181. Subsection (v) provides that Pennsylvania will not approve additional financial guarantees after the program is discontinued and that outstanding financial guarantees will remain in effect until released. We have determined that subsections (t), (u), and (v) have no direct Federal counterpart, but because they operate as additional mechanisms to promote solvency of the LRFG Account, we deem them no less effective than the Federal regulations at 30 CFR 800.11(e). The ability to suspend or discontinue issuance of financial guarantees to protect the solvency of the fund is consistent with the Federal regulations at 30 CFR 800.11(e)(1).

Section 86.162b includes numerous provisions implementing the LRFG Account and ensuring orderly program administration. Subsections (a) through (v) detail these additions and, as described in this *Finding*, are consistent with SMCRA and achieve the objectives of 30 CFR 800.11(e). For all these reasons, we are approving the addition of section 86.162b.

Finding 5: 25 Pa. Code 86.165. Failure To Maintain Proper Bond

Pennsylvania revised this section to add a provision that if an operator fails to pay annual premiums for LRFGs as

required by section 86.162b, then Pennsylvania will issue a notice of violation. If the operator does not correct the violation within 15 days of the notice, Pennsylvania will issue a cessation order.

OSMRE Finding: We have determined that the provision in this section does not have a Federal counterpart. However, the provision aids Pennsylvania in assuring LRFG Account solvency, and we deem it no less effective than the Federal regulation at 30 CFR 800.11(e)(1). Therefore, we are approving the change to 25 Pa. Code 86.165(a).

Finding 6: 25 Pa. Code 86.187. Use of Money

Pennsylvania revised this section to remove a reference to sum-certain financial guarantees under the predecessor program and replace it with a reference to LRFGs as implemented by section 86.162b. This replacement allows Pennsylvania to deposit fees collected for the LRFGs into the Trust Account. In conjunction with section 86.162b, the changes in section 86.187 referencing the LRFG allow the transfer of fees from the CAP. This section also changes a citation to PASMCR to reflect the addition of 52 P.S. 1396.19b and changes 'monies' to 'moneys.'

OSMRE Finding: We have determined that the reference to the LRFGs does not have a direct Federal counterpart. However, it accommodates the change from the previous CAP to the new LRFG program approved in *Finding 4* and provides an additional mechanism to ensure solvency, consistent with 30 CFR 800.11(e). The other changes are non-substantive and require no findings. Therefore, we are approving the changes to 25 Pa. Code 86.187(a) and (a)(iii).

Provisions on Bioenergy Crop Bonding

Finding 7: Subsection 4(a)(2)(C) of PASMCR

Pennsylvania, through Act 95, revised section 4 of PASMCR by adding a sentence at the end of subsection 4(a)(2)(C) directing PADEP to encourage and promote the use of various bioenergy crops, including switchgrass, camelina, and canola for the revegetation of surface mining sites and providing that Pennsylvania will consider such sites to have a postmining land use of cropland.

OSMRE Finding: We have determined that these changes are no less stringent than SMCRA and no less effective than its implementing regulations. Section 515(b)(19) of SMCRA (30 U.S.C. 1265(b)(19)) states that all surface mining operations must establish a

diverse, effective, and permanent vegetative cover of a native variety, except that introduced species may be used where desirable and necessary to achieve the approved postmining land use. Further, Section 515(b)(20) of SMCRA (30 U.S.C. 1265(b)(20)) states that when the regulatory authority approves an agricultural postmining land use, the authority may grant exceptions to the provisions of section 515(b)(19). Directing PADEP to encourage and promote the use of bioenergy fuels is consistent with these statutory provisions. We conclude that Pennsylvania's proposal to promote agricultural postmining land use in the form of bioenergy crops is no less stringent than SMCRA, and we are approving the changes to section 4(a)(2)(C) of PASMCR.

Finding 8: Section 4.14 of PASMCR

Pennsylvania revised PASMCR by adding section 4.14, which directs PADEP to make available sum-certain financial guarantees to cover Stage III reclamation liability for remining sites revegetated with bioenergy crops, to the extent that funds are available for the financial guarantees. Pennsylvania describes the implementation of the financial guarantees in additional statutory changes and in new chapters of the Pennsylvania Code.

OSMRE Finding: We have determined that this section has no direct Federal counterpart but is no less effective than the Federal regulations at 30 CFR 800.13 (regarding the duration of performance bond liability), 800.30 (governing approval of replacement bonds), and 816.116 (providing standards for successful revegetation). The effectiveness of this statutory provision is enhanced by its operating in conjunction with the proposed regulations in subsection 86.162c, which implement the bioenergy provisions of Act 95, as discussed in *Finding 9*. Therefore, we are approving the addition of section 4.14 of PASMCR.

Finding 9: 25 Pa. Code 86.162c

Pennsylvania added this section to chapter 86 of its administrative code, providing for the issuance of financial guarantees in the form of bioenergy crop bonding. Section 86.162c would provide operators at remining sites with an incentive to plant bioenergy crops, consistent with section 4.14 of PASMCR. Pennsylvania releases bonds in three stages. Stage 1 release occurs after the site has been regraded to the approximate original contour and drainage control installation has occurred. Stage 2 release occurs after

successful revegetation of the permit area. Stage 3 release occurs after final completion of the reclamation plan and a minimum of five years following Stage 2 bond release. The proposed bioenergy crop bond would release the operator's Stage 3 bonds and replace them with a financial guarantee.

Paragraph (a) describes the eligibility requirements for the bond. Operators may apply for the bioenergy crop bonding at remining sites after Stage 2 bond release and after demonstrating successful growth of bioenergy crops including switchgrass, camelina, and canola. Operators may not apply for bioenergy crop bonding if water treatment liability has been triggered under Pennsylvania's regulations on remining areas with pollutional discharges.

Paragraph (b) describes the application requirements for the bond. Applications must include verification that the permitted area has achieved Stage 2 bond release, demonstration that the operator is growing bioenergy crops at an acceptable yield, demonstration that temporary structures have been reclaimed, that there are no postmining pollutional discharges or that all liabilities for discharges are covered with a full-cost bond, and a statement that the operator intends to apply for release of bioenergy crop bonding in a timely manner.

Paragraphs (c) through (f) establish the procedures for approving bioenergy crop bonding. Only after approval may Pennsylvania release the operator's existing Stage 3 bond. Bioenergy crop bonding cannot exceed five years and will expire within 120 days of the expiration of the liability period. If final bond release does not occur until after expiration of bioenergy crop bonding, replacement bioenergy crop bonding is required.

OSMRE Finding: We have determined that this section has no direct Federal counterpart. However, after considering the probable effects of this section on the overall Pennsylvania program, we find that this section is no less effective than the Federal regulations, in particular, 30 CFR 800.11(e)(2) (requiring incentives for reclamation compliance), 800.13 (regarding the duration of performance bond liability), 800.30 (governing approval of replacement bonds), and 816.116 (providing standards for successful revegetation).

Subsection 86.162c implements the statutory provisions in section 4.14 of PASMCR, which establishes bioenergy crop bonding as a financial incentive to encourage the growth of bioenergy crops at remining sites. To provide a

substantial incentive, Pennsylvania is providing full-cost guarantees to replace the operator's Stage 3 liability. We conclude this incentive is no less effective than the Federal regulations at 30 CFR 800.11(e)(2) requiring substantial incentives for reclamation compliance. Because the full cost of reclamation is covered by this guarantee, the bond replacement is no less effective than the Federal regulations at 30 CFR 800.30. Further, bioenergy crop bonding liabilities are funded by separate general appropriations. Therefore, forfeiture and reclamation costs at bioenergy crop bonding sites will not affect the overall funding levels of the Pennsylvania regulatory program. The requirement for Stage 2 bond release to occur before approving bioenergy crop bonding and the restriction against long-term pollutional discharges in the program further limit Pennsylvania's risk and ensure that the operator has already committed to bioenergy crop growth at the site.

We conclude the minimum five-year liability period for bioenergy crop bonding is no less effective than 30 CFR 816.116(c)(2), which requires that sites which receive at least 26 inches of annual average precipitation have liability periods of five years, except in the case of reining sites, where the period of liability is two years. Further, subsection 816.116(b)(5) of the Federal regulations requires vegetation at reining sites to match or exceed the previous extent of ground cover and be adequate to control erosion. The density of vegetation in a cropland safely meets these standards. For these reasons, we are approving section 86.162c.

Minor Statutory and Regulatory Changes

There were numerous non-substantive changes as to which OSMRE makes no findings. These changes may be found in PADEP's July 26, 2017, letter (Administrative Record No. PA 900.00) (pp. 3 to 29).

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment and did not receive any during the comment period.

Federal Agency Comments

On August 7, 2017, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program

(Administrative Record No. PA 900.01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Pennsylvania proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on August 7, 2017, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. PA 900.01). The EPA responded on December 11, 2017 (Administrative Record No. PA 900.03) with no comments on the amendment.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On August 7, 2017, we requested comments on the Pennsylvania amendment (Administrative Record No. 900.01). Neither the SHPO nor ACHP responded with any comments.

V. OSMRE's Decision

Based on the above findings, we are approving the Pennsylvania amendment sent to us on July 26, 2017 (Administrative Record No. PA 900.00). To implement this decision, we are amending the Federal regulations at 30 CFR part 938 that codify decisions concerning the Pennsylvania program. In accordance with the Administrative Procedure Act, this rule will take effect 30 days after the date of publication.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule would not effect a taking of private property or otherwise have taking implications that would result in public property being taken for government use without just compensation under the law. Therefore, a takings implication assessment is not required. This determination is based on

an analysis of the corresponding Federal regulations.

Executive Orders 12866—Regulatory Planning and Review. 13563—Improving Regulation and Regulatory Review. 14094—Modernizing Regulatory Review

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993 (OMB Memo M–94–3), the approval of State program amendments is exempted from OMB review under Executive Order 12866, as amended by Executive Order 14094. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by section 3 of Executive Order 12988. The Department determined that this **Federal Register** notice meets the criteria of section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency's legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive order to the quality of this **Federal Register** notice and to changes to the Federal regulations. The review under this Executive order did not extend to the language of the State regulatory program or to the program amendment that Pennsylvania drafted.

Executive Order 13132—Federalism

This rule has potential Federalism implications as defined under section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to "grant the States the maximum administrative discretion possible" with respect to Federal statutes and regulations administered by the States. Pennsylvania, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the State level. This rule approves an amendment to the Pennsylvania State program submitted and drafted by the State, and

thus is consistent with the direction to provide maximum administrative discretion to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department’s consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Tribes or on the distribution of power and responsibilities between the Federal government and Tribes. The basis for this determination is that our decision on the Pennsylvania program does not include Indian lands, as defined by SMCRA, or regulation of activities on Indian lands. Indian lands are regulated independently under the applicable Federal program. The Department’s consultation policy also acknowledges that our rules may have Tribal implications where the State proposing the amendment encompasses ancestral lands in areas with mineable coal. We are currently working to identify and engage appropriate Tribal stakeholders to devise a constructive approach for consulting on these amendments.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not significant energy action under the definition in Executive Order 13211, a

Statement of Energy Effects is not required.

National Environmental Policy Act

Consistent with sections 501(a) and 702(d) of SMCRA (30 U.S.C. 1251(a) and 1292(d), respectively) and the U.S. Department of the Interior Departmental Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) does not have an annual effect on the economy of \$100 million; (b) will not cause a major increase in costs or prices for consumers,

individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,
Regional Director, North Atlantic-Appalachian Region.

For the reasons set out in the preamble, 30 CFR part 938 is amended as set forth below:

PART 938—PENNSYLVANIA

- 1. The authority citation for part 938 continues to read as follows:
Authority: 30 U.S.C. 1201 *et seq.*
- 2. Section 938.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:
§ 938.15 Approval of Pennsylvania regulatory program amendments.
* * * * *

Original amendment submission date	Date of final publication	Citation/description
* July 26, 2017	* August 8, 2024	* PASMCRa sec. 4(d), 19.2 Authorizing LRFG program; PASMCRa sec. 4(a)(2)(C), 4.14, authorizing bioenergy crop bonding; PASMCRa sec. 3 definitions, 18(a.1), 19, minor changes; 25 Pa. Code 86.17(e)(2), 86.162b, 86.165(a) and (a)(iii), implementing the LRFG program; 25 Pa. Code 86.162c, implementing the bioenergy crop bonding program; 25 Pa. Code 86.1 definition of <i>Acts</i> , 86.6(a), 86.12(a)(3), 86.121, 86.155, 86.159(k)(2)(A), 86.182(h)(2), 86.185, 86.232 definition of <i>coal mining laws</i> , 86.252 definition of <i>Act</i> , 86.358(a)(3), 87.1 definition of <i>SMCRa</i> , 87.205(b), 88.482 definition of <i>operator</i> , 88.505(b), 89.5 definition of <i>operator</i> , and 90.305(b), citation changes and other minor changes.

[FR Doc. 2024–17336 Filed 8–7–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[SATS No. PA–170–FOR; Docket ID: OSM–2108–0007; S1D1S SS08011000 SX064A000 234S180110 S2D2S SS08011000 SX064A000 23XS501520]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving a request from Pennsylvania for the removal of a required amendment to the Pennsylvania regulatory program (hereinafter, the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The required amendment directed Pennsylvania to submit regulations requiring that siltation structures (e.g., sedimentation ponds) not be removed any sooner than two years after the last augmented seeding.

DATES: The effective date is September 9, 2024.

FOR FURTHER INFORMATION CONTACT: Ben Owens, Acting Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, Telephone: (412) 937–2827. Email: bowens@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Pennsylvania Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

I. Background on the Pennsylvania Program

Subject to OSMRE oversight, Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). Based on these criteria, the Secretary of the Interior conditionally approved the

Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania's program and program amendments at 30 CFR 938.11, 938.12, 938.13, 938.15, and 938.16.

II. Submission of the Amendment

By letter dated August 9, 2018 (Administrative Record No. PA 903.00), Pennsylvania requested removal of a required amendment from its program. This amendment, 30 CFR 938.16(rrr), requires Pennsylvania to amend three subsections in title 25 of the Pennsylvania Code (Pa. Code), specifically subsections 87.108(c), *Hydrologic balance: sedimentation ponds* (applicable to surface coal mining), 89.24(c), *Performance Standards: Sedimentation ponds* (applicable to underground coal mining), and 90.108(c), *Hydrologic balance: sedimentation ponds* (applicable to coal refuse disposal sites), or otherwise to amend its program to require, without exception, that sedimentation ponds not be removed sooner than two years after the last augmented seeding.

We gave notice of receipt of Pennsylvania's August 9, 2018, request in the May 1, 2019, **Federal Register** (84 FR 18435). In the same notice, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because none was requested. The public comment period ended on May 31, 2019. We received no comments.

III. OSMRE's Findings

We are approving Pennsylvania's request to eliminate the required amendment as described below and approving language we previously rejected as being less effective than the Federal regulations. The following are findings we made concerning Pennsylvania's request under SMCRA at 30 U.S.C. 1253, *State Programs*, and the Federal regulations at 30 CFR 732.15, *Criteria for approval or disapproval of State programs*, and 732.17, *State program amendments*.

A. Pennsylvania's Rationale

With this request, Pennsylvania presents a number of reasons why the required amendment should be removed and why previously submitted language revising 25 Pa. Code 87.108(c)—

Sedimentation Ponds: Surface Coal Mines; 89.24(c)—Sedimentation Ponds: Underground Mines and Coal Preparation Facilities; and 90.108(c)—Sedimentation Ponds: Coal Refuse Disposal should be approved. The previously submitted revised language required that sedimentation ponds be maintained until the disturbed area has been stabilized and revegetated and removal is approved by the Department, and that the ponds may not be removed sooner than 2 years after the last augmented seeding unless the Department finds that the disturbed area has been sufficiently revegetated and stabilized.

1. Use of Best Technology Currently Available (BTCA)

In support of removing the required amendment and accepting the revised language, Pennsylvania identifies the 1985 court decision in *In re Permanent Surface Mining Regulation Litigation*, 620 F. Supp. 1519 (D.D.C.), as well as our 1986 rule suspending 30 CFR 816.46(b)(2) and 817.46(b)(2), and reasons that 30 CFR 816.46(b)(1) now governs sediment control. Pennsylvania also notes that when a pond is removed prior to two years after the last augmented seeding, its program requires that sediment control measures that have been determined by the Pennsylvania Department of Environmental Protection (PADEP) to constitute BTCA must at that point be in place. 25 Pa. Code 87.108(i), 90.108(j). Pennsylvania also notes that its program establishes vegetation standards (25 Pa. Code 87.147–87.153, 87.155, 87.156, 89.86, 90.151–90.157, 90.159, and 90.160) as the BTCA. For example, 25 Pa. Code 87.147(b) requires the establishment of “a diverse, effective and permanent vegetative cover of the same seasonal variety native to the area of land to be affected and capable of self-regeneration and plant succession at least equal in extent of cover to the natural vegetation of the area. . . .”

Pennsylvania's submission also references Montana and Ohio as successfully amending their programs and receiving OSMRE approval to allow removal of sedimentation ponds sooner than two years after last augmented seeding if replaced by BTCA. See 55 FR 19727 (May 11, 1990) (regarding the Montana program); 59 FR 58778 (November 15, 1994) (regarding the Ohio program).

2. Approval Required Prior to Removal

In support of removing the required amendment and accepting the revised language, Pennsylvania also indicates that 25 Pa. Code 87.108(c), 89.24(c), and

90.108(c) require the regulatory authority to approve the removal of the ponds as required by 30 CFR 816.46(b)(5), which we infer reflects Pennsylvania's view that the required approval provides a safeguard against the possibility that sedimentation ponds would be removed prematurely.

3. Revegetation Experience

In further support of removing the required amendment and accepting the revised language, Pennsylvania recounts its experience with revegetation and notes that revegetation is often established in less than two years. Pennsylvania adds that because siltation structures pose reclamation liability and, in some cases, a potential public safety hazard, they should be removed as soon as they are no longer necessary, which is often less than two years.

4. No Statutory Prohibition

Finally, in support of removing the required amendment and accepting the revised language, Pennsylvania states that there is no statutory prohibition to Pennsylvania's approach.

In conclusion, Pennsylvania asserts that its program's approach, with the revised language and without the required amendment, is no less effective than the Federal program for the reasons mentioned above. Therefore, Pennsylvania is requesting that the required program amendment at 30 CFR 938.16(rrr) be removed and proposed revisions to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c) be approved.

B. Background of Regulatory Scheme

The Federal regulations at 30 CFR parts 816 and 817 (Permanent program performance standards for surface mining and underground mining, respectively) require operators to minimize disturbance of the hydrologic balance within the permit and adjacent areas and to prevent material damage to the hydrologic balance outside the permit area during mining and reclamation activities. 30 CFR 816.41(a) and 817.41(a). The standards address groundwater and surface water protections and include a requirement that additional contributions to streamflow of suspended solids or runoff outside the permit area be prevented to the extent possible using the BTCA. 30 CFR 816.45(a)(1) and 817.45(a).

To assist in achieving these objectives, operators often construct siltation structures for sediment control of surface drainage. The Federal regulations define a siltation structure as "a sedimentation pond, a series of

sedimentation ponds, or other treatment facility." 30 CFR 701.5. Siltation structures were originally considered by OSMRE to be the BTCA. They are designed, constructed, and maintained to provide adequate sediment storage volume and adequate detention time to allow the effluent from the ponds to meet State and Federal effluent limitations. As discussed below, the Federal regulation at 30 CFR 816.46(b)(5) specifically prohibits removal of siltation structures sooner than two years after the last augmented seeding.

Challengers of a 1983 Federal rule that, in part, expanded the definition of "siltation structure" to include "other treatment facilities" (51 FR 41952) asserted in litigation that, in certain circumstances, siltation structures of any type can cause adverse effects on the hydrologic balance. The court concluded that the preamble to the final rule failed to provide sufficient rationale for requiring siltation structures in every instance. *In re Permanent Surface Mining Reclamation Litigation*, 620 F. Supp. 1519, 1568 (D.D.C. 1985). Consequently, the court remanded the challenged regulations at 30 CFR 816.46(b)(2) and 817.46(b)(2) to the Secretary for further analysis and explanation. In response, OSMRE suspended the remanded rules. 51 FR 41952, 41957–41958 (November 20, 1986). The effect of this suspension was to require that sediment control of surface drainage be governed by BTCA rather than requiring such drainage to be passed specifically through siltation structures. We concluded that when measures other than siltation structures (which under Federal regulations include vegetation, *see* 30 CFR 701.5) are determined to be BTCA, the performance standards of 30 CFR 816.45 and 817.45 will control. 51 FR 41957–41958. We also concluded that where siltation structures are determined to be BTCA, the performance standards in 30 CFR 816.46(b)–(d) and 817.46(b)–(d) will continue to apply. *Id.*

Since the suspension in 1986, OSMRE has approved revisions to two State programs (Montana and Ohio) to allow the removal of siltation structures sooner than two years after last augmented seeding if replaced by BTCA. In 1990, OSMRE approved a revision to Montana's program and the two-year retention requirement for sedimentation ponds and siltation structures. *See* 55 FR 19727 (May 11, 1990). Montana proposed to require that sedimentation ponds and other treatment facilities not be removed sooner than two years after the last augmented seeding within the drainage

unless otherwise approved by the State in compliance with water quality performance standards/regulations and sediment control standards/regulations. The revision required that a pond removed sooner than two years after the last augmented seeding within the drainage area must be replaced by a sediment control measure determined by the regulatory authority to constitute BTCA. In 1994, OSMRE approved a revision to Ohio's program and the two-year retention requirement for sedimentation ponds and siltation structures. *See* 59 FR 58778 (Nov. 15, 1994). OSMRE approved Ohio's proposal revising its regulations to authorize removal of siltation structures sooner than two years after the last augmented seeding, upon a demonstration that revegetation is the BTCA for sediment control.

The required amendment Pennsylvania seeks to remove here was imposed by OSMRE in response to a 1996 proposed amendment by PADEP. The proposed amendment covered a number of provisions and a range of topics including revisions to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c), which would have allowed reclamation of sedimentation ponds in less than two years. *See* 62 FR 60169 (November 7, 1997). Specifically, the 1996 proposal required that sedimentation ponds be maintained until the disturbed area is stabilized and revegetated and removal is approved by PADEP. Pennsylvania also proposed to delete related references to "other treatment facilities." We presumed at the time that this deletion was proposed because the Pennsylvania regulations at 25 Pa. Code sections 87.108, 89.24, and 90.08 require all draining to be passed through sedimentation ponds rather than by any other treatment method. 62 FR 60172. OSMRE approved the removal of references to "other treatment facilities." *Id.*

Unlike the Montana and Ohio revisions, referenced above, Pennsylvania's 1996 submission made no reference to any requirement that removal of siltation structures sooner than two years after the last augmented seeding would be approved upon a demonstration that revegetation is the BTCA for sediment control.

Because Pennsylvania's proposal presumptively precluded the use of any "other treatment facilities" and required the use of sedimentation ponds rather than any other treatment method, OSMRE did not approve an exception to the temporal requirement related to siltation structure removal. Therefore, OSMRE did not approve revisions to 25 Pa. Code sections 87.108(c), 89.24(c),

and 90.108(c) and further directed the State to amend its program to address the perceived deficiencies.

C. OSMRE Findings

In its request to remove required amendment 30 CFR 938.16(rrr), Pennsylvania presents a more robust justification for why the required amendment should be removed and why Pennsylvania's approach, including the revisions to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c), should be approved.

1. Use of BTCA

The Federal regulation at 30 CFR 816.46(b)(5) requires that siltation structures not be removed sooner than two years after the last augmented seeding. However, the Federal regulations at 30 CFR 816.46(b)(2) and 817.46(b)(2), which mandated use of siltation structures, were suspended on November 29, 1986 (51 FR 41952) because the preamble failed to provide a sufficient rationale for requiring siltation structures in every instance. Explaining the effect of the suspensions, OSMRE stated that the "regulatory authority must determine on a case-by-case basis what constitutes the 'best technology currently available' as required by the Act and 30 CFR 701.5 which defines BTCA." 51 FR 41957.

The effect of this suspension is to require that sediment control of surface drainage be governed by BTCA rather than requiring such drainage to be passed specifically through siltation structures for two years. In the 1986 rulemaking, OSMRE announced, in light of the change, that when measures other than siltation structures (which would include vegetation) are determined to be BTCA, the performance standards of 30 CFR 816.45 will control. 51 FR 41957. OSMRE then explained that where siltation structures are determined to be BTCA, the performance standards in 30 CFR 816.46(b)–(d) will control. 51 FR 41957–41958.

Under Pennsylvania's current program, if PADEP determines that a disturbed area featuring a siltation structure has been sufficiently revegetated and stabilized, it may conclude that vegetation has become BTCA, regardless of whether the siltation structure has been in place for two years from the last augmented seeding. This conclusion is consistent with the 1986 rulemaking, in which we indicated that "the regulatory authority must determine on a case-by-case basis what constitutes the 'best technology currently available.'" 51 FR 41957. It is also consistent with our determinations in the Montana and Ohio rulemakings

where we approved rules that allowed removal of siltation structures in less than two years if replaced by measures determined to be BTCA. BTCA is defined in the Federal regulations at 30 CFR 701.5 as:

equipment, devices, systems, methods, or techniques which will (a) prevent, to the extent possible, additional contributions of suspended solids to stream flow or runoff outside the permit area, but in no event result in contributions of suspended solids in excess of requirements set by applicable State or Federal laws; and (b) minimize, to the extent possible, disturbances and adverse impacts on fish, wildlife and related environmental values, and achieve enhancement of those resources where practicable.

30 CFR 701.5 adds that BTCA includes use of "vegetative selection and planting requirements" and provides that the regulatory authority has "discretion to determine the best technology currently available on a case-by-case basis, as authorized by the Act and this chapter." We recognize that a State may employ different types of BTCA to address effluent limitations and sediment storage requirements. We also recognize that the Pennsylvania program, without the required amendment at 30 CFR 938.16(rrr), still requires that water quality criteria and effluent limitations be satisfied, whether by use of siltation structures or another form of BTCA. 25 Pa. Code 87.106 (BTCA requirement); 25 Pa. Code 87.102(a) (water quality criteria); 25 Pa. Code 87.102(b) (effluent limitations).

2. Approval Required Prior to Removal

The Federal regulations require the approval of the regulatory authority before siltation structures can be removed. As noted, Pennsylvania's submission points out that siltation structures must be maintained until the regulatory authority finds the disturbed area has been stabilized and revegetated. See 25 Pa. Code 87.108(c), 89.24(c), 90.108(c). Although Pennsylvania's submission does not explicitly say so, we think this requirement, in conjunction with use of BTCA, provide an adequate safeguard against the possibility that sedimentation ponds would be removed prematurely.

3. No Statutory Prohibition

Pennsylvania asserts that there are no Federal statutory prohibitions that preclude approval of its request to allow removal of siltation structures sooner than two years following last augmented seeding. We recognize that the SMCRA provisions at 30 U.S.C. 1265(b)(10)(B)(i) and 1266(b)(9)(B) do not prescribe the type of BTCA to be used to control

sediment. As discussed in the November 20, 1986, **Federal Register** notice, we anticipated that siltation structures will most likely constitute the "Best Technology Currently Available"; however, case-by-case determinations should be made by the regulatory authority to determine if siltation structures are necessary to control surface water runoff. Pennsylvania's submission references revegetation standards that must be met before the regulatory authority determines that any siltation structures are not required on the site. Through this determination, if the site has been successfully reclaimed and revegetated with no surface runoff exceeding Federal or State effluent standards, then removal of the siltation structures would be approved because they would not be required to collect surface runoff from the site. Under these standards, Pennsylvania's program would establish reclamation and revegetation as the BTCA for controlling surface runoff.

For the reasons explained above, we find that removal of the required amendment at 30 CFR 938.16(rrr) and approval of the revised language to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c), would result in a program that is no less effective than the Federal regulations at 30 CFR 816.46(b)(1) and 816.46(b)(5) and that is consistent with SMCRA, and we are thus approving the request to remove the required amendment and approving the proposed revisions to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c).

IV. Summary and Disposition of Comments

Public Comments

In the May 1, 2019, **Federal Register** notice announcing our receipt of this amendment, we asked for public comments (Administrative Record No. PA–903.05). The comment period closed on May 31, 2019. No requests for public meetings or hearings were received. We did not receive any comments.

Federal Agency Comments

On August 27, 2018, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program (Administrative Record No. PA 903.01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). Although we sought EPA concurrence in the Montana and Ohio rulemakings, we do not interpret section 30 CFR 732.17(h)(11)(ii) (including the undefined phrase “relate to . . . water quality standards”) to apply in this instance because the Pennsylvania program’s requirement that operators comply with State water quality and effluent standards (25 Pa. Code 87.106, 87.102) is not affected by this rule. Without the required amendment at 30 CFR 938.16(rrr), the program still mandates that water quality criteria and effluent limitations in section 87.102 be met through some form of BTCA. *See* 25 Pa. Code 87.106. Nonetheless, on August 27, 2018, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. PA 900.01). No comments were received.

V. OSMRE’s Decision

Based on the above findings, we are approving the request from Pennsylvania sent to us on August 6, 2018 (Administrative Record No. PA 903.00). To implement this decision, we are amending the Federal regulations at 30 CFR 938.16 that codify decisions concerning the Pennsylvania program by removing subsection 938.16(rrr). We are also approving the proposed revisions to 25 Pa. Code sections 87.108(c), 89.24(c), and 90.108(c). In accordance with the Administrative Procedure Act, this rule will take effect 30 days after the date of publication. Section 503(a) of SMCRA requires that the State’s program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. SMCRA requires consistency of State and Federal standards, and we have determined that Pennsylvania’s program, without the required amendment, achieves this.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule would not effect a taking of private property or otherwise have

taking implications that would result in private property being taken for government use without just compensation under the law. Therefore, a takings implication assessment is not required. This determination is based on an analysis of the corresponding Federal regulations.

Executive Orders 12866—Regulatory Planning and Review, 13563—Improving Regulation and Regulatory Review, and 14094—Modernizing Regulatory Review

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993 (OMB Memo M–94–3), the approval of State program and/or plan amendments is exempted from OMB review under Executive Order 12866, as amended by Executive Order 14094. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by Section 3 of Executive Order 12988. The Department determined that this **Federal Register** document meets the criteria of Section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency’s legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because Section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive Order to the quality of this **Federal Register** document and to changes to the Federal regulations. The review under this Executive Order did not extend to the language of the State regulatory program and/or plan to the program and/or amendment that Pennsylvania drafted.

Executive Order 13132—Federalism

This rule has no potential Federalism implications as defined under Section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to “grant the States the maximum administrative discretion possible” with respect to Federal statutes and regulations administered by the States.

Pennsylvania, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the State level. This rule only corrects the CFR to reflect our prior approvals of the Pennsylvania program submitted and drafted by the State and, thus, has no effect on the maximum administrative discretion we are directed to give to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department’s consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on the distribution of power and responsibilities between the Federal Government and Tribes. The basis for this determination is that our decision on the Pennsylvania program does not include Indian lands as defined by SMCRA or other Tribal lands and it does not affect the regulation of activities on Indian lands or other Tribal lands. Indian lands under SMCRA are regulated independently under the applicable Federal Indian program. The Department’s consultation policy also acknowledges that our rules may have Tribal implications where the State proposing the amendment encompasses ancestral lands in areas with minable coal. We are currently working to identify and engage appropriate Tribal stakeholders to devise a constructive approach for consulting on these amendments.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not a significant energy action under the definition in Executive Order 13211, a Statement of Energy Effects is not required.

National Environmental Policy Act

Consistent with sections 501(a) and 702(d) of SMCRA (30 U.S.C. 1251(a) and 1292(d), respectively, and the U.S. Department of the Interior Departmental Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a

significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) does not have an annual effect on the economy of \$100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or

unique effect on State, local, or Tribal governments or the private sector. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,

Regional Director, North Atlantic—
Appalachian Region.

For the reasons set out in the preamble, 30 CFR part 938 is amended as set forth below:

PART 938—PENNSYLVANIA

■ 1. The authority citation for part 938 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 938.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 938.15 Approval of Pennsylvania regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* August 9, 2018	* September 8, 2024	* 25 Pa. Code 87.108(c), 89.24(c), and 90.108(c); removal of sedimentation ponds before 2 years if replaced by BTCA.

§ 938.16 [Amended]

■ 3. Section 938.16 is amended by removing paragraph (rrr).

[FR Doc. 2024–17330 Filed 8–7–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[SATS No. WV–127–FOR; Docket No. OSM–2020–0003; S1D1S SS08011000 SX064A000 201S180110; S2D2S SS08011000 SX064A000 20XS501520]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the West Virginia regulatory program (the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). This amendment revises West Virginia’s regulatory program provisions related to entities authorized to issue surety bonds and the repair and compensation of damage resulting from subsidence.

DATES: Effective September 9, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Castle, Acting Director, Charleston Field Office Telephone: (304) 347–7158. Email: osm-chfo@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia Program
- II. Submission of the Amendment

- III. OSMRE’s Findings
- IV. Summary and Disposition of Comments
- V. OSMRE’s Decision
- VI. Statutory and Executive Order Reviews

I. Background on the West Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the West Virginia program on January 21, 1981. You can find additional background

information on the West Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning the West Virginia program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Submission of the Amendment

By letter dated May 5, 2020 (Administrative Record No. 1640), West Virginia sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*), docketed as WV-127-FOR. The amendment consists of revisions made by West Virginia House Bill 4217 (HB 4217), which was signed by the Governor on March 25, 2020. HB 4217 seeks to modify language in West Virginia's regulations relating to companies that execute surety bonds and modify language relating to the correction of material damage from subsidence to a landowner's structures or facilities.

We announced receipt of the proposed amendment in the December 16, 2020, **Federal Register** (85 FR 81436). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. Due to the COVID-19 restrictions, a virtual public hearing was held on January 14, 2021. The public comment period ended on January 15, 2021.

III. OSMRE's Findings

The following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. The full text of the program amendment is available for review at <https://www.regulations.gov>.

A. Surety Bonds—CSR 38–2–11.3.a.3

West Virginia seeks to revise CSR 38–2–11.3.a.3, which requires any company that executes surety bonds in the State to either: (i) be included on the United States Department of the Treasury's (Treasury Department) listing of approved sureties; or (ii) to submit proof to the West Virginia Department of Environmental Protection (WVDEP) that it holds a valid license issued by the West Virginia Insurance Commissioner and meets certain reporting obligations. The existing provision further requires any company not included on the Treasury Department's listing of approved sureties to diligently pursue

application for such listing, submit proof of its efforts, and become listed within 4 years. The revision would specify that only those companies electing to qualify under the first part must diligently pursue application for listing with the Treasury Department if they do not currently possess that certification. In other words, companies that elect to submit proof of a valid license from the West Virginia Insurance Commissioner and meet certain reporting obligations would no longer be required to diligently pursue application for listing or be listed with the Treasury Department.

OSMRE Finding: West Virginia's existing requirement has no counterpart under SMCRA or the Federal implementing regulations. Section 509(b) of SMCRA, 30 U.S.C. 1259(b), requires that a coal mining operator execute a surety bond with a corporate surety licensed to do business in the State where the operation is located. *See also* 30 CFR 800.20(a). West Virginia first began requiring surety companies to hold a current certificate of authority from the Treasury Department in 2001. *See* 68 FR 67035, 67038 (Dec. 1, 2003). WVDEP stated at the time that the requirement "was adopted to address concerns about the financial solvency of sureties providing reclamation bonds in West Virginia. The WVDEP did not have the necessary resources or expertise to regularly and timely monitor the financial condition of sureties doing business in West Virginia." 70 FR 77321, 77321–22 (Dec. 30, 2005). West Virginia then modified the requirement in 2005 to allow surety companies to diligently pursue a certificate from the Treasury Department, thereby removing a barrier to sureties that were in good financial condition but did not yet have the Treasury Department certificate, from providing reclamation bonds in West Virginia. West Virginia filed an emergency rule with the West Virginia Secretary of State on September 21, 2005, which the Secretary of State approved on an emergency basis on October 11, 2005. WVDEP also filed a legislative rule containing the same language with the Secretary of State on September 21, 2005 (Administrative Record No. WV-1442). WVDEP provided OSMRE with a copy of that proposed rule for an informal review, and we recommended revisions. West Virginia adopted our suggested revisions, and we approved the amendment on December 30, 2005 (70 FR 77321).

Since 2005, WVDEP has learned that under W.Va. Code sec. 33–4–14, corporate sureties must annually submit to the West Virginia Insurance

Commissioner a true quarterly statement of their financial condition, transactions, and affairs as of March 31, June 30, and September 30 in order to do business in West Virginia. As a consequence of the current amendment, WVDEP will be relying on the expertise and review of the West Virginia Insurance Commission, because it is responsible for the licensing, financial monitoring, and financial examination of the companies admitted to do business in West Virginia. As amended, we find the revision to be no less effective than the Federal regulation at 30 CFR 800.20(a), which states that a surety bond shall be executed by the operator and a corporate surety licensed to do business in the State where the operation is located, and no less stringent than section 509(b) of SMCRA. Therefore, we approve this amendment.

B. Owner Compensation—CSR 38–2–16.2.c.2

West Virginia seeks to revise CSR 38–2–16.2.c.2 relating to the correction of material damage to any structures or facilities resulting from subsidence. The existing regulation requires operators to either repair the damage or compensate the owner for the full amount of diminution in value resulting from the subsidence. West Virginia proposes to revise this provision to state explicitly that the choice of remedy is the owners' and to replace the option of repair with an option to be compensated in the amount of the repair, subject to the limitation that the compensation not exceed one hundred and twenty percent (120%) of the pre-mining value of the structure or facility. The proposal also inserts new language clarifying that this section neither creates additional property rights nor can it be construed as vesting in WVDEP's secretary the jurisdiction to adjudicate property rights disputes.

OSMRE Finding: Currently, the language of West Virginia's requirement at CSR 38–2–16.2.c.2 is substantively identical to section 720(a)(1) of SMCRA, 30 U.S.C. 1309a(a)(1), and 30 CFR 817.121(c)(2). Section 720(a)(1) of SMCRA states that underground coal mining operations must promptly repair, or compensate for, material damage resulting from subsidence caused to any occupied residential dwelling and related structures and any noncommercial buildings. Section 720(a)(1) further elaborates that repair includes rehabilitation, restoration, or replacement; that compensation must be in the full amount of the diminution in value resulting from the subsidence; and that compensation may be accomplished by the purchase, prior to

mining, of a noncancellable premium-prepaid insurance policy.

OSMRE revised its subsidence control regulations in 1995 to implement the Energy Policy Act of 1992 (the Energy Policy Act), enacted on October 24, 1992, which amended SMCRA by adding section 720. 60 FR 16722 (Mar. 31, 1995). Section 720(a) of SMCRA itself specifically focuses on the operators' obligations, providing, in relevant part: "Underground coal mining operations . . . shall comply with each of the following requirements: (1) Promptly repair, or compensate for, material damage resulting from subsidence. . . ." 30 U.S.C. 1309a(a). The final regulation did likewise, providing in relevant part: "The permittee must promptly repair, or compensate the owner for, material damage resulting from subsidence. . . ." 30 CFR 817.121(c)(2). These provisions only reference the owners of materially damaged structures with respect to how they must be compensated should compensation occur in lieu of repair. While the preamble to our 1995 final rule did not explicitly state that the option to repair or replace is the operator's, that interpretation is evident in our discussion of 30 CFR 817.121(c)(5) (Adjustment of bond amount for subsidence damage), in which we state: "Further, the final rule provides that if the permittee intends to repair the damage, the required additional bond would amount to the estimated cost of the repairs. If the permittee intends to compensate the owner, the additional bond would amount to the diminution in value of the protected land or structures." 60 FR at 16741. This reading is also consistent with the preamble to our initial program regulations, written before the Energy Policy Act was enacted, which indicated the operator had the choice between repair and compensation. See 44 FR 14902, 15275 (March 13, 1979) (explaining that "insurance is one alternative from which operators can choose to meet the requirements of this Section," and further explaining the elimination of landowner "consultation" from the proposed regulation in favor of options for the operator and protections for the surface owner).

OSMRE has approved alternatives to the options provided under SMCRA, including Pennsylvania's omission of compensation for the decrease in value of the structure in favor of compensation for the reasonable cost of repair or reasonable cost of replacement. See 66 FR 67010, 67020, 67037 (Dec. 27, 2001). As OSMRE acknowledged in its

2001 approval of Pennsylvania's provisions, and as one commenter to this amendment points out, the cost of repair or replacement may in some cases greatly exceed the diminution in the structure or facility's value. (See 66 FR at 67020). However, as discussed above, section 720(a) of SMCRA allows the operator to choose the remedy. Under most circumstances, an operator would be expected to, and is only required to, choose the remedy with the lesser cost. In other words, under SMCRA, if the cost to repair or replace a structure far exceeds the pre-mining value of the structure, a mining operator who materially damages the structure need only compensate the owner for the loss in value. OSMRE's 2001 approval of Pennsylvania's provisions is consistent. Pennsylvania's provisions do not require compensation for repair or replacement at any cost but instead only require compensation for "reasonable" cost of repair or "reasonable" cost of replacement. The operator's option to fulfill the requirement by obtaining a premium-prepaid insurance policy is also evidence that the operator's liability is not without limit.

In West Virginia, if the cost of repair or replacement exceeds 120% of the pre-mining value of the structure, the operator retains the alternative option to compensate the owner for the loss in value rather than pursue repair or replacement. By allowing the landowner to choose the greater compensation that would otherwise be available under section 720(a)(1) of SMCRA, though not without limit, West Virginia's proposed amendment is not less stringent than SMCRA nor less effective than 30 CFR 817.121, and, therefore, we are approving it. We are also approving the revision clarifying that CSR 38–2–16.2.c.2 does not create additional property rights or vest in the WVDEP Secretary the jurisdiction to adjudicate property rights. Nothing in SMCRA creates property rights or vests in, or requires, any State regulatory authority to adjudicate property rights, which are typically adjudicated in State court.

IV. Summary and Disposition of Comments

Public Comments

On December 16, 2020, we published a **Federal Register** notice (85 FR 81436) (Administrative Record Number 1652) and requested comments on the proposed revisions to the program. We received comments from West Virginia Coal Association (WVCA) by hardcopy and one comment by a citizen through a public meeting held virtually on

January 14, 2022. These comments are summarized and addressed below.

A. WVCA stated in its letter that the plain language of the Federal regulations make clear that the operator decides whether to repair a structure or facility or pay compensation in the amount of the diminution in value. WVCA traced much of the regulatory history of our regulation at 30 CFR 817.121 from 1979 to present in support of its assertion. WVCA asserts that the current amendment, which gives the surface landowner the power to choose the remedy, makes CSR 38–2–16.2.c.2 more stringent than the Federal requirement and strikes a fair and equitable balance between common law property rights and the duty to protect surface owners from the potentially adverse impacts of coal extraction.

OSMRE Response: Because the comments support the approval of the amendment, a position with which OSMRE agrees, we are making no response. A discussion of our findings is in Section III.B., above.

B. WVCA stated that the revision to CSR 38–2–11.3.a.3 makes this regulation functionally identical to the corresponding provision of the Federal regulations and supports its approval.

OSMRE Response: Because the comments support the approval of the amendment, a position with which OSMRE agrees, we are making no response. A discussion of our findings is in section III.A., above.

C. A commenter stated that the rights of the surface and mineral owners and other persons with legal interest in the land should be adequately protected. The commenter noted that CSR 38–2–16.2.c.2 is similar, if not verbatim, to the correlating Federal regulation and asserted that under these provisions, if a monetary settlement cannot be reached, the surface owner can require the coal operator to repair the structures or facilities without a stated restriction as to cost. The commenter argued that eliminating the operator's obligation to repair the structure or facility and placing a limit on the amount of compensation for repair is inequitable due to the variability and difficulty of appraising the value of certain structures and facilities, including homes on different acreages, barns, utility buildings, and bridges that allow access to the property. The commenter stated that this has led to scenarios where the cost of repair greatly exceeded 120% of the pre-mining value of the structure or facility.

OSMRE Response: While we acknowledge that under certain circumstances the cost to repair a structure or facility could exceed 120%

of both the pre-mining value and the diminution in value, we disagree that the Federal program allows the surface landowner to require repair without any stated restriction as to cost. We have never interpreted section 720(a)(1) to require an operator to repair a structure or facility at any cost, as evidenced by the regulatory history of 30 CFR 817.121 and the operator's option under section 720(a)(1) to fulfill this requirement with a premium-prepaid insurance policy. We agree that variability and difficulties exist in the process of appraising the value of structures and facilities, but operators and landowners that disagree over those issues may seek resolution in a court with jurisdiction to adjudicate them.

Federal Agency Comments

On May 5, 2020 (Administrative Record No. WV-1646), under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the West Virginia program. We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). OSMRE determined that none of the proposed State revisions pertained to air or water quality standards; therefore, EPA's concurrence was not requested on this amendment. EPA did not respond with any comments to this amendment.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On May 5, 2020, we requested comments on West Virginia's amendment (Administrative Record No. 1646). We did not receive comments from the SHPO or ACHP.

V. OSMRE's Decision

Based on the above findings, we are approving the West Virginia amendment that was submitted on May 5, 2020 (Administrative Record No. 1640). To implement this decision, we are amending the Federal regulations at 30 CFR part 948 that codify decisions

concerning the West Virginia program. In accordance with the Administrative Procedure Act (5 U.S.C. 533), this rule will take effect 30 days after the date of publication.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This rule would not effect a taking of private property or otherwise have taking implications that would result in public property being taken for government use without just compensation under the law. Therefore, a takings implication assessment is not required. This determination is based on an analysis of the corresponding Federal regulations.

Executive Orders 12866—Regulatory Planning and Review, Executive Order 13563—Improving Regulation and Regulatory Review, and Executive Order 14094—Modernizing Regulatory Review

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993 (OMB Memo M-94-3), the approval of State program amendments is exempted from OMB review under Executive Order 12866, as amended by Executive Order 14094. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by section 3 of Executive Order 12988. The Department determined that this **Federal Register** document meets the criteria of section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency's legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive Order to the quality of this **Federal Register** document and to changes to the Federal regulations. The

review under this Executive Order did not extend to the language of the State regulatory program or the amendment that the State of West Virginia drafted.

Executive Order 13132—Federalism

This rule has potential Federalism implications as defined under section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to "grant the States the maximum administrative discretion possible" with respect to Federal statutes and regulations administered by the States. West Virginia, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the State level. This rule approves an amendment to the West Virginia program submitted and drafted by the State, and thus is consistent with the direction to provide maximum administrative discretion to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on the distribution of power and responsibilities between the Federal government and Tribes. The basis for this determination is that our decision on the West Virginia program does not include Indian lands as defined by SMCRA or other Tribal lands and it does not affect the regulation of activities on Indian lands or other Tribal lands. Indian lands under SMCRA are regulated independently under the applicable approved Federal Indian program. The Department's consultation policy also acknowledges that our rules may have Tribal implications where the State proposing the amendment encompasses ancestral lands in areas with mineable coal. We are currently working to identify and engage appropriate Tribal stakeholders to devise a constructive approach for consulting on these amendments.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is

(1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not a significant energy action under the definition in Executive Order 13211, a Statement of Energy Effects is not required.

National Environmental Policy Act

Consistent with sections 501(a) and 702(d) of SMCRA (30 U.S.C. 1251(a) and 1292(d), respectively) and the U.S. Department of the Interior Departmental Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601

et seq.). The State submittal, which is the subject of this rule, is based upon corresponding Federal regulations for which an economic analysis was prepared, and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) does not have an annual effect on the economy of \$100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or

Tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,

Regional Director, North Atlantic—Appalachian Region.

For the reasons set out in the preamble, 30 CFR part 948 is amended as set forth below:

PART 948—WEST VIRGINIA

■ 1. The authority citation for part 948 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 948.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 948.15 Approval of West Virginia regulatory program amendment.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
May 5, 2020	August 8, 2024	11.3.a.3—(Surety Bonds; quarterly statements; corporate surety licensed in the State.) 16.2.c.2—(Owner Compensation; repair)

[FR Doc. 2024–17334 Filed 8–7–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0695]

RIN 1625–AA00

Safety Zone; Upper Mississippi River, Mile Marker 497.6—497.2 LeClaire, IA and Port Byron, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Upper Mississippi River from mile marker 497.6 to 497.2. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the Great River Tug Fest and Firework display. Entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port, Sector Upper Mississippi River, or a designated representative.

DATES: This rule is effective from 8:30 p.m. August 9, 2024 through 11 p.m. August 10, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0695 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Lars Okmark, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email Lars.Okmark@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 NPRM Notice of proposed rulemaking
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule, as doing so would be impracticable. This is because we must establish this safety zone by August 9, 2024 to protect the personnel, vessels, and the marine environment from the potential dangers associated with fireworks and the festival events including a tug of war across the river. We therefore lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because rapid action is needed to respond to the potential hazards created by heavy recreational and commercial marine traffic, a fireworks display, and the “tug of war” and other events associated with the Great River Tug Fest and Firework display starting August 9, 2024.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Upper Mississippi River (COTP) has determined a safety zone is necessary to protect personnel, vessels, and the marine environment in the navigable waters from potential hazards created by the Great River Tug Fest and Firework display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on the waters of the Upper Mississippi River from mile markers 497.6 to 497.2 in LeClaire, IA and Port Byron, IL, from 8:30 p.m. August 9, 2024 to 11 p.m. on August 10, 2024. The

safety zone is subject to enforcement during the following times: 8:30 p.m. to 11 p.m. on August 9, 2024; 10:30 a.m. to 4 p.m. on August 10, 2024; and 8:30 p.m. to 11 p.m. on August 10, 2024. Fireworks are scheduled for the evening of August 9, 2024, with a rain date scheduled for the evening of August 10, 2024. Other Tug Fest activities requiring a safety zone are occurring late morning through late afternoon of August 10, 2024. The duration of this safety zone is intended to protect personnel, vessels, and the marine environment from potential hazards created by the Great River Tug Fest and Firework display. This rule resulted from concerns about the high number of recreational vessels attending the festival and fireworks display that will create unsafe conditions when combined with passing barge traffic on the Upper Mississippi River from MM 497.6 to 497.2. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. As used in this section, a designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Upper Mississippi River or a Federal, State, or local officer designated by or assisting the COTP. The COTP or a designated representative will inform the public of the enforcement date and times for these safety zones, as well as any emergent safety concerns that may delay the enforcement of the zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, and duration of the temporary safety zone. This action involves a safety zone to protect

personnel, vessels, and the marine environment from potential hazards created by the Great River Tug Fest and Firework display. This rule resulted from concerns about a high number of recreational vessels attending the fest and firework display that will create unsafe conditions when combined with passing barge traffic on the Upper Mississippi River from MM 497.6 to 497.2. In addition, the rule will only close the river for short periods of time for two days. Moreover, the Coast Guard will publish a Local Notice to Mariners and mariners may seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain

about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone on the Upper Mississippi River from MM 497.6 to 497.2 for short periods of time over two days. It is

categorically excluded from further review under paragraph L60(a) of appendix A, table 1 of DHS Instruction Manual 023–01–001–01, Rev. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0695 to read as follows:

§ 165.T08–0695 Safety Zone; Upper Mississippi River, Mile Markers 497.6 to 497.2 LeClaire, IA and Port Byron, IL.

(a) *Location.* The following area is a safety zone: all navigable waters within the Upper Mississippi River from Mile Marker 497.6 to 497.2.

(b) *Enforcement period.* This section will be subject to enforcement from 8:30 p.m. to 11 p.m. on August 9, 2024, from 10:30 a.m. to 4 p.m. on August 10, 2024, and from 8:30 p.m. to 11 p.m. on August 10, 2024.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated

representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: July 31, 2024.

A.R. Bender,

Captain, U.S. Coast Guard, Captain of the Port, Sector Upper Mississippi River.

[FR Doc. 2024–17368 Filed 8–7–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2022–0939; FRL–11911–01–OCSPP]

Ophioglossum pendulum IPD079Ea Protein; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Ophioglossum pendulum* IPD079Ea protein (hereafter IPD079Ea protein) when used as a plant incorporated protectant (PIP) in or on the food and feed commodities of corn: corn, field; corn, sweet, and corn, pop. Pioneer Hi-Bred International, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of IPD079Ea protein.

DATES: This regulation is effective August 8, 2024. Objections and requests for hearings must be received on or before October 7, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0939, is

available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and for the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Madison Le, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–

OPP–2022–0939 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 7, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0939, by one of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of January 3, 2023 (88 FR 38) (FRL–9410–08), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F9010 by Pioneer Hi-Bred International, Inc., 7100 NW 62 Avenue, P.O. Box 1000, Johnston, IA 50131–1000). The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of *Ophioglossum pendulum* IPD079Ea insecticidal protein in or on corn. That document referenced a summary of the petition prepared by the petitioner Pioneer Hi-Bred International, Inc., which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other factors, “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicity and exposure data on IPD079Ea protein and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Product Characterization Review and Human Health Risk Assessment of the Insecticidal Plant-Incorporated Protectant Active Ingredient *Ophioglossum pendulum* IPD079Ea Protein and the Genetic Material Necessary (PHP83175) for its Production in DP–915635–4 maize and Establishment of a Permanent Tolerance Exemption” (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA–HQ–OPP–2022–0939.

The IPD079Ea protein, encoded by the *ipd079Ea* gene from *Ophioglossum pendulum* (common name: ribbon fern), a Southeast Asian epiphyte, confers control of *Diabrotica virgifera virgifera* (Western Corn Rootworm) when expressed in corn plants. An assessment of the toxic and allergenic potential of the IPD079Ea protein indicates that the IPD079Ea protein is not likely to be a potential toxin or allergen by any route of exposure. Dietary exposure is deemed the most relevant route for assessing human health risk of IPD079Ea protein, as corn products are made from grains and are consumed regularly by the American public. However, exposure to IPD079Ea protein through consumption of corn products containing the protein is expected to be very low given its very low levels of expression in grain. Oral exposure to IPD079Ea protein via drinking water is considered unlikely because the protein is already expressed at very low levels in the whole corn plant. Further, leaching into the soil and groundwater, combined with environmental conditions and microbial activity, is expected to further reduce its presence in drinking water. Although there may be dietary exposure to residues of IPD079Ea protein, such exposure presents no concern for adverse effects. Acute oral toxicity data demonstrated a lack of mammalian toxicity at high levels of exposure to pure IPD079Ea protein, and a bioinformatics analysis showed no similarities between the IPD079Ea protein and known toxic proteins that would raise a safety concern. Likewise, the potential for allergenicity is low because (1) there is no information in the literature indicating that *Ophioglossum pendulum* is a known source of allergenic proteins, (2) a bioinformatics analysis showed that the IPD079Ea protein does not have significant homology with known or putative allergens, (3) the IPD079Ea protein degrades rapidly (within 30 seconds) in the presence of simulated gastric fluid, indicating the protein will not be intact after stomach digestion, (4) the IPD079Ea protein is inactivated at high temperatures (50 °C/122 °F), such as those experienced by cooking corn products, and (5) the protein is not glycosylated, which further reduces its allergenicity potential. Glycosylation is an enzymatic post-translational process in which carbohydrates (glycans) link to proteins, creating structures which could lead to an immune response in humans.

Residential and non-occupational exposures are expected to be minimal given that the IPD079Ea protein is a

plant-incorporated protectant in corn. The only possible route of non-occupational exposure other than dietary is via handling of the plants and plant products. Exposures via the skin or inhalation are expected to be minimal given that the IPD079Ea protein is embedded in the matrix of the plant, which essentially eliminates or reduces dermal and inhalation routes of exposure to negligible levels. Furthermore, IPD079Ea protein expression in leaf tissue, forage, and pollen is very low. Together, there are no risks associated with these exposure routes because IPD079Ea protein is present in the plant at low levels and is not toxic or allergenic. These findings are discussed in more detail in the Human Health Risk Assessment.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” EPA has not found the IPD079Ea protein to share a common mechanism of toxicity with any other substances, and the IPD079Ea protein does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has assumed that IPD079Ea protein does not have a common mechanism of toxicity with other substances.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity and allergenicity of the IPD079Ea protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation described above and in the Human Health Risk Assessment, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the IPD079Ea protein. Therefore, an exemption from the requirement of a tolerance is established for residues of the IPD079Ea protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as a plant-incorporated protectant in corn.

B. Analytical Enforcement Methodology

EPA has determined that an analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any

numerical limitation. Nonetheless, a protocol for a lateral flow test kit was submitted for detection of IPD079Ea protein. The submitted protocol adequately describes the methodology.

IV. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order

13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 25, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

- 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

- 2. Add § 174.547 to subpart W to read as follows:

§ 174.547 *Ophioglossum pendulum* IPD079Ea protein; exemption from the requirement of a tolerance.

Residues of *Ophioglossum pendulum* IPD079Ea protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–17419 Filed 8–7–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0079; FRL–11964–01–OCSPP]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on multiple crops listed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 8, 2024. Objections and requests for hearings must be received on or before October 7, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0079, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document

applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Office of the Federal Register’s e-CFR site at: <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2023–0079 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 7, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2023–0079, by one of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets>.

www.epa.gov/dockets/where-send-comments-epa-dockets.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, are available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 29, 2024 (89 FR 14795) (FRL-11682-01-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E9044) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to amend 40 CFR part 180 by establishing tolerances for residues of indoxacarb in or on the raw agricultural commodities *Brassica*, leafy greens, subgroup 4-16B at 12 parts per million (ppm); Celtnce at 14 ppm; Chickpea, dry seed at 0.2 ppm; Coffee, green bean at 0.03 ppm; Cottonseed subgroup 20C at 2 ppm; Fennel, Florence, fresh leaves and stalk at 14 ppm; Field corn subgroup 15-22C at 0.02 ppm; Fruit, pome, group 11-10, except pear at 1 ppm; Fruit, stone, group 12-12 at 1 ppm; Kohlrabi at 12 ppm; Leaf petiole vegetable subgroup 22B at 14 ppm; Leafy greens subgroup 4-16A at 14 ppm; Pear, asian at 0.2 ppm; Strawberry at 4 ppm; Sunflower subgroup 20B at 1.5 ppm; Sweet corn subgroup 15-22D at 0.02 ppm; Vegetable, *brassica*, head and stem, group 5-16 at 12 ppm; Vegetable, legume, bean, edible podded, subgroup 6-22A at 0.9 ppm; Vegetable, legume, bean, succulent shelled, subgroup 6-22C at 0.9 ppm; Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E at 0.2 ppm; and Vegetable, fruiting, group 8-10 at 0.5 ppm.

The petition also proposed to remove established tolerances for residues of indoxacarb in or on the following: Bean, dry seed; Bean, succulent; Corn, field, grain; Corn, pop, grain; Corn, sweet, kernel plus cob with husk removed; Cotton, undelinted seed; Fruit, pome, except pear, group 11; Fruit, stone, group 12; Okra; Pea, southern, seed; Pear, oriental; Turnip, greens; Vegetable, *Brassica*, leafy, group 5; Vegetable, fruiting, group 8; and Vegetable, leafy, except *Brassica*, group 4.

That document referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indoxacarb including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with indoxacarb follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published several tolerance rulemakings for indoxacarb, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to indoxacarb and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the

studies received and the nature of the adverse effects caused by indoxacarb, can be found in the document titled “Indoxacarb. Human Health Risk Assessment for Section 3 Registration in/on Coffee, Strawberry, and Sunflower Crop Subgroup 20B; and Crop Group Conversions and Expansions” which is available in the docket for this action at <https://www.regulations.gov>.

Toxicological profile. For a discussion of the Toxicological Profile of indoxacarb, see Unit III.A. of the rulemaking published in the **Federal Register** of December 8, 2017 (82 FR 57860) (FRL-9970-39).

Toxicological points of departure/ Levels of concern. For a summary of the Toxicological Points of Departure/ Levels of Concern used for the safety assessment of indoxacarb, see Unit III.B. of the December 8, 2017, rulemaking.

Exposure assessment. Much of the exposure assessment remains unchanged from the rulemaking published on December 8, 2017, although the new exposure assessment incorporates the additional dietary exposure from the petitioned-for tolerances. Other changes are described below.

Acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). Partially refined acute probabilistic and chronic dietary analyses were conducted using percent crop treated data. For food commodities, residue distribution files were constructed from field trial residues for the probabilistic acute dietary assessment as appropriate, and average residues were computed for blended commodities and for the chronic dietary assessment.

Anticipated residue and percent crop treated information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized

under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.

- *Condition c:* Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute dietary risk assessment, the following maximum PCT estimates were used: apples (15%); apricots (15%); broccoli (40%), cabbage (35%); cauliflower (50%); celery (10%); cherries (2.5%); corn (2.5%); cotton (2.5%); cucumbers (10%); lettuce (15%); nectarines (40%); peaches (15%); peanuts (5%); peppers (20%); plums/prunes (15%); potatoes (2.5%); pumpkins (2.5%); soybeans (2.5%); spinach (2.5%); squash (10%); sweet corn (5%); tomatoes (15%); and watermelons (2.5%).

For the chronic dietary assessment, the following average PCT estimates were used: apples (10%); apricots (2.5%); broccoli (30%), cabbage (20%); cauliflower (25%); celery (5%); cherries (1%); corn (1%); cotton (1%); cucumbers (2.5%); lettuce (5%); nectarines (30%); peaches (10%); peanuts (1%); peppers (10%); plums (5%); potatoes (1%); prunes (1%); pumpkins (1%); soybeans (1%); spinach (1%); squash (2.5%); sweet corn (1%); tomatoes (10%); and watermelons (1%).

For all other crop commodities with indoxacarb uses and for the proposed new uses of indoxacarb, the assessment assumed that 100% of the crop was treated.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10

years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5% as the average PCT value, respectively. In those cases, the Agency would use 1% or 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses 2.5% as the maximum PCT.

The Agency believes that Conditions a, b, and c discussed above have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which indoxacarb may be applied in a particular area.

Drinking water and non-occupational exposures. For a summary of the drinking water numbers used, see Unit III.A. of the November 16, 2020, rulemaking (85 FR 72968) (FRL-10012-78). An acute estimated drinking water concentration (EDWC) of 131 parts per billion (ppb) and a chronic EDWC of 123 ppb were used in the acute and chronic dietary exposure assessments, respectively.

There are no residential/non-occupational uses of indoxacarb

proposed for the current action, however, there are currently registered uses of indoxacarb that may result in residential handler and post-application exposures. The residential exposure scenarios used in the aggregate exposure assessment are as follows: the short-term residential exposure for use in the child (1 to less than 2 years old) aggregate assessment is incidental oral (hand to mouth) exposures from post-application exposure resulting from spot (course/pin stream) applications to hard/carpeted surfaces and the intermediate-/long-term residential exposure for use in the child (1 to less than 2 years old) aggregate assessment is incidental oral (hand to mouth) exposures from post-application exposure to treated pets (dogs).

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to indoxacarb and any other substances and indoxacarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that indoxacarb has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D. of the December 8, 2017, rulemaking.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD;

they are 57% of the aPAD for children 1 to 2 years old, which is the population subgroup with the highest exposure estimate. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD; they are 50% of the cPAD for all infants less than one year old, which is the population subgroup with the highest exposure estimate.

The short- and intermediate-term aggregate risks combine chronic dietary (food and drinking water) and short- and intermediate-term residential exposures. For the short-term aggregate risk for children 1 to less than 2 years old, the aggregate MOE is 120. For the intermediate/long-term aggregate risk for children 1 to less than 2 years old, the aggregate MOE is 250. MOEs below 100 are of concern; these MOEs are above 100 and therefore are not of concern.

Because indoxacarb is classified as "not likely to be carcinogenic to humans", EPA has concluded that aggregate exposure to indoxacarb is not likely to pose a cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to indoxacarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the November 16, 2020, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The U.S. and Codex are harmonized with respect to the residue definition for the commodities included in this petition. There are no Codex MRLs for sunflower, coffee, and strawberry. The U.S. tolerance for residues of indoxacarb in or on stone fruit group 12–12 is harmonized with the Codex MRL for stone fruits at 1 ppm, and the U.S. tolerance for residues of indoxacarb in or on Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E is harmonized with the Codex MRL for mung bean (dry) at 0.2 ppm.

The U.S. tolerance levels are not harmonized with Codex commodity MRLs for the following groups/subgroups: Cottonseed subgroup 20C; Fruit, pome, group 11–10, except pear; Leafy greens subgroup 4–16A; Vegetable, *brassica*, head and stem, group 5–16; dry cowpea (part of Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E); and Vegetable, fruiting, group 8–10. Based on available residue data, use by U.S. growers consistent with approved label instructions would result in residues that exceed the Codex MRL. Harmonizing with these Codex MRLs could put U.S. growers at risk of violative residues despite legal use of indoxacarb. Moreover, EPA's regulations (40 CFR 152.112(g)) require adequate tolerances to be in place in order to register a pesticide for use on food. Tolerances harmonized with the Codex MRL would not be adequate to cover residues associated with the labeled use of the pending pesticide application with which these tolerances are associated. Since EPA has determined these tolerances are safe, EPA is establishing these tolerances despite the lack of harmonization with the related Codex MRLs.

V. Conclusion

Therefore, tolerances are established for residues of indoxacarb in or on *Brassica*, leafy greens, subgroup 4–16B at 12 ppm; Celtuce at 14 ppm; Chickpea, dry seed at 0.2 ppm; Coffee, green bean at 0.03 ppm; Cottonseed subgroup 20C at 2 ppm; Fennel, florence, fresh leaves and stalk at 14 ppm; Field corn subgroup 15–22C at 0.02 ppm; Fruit, pome, group 11–10, except pear at 1 ppm; Fruit, stone, group 12–12 at 1 ppm; Kohlrabi at 12 ppm; Leaf petiole vegetable subgroup 22B at 14 ppm; Leafy greens subgroup 4–16A at 14 ppm; Pear, asian at 0.2 ppm; Strawberry at 4 ppm; Sunflower subgroup 20B at 1.5 ppm; Sweet corn subgroup 15–22D at 0.02 ppm; Vegetable, *brassica*, head and stem, group 5–16 at 12 ppm; Vegetable, fruiting, group 8–10 at 0.5 ppm; Vegetable, legume, bean, edible podded, subgroup 6–22A at 0.9 ppm; Vegetable, legume, bean, succulent shelled, subgroup 6–22C at 0.9 ppm; and Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E at 0.2 ppm.

Additionally, the established tolerances on Bean, dry seed; Bean, succulent; Corn, field, grain; Corn, pop, grain; Corn, sweet, kernel plus cob with husk removed; Cotton, undelinted seed; Fruit, pome, except pear, group 11; Fruit, stone, group 12; Okra; Pea, southern, seed; Pear, oriental; Turnip,

greens; Vegetable, *Brassica*, leafy, group 5; Vegetable, fruiting, group 8; and Vegetable, leafy, except *Brassica*, group 4, are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal

Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 31, 2024.
Charles Smith,
Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.564, is amended by revising and republishing table 1 to paragraph (a)(1) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa, forage	10
Alfalfa, hay	50
Almond, hulls	8
Apple, wet pomace	3.0
Beet, garden, roots	0.30
Beet, garden, tops	6.0
Berry, low growing, except strawberry, subgroup 13–07H	1
Brassica, leafy greens, subgroup 4–16B	12
Bushberry subgroup 13–07B	1.5
Cattle, fat	1.5
Cattle, meat	0.05
Cattle, meat byproducts	0.03
Celtuce	14
Chickpea, dry seed	0.2
Coffee, green bean	0.03
Corn, field, forage	6.0
Corn, field, stover	15
Corn, pop, stover	15
Corn, sweet, forage	10
Corn, sweet, stover	15
Cotton, gin byproducts	15
Cottonseed subgroup 20C	2
Cowpea, forage	50
Cowpea, hay	100
Fennel, florence, fresh leaves and stalk	14
Field corn subgroup 15–22C	0.02
Fruit, pome, group 11–10, except pear	1
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2
Fruit, stone, group 12–12	1
Goat, fat	1.5
Goat, meat	0.05
Goat, meat byproducts	0.03
Grain, aspirated fractions	45
Grape, raisin	5.0
Hog, fat	1.5
Hog, meat	0.05
Hog, meat byproducts	0.03
Horse, fat	1.5
Horse, meat	0.05
Horse, meat byproducts	0.03
Kohlrabi	12
Leaf petiole vegetable subgroup 22B	14
Leafy greens subgroup 4–16A	14
Milk	0.15
Milk, fat	4.0
Nut, tree, group 14–12	0.08
Peanut	0.01

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Peanut, hay	40
Pear	0.20
Pear, asian	0.2
Peppermint, tops	11
Sheep, fat	1.5
Sheep, meat	0.05
Sheep, meat byproducts	0.03
Soybean, hulls	4.0
Soybean, seed	0.80
Spearmint, tops	11
Strawberry	4
Sunflower subgroup 20B	1.5
Sweet corn subgroup 15–22D	0.02
Vegetable, <i>brassica</i> , head and stem, group 5–16	12
Vegetable, cucurbit, group 9	0.60
Vegetable, fruiting, group 8–10	0.5
Vegetable, legume, bean, edible podded, subgroup 6–22A	0.9
Vegetable, legume, bean, succulent shelled, subgroup 6–22C	0.9
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E	0.2
Vegetable, tuberous and corm, subgroup 1–C	0.01

* * * *

[FR Doc. 2024–17371 Filed 8–7–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 102****RIN 0991–AC34****Annual Civil Monetary Penalties Inflation Adjustment**

AGENCY: Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalty (CMP) amounts in its statutes and regulations, under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES:

Effective date: This final rule is effective August 8, 2024.

Applicability date: The adjusted civil monetary penalty amounts apply to penalties assessed on or after August 8, 2024, if the violation occurred on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT:

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Avenue SW, Washington, DC 20201; (202) 260–6677.

SUPPLEMENTARY INFORMATION:**I. Background**

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74) (the “2015 Act”) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890 (1990)), which is intended to improve the effectiveness of CMPs and to maintain the deterrent effect of such penalties, requires agencies to adjust the CMPs for inflation annually.

HHS lists the CMP authorities and the amounts administered by all of its agencies in tabular form in 45 CFR 102.3, which was issued in an interim final rule published in the September 6, 2016, issue of the **Federal Register** (81 FR 61538). Annual adjustments were subsequently published in the **Federal Register** on February 3, 2017 (82 FR 9175), October 11, 2018 (83 FR 51369), November 5, 2019 (84 FR 59549), January 17, 2020 (85 FR 2869), November 15, 2021 (86 FR 62928), March 17, 2022 (87 FR 15100), and October 6, 2023 (88 FR 69531).

II. Calculation of Annual Inflation Adjustment and Other Updates

The annual inflation adjustment for each applicable CMP is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each CMP was most recently established or modified. In the December 19, 2023, Office of

Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M–24–07, “Implementation of Penalty Inflation Adjustments for 2024, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,” OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2024, based on the CPI–U for the month of October 2023, not seasonally adjusted, is 1.03241. The multiplier is applied to each applicable penalty amount that was updated and published for fiscal year (FY) 2023 and is rounded to the nearest dollar.

In addition to the inflation adjustments for 2023, this final rule makes a few non-substantive changes to punctuation in the table in 45 CFR 102.3.

III. Statutory and Executive Order Reviews and Waiver of Proposed Rulemaking

The 2015 Act requires Federal agencies to publish annual penalty inflation adjustments notwithstanding section 553 of the Administrative Procedure Act (APA). Section 4(a) of the 2015 Act directs Federal agencies to publish annual adjustments no later than January 15th of each year thereafter. In accordance with section 553 of the APA, most rules are subject to notice and comment and are effective no earlier than 30 days after publication in the **Federal Register**. However, section 4(b)(2) of the 2015 Act provides that each agency shall make the annual inflation adjustments “notwithstanding

section 553” of the APA. According to OMB’s Memorandum M–24–07, the phrase “notwithstanding section 553” in section 4(b)(2) of the 2015 Act means that “the public procedure the APA generally requires—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.”

Consistent with the language of the 2015 Act and OMB’s implementation guidance, the inflation adjustments set out in this rule are not subject to notice and an opportunity for public comment and will be effective immediately upon publication.

Pursuant to OMB Memorandum M–24–07, HHS has determined that the annual inflation adjustment to the civil monetary penalties in its regulations does not trigger any requirements under

procedural statutes and Executive Orders that govern rulemaking procedures.

IV. Effective and Applicability Dates

This rule is effective on the date specified in the **DATES** section of this final rule. The adjusted civil monetary penalty amounts apply to penalties assessed on or after the date specified in the **DATES** section of this final rule, if the violation occurred on or after November 2, 2015 (*i.e.*, the date of enactment of the 2015 Act). If the violation occurred before November 2, 2015, or a penalty was assessed before September 6, 2016, the pre-adjustment civil penalty amounts in effect before September 6, 2016, will apply.

List of Subjects in 45 CFR Part 102

Administrative practice and procedure, Penalties.

For reasons discussed in the preamble, the Department of Health and Human Services amends subtitle A, title 45 of the Code of Federal Regulations as follows:

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 1. The authority citation for part 102 continues to read as follows:

Authority: Pub. L. 101–410, Sec. 701 of Pub. L. 114–74, 31 U.S.C. 3801–3812.

■ 2. Amend § 102.3 by revising table 1 to read as follows:

§ 102.3 Penalty adjustment and table.

* * * * *

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$) ⁴	2024 Maximum adjusted penalty (\$) ⁴
21 U.S.C.:						
333(b)(2)(A)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	2023	123,965	127,983
333(b)(2)(B)		FDA	Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	2023	2,479,282	2,559,636
333(b)(3)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	2023	247,929	255,964
333(f)(1)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	2023	33,483	34,568
333(f)(2)(A)		FDA	Penalty for aggregate of all violations related to devices in a single proceeding.	2023	2,232,281	2,304,629
		FDA	Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350i.	2023	94,128	97,179
		FDA	Penalty in the case of any other person (other than an individual) for such introduction or delivery of adulterated food.	2023	470,640	485,893
		FDA	Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	2023	941,280	971,787
333(f)(3)(A)		FDA	Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(j) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C. 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D).	2023	14,262	14,724
333(f)(3)(B)		FDA	Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	2023	14,262	14,724
333(f)(4)(A)(i)		FDA	Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355-1 (REMS).	2023	356,580	368,137
333(f)(4)(A)(ii)		FDA	Penalty for aggregate of all such above violations in a single proceeding	2023	1,426,319	1,472,546
		FDA	Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	2023	356,580	368,137
		FDA	Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2023	1,426,319	1,472,546
		FDA	Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2023	14,263,186	14,725,456
333(f)(9)(A)		FDA	Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2023	20,678	21,348
		FDA	Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2023	1,378,541	1,423,220
333(f)(9)(B)(i)(I)		FDA	Penalty per violation related to violations of tobacco requirements	2023	344,636	355,806
333(f)(9)(B)(i)(II)		FDA	Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2023	1,378,541	1,423,220
		FDA	Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	2023	344,636	355,806
		FDA	Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2023	1,378,541	1,423,220
		FDA	Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2023	13,785,420	14,232,205

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
333(f)(9)(B)(ii)(I)		FDA	Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products. Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2023	344,636	355,806
333(f)(9)(B)(ii)(II)		FDA	Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation. Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	2023	1,378,541	1,423,220
		FDA	Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2023	344,636	355,806
333(g)(1)		FDA	Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	2023	1,378,541	1,423,220
333 note		FDA	Penalty for each subsequent above violation in any 3-year period	2023	13,785,420	14,232,205
		FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	2023	356,580	368,137
		FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	713,160	736,274
		FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	345	356
		FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	2023	687	709
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2023	2,757	2,846
		FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	2023	6,892	7,115
		FDA	Penalty in the case of a second violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 12-month period.	2023	13,785	14,232
		FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	345	356
		FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	687	709
		FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	1,379	1,424
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2023	2,757	2,846
335b(a)		FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	2023	6,892	7,115
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2023	13,785	14,232
		FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	2023	525,406	542,434

360pp(b)(1)	FDA	Penalty in the case of any other person (other than an individual) per above violation.	2023	2,101,618	2,169,731
	FDA	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	2023	3,446	3,558
	FDA	Penalty imposed for any related series of violations of requirements relating to electronic products.	2023	1,174,880	1,212,751
42 U.S.C	FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	2023	270,180	278,937
262(d)	FDA	Penalty for failure to obtain a mammography certificate as required	2023	21,018	21,699
263b(h)(3)	FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	2023	270,180	278,937
300aa-28(b)(1)	HRSA	Penalty for each instance of overcharging a 340B covered entity	2023	6,813	7,034
256b(d)(1)(B)(vi)	AHRQ	Penalty for using or disclosing identifiable information obtained in the course of activities undertaken pursuant to Title IX of the Public Health Service Act, for a purpose other than that for which the information was supplied, without consent to do so.	2023	17,717	18,291
299c-3(d)					
653(l)(2)	ACF	Penalty for Misuse of Information in the National Directory of New Hires	2023	1,818	1,877
262a(i)(1)	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2023	410,932	424,250
	OIG	Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2023	821,868	848,505
300jj-51	OIG	Penalty per violation for committing information blocking	2023	1,252,992	1,293,601
1320a-7a(a)	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	2023	24,164	24,947
	OIG	Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	2023	24,164	24,947
	OIG	Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	2023	36,246	37,421
42 CFR 1003.210(a)(2)	OIG	Penalty for an excluded party retaining ownership or control interest in a participating entity.	2023	24,164	24,947
42 CFR 1003.210(a)(3)	OIG	Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	2023	24,164	24,947
42 CFR 1003.1010	OIG	Penalty for employing or contracting with an excluded individual	2023	24,164	24,947
42 CFR 1003.210(a)(4)	OIG	Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	2023	120,816	124,732
42 CFR 1003.310(a)(3)	OIG	Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2023	24,164	24,947
42 CFR 1003.210(a)(1)	OIG	Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2023	120,816	124,732
42 CFR 1003.210(a)(6)	OIG	Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2023	24,164	24,947
42 CFR 1003.210(a)(8)	OIG	Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2023	68,128	70,336
42 CFR 1003.210(a)(7)	OIG	Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2023	36,246	37,421
42 CFR 1003.210(a)(9)	OIG	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2023	6,040	6,236
1320a-7a(b)	OIG	Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2023	6,040	6,236
	OIG	Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	2023		
42 CFR 1003.210(a)(10)	OIG	Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	2023	12,081	12,473
1320a-7a(o)	OIG		2023	11,784	12,166

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 1003.710(a)(2)	OIG	Penalty for knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	2023	58,921	60,831
	42 CFR 1003.710(a)(3)	OIG	Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	2023	58,921	60,831
	42 CFR 1003.710(a)(4)	OIG	Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation, per each false record or statement.	2023	61,458	63,450
	42 CFR 1003.710(a)(5)	OIG	Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation, per day.	2023	12,308	12,707
	42 CFR 1003.710(a)(5)	OIG	Penalty for failure to grant timely access, upon reasonable request, to the I.G. for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	2023	17,677	18,250
1320a–7e(b)(6)(A)	42 CFR 1003.810	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	2023	46,102	47,596
1320b–10(b)(1)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2023	12,397	12,799
1320b–10(b)(2)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2023	61,982	63,991
1395i–3(b)(3)(B)(ii)(1)	42 CFR 1003.210(a)(11)	OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2023	2,586	2,670
1395i–3(b)(3)(B)(ii)(2)	42 CFR 1003.210(a)(11)	OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2023	12,924	13,343
1395i–3(g)(2)(A)	42 CFR 1003.1310	OIG	Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2023	5,171	5,339
1395w–27(g)(2)(A)	42 CFR 1003.410	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	2023	47,061	48,586
		OIG	Penalty for a Medicare Advantage organization that charges excessive premiums.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	184,412	190,389
		OIG	Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	27,661	28,557
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	2023	184,412	190,389
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	2023	46,102	47,596
		OIG	Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	2023	46,102	47,596

1395w-141(i)(3)		OIG		Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2023	46,102	47,596
1395cc(g)		OIG		Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2023	46,102	47,596
1395dd(d)(1)		OIG		Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2023	46,102	47,596
1395mm(i)(6)(B)(i)		OIG		Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	2023	46,102	47,596
42 CFR 1003.210(a)(5)		OIG		Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2023	16,108	16,630
42 CFR 1003.510		OIG		Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	2023	6,266	6,469
42 CFR 1003.410		OIG		Penalty for a hospital with 100 beds or more or responsible physician dumping patients needing emergency medical care.	2023	129,232	133,420
1395nn(g)(3)		OIG		Penalty for a hospital with less than 100 beds dumping patients needing emergency medical care.	2023	64,618	66,712
1395nn(g)(4)		OIG		Penalty for a HMO or competitive medical plan if such plan substantially fails to provide medically necessary, required items or services.	2023	64,618	66,712
1395ss(d)(1)		OIG		Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	2023	64,618	66,712
1395ss(d)(2)		OIG		Penalty for a HMO or competitive medical plan that expels or refuses to enroll an individual per prescribed conditions.	2023	64,618	66,712
1395ss(d)(3)(A)(i)		OIG		Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	2023	258,464	266,841
1395ss(d)(3)(A)(ii)		OIG		Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	2023	37,190	38,395
1395ss(d)(4)(A)		OIG		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	2023	258,464	266,841
1396b(m)(5)(B)(i)		OIG		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	2023	64,618	66,712
1396(b)(3)(B)(ii)(I)		OIG		Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	2023	64,618	66,712
		OIG		Penalty for HMO that employs or contracts with excluded individual or entity for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	2023	59,316	61,238
		OIG		Penalty for circumvention schemes in violation of the Stark Law's restrictions on physician self-referrals.	2023	29,899	30,868
		OIG		Penalty for a material misrepresentation regarding Medicare compliance policies.	2023	199,338	205,799
		OIG		Penalty for selling Medicare policy under false pretense	2023	12,397	12,799
		OIG		Penalty for an issuer that sells health insurance policy that duplicates benefits.	2023	12,397	12,799
		OIG		Penalty for someone other than issuer that sells health insurance that duplicates benefits.	2023	55,808	57,617
		OIG		Penalty for using mail to sell a non-approved Medicare insurance policy	2023	33,483	34,568
		OIG		Penalty for a Medicare MCO that substantially fails to provide medically necessary, required items or services.	2023	12,397	12,799
		OIG		Penalty for a Medicare MCO that charges excessive premiums	2023	61,982	63,991
		OIG		Penalty for a Medicare MCO that improperly expels or refuses to reenroll a beneficiary.	2023	247,929	255,964
		OIG		Penalty per individual who does not enroll as a result of a Medicare MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	37,190	38,395
		OIG		Penalty for a Medicare MCO misrepresenting or falsifying information to the Secretary.	2023	247,929	255,964
		OIG		Penalty for a Medicare MCO misrepresenting or falsifying information to an individual or another entity.	2023	61,982	63,991
		OIG		Penalty for a Medicare MCO that fails to comply with contract requirements with respect to physician incentive plans.	2023	55,808	57,617
		OIG		Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	2023	2,586	2,670

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1396(b)(3)(B)(ii)(II)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	2023	12,924	13,343
1396(g)(2)(A)(i)	42 CFR 1003.1310	OIG	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2023	5,171	5,339
1396r–8(b)(3)(B)	42 CFR 1003.1210	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	2023	223,229	230,464
1396r–8(b)(3)(C)(i)	42 CFR 1003.1210	OIG	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	2023	22,324	23,048
1396r–8(b)(3)(C)(ii)	42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	2023	223,229	230,464
1396(i)(3)(A)	42 CFR 1003.1310	OIG	Penalty for notifying home and community-based providers or settings of survey.	2023	4,465	4,610
11131(c)	42 CFR 1003.810	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	2023	27,018	27,894
11137(b)(2)	42 CFR 1003.810	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	2023	27,018	27,894
299b–22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2023	14,960	15,445
1320(d)–5(a)	45 CFR 160.404(b)(1)(i), (ii)	OCR	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	2023	187	193
1320(d)–5(a)	45 CFR 160.404(b)(2)(i)(A), (B)	OCR	Calendar Year Cap	2023	47,061	48,586
			Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision.	2023	137	141
			Minimum	2023	68,928	71,162
			Maximum	2023	2,067,813	2,134,831
	45 CFR 160.404(b)(2)(ii)(A), (B)	OCR	Calendar Year Cap	2023		
			Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect.	2023		
			Minimum	2023	1,379	1,424
			Maximum	2023	68,928	71,162
	45 CFR 160.404(b)(2)(iii)(A), (B)	OCR	Calendar Year Cap	2023	2,067,813	2,134,831
			Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred.	2023		
			Minimum	2023	13,785	14,232
			Maximum	2023	68,928	71,162
	45 CFR 160.404(b)(2)(iv)(A), (B)	OCR	Calendar Year Cap	2023	2,067,813	2,134,831
			Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred.	2023		
			Minimum	2023	68,928	71,162
			Maximum	2023	2,067,813	2,134,831
42 U.S.C. 300gg–18, 42 U.S.C. 1302	45 CFR 180.90	CMS	Calendar Year Cap	2023	323	333
			Penalty for a hospital's non-compliance with making public standard charges for hospital items and services.	2023		
			Per Day (Maximum)	2023	5,926	6,118

45 CFR 180.90(c)(2)(i)	CMS	Per day penalty for a hospital's noncompliance with making public standard charges for hospital items and services.	328	339
45 CFR 180.90(c)(2)(ii)(A)	CMS	Per day penalty for hospitals with equal to or less than 30 beds	323	333
45 CFR 180.90(c)(2)(ii)(B)	CMS	Per day, per bed penalty for hospitals having at least 31 and up to and including 550 beds.	11	11
45 CFR 180.90(c)(2)(ii)(C)	CMS	Per day penalty for hospitals having greater than 550 beds	2,926	3,021
45 CFR 182.70	CMS	Penalty for a provider's non-compliance with price transparency requirements regarding diagnostic tests for COVID-19.	2023	2023
42 CFR 493.1834(d)(2)(i)	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy.	323	333
42 CFR 493.1834(d)(2)(ii)	CMS	Minimum	7,562	7,807
42 CFR 493.1834(d)(2)(ii)	CMS	Maximum	24,793	25,597
42 CFR 493.1834(d)(2)(iii)	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy.	125	129
45 CFR 147.200(e)	CMS	Minimum	7,437	7,678
45 CFR 158.606	CMS	Maximum	1,362	1,406
45 CFR 180.90	CMS	Penalty for a clinical laboratory's failure to meet SARS-CoV-2 test reporting requirements.	136	140
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	First day of noncompliance	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Each additional day of noncompliance	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Failure to provide the Summary of Benefits and Coverage	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Price against hospital identified by CMS as noncompliant according to §182.50 with respect to price transparency requirements regarding diagnostic tests for COVID-19.	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalties for failure to comply with No Surprises Act requirements on providers, facilities, providers of air ambulance services.	11,445	11,816
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests.	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Minimum	1,362	1,406
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Maximum	13,625	14,067
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Calendar Year Cap	204,384	211,008
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests.	2023	2023
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Minimum	13,625	14,067
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Maximum	136,258	140,674
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Calendar Year Cap	1,362,567	1,406,728
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Requirements for the closure of a facility.	136,258	140,674
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	681	703
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2,045	2,111
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	4,087	4,219
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	9,966	10,289
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for violation of 42 U.S.C. 1320a-8(a)(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	9,399	9,704
42 U.S.C. 300gg-118 note, 300gg-134, 1320a-7h(b)(1)	CMS	Penalty for a representative payee (under 42 U.S.C. 405(i), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	7,805	8,058

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1320b–25(c)(1)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	2023	272,514	281,346
1320b–25(c)(2)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	2023	408,769	422,017
1320b–25(d)(2)		CMS	Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	2023	272,514	281,346
1395b–7(b)(2)(B)	42 CFR 402.105(g)	CMS	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	2023	184	190
1395i–3(h)(2)(B)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements.	2023		
			Minimum	2023	129	133
			Maximum	2023	7,752	8,003
			Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.	2023		
			Minimum	2023	2,586	2,670
			Maximum	2023	25,847	26,685
			Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements.	2023		
			Minimum	2023	7,884	8,140
			Maximum	2023	25,847	26,685
			Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility.	2023		
			Minimum	2023	2,586	2,670
			Maximum	2023	25,847	26,685
			Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.	2023		
			Per Day (Minimum)	2023	7,884	8,140
			Per Day (Maximum)	2023	25,847	26,685
			Per Instance (Minimum)	2023	2,586	2,670
			Per Instance (Maximum)	2023	25,847	26,685
			Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day.	2023		
			Minimum	2023	7,884	8,140
			Maximum	2023	25,847	26,685
			Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day.	2023		
			Minimum	2023	129	133
			Maximum	2023	7,752	8,003
			Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements.	2023		
			Minimum	2023	2,586	2,670
			Maximum	2023	25,847	26,685
			Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2).	2023		
			First occurrence	2023	1,158	1,196
			Incremental increases for each subsequent occurrence	2023	579	598
			Penalty for noncompliance by hospice program with requirements specified in section 1395x(dd) of 42 U.S.C.	2023	10,775	11,124
1395i–6(c)(5)(B)(i)	42 CFR 488.1245	CMS				

42 CFR 488.1245(b)(2)(iii)	CMS	Adjustment to penalties. Maximum penalty assessment for each day a hospice is not in substantial compliance with one or more conditions of participation.	2023	10,775	11,124
42 CFR 488.1245(b)(3)	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.			
		Minimum			
		Maximum	2023	9,158	9,455
42 CFR 488.1245(b)(3)(i)	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	10,775	11,124
42 CFR 488.1245(b)(3)(ii)	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	10,775	11,124
42 CFR 488.1245(b)(3)(iii)	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	9,697	10,011
42 CFR 488.1245(b)(4)	CMS	Penalty imposed for hospice repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes. These amounts represent the middle range of penalty.	2023	9,158	9,455
		Minimum			
		Maximum	2023	1,616	1,668
42 CFR 488.1245(b)(5)	CMS	Penalty imposed for hospice repeat or condition-level deficiency or both that does not constitute immediate jeopardy and are related predominantly to structure or process-oriented conditions rather than directly related to patient outcomes. These amounts represent the lower range of penalty.	2023	9,158	9,455
		Minimum			
		Maximum	2023	539	556
42 CFR 488.1245(b)(6)	CMS	Penalty range imposed for per instance of hospice noncompliance	2023	4,310	4,450
		Minimum			
		Maximum	2023	1,077	1,112
42 CFR 488.1245(d)(1)(ii)	CMS	Penalty for each per instance of hospice noncompliance, maximum per day per hospice program.	2023	10,775	11,124
42 CFR 402.105(d)(2)(i)	CMS	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	10,775	11,124
1395(h)(5)(D)		Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	2023	18,825	19,435
1395(i)(6)	CMS	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2023	4,960	5,121
42 CFR 402.105(a)	CMS	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	4,745	4,899
42 CFR 402.1(c)(4), 402.105(d)(2)(ii)	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
42 CFR 402.1(c)(5), 402.105(d)(2)(iii)	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
42 CFR 402.1(c)(6), 402.105(d)(2)(iv)	CMS	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowing and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(1)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
42 CFR 402.1(c)(8), 402.105(d)(2)(vi)	CMS		2023	18,825	19,435

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395m(j)(2)(A)(iii)		CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	2023	1,993	2,058
1395m(j)(4)	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395m–1(a)	42 CFR 414.504(e)	CMS	Penalty for an applicable entity that has failed to report or made a misrepresentation or omission in reporting applicable information with respect to a clinical diagnostic laboratory test.	2023	12,551	12,958
	42 CFR 402.1(c)(31), 402.105(d)(3) ...	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395m(j)(6)	42 CFR 402.1(c)(32), 402.105(d)(4) ...	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(b)(18)(B)	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(j)(2)(B)	42 CFR 402.1(c)	CMS	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a–7a(a)).	2023	18,825	19,435
1395u(k)	42 CFR 402.1(c)(12), 402.105(d)(2)(ix), 1834A(a)(9) and 42 CFR 414.504(e).	CMS	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(l)(3)	42 CFR 402.1(c)(13), 402.105(d)(2)(x)	CMS	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(m)(3)	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	CMS	Penalty for any nonparticipating physician charging more than \$500 who does not accept payment for an elective surgical procedure on an assignment-related basis and who knowingly and willfully fails to disclose the required information regarding charges and insurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(n)(3)	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	CMS	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435

1395u(o)(3)(B)	42 CFR 414.707(b)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395u(p)(3)(A)		CMS	Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	2023	4,960	5,121
1395w-3a(d)(4)(A)	42 CFR 414.806	CMS	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	2023	16,108	16,630
1395w-4(g)(1)(B)	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	CMS	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395w-4(g)(3)(B)	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	CMS	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395w-27(g)(3)(A); 1857(g)(3); 1860D-12(b)(3)(E).	42 CFR 422.760(b); 42 CFR 423.760(b).	CMS	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.	2023	46,102	47,596
1395w-27(g)(3)(B); 1857(g)(3); 1860D-12(b)(3)(E).		CMS	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	2023	18,442	19,040
1395w-27(g)(3)(D); 1857(g)(3); 1860D-12(b)(3)(E).		CMS	Penalty for a Medicare Advantage organization or Part D sponsor's early termination of its contract.	2023	171,257	176,807
1395y(b)(3)(C)	42 CFR 411.103(b)	CMS	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	2023	11,162	11,524
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20), 42 CFR 402.105(b)(2).	CMS	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	2023	1,818	1,877
1395y(b)(6)(B)	42 CFR 402.1(c)(20), 402.105(a)	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2023	3,988	4,117
1395y(b)(7)(B)(i)	42 CFR 402.1(c)(21), 402.105(a)	CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2023	1,428	1,474
1395y(b)(8)(E)		CMS	Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	2023	1,428	1,474
1395nn(g)(5)	42 CFR 411.361	CMS	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	2023	23,727	24,496
1395pp(h)	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)).	2023	18,825	19,435
1395ss(a)(2)	402.102(f)(1)	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	2023	64,617	66,711
1395ss(d)(3)(A)(vi) (I)	42 CFR 402.1(c)(25), 402.105(e), 402.105(f)(2).	CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	2023	33,483	34,568
		CMS	Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	2023	55,808	57,617

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395ss(d)(3)(B)(iv)		CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	2023	33,483	34,568
1395ss(p)(8)	42 CFR 402.1(c)(25), 402.105(e)	CMS	Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	2023	55,808	57,617
.....	42 CFR 402.1(c)(25), 405402.105(f)(2).	CMS	Penalty for someone other than issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2023	33,483	34,568
1395ss(p)(9)(C)	42 CFR 402.1(c)(26), 402.105(f)(3), (4).	CMS	Penalty for an issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2023	55,808	57,617
.....	402.105(f)(3),(4)	CMS	Penalty for someone other than issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2023	33,483	34,568
1395ss(q)(5)(C)	402.105(f)(5)	CMS	Penalty for an issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2023	55,808	57,617
1395ss(r)(6)(A)	402.105(f)(6)	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	2023	55,808	57,617
1395ss(s)(4)	42 CFR 402.1(c)(29), 402.105(c)	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(f)(1)(B).	2023	23,692	24,460
1395ss(t)(2)	42 CFR 402.1(c)(30), 402.105(f)(7)	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	2023	55,808	57,617
1395ss(v)(4)(A)		CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	2023	24,163	24,946
1395bb(b)(c)(1)	42 CFR 488.725(c)	CMS	Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	2023	40,272	41,577
1395bb(b)(2)(A)(i)	42 CFR 488.845(b)(2)(iii) 42 CFR 488.845(b)(3)–(6); and 42 CFR 488.845(d)(1)(ii).	CMS	Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2023	5,171	5,339
.....	42 CFR 488.845(b)(3)	CMS	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	2023	24,793	25,597
.....	42 CFR 488.845(b)(3)(i)	CMS	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	2023		
.....	42 CFR 488.845(b)(3)(i)	CMS	Penalty per day for home health agency's noncompliance (Upper Range)	2023	21,074	21,757
.....	42 CFR 488.845(b)(3)(ii)	CMS	Minimum	2023	24,793	25,597
.....	42 CFR 488.845(b)(3)(ii)	CMS	Maximum	2023	24,793	25,597
.....	42 CFR 488.845(b)(3)(iii)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	2023	22,313	23,036
.....	42 CFR 488.845(b)(4)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	2023	21,074	21,757
.....		CMS	Penalty for an isolated incident of noncompliance in violation of established HHA policy.	2023		
.....		CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range).	2023	3,720	3,841
.....			Minimum	2023	21,074	21,757
.....			Maximum	2023		

42 CFR 488.845(b)(5)	CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range).	2023	1,240	1,280
		Minimum		2,479	2,559
		Maximum			
42 CFR 488.845(b)(6)	CMS	Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey.	2023	2,479	2,559
		Penalty for each day of noncompliance (Minimum)	2023	24,793	25,597
		Penalty for each day of noncompliance (Maximum)	2023	24,793	25,597
42 CFR 488.845(d)(1)(ii)	CMS	Penalty for PACE organization that discriminates in enrollment or disenrollment, or engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, on the basis of health status or the need for services.	2023	46,102	47,596
42 CFR 460.46	CMS	For each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.	2023		
		Minimum			
		Maximum		17,370	17,933
		Penalty for a PACE organization that charges excessive premiums	2023	115,802	119,555
		Penalty for a PACE organization misrepresenting or falsifying information to CMS or the State.	2023	46,102	47,596
		Penalty for any other violation specified in 42 CFR 460.40	2023	184,412	190,389
42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet a Category 2 Certification.	2023	46,102	47,596
		Minimum			
		Maximum		129	133
42 CFR 488.408(d)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 2 certification.	2023	7,752	8,003
		Minimum			
		Maximum		2,586	2,670
42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet Category 3 certification	2023	25,847	26,685
		Minimum			
		Maximum		7,884	8,140
42 CFR 488.408(e)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification.	2023	25,847	26,685
		Minimum			
		Maximum		2,586	2,670
42 CFR 488.408(e)(2)(ii)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.	2023	25,847	26,685
		Minimum			
		Maximum		2,586	2,670
42 CFR 488.438(a)(1)(i)	CMS	Penalty per day for nursing facility's failure to meet certification (Upper Range).	2023	25,847	26,685
		Minimum			
		Maximum		7,884	8,140
42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day for nursing facility's failure to meet certification (Lower Range).	2023	25,847	26,685
		Minimum			
		Maximum		129	133
42 CFR 488.438(a)(2)	CMS	Penalty per instance for nursing facility's failure to meet certification	2023	7,752	8,003
		Minimum			
		Maximum		2,586	2,670
42 CFR 488.447	CMS	Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2).	2023	25,847	26,685
		First occurrence (Minimum)	2023		
		Incremental increases for each subsequent occurrence	2023	1,158	1,196
42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	CMS	Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than \$5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	2023	579	598
			2023	12,924	13,343

1395eee(e)(6)(B); 1396u-4(e)(6)(B).

1396(h)(3)(C)(ii)(i)

1396(f)(2)(B)(iii)(i)(c)

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1396(h)(3)(C)(ii)(I)	42 CFR 483.151(c)(2)	CMS	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP “not less than \$5,000” [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	2023	12,924	13,343
1396(j)(2)(C)		CMS	Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care.	2023		
.....			Minimum			
.....			Maximum			
1396u–2(e)(2)(A)(i)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	2023	22,324	23,048
.....		CMS	Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	2023	46,102	47,596
.....		CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	2023	46,102	47,596
.....		CMS	Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	2023	46,102	47,596
1396u–2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	2023	46,102	47,596
.....		CMS	Penalty for a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2023	184,412	190,389
1396u–2(e)(2)(A)(iv)	42 CFR 438.704	CMS	Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2023	184,412	190,389
.....		CMS	Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2023	27,661	28,557
1396u(h)(2)	42 CFR part 441, subpart I	CMS	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	2023	25,847	26,685
1396w–2(c)(1)	42 U.S.C. 300gg–22(b)(2)(C)(i), 45 CFR 150.315	CMS	Penalty for each day, for each individual affected by the failure of a health insurance issuer or non-Federal governmental group health plan to comply with federal market reform provisions in part A or D of title XXVII of the PHS Act 2022(174) 177.	2023	13,785	14,232
18041(c)(2)	45 CFR 156.805(c)	CMS	Failure to comply with ACA requirements related to risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards; Penalty for violations of rules or standards of behavior associated with issuer compliance with risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards.	2023	187	193
.....			Penalty for each day, for each individual affected by the failure of a health insurance issuer or non-Federal governmental group health plan to comply with federal market reform provisions in part A or D of title XXVII of the PHS Act.	2023	177	183
42 U.S.C. 300gg–22(b)(2)(C)(i) ...	45 CFR 150.315	CMS	Penalty for providing false information on Exchange application	2023	34,065	35,169
18081(h)(1)(A)(i)(II)	45 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2023	340,641	351,681
18081(h)(1)(B)	45 CFR 155.285	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2023		
18081(h)(2)	45 CFR 155.260	CMS	Change.	2023		
.....			Maximum	2023	34,065	35,169
.....			Minimum	2023	348	359
18041(c)(2)	45 CFR 155.206(i)	CMS	Penalties for violation of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges.	2023	41,774	43,128
.....			Maximum (Per Day)	2023	115	119
31 U.S.C.		HHS	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	2023	348	359
1352	45 CFR 93.400(e)		Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure.	2023	23,727	24,496
.....			Minimum	2023	23,727	24,496

3801–3812	45 CFR part 93, Appendix A	HHS	Maximum	2023	237,268	244,958
			Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	2023	23,727	24,496
			Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances.	2023	237,268	244,958
		HHS	Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers.	2023	23,727	24,496
	45 CFR 79.3(a)(1)(iv)	HHS	Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions.	2023	23,727	24,496
		HHS	Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2023	12,398	12,800
	45 CFR 79.3(b)(1)(ii)	HHS	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2023	12,398	12,800

¹ Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

² The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

³ Statutory or Inflation Act Adjustment.

⁴ OMB Memorandum M–16–06, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published February 24, 2016, guided agencies on initial “catch-up” adjustment requirements, and M–17–11, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 16, 2016, followed by M–18–03, M–19–04, M–20–05, M–22–07, M–23–05, and M–24–07 guided agencies on annual adjustment requirements.

⁵ OMB Circular A–136, Financial Reporting Requirements, Section II.4.9, directs that agencies must make annual inflation adjustments to civil monetary penalties and report on the adjustments in the Agency Financial Report (AFR) or Performance and Accountability Report (PAR).

⁶ Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, § 701(b)(1)(A) (codified as amended at 28 U.S.C. 2461 note).

⁷ Annual inflation adjustments are based on the percent change between each published October’s CPI–U. In this case, October 2023 CPI–U (307.671)/October 2022 CPI–U (298.012) = 1.03241.

Xavier Becerra,
Secretary, Department of Health and Human
Services.

[FR Doc. 2024–17466 Filed 8–7–24; 8:45 am]

BILLING CODE 4150–24–P

FEDERAL MARITIME COMMISSION

46 CFR Parts 502 and 535

[Docket No. FMC–2024–0014]

Policy Statement on the Potential Use of an Investigatory Process To Support Determinations Regarding Filed Agreements That May Present Anticompetitive Features

AGENCY: Federal Maritime Commission.

ACTION: Notification of availability.

SUMMARY: The Federal Maritime Commission (Commission) is issuing this document to advise the public of the availability of a new policy statement. The policy statement describes the potential future use of the agency's administrative investigation process to enhance its determinations regarding agreements filed by ocean common carriers or marine terminal operators that may present anticompetitive features under the Shipping Act.

DATES: Policy statement *On the Potential Use of an Investigatory Process to Support Determinations under 46 U.S.C. 41307(b)* announced in this document was issued on July 30, 2024.

ADDRESSES: The policy statement can be found at the following link: <https://www2.fmc.gov/readingroom/proceeding/24-25/>.

FOR FURTHER INFORMATION CONTACT: David Eng, Secretary; Phone: (202) 523–5725; Email: Secretary@fmc.gov.

SUPPLEMENTARY INFORMATION: On July 30, 2024, the Commission issued a policy statement to provide guidance about the agency's potential future use of its administrative investigation process to enhance its determinations regarding agreements filed by ocean common carriers or marine terminal operators that may present anticompetitive features.

As the policy statement explains, such an administrative process can aid in the Commission's competition analysis and enable it to present a more comprehensive, well-supported determination in any later court proceeding seeking injunctive relief under 46 U.S.C. 41307(b). This process would occur under 46 U.S.C. 41302–04 and applicable FMC regulations.

The policy statement can be found at the following link: <https://www2.fmc.gov/readingroom/proceeding/24-25/>.

www2.fmc.gov/readingroom/proceeding/24-25/.

This document is issued under authority of 5 U.S.C. 552 and 46 U.S.C. 41302–04, 41307(b).

By the Commission.

David Eng,

Secretary.

[FR Doc. 2024–17201 Filed 8–7–24; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 52

[WC Docket Nos. 13–97, 07–243, 20–67; IB Docket No. 16–155; FCC 23–75; FR ID 236587]

Numbering Policies for Modern Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Wireline Competition Bureau (Bureau) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with the Commission's revised Numbering Authorization Application rules. This document is consistent with *Numbering Policies for Modern Communications, Second Report and Order*, FCC 23–75, which stated that the rules subject to OMB approval would become effective upon an announcement in the **Federal Register** announcing their effective date.

DATES: The amendments to 47 CFR 52.15(g)(3)(ii)(B) through (F), (I), (K), (L), and (N) and (g)(3)(x)(A) (amendatory instruction 3), published at 88 FR 80617, November 20, 2023, are effective on August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Jordan Reth, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1418, or email: Jordan.Reth@fcc.gov. For additional information concerning the Paperwork Reduction Act information collection requirements, contact Nicole Ongele at (202) 418–2991 or Nicole.Ongele@fcc.gov.

SUPPLEMENTARY INFORMATION: On September 21, 2023, the Commission adopted *Numbering Policies for Modern Communications, Second Report and Order*, FCC 23–75, published at 88 FR 80617, November 20, 2023. In the *Second Report and Order*, the Commission adopted revisions to 47

CFR 52.15(g). Section 52.15(g) allows interconnected Voice over internet Protocol (VoIP) providers to apply for a blanket authorization from the Commission that, once granted, will allow them to demonstrate that they have the authority to provide service in specific areas, thus enabling them to request numbers directly from the Numbering Administrators. This information collection covers the information and certifications that applicants must submit in order to comply with the Numbering Authorization Application process. The data, information, and documents acquired through this collection will allow interconnected VoIP providers to obtain numbers with minimal burden or delay while also preventing providers from obtaining numbers without first demonstrating that they can deploy and properly utilize such resources. The revisions the *Second Report and Order* to this information collection are necessary to further stem the tide of illegal robocalls perpetrated by interconnected VoIP providers, to protect the nation's numbering resources from abuse by foreign bad actors, and to advance other important public policy objectives tied to the use of our nation's limited numbering resources. The Commission stated that these rule changes may contain new or modified information collection requirements that the Bureau determined is required under the Paperwork Reduction Act.

On April 19, 2024, OMB approved, for a period of three years, the information collection requirements relating to the Numbering Authorization Application rules contained in the *Second Report and Order*. The OMB Control Number is 3060–1214. The Bureau publishes this document as an announcement of the effective date of the direct access authorization rules adopted in the *Second Report and Order*. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, 45 L Street NE, Washington, DC 20554. Please include the OMB Control Number 3060–1214 in your correspondence. The Commission also will accept your comments via email at PRA@fcc.gov. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs

Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Bureau is notifying the public that it received final OMB approval on April 19, 2024, for the information collection requirements contained in the modifications to the Commission's direct access authorization rules in 47 CFR part 52.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number.

The foregoing notification is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the affected respondents are as follows:

OMB Control Number: 3060–1214.

OMB Approval Date: April 19, 2024.

OMB Expiration Date: April 30, 2027.

Title: Direct Access to Numbers

Order, FCC 15–70, Conditions.

Form Number: N/A.

Type of Review: Revision of a currently-approved collection.

Respondents: Business or other for-profit entities.^z

Number of Respondents and

Responses: 20 respondents; 20 responses.

Estimated Time per Response: 10–35 hours.

Frequency of Response: One-time, ongoing and biannual reporting requirements.

Obligation to Respond: Voluntary. Statutory authority for these collections are contained in 47 U.S.C. 251(e)(1) and section 6(a) of the TRACED Act.

Total Annual Burden: 1,100 hours.

Total Annual Cost: No Cost.

Needs and Uses: On June 18, 2015, the Commission adopted a Report and Order establishing the Numbering Authorization Application, which allows interconnected VoIP providers to apply for a blanket authorization from the FCC that, once granted, will allow them to demonstrate that they have the authority to provide service in specific areas, thus enabling them to request

numbers directly from the Numbering Administrators. The collection covers the information and certifications that applicants must submit in order to comply with the Numbering Authorization Application process. On September 21, 2023, the Commission adopted a Second Report and Order that strengthens this application process by revising this information collection to ensure the Commission receives sufficient detail from interconnected VoIP applicants to make informed, public-interest-driven decisions about their direct access applications and thereby protect the public from bad actors. This information will continue help the Commission stem the tide of illegal robocalls, protect national security and law enforcement, safeguard the nation's finite numbering resources, reduce the opportunity for regulatory arbitrage, and further promote public safety.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2024–17346 Filed 8–7–24; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 89, No. 153

Thursday, August 8, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2024-2011; Project Identifier AD-2023-01121-R]

RIN 2120-AA64

Airworthiness Directives; MD Helicopters, LLC, Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain MD Helicopters, LLC (MDHI), Model 369, 369A, 369D, 369E, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters. This proposed AD was prompted by a report of a seized and damaged roller bearing in the pilot interconnecting cyclic torque tube (torque tube) assembly. This proposed AD would require repetitively inspecting the torque tube assembly for corrosion and cracks and the roller bearings for corrosion and degradation. This proposed AD would also require repetitively inspecting the torque tube assembly for freedom-of-movement. Depending on the results, this proposed AD would require replacing parts or accomplishing additional inspections. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 23, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-

30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-2011; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Eduardo Orozco-Duran, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (562) 627-5264; email: eduardo.orozco-duran@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2024-2011; Project Identifier AD-2023-01121-R" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to [regulations.gov](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial

information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Eduardo Orozco-Duran, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (562) 627-5264; email: eduardo.orozco-duran@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA received a report of a seized and damaged roller bearing assembly in the torque tube assembly of an MDHI Model MD369E helicopter. This damage did not allow the torque tube to rotate as designed, which initiated a crack and resulted in an emergency landing. The seized roller bearings were due to rust compounded with dried grease residue and an aggressive chemical environment. Because the seized roller bearings did not allow the torque tube to rotate freely, additional torsional stresses occurred on the torque tube, causing a crack to initiate and eventually propagate until the part failed and longitudinal control was lost. Since MDHI Model 369, 369A, 369D, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters have the same torque tube assembly installed, they are also affected by this unsafe condition.

Accordingly, this proposed AD would require repetitively visually inspecting the torque tube for corrosion and cracks, repetitively visually inspecting the roller bearings for corrosion and degradation, performing a repetitive freedom-of-movement inspection of the torque tube assembly for binding or ratcheting, and corrective or additional action as necessary. This condition, if not addressed, could result in reduced controllability and subsequent loss of control of the helicopter.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition

described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require repetitive visual inspections of the torque tube assembly for cracks and corrosion and the roller bearings for corrosion and degradation. This proposed AD would also require repetitively inspecting the freedom of movement of the torque tube assembly for binding and ratcheting. Depending on the results, this proposed AD would require replacing parts or accomplishing additional inspections.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 353 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD. Labor costs are estimated at \$85 per work-hour.

Visually inspecting the torque tube and roller bearings would take approximately 1 work-hour for an estimated cost of \$85 per helicopter and \$30,005 for the U.S. fleet, per inspection cycle. Inspecting the torque tube assembly for freedom of movement would take approximately 0.75 work-hour for an estimated cost of \$64 per helicopter and \$22,595 for U.S. fleet cost, per inspection cycle. If required, a more in-depth inspection of the roller bearings would take approximately 0.25 work-hour for an estimated cost of \$21 per helicopter, per instance.

If required, replacing a torque tube would take approximately 6 work-hours and parts would cost approximately \$4,773 for an estimated cost of \$5,283 per torque tube replacement. Replacing a roller bearing would take approximately 6 work-hours and parts would cost approximately \$210 for an estimated cost of \$720 per roller bearing replacement.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more

detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

MD Helicopters, LLC: Docket No. FAA–2024–2011; Project Identifier AD–2023–01121–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 23, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MD Helicopters, LLC, Model 369, 369A, 369D, 369E, 369F, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters, certificated in any category, with a pilot interconnecting cyclic torque tube (torque tube) part number 369H7133–7 installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by a report of a seized and damaged roller bearing in the torque tube assembly. The FAA is issuing this AD to prevent failure of the torque tube assembly. The unsafe condition, if not addressed, could result in reduced controllability and subsequent loss of control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

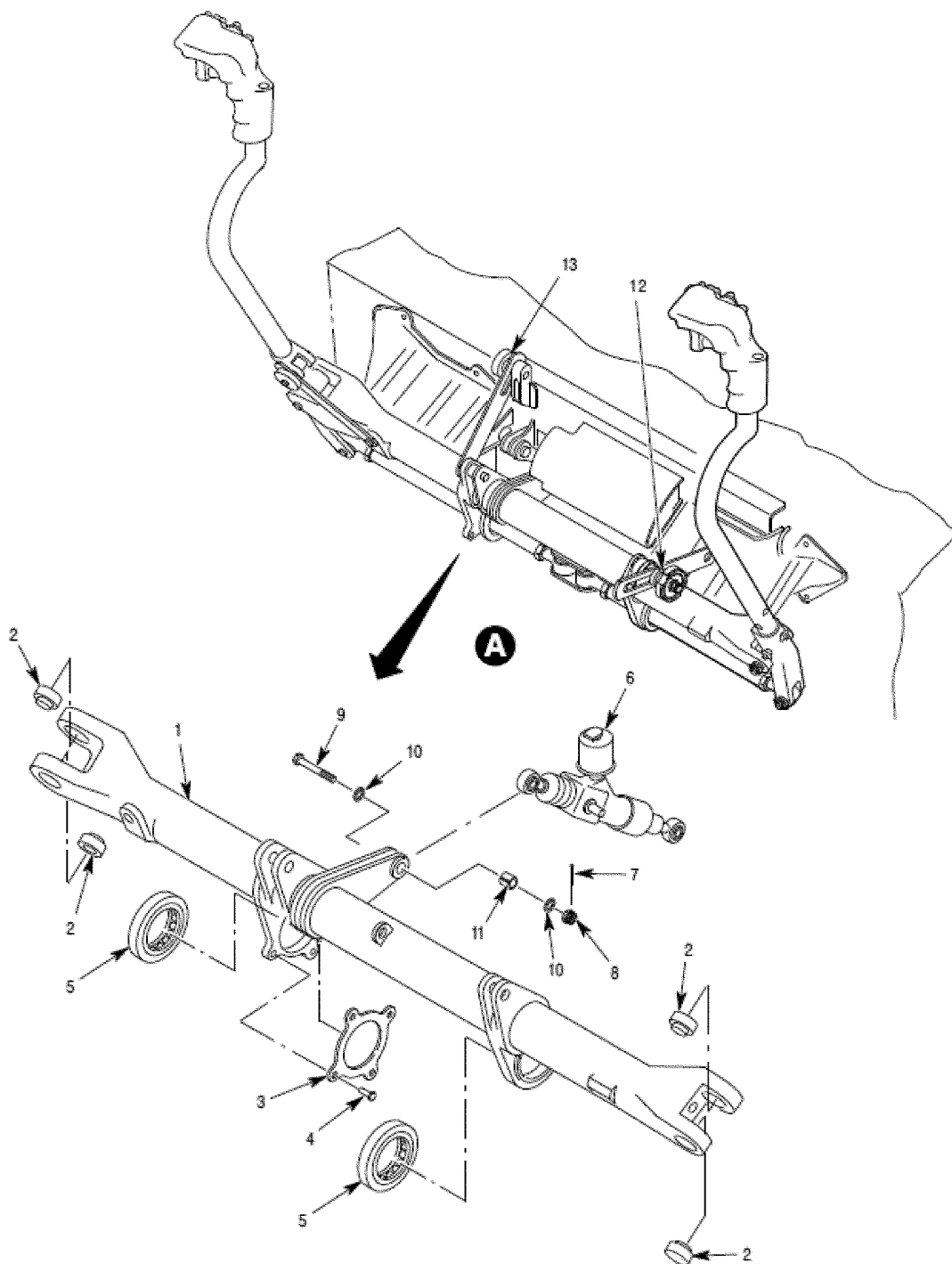
(g) Required Actions

(1) Within 100 hours time-in-service (TIS) or within one year after the effective date of this AD, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS, accomplish the actions required by paragraphs (g)(1)(i) and (ii) of this AD.

(i) Using a flashlight and mirror, visually inspect the torque tube for corrosion and cracks. If there is any corrosion or a crack, before further flight, remove the torque tube from service and install an airworthy torque tube.

(ii) Visually inspect each roller bearing (number 5) as depicted in Figure 1 to paragraph (g)(1) of this AD for corrosion and degradation. If a roller bearing has any corrosion or degradation, before further flight, remove the roller bearing from service and install an airworthy roller bearing.

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**BILLING CODE 4910-13-C**

(2) Before the helicopter accumulates 3,000 total hours TIS or within 100 hours TIS after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 100 hours TIS, perform a freedom-of movement inspection on the torque tube assembly by accomplishing the actions required by paragraphs (g)(2)(i) through (v) of this AD.

(i) Disconnect the one-way lock (number 6) of the torque tube by removing the cotter pin (number 7), nut (number 8), bolt (number 9), washers (number 10), and slotted bushing

(number 11) from the torque tube assembly as depicted in Figure 1 to paragraph (g)(1) of this AD.

(ii) Loosen the longitudinal cyclic friction knob (number 12 or 13) of the torque tube assembly as depicted in Figure 1 to paragraph (g)(1) of this AD.

(iii) While moving the cyclic control forward and aft to allow the torque tube assembly to rotate through its full range of motion, inspect the torque tube assembly for binding and ratcheting.

(A) If there is any binding or ratcheting as a result of the action required by paragraph

(g)(2)(iii) of this AD, before further flight, inspect each roller bearing (number 5) as depicted in Figure 1 to paragraph (g)(1) of this AD for damage. For the purposes of this inspection, damage may be indicated by corrosion, lack of lubrication (dry exterior surface), or material degradation.

(B) If any roller bearing (number 5) as depicted in Figure 1 to paragraph (g)(1) of this AD has any damage, before further flight, remove the roller bearing from service and install an airworthy roller bearing.

(iv) If there is not any binding or ratcheting as a result of the action required by

paragraph (g)(2)(iii) of this AD or after accomplishing the action required by paragraph (g)(2)(iii)(B) of this AD, as applicable, tighten the cyclic friction knob (number 12 or 13) as depicted in Figure 1 to paragraph (g)(1) of this AD.

(v) Connect the one-way lock (number 6) as depicted in Figure 1 to paragraph (g)(1) of this AD by accomplishing the actions required by paragraphs (g)(2)(v)(A) and (B).

(A) Install the slotted bushing (number 11), washers (number 10), bolt (number 9), nut (number 8), and new (zero total hours TIS) cotter pin (number 7) as depicted in Figure 1 to paragraph (g)(1) of this AD.

(B) Ensure the edge of the slotted bushing (number 11) protrudes 0.010 to 0.080 inch (0.25 to 2.03 mm) above the surface of the cyclic torque tube after the nut is tightened.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, West Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the West Certification Branch, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Additional Information

For more information about this AD, contact Eduardo Orozco-Duran, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (562) 627-5264; email: eduardo.orozco-duran@faa.gov.

(j) Material Incorporated by Reference

None.

Issued on July 31, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024-17339 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2024-2012; Project Identifier MCAI-2023-01208-T]

RIN 2120-AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all MHI RJ Aviation ULC Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. This proposed AD was prompted by the discovery of ten ultrasonic inspections associated with airworthiness limitations (AWL) tasks and structural deviation inspection requirements (SDIR) tasks potentially not detecting cracks. This proposed AD would require repetitive ultrasonic inspections of certain structural areas for cracking as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR), and repair of cracking, as applicable. This proposed AD would also prohibit use of the previous revisions of certain procedures and mandate the use of the revised procedures when performing the inspections required by the associated AWL and SDIR tasks. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 23, 2024.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- **Federal eRulemaking Portal:** Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- **Fax:** 202-493-2251.

- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-2012; or in person at Docket Operations between 9 a.m. and

5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Transport Canada material in this proposed AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888-663-3639; email TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca. You may find this material on the Transport Canada website at tc.canada.ca/en/aviation. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-2012.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

FOR FURTHER INFORMATION CONTACT: Yaser Osman, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228-7300; email: 9-avs-nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2024-2012; Project Identifier MCAI-2023-01208-T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to [regulations.gov](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act

(FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Yaser Osman, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228–7300; email 9-avs-nyaco-cos@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2023–74, dated November 21, 2023 (Transport Canada AD CF–2023–74) (also referred to as the MCAI), to correct an unsafe condition for all MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states MHI RJ Aviation ULC discovered ten ultrasound (*i.e.*, ultrasonic) inspection procedures in Part 4 of the non-destructive testing manual (NDTM), which is associated with AWL tasks and SDIR tasks, could potentially not detect cracks. The MCAI stated this is due to differences in sound attenuation between airplane structures assembled with faying surface sealant and the calibration reference standards used to calibrate the ultrasonic testing probes which were assembled without faying surface sealant.

The FAA is proposing this AD to address undetected cracks in certain structural areas. The unsafe condition, if

not addressed, could result in structural failure of the airplane. You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–2012.

Material Incorporated by Reference Under 1 CFR Part 51

Transport Canada AD CF–2023–74 specifies procedures for repetitive ultrasonic inspections of certain structural areas for cracking. The structural areas include, but are not limited to, certain lateral beam web and lower cap flanges, engine support beam cap angles, engine support beams, webs, and doublers. Transport Canada AD CF–2023–74 also prohibits the use of the previous revisions of certain ultrasonic inspection procedures specified in Part 4 of the NDTM and mandates the use of revised procedures when performing the inspections required by the associated AWL and SDIR tasks.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2023–74 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD, and except as discussed under

“Differences Between this NPRM and the MCAI.”

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2023–74 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–74 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Material required by Transport Canada AD CF–2023–74 for compliance will be available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2024–2012 after the FAA final rule is published.

Differences Between This NPRM and the MCAI

Transport Canada AD CF–2023–74 requires repetitive inspections for cracking but does not specify accomplishing a corrective action if any cracking is found. Therefore, this proposed AD would require repairing any cracking found using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC’s Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 395 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
5 work-hours × \$85 per hour = \$425	\$0	\$425	\$167,875

The FAA has received no definitive data on which to base the cost estimates for the repairs specified in this proposed AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII:

Aviation Programs, describes in more detail the scope of the Agency’s authority.
The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section

44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.):
Docket No. FAA–2024–2012; Project Identifier MCAI–2023–01208–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 23, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all MHI RJ Aviation ULC (Type Certificate previously held by Bombardier, Inc.) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by the discovery of ten ultrasonic inspections associated with airworthiness limitations (AWL) tasks and structural deviation inspection requirements (SDIR) potentially not detecting cracks. The FAA is issuing this AD to address undetected cracks in certain structural areas. The unsafe condition, if not addressed, could result in structural failure of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–74, dated November 21, 2023 (CF–2023–74).

(h) Exception to Transport Canada AD CF–2023–74

(1) Where Transport Canada AD CF–2023–74 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph A. of Transport Canada AD CF–2023–74 specifies to perform AWL tasks and SDIR tasks, for this AD, the initial compliance time for the tasks is at the time specified in paragraph A. of Transport Canada AD CF–2023–74 or within 30 days after the effective date of this AD, whichever occurs later.

(3) Where paragraph B. of Transport Canada AD CF–2023–74 refers to phase-in compliance times in Table 1 of Transport Canada AD CF–2023–74, this AD requires using the applicable phase-in time identified in Table 1 of Transport Canada AD CF–2023–74, or within 30 days after the effective date of this AD, whichever occurs later.

(4) If, during any inspection required by paragraph (g) of this AD, any cracking is found, repair before further flight using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC’s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or

responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: 9-AVS-NYACO-COS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC’s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact Yaser Osman, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228–7300; email 9-avs-nyaco-cos@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Transport Canada AD CF–2023–74, dated November 21, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–74, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca. You may find this Transport Canada AD on the Transport Canada website at tc.canada.ca/en/aviation.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on July 31, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–17361 Filed 8–7–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2024–2031; Airspace
Docket No. 24–AEA–6]

RIN 2120–AA66

**Amendment of Domestic Very High
Frequency Omnidirectional Range
(VOR) Federal Airways; Eastern United
States**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to amend domestic Very High Frequency Omnidirectional Range (VOR) Federal Airways V–16, V–103, V–375, and V–473 in the eastern United States. The FAA is taking this action due to the planned decommissioning of the Roanoke, VA (ROA), VOR/Distance Measuring Equipment (VOR/DME). This action is in support of the FAA’s VOR Minimum Operational Network (MON) Program.

DATES: Comments must be received on or before September 23, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2031 and Airspace Docket No. 24–AEA–6 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and

subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT:

Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the route structure to maintain the efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is

possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA’s web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, GA 30337.

Incorporation by Reference

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the Roanoke, VA (ROA), VOR/DME in June 2025. The Roanoke VOR/DME is a candidate navigational aid (NAVAID) identified for discontinuance by the FAA’s VOR MON program and listed in the Final policy statement notice, “Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-

Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),” published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

The Air Traffic Service (ATS) routes affected by the planned NAVAID decommissioning are VOR Federal Airways V–16, V–103, V–375, and V–473. With the planned decommissioning of the Roanoke, VA (ROA), VOR/DME, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected ATS routes. As such, proposed modifications to V–375 and V–473 would result in the airways being shortened; and to V–16 and V–103 would result in a gap being created.

To overcome the proposed modifications to the affected routes, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways or receive air traffic control (ATC) radar vectors to fly through or circumnavigate the affected area. Additionally, IFR pilots with Area Navigation (RNAV)-equipped aircraft could also use the adjacent RNAV Routes T–315, T–424, T–426, and T–479; or navigate point-to-point using the existing fixes that will remain in place to support continued operations through the affected area. Visual flight rules (VFR) pilots who elect to navigate via airways through the affected area could also take advantage of ATC services listed previously.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend domestic VOR Federal Airways V–16, V–103, V–375, and V–473 to support the planned decommissioning of the Roanoke, VA (ROA), VOR/DME. This action is in support of the FAA’s VOR MON Program.

V–16: V–16 currently extends between the Los Angeles, CA (LAX), VOR/Tactical Air Navigation (VORTAC) and the Holly Springs, MS (HLI), VORTAC; between the Shelbyville, TN (SYI), VOR/DME, and the Richmond, VA (RIC), VORTAC; and between the Smyrna, DE (ENO), VORTAC and the intersection of the Calverton, NY (CCC), VOR/DME 044°, and the Madison, CT (MAD), VOR/DME 142° radials (CREAM Fix). The airspace within restricted areas R–5002A, R–5002C, and R–5002D is excluded during their times of use. The FAA proposes to remove the airway segments between the Pulaski, VA (PSK), VORTAC and the Lynchburg, VA (LYH), VOR/DME due to the scheduled decommissioning of the Roanoke, VA (ROA), VOR/DME.

Additionally, the FAA proposes to add to the description that the airspace

within restricted area R–5002F is excluded during its time of use as R–5002F is adjacent to VOR Federal Airway V–16 and must be excluded. As amended, the airway would be changed to extend between the Los Angeles VORTAC and the Holly Springs VORTAC; between the Shelbyville VOR/DME and the Pulaski VORTAC; between the Lynchburg VOR/DME and the Richmond VORTAC; and between the Smyrna VORTAC and the CREAM Fix. The airspace within restricted areas R–5002A, R–5002C, R–5002D, and R–5002F is excluded during their times of use.

V–103: V–103 currently extends between the Chesterfield, SC (CTF), VOR/DME and the Akron, OH (ACO), VOR/DME. In the description of V–103, the route segments between the Greensboro, NC (GSO), VORTAC and the Roanoke, VA (ROA), VOR/DME is further described as the Greensboro VORTAC 357° and the Roanoke VOR/DME 181° radials. The FAA proposes to remove the airway segments between the intersection of the Greensboro, NC (GSO), VORTAC 357° True (T)/360° Magnetic (M) and the South Boston, VA (SBV), VORTAC 247° T/252° M radials (MAYOS Fix) and the Elkins, WV (EKN), VORTAC due to the scheduled decommissioning of the Roanoke VOR/DME. As amended, the airway would be changed to extend between the Chesterfield VOR/DME and the MAYOS Fix; and between the Elkins VORTAC and the Akron VOR/DME.

V–375: V–375 currently extends between the Roanoke, VA (ROA), VOR/DME and the intersection of the Gordonsville, VA (GVE), VORTAC 034° and Casanova, VA (CSN), VORTAC 142° radials (FLUKY Fix). The FAA proposes to remove the airway segments between the Roanoke VOR/DME and the Gordonsville VORTAC due to the scheduled decommissioning of the Roanoke VOR/DME. As amended, the airway would be changed to extend between the Gordonsville VORTAC and the FLUKY Fix.

V–473: V–473 currently extends between the Roanoke, VA (ROA), VOR/DME and the Gordonsville, VA (GVE), VORTAC. The FAA proposes to remove the airway segments between the Roanoke VOR/DME and the Montebello, VA (MOL), VOR/DME due to the scheduled decommissioning of the Roanoke VOR/DME. As amended, the airway would be changed to extend between the Montebello VOR/DME and the Gordonsville VORTAC.

The full descriptions of the above routes are set forth below in the proposed amendments to part 71. The NAVAID radials listed in the VOR

Federal airway description regulatory text of this final rule are stated in degrees True north. Additionally, minor editorial corrections to the airway descriptions are made to comply with ATS route formatting requirements.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

*Paragraph 6010(a) Domestic VOR
Federal Airways.*

* * * * *

V-16 [Amended]

From Los Angeles, CA; Paradise, CA; Palm Springs, CA; Blythe, CA; Buckeye, AZ; Phoenix, AZ; INT Phoenix 155° and Stanfield, AZ, 105° radials; Tucson, AZ; San Simon, AZ; INT San Simon 119° and Columbus, NM, 277° radials; Columbus; El Paso, TX; Salt Flat, TX; Wink, TX; INT Wink 066° and Big Spring, TX, 260° radials; Big Spring; Abilene, TX; Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Pine Bluff, AR; Marvell, AR; to Holly Springs, MS. From Shelbyville, TN; Hinch Mountain, TN; Volunteer, TN; Holston Mountain, TN; to Pulaski, VA. From Lynchburg, VA; Flat Rock, VA; to Richmond, VA. From Smyrna, DE; Cedar Lake, NJ; Coyle, NJ; INT Coyle 036° and Kennedy, NY, 209° radials; Kennedy; INT Kennedy 040° and Calverton, NY, 261° radials; Calverton; to INT Calverton 044° and Madison, CT, 142° radials. The airspace within Mexico and the airspace below 2,000 feet MSL outside the United States is excluded. The airspace within Restricted Areas R-5002A, R-5002C, R-5002D, and R-5002F is excluded during their times of use.

* * * * *

V-103 [Amended]

From Chesterfield, SC; Greensboro, NC; to INT of Greensboro 357° T/360° M and South Boston, VA, 247° T/252° M radials. From Elkins, WV; Clarksburg, WV; Bellaire, OH; INT Bellaire 327° and Akron, OH, 181° radials; to Akron.

* * * * *

V-375 [Amended]

From Gordonsville, VA; to INT Gordonsville 034° and Casanova, VA, 142° radials.

* * * * *

V-473 [Amended]

From Montebello, VA; to Gordonsville, VA.

* * * * *

Issued in Washington, DC, on August 2, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024-17483 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-13-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0059; FRL-11682-06-
OCSPP]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities (June 2024)

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice of filing of petition and
request for comment.

SUMMARY: This document announces the Agency's receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before September 9, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2024-0059, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Madison H. Le, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566-1400, email address: BPPDFRNotices@epa.gov; or Dan Rosenblatt, Registration Division (RD) (7505T), main telephone number: (202) 566-2875, email address: RDFRNotices@epa.gov. The mailing address for each contact person is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is

not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food

commodities. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available at <https://www.regulations.gov>.

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

A. Notice of Filing—New Tolerance Exemptions for PIPs

PP 3F9096. EPA–HQ–OPP–2024–0293. Bayer CropScience LP, 800 North Lindbergh Boulevard, Saint Louis, MO 63198, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 174 for residues of the plant-incorporated protectants (PIPs) *Bacillus thuringiensis* Cry1A.2 and Cry1B.2 proteins in or on soybean. The petitioner believes no analytical method is needed because this petition is an exemption from the requirement of a tolerance without numerical limitation, thus an analytical detection method should not be required. *Contact:* BPPD.

B. New Tolerances for Non-Inerts

PP 4E9129. EPA–HQ–OPP–2024–0220. United States Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–1032, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide, cypermethrin, in or on durian at 1.0 parts per million (ppm). The Gas Chromatography with Electron Capture Detection (GC/ECD) is used to measure and evaluate the cypermethrin residues. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: July 25, 2024.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2024–17125 Filed 8–7–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WT Docket No. 24–186; FCC 24–77; FR ID 234719]

Promoting Consumer Choice and Wireless Competition Through Handset Unlocking Requirements and Policies

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) explores the use of handset unlocking policies as a means to improve consumer choice and flexibility and to enhance competition across the mobile wireless marketplace as part of the Commission's ongoing efforts to carry out its statutory obligations to ensure a competitive marketplace for mobile wireless services. Specifically, the Commission proposes to require all mobile wireless service providers to unlock handsets 60 days after a consumer's handset is activated with the provider, unless within the 60-day period the service provider determines the handset was purchased through fraud.

DATES: Interested parties may file comments on or before September 9, 2024, and reply comments on or before September 23, 2024. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public, the Office of Management and Budget, and other interested parties on or before October 7, 2024. Written comments on the Initial Regulatory Flexibility Analysis (IRFA) must have a separate and distinct heading designating them as responses to the IRFA and must be submitted by the public on or before September 9, 2024.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's

Electronic Comment Filing System (ECFS). You may submit comments, identified by WT Docket No. 24–186, by any of the following methods:

- **Electronic Filers:** Comments may be filed electronically using the internet by accessing the ECFS: <https://www.fcc.gov/ecfs>.

- **Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing.

- Filings can be sent by hand or messenger delivery, by commercial courier, or by the U.S. Postal Service. All filings must be addressed to the Secretary, Federal Communications Commission.

- Hand-delivered or messenger-delivered paper filings for the Commission's Secretary are accepted between 8 a.m. and 4 p.m. by the FCC's mailing contractor at 9050 Junction Drive, Annapolis Junction, MD 20701. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

- Commercial courier deliveries (any deliveries not by the U.S. Postal Service) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. Filings sent by U.S. Postal Service First-Class Mail, Priority Mail, and Priority Mail Express must be sent to 45 L Street NE, Washington, DC 20554.

- **People with Disabilities.** To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at 202–418–0530.

FOR FURTHER INFORMATION CONTACT: Eli Johnson, Attorney Advisor, Competition and Infrastructure Policy Division, Wireless Telecommunications Bureau, at 202–418–1395 or Eli.Johnson@fcc.gov or Jennifer Salhus, Attorney Advisor, Competition and Infrastructure Policy Division, Wireless Telecommunications Bureau, at 202–418–2823 or Jennifer.Salhus@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), in WT Docket No. 24–186, FCC 24–77, adopted on July 18, 2024, and released on July 19, 2024. The full text of this document is available for public inspection and can be downloaded at <https://docs.fcc.gov/public/attachments/FCC-24-77A1.pdf>.

Regulatory Flexibility Act. The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that “the rule

will not, if promulgated, have a significant economic impact on a substantial number of small entities.” Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the possible impact of the rule and policy changes contained in the Notice of Proposed Rulemaking. Written public comments are requested on the IRFA. Comments must be filed by the deadlines for comments on the Notice of Proposed Rulemaking indicated in the **DATES** section of this document and must have a separate and distinct heading designating them as responses to the IRFA and must be filed in WT Docket No. 24–186.

Paperwork Reduction Act. This document contains proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Ex Parte Rules. This proceeding shall be treated as a “permit-but-disclose” proceeding in accordance with the Commission’s *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter’s written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents

shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b), 47 CFR 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission’s *ex parte* rules.

Providing Accountability Through Transparency Act. Consistent with the Providing Accountability Through Transparency Act, Public Law 118–9, a summary of the Notice of Proposed Rulemaking will be available on <https://www.fcc.gov/proposed-rulemakings>.

Synopsis

I. Introduction

1. With the NPRM, the Commission explores the use of handset unlocking policies as a means to improve consumer choice and flexibility and to enhance competition across the mobile wireless marketplace as part of the Commission’s ongoing efforts to carry out its statutory obligations to ensure a competitive marketplace for mobile wireless services. Handset unlocking, which allows consumers to take their existing handset with them when they switch from one mobile wireless service provider to another, can be an important tool in facilitating competition and reducing barriers for consumers to switch between wireless providers. Over the past two decades, the Commission has adopted handset unlocking requirements for particular providers in specific circumstances, upon finding that doing so was justified in each of those instances. In the NPRM, the Commission tentatively concludes that adopting a broadly applicable set of handset unlocking requirements for all mobile wireless service providers would serve the public interest, and we seek comment on which requirements would best facilitate competition and consumer choice. Specifically, the Commission proposes to require all mobile wireless service providers to unlock handsets 60 days after a consumer’s handset is activated with the provider, unless within the 60-day period the service provider determines the handset was purchased through fraud.

II. Background

2. Unlocking a handset allows consumers to take their existing handset with them when they switch from one mobile wireless service provider to another, as long as the consumer’s handset is compatible with the new provider’s wireless network. In some instances, handsets are sold with discounts in exchange for a required service plan commitment, often months or years in length, or pursuant to a handset financing plan. Locking software generally is intended to ensure that handsets will remain active on the network of the provider that sold the handset (with a discount or with a handset installment plan) for a certain period of time or amount of usage. A locked handset cannot be used on a competing service provider’s compatible network without the handset first being unlocked. The unlocking process varies by handset and by service provider. A service provider may automatically unlock a handset after certain conditions are met, send instructions to customers on how to unlock a handset upon request, or complete the unlocking process in-store. The Commission has found that “[m]obile device unlocking facilitates consumer choice among mobile broadband providers by freeing consumers from having to replace their handset to use another network, thereby reducing switching costs.”

3. The wireless industry has established six general handset unlocking commitments as part of the CTIA Consumer Code for Wireless Service (CTIA Unlocking Commitments). Wireless service providers, such as AT&T, T-Mobile, and Verizon, who have voluntarily agreed to abide by these commitments will unlock handsets in a timely manner when they receive a request from a consumer to unlock a handset once certain conditions are met. These commitments assist consumers by enhancing transparency and disclosure of service provider locking policies. These commitments cover: (1) disclosure; (2) postpaid unlocking policy; (3) prepaid unlocking policy; (4) notice; (5) response time; and (6) deployed personnel unlocking policy. In summary, service providers who abide by these commitments unlock handsets one year after activation for prepaid, and after fulfillment of a service contract, handset financing plan, or payment of an early termination fee for postpaid.

4. In addition to the industry’s voluntary unlocking standards, certain wireless service providers, as discussed below, are subject to unlocking requirements as a result of rules specific

to certain frequency bands or to merger commitments. These Government-imposed unlocking requirements are more stringent than the industry's voluntary unlocking standards. In addition, the providers subject to these requirements could face possible enforcement action if they were found to be out of compliance.

5. Section 27.16(e) of the Commission's rules prohibits the locking of handsets that operate on the 700 MHz C Block frequency bands. Under this rule, no C Block licensee "may disable features on handsets it provides to customers, to the extent such features are compliant with the licensee's standards . . . nor configure handsets it provides to prohibit use of such handsets on other providers' networks." The Commission adopted this rule in the 2007 700 MHz *Second Report and Order* (72 FR 48814, Aug. 24, 2007) as part of a set of "open platform" requirements imposed upon C Block licensees. Specifically, the Commission determined that C Block licensees "will not be allowed to disable features or functionality in handsets where such action is not related to reasonable network management and protection, or compliance with applicable regulatory requirements." As an example of this open platform requirement, the Commission stated that C Block licensees "may not 'lock' handsets to prevent their transfer from one system to another." The Commission noted that "[h]andset or phone 'locking' . . . is one practice that arguably prevents consumers from migrating otherwise technically compatible equipment from one wireless service provider to another."

6. As one of the 700 MHz C Block licensees, Verizon must comply with this requirement. In 2019, however, the Wireless Telecommunications Bureau granted Verizon a partial waiver of this unlocking requirement to better combat identity theft and other types of handset-related fraud. The waiver allows Verizon to lock handsets that operate on the 700 MHz C Block frequencies for 60 days from the date the handsets become active on its network. The Bureau found that allowing handsets to be locked for 60 days to combat handset fraud would not significantly interfere with the policy objective of enabling consumers to be able to migrate from one service provider to another on compatible networks.

7. Further, as part of the *Verizon-TracFone Order*, Verizon agreed to extend its 60-day unlocking policy to all 700 MHz C Block handsets purchased from TracFone subject to a two-year

waiver of the automatic unlocking requirement to allow manual unlocking for those TracFone handsets that did not have automatic unlocking capabilities. For 700 MHz C Block TracFone handsets that operate on its network and lack an automatic unlocking capability, Verizon agreed to provide these customers with manual means to unlock their handsets 60 days after activation. Verizon also agreed that after a two-year period, any new 700 MHz C Block TracFone handsets that Verizon offered and that operate on its network would be capable of automatically unlocking.

8. As a result of these Commission-imposed unlocking conditions, Verizon, after the expiration of the initial 60-day period, must automatically unlock a customer's handset regardless of whether: (1) the customer asks for the handset to be unlocked or (2) the handset is fully paid off. With respect to the Verizon unlocking requirements, the Commission has stated that limiting handset locking periods reduces barriers to consumers being able to switch between wireless service providers.

9. Similarly, T-Mobile operates under an unlocking requirement imposed as a merger condition in connection with the *T-Mobile—Sprint* merger. Under merger conditions imposed by the Department of Justice in connection with the Amended Final Judgment, T-Mobile is required to unlock prepaid handsets within a year of activation on its wireless network. The Amended Final Judgment states that T-Mobile must "unlock prepaid mobile wireless devices no later than one (1) year after initial activation, consistent with reasonable time, payment, or usage requirements." With respect to postpaid handsets, the Amended Final Judgment requires T-Mobile to unlock these handsets only after a customer fulfills the term of the postpaid service contract or handset financing plan, or pays any applicable early termination fee.

10. Further, as part of the recent *T-Mobile-Mint Mobile/Ultra Mobile Order*, T-Mobile made commitments, which were imposed as merger conditions, to implement a 60-day handset unlocking period, subject to certain limitations and exceptions, for all Mint Mobile and Ultra Mobile handsets activated on the T-Mobile network both before and after the closing of the transaction. Handsets subject to a financing plan are not subject to this policy unless a customer pays off the handset early. T-Mobile agreed to automatically unlock new and existing Mint Mobile and Ultra Mobile handsets that are capable of automatic unlocking or provide a means to manually unlock these handsets if they are not capable of automatic unlocking

if the handsets have been activated on the T-Mobile network for at least 60 days and are not currently on a handset financing plan. No later than 24 months after the closing of the transaction, T-Mobile will ensure that all new Mint Mobile and Ultra Mobile handsets that the company offers will be capable of automatic unlocking.

11. With the exception of these specific Government-enforced unlocking requirements, mobile wireless service providers are free to adjust their unlocking requirements, including increasing the unlocking waiting period. For instance, T-Mobile recently increased its locking period for one of its brands, Metro by T-Mobile, from 180 days to 365 days.

III. Discussion

12. In the NPRM, we tentatively conclude that adopting a broadly applicable set of handset unlocking requirements for all mobile wireless service providers would serve the public interest, and we seek comment on which specific requirements would best facilitate competition and consumer choice. We propose to require all mobile wireless service providers to unlock handsets 60 days after a consumer's handset is activated with the provider, unless within the 60-day period the service provider determines the handset was purchased through fraud. We find that there are several factors favoring our proposed unlocking policy.

13. First, having a uniform unlocking policy increases market transparency. We recognize that the CTIA Unlocking Commitments require service providers to post on their websites their policies on postpaid and prepaid handset unlocking. Nonetheless, we tentatively conclude that imposing a uniform handset unlocking policy is likely to increase the information available to consumers, reduce possible consumer confusion, and improve consumer choice through improved information.

14. Second, the locking of handsets can pose a barrier to consumers' ability to switch service providers. Reducing the period during which a provider can lock a handset should reduce switching costs and increase a consumer's ability to change providers in response to changing market prices and service characteristics, new technology, or changes in a consumer's circumstances or needs, which should increase consumer welfare. As a result, consumers will incur fewer direct costs when they do switch and will be less likely to be deterred from switching because of the locked handset.

15. Third, by reducing switching costs and increasing consumers' ability to switch, restrictions on handset locking can increase competition among wireless providers, which can lead to lower prices, more attractive service characteristics, and improved service performance. In this regard, we note that the Commission has found that handset locking may inhibit competition by making it more difficult for consumers to switch among service providers, and, in order to encourage competition and preserve consumer choice and flexibility, it has adopted handset unlocking requirements in the context of rules for specific spectrum bands and as merger commitments. Service providers' handset unlocking practices have also been the subject of consumer complaints and inquiries received by the Commission.

16. Finally, to the extent the Commission adopts this proposal, this change would result in all wireless providers facing the same regulatory constraints, which should reduce regulatory asymmetries and result in more competitively neutral regulation.

17. We note that regulators in other countries have restricted or prohibited handset locking on the grounds that it limits consumer choice and reduces competition. For example, in 2017, the Canadian Radio-television and Telecommunication Commission (CRTC) required that all mobile wireless devices provided to consumers by wireless service providers must be unlocked, and for already locked devices, the providers were required to unlock the device upon request without charge. In adopting this requirement, the CRTC found that "[un]locked devices offer more consumer choice and convenience, contribute to a decreased risk of bill shock by providing options to consumers while travelling abroad, and reduce a significant barrier to switching wireless service providers by improving device portability." Similarly, Ofcom, the United Kingdom's telecom regulatory agency, banned the sale of locked handsets in 2020, with the ban becoming effective in December 2021. Ofcom found, *inter alia*, that handset locking: (1) imposed costs and delays on customers seeking to unlock a device and switch providers; (2) deterred some customers from switching providers; and (3) reduced competition. Other countries have also placed limits on the ability of wireless providers to lock customers' handsets. For example, in 2015, Japan required all wireless providers to sell wireless devices with their Subscriber Identity Module or SIM cards unlocked if a customer asked for it. Singapore banned mobile operators

from selling SIM locked devices in 1997 in an effort to facilitate competition and improve consumer choice.

18. Economic theory also suggests that switching costs, of which handset locking is a form, may reduce competition by locking in customers to a particular provider. Large switching costs tend to lock in buyers when they make an initial purchase, so that they are effectively buying a series of goods over time. While competition, in certain circumstances, may be efficient even in the presence of switching costs, in certain instances, it will not be efficient. For example, consumers may incur direct costs if they switch providers or they may be deterred from switching to the provider that best serves their needs at the lowest price. In addition, while high switching costs may increase a provider's incentive to compete for a customer initially, it may reduce its incentive to lower prices in subsequent periods after a customer is locked in. Thus, a consumer may enjoy lower prices during the initial period, but then have to pay higher prices in subsequent periods, or not be able to switch to a provider offering a superior service or lower price.

19. Consumer groups also support restricting handset locking. They have "long argued that 'the practice of locking phones can reduce wireless competition by making it more difficult for consumers to change carriers, and by reducing the number of devices available on the secondary market.'" For example, consumers may incur direct costs if they actually switch, and if they do not, they may not end up purchasing from their preferred provider. Consumer groups further note that "[s]maller carriers, new entrants, and [mobile virtual network operators or] MVNOs in particular may be disadvantaged in the marketplace due to a lack of handset availability." Further, they explain that "[l]ocked phones, particularly those tied to pre-paid plans, can disadvantage low-income customers most of all, since they may not have the resources to switch carriers or purchase new phones." In addition, in an *ex parte* letter filed in the recent T-Mobile-Mint Mobile/Ultra Mobile proceeding, Verizon contends that the Commission's approach of imposing handset unlocking requirements on a piecemeal basis has resulted in asymmetrical regulation and unequal marketplace conditions among service providers and that such conditions harm consumers and competition. Another recent *ex parte* letter from a group of consumer advocacy organizations and service providers contends that adopting a uniform handset unlocking policy that

applies to all providers would benefit consumers and promote competition among service providers.

20. Based on the above discussion, we tentatively conclude that we should adopt a broadly applicable handset unlocking requirement for all mobile wireless service providers, and we propose to require all mobile wireless service providers to unlock handsets 60 days after a consumer's handset is activated with the provider, unless within the 60-day period the service provider determines the handset was purchased through fraud. We tentatively conclude that imposing a broadly applicable handset unlocking requirement would have a larger impact by promoting greater competitive choices for all mobile wireless subscribers. We seek comment on this view and on the importance of adopting a more broadly applicable handset unlocking requirement for promoting consumer choice and competition. Additionally, we tentatively conclude that adopting such a requirement would have the benefit of providing for uniform regulation of all mobile wireless providers.

21. More specifically, we seek comment on whether, in addition to allowing greater consumer choice, our proposal would increase competition both with respect to prepaid and postpaid service plans. We also seek comment on how our proposal might affect the incentive and ability of wireless providers to continue offering discounts on handsets, particularly in connection with extended payment plans, and lower prices on plans with minimum term commitments. We note in this regard that Verizon, which is subject to a 60-day handset unlocking requirement, continues to offer discounts on devices purchased under extended payment plans. In addition, we seek comment on how our proposed policy might affect lower-income consumers or those with poorer credit ratings. We also seek comment on other consumer impacts of the proposed unlocking requirement, including any digital equity implications. How would a 60-day device unlocking requirement impact efforts by the Commission, wireless providers, or other stakeholders to close the digital divide? Would such a requirement increase or decrease consumer access to or selection of handsets? Further, we seek comment on whether current handset locking policies have dissuaded consumers from switching providers to more competitive service offerings. Are there other practices that may hinder consumer choice when switching mobile wireless service providers that the Commission

should address? Finally, we seek comment on any alternative approaches to handset unlocking that would achieve our objective of promoting consumer choice and competition.

22. *Time Period for Unlocking to Address Handset Fraud.* While the Commission has found that handset unlocking reduces barriers to changing service providers, the Commission also has determined that allowing handsets to be locked for 60 days to combat handset fraud does not significantly interfere with this policy objective. Along these lines, we propose to require that all mobile wireless service providers unlock handsets 60 days after a consumer initiates service with the provider, unless within the 60-day period the service provider determines the handset was purchased through fraud. Under this approach, the handset unlocking requirement would apply to all mobile wireless service providers prospectively and would require them to unlock all handsets that are activated on their networks after 60 days. The 60-day period would be consistent with the 60-day handset unlocking requirement that the Commission has applied previously as described above.

23. We seek comment on this proposal. Commenters supporting a handset unlocking rule should provide examples of how the rule should read. Our proposal includes an exception to the 60-day unlocking requirement, if during the 60-day locking period a service provider determines that a handset was purchased through fraud. We seek comment on how a service provider would determine if a handset was purchased through fraud. What criteria should the service provider use? Should the rule permit any other exceptions to deter fraud including instances where individuals or groups illegally obtain devices and resell them to the public (*i.e.*, handset trafficking)? For example, should lost or stolen phones also fall under an exception to the 60-day unlocking requirement? We seek comment on the potential economic impact or burdens of a 60-day unlocking requirement, particularly for small and rural wireless service providers. Would such a general unlocking requirement affect small and rural wireless service providers and wireless resellers differently as compared to national service providers and, if so, how? Is there a different approach to achieving our objective of promoting consumer choice and competition that we should consider?

24. Alternatively, should we require service providers to unlock handsets after a period shorter or longer than 60 days? For example, should we require

all handsets to be unlocked by default upon activation? Or, should we require all handsets to be unlocked after the end of the handset's return period or after the first payment on the handset has been processed? Would a standardized time period of a certain number of days be easier to implement and enforce than non-standardized time periods based on return periods or billing cycles? What is the minimum amount of time service providers need to protect themselves from handset fraud? Rather than locking handsets, are there other ways service providers can protect themselves from handset fraud that would allow the Commission to prohibit the locking of handsets altogether?

25. How prevalent is handset fraud and would adopting a 60-day handset unlocking requirement be sufficient to deter fraud? How prevalent is handset trafficking and would adopting a 60-day handset unlocking requirement be sufficient to deter trafficking? Commenters that argue that handset fraud or handset trafficking is common should provide data supporting this assertion. If a wireless service provider determines that a handset has been fraudulently purchased, can the service provider remotely lock the handset at issue or deactivate the handset so it will no longer operate on the provider's network or any other wireless network? Do the security features of smartphones sold today include adequate protection against theft so that service providers no longer need to lock the handset to prevent theft or trafficking? For example, could a service provider remotely lock or deactivate a handset if it determined that it was obtained fraudulently or stolen? More generally, are there other ways service providers could protect against fraud or trafficking that would not involve handset locking? Could a criminal override any of these alternative methods of fraud or trafficking prevention?

26. *Impacts on Contractual Arrangements.* As stated above, we propose to apply this requirement prospectively, and we seek comment on whether this approach would avoid interfering with current contractual arrangements between service providers and consumers. What impact would the rule have on contractual arrangements already in existence between service providers and consumers? For handsets that have already been activated on a wireless provider's network, should we continue to rely on the voluntary unlocking commitments and the Government-imposed unlocking conditions?

27. We also seek comment on the impact of a 60-day unlocking

requirement in connection with service providers' incentives to offer discounted handsets for postpaid and prepaid service plans. Verizon, for example, suggests that providers may rely on handset locking to sustain their ability to offer handset subsidies and that such subsidies may be particularly important in prepaid environments. Public interest groups, on the other hand, argue that locked handsets tied to prepaid plans can disadvantage low-income customers most of all since they may not have the resources to switch service providers or purchase new handsets. They also note that unlocked handsets "facilitate a robust secondary market for used devices, providing consumers with more affordable options." We seek comment on these arguments. We also seek comment on the impact of a 60-day unlocking requirement on the incentive and ability of a provider to offer term contracts at discounts.

28. What factors should the Commission consider in determining how best to balance the needs of service providers to ensure that they are reimbursed for the handsets that they have subsidized and the needs of consumers with locked handsets to be able to take their handsets to another mobile wireless service provider? Given that a 60-day unlocking requirement already applies to Verizon and Verizon continues to remain competitive in the marketplace, we anticipate that a rule requiring unlocking after a 60-day period would maintain provider incentives to offer handset subsidies while reducing barriers for consumers to switch among service providers. We seek comment on this view. Do commenters agree with arguments that such a requirement would benefit smaller providers, new entrants, and MVNOs, by increasing the number of handsets available on the secondary market? Would it help consumers by providing them with more affordable handset options? Should the Commission consider adopting a different handset unlocking rule for prepaid and postpaid handsets?

29. *Transition Period and Implementation.* If we were to adopt a 60-day unlocking requirement, we seek comment on an appropriate transition period and on any implementation issues we should consider. Should the unlocking requirement become effective upon publication of the order adopting it in the **Federal Register** or should the Commission provide for a longer transition period? As noted above, the unlocking process may vary with different types of handsets. Depending on the handset, a service provider may automatically unlock the handset, send

instructions to a customer on how to unlock a handset upon request, or complete the unlocking process in-store. Given these differences, would a longer transition period be warranted? If so, what transition period should we adopt? Are there reasons why we should allow a longer transition period for non-nationwide service providers, such as small and rural service providers, as compared to nationwide service providers? What are the percentages of handsets that are currently locked and unlocked to wireless networks? Should we require automatic unlocking for those handsets that can be unlocked automatically?

30. Should we also require that mobile wireless service providers transition to provide for automatic unlocking of all new handsets that they offer? The Commission adopted such a requirement as part of the handset unlocking conditions imposed in the Verizon/TracFone and the T-Mobile-Mint Mobile/Ultra Mobile transactions. In those cases, Verizon and T-Mobile, respectively, were required to commit to ensuring that all new handsets activated on their network would be capable of automatic unlocking after a two-year period. If we adopt a handset unlocking requirement generally for all mobile wireless service providers, should we also require them to ensure that, after a two-year period, all new handsets activated on their networks will be capable of automatic unlocking? If so, would automatic unlocking be accomplished through a software push to a handset or is there another way to accomplish automatic unlocking? We seek comment on whether there are any technical or other implementation issues associated with such an approach and whether these implementation issues might be different for small or rural service providers.

31. Further, we seek comment on how customers should be informed about a service provider's unlocking policies and whether we should require service providers to notify their customers when their handset locking period has ended or when their handsets have been automatically unlocked. Along these lines, should we require service providers to post on their websites their unlocking policies? Should we also adopt a requirement that the unlocking policy be expressed using clear and easy to understand language? In addition to requiring service providers to post their unlocking policies on their websites, should we require service providers to post their unlocking policies in their stores and that store employees be available to explain the service provider's unlocking policies to

customers at the time they purchase handsets? How do we ensure that service providers fully disclose to their customers their unlocking policies at the time a customer purchases a handset? Further, should we require service providers to notify their customers when their handsets are ready to be unlocked or that their handsets have been automatically unlocked? For instance, should we require service providers to send a text message to a customer's handset when the locking period for the handset has expired or when the customer's handset has been automatically unlocked? Should we also require that the service provider contact the customer by email or by a letter sent to the customer's billing address? How do we ensure that service providers fully disclose their unlocking policies to their customers and that customers are aware that the locking period for their handsets has ended or that their handsets have been automatically unlocked?

32. *Legal Authority.* We propose to rely on our legal authority under title III of the 1934 Communications Act, as amended (the Act) to protect the public interest through spectrum licensing and regulations to require mobile wireless service providers to provide handset unlocking. The Commission relied previously on its title III authority in prohibiting 700 MHz C Block licensees from locking handsets as part of a broader set of open platform requirements that were intended to foster consumer choice and the development of innovative handsets and applications. In doing so, the Commission noted that its authority under title III allowed it to establish license conditions and operational obligations, if the condition or obligation will further the goals of the Communications Act without contradicting any basic parameters of the agency's authority.

33. We tentatively conclude that title III also would permit the Commission to more broadly require unlocking of handsets for all mobile wireless service providers. For example, section 303(b) directs the Commission, as required by the public interest, to "[p]rescribe the nature of the service to be rendered by each class of licensed stations and each station within any class." Section 303(g) authorizes the Commission to "generally encourage the larger and more effective use of radio in the public interest." Section 303(r) provides the Commission authority to "make such rules and regulations and prescribe such restrictions and conditions, not inconsistent with law, as may be necessary to carry out the provisions of

[the Act]." In addition, section 316 authorizes the Commission to adopt new conditions on existing licenses if it determines that such action "will promote the public interest, convenience, and necessity."

34. We propose to rely on this authority to require mobile wireless service providers to unlock handsets. Our proposal to require unlocking of handsets would prescribe the nature of service that a mobile wireless service provider must offer when providing mobile wireless services. By giving consumers greater freedom to switch between mobile wireless service providers, the proposed requirement would serve the public interest and help the Commission meet its responsibility to ensure the availability of communications services. We tentatively conclude that such requirements would also be supported by section 332(c)(1) and provisions of title II, which require common carriers' practices to be "just and reasonable," and prohibit and authorize the Commission to "prescribe rules and regulations as may be necessary in the public interest to carry out the provisions of [the Act]." We seek comment on this analysis and on other sources of authority for handset unlocking requirements.

35. *Promoting Digital Equity and Inclusion.* The Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations, and invites comment on any benefits (if any) that may be associated with the issues discussed herein. Specifically, we seek comment on how the potential approaches discussed herein may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well as the scope of the Commission's relevant legal authority.

IV. Initial Regulatory Flexibility Analysis

36. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Federal Communications Commission (Commission) has prepared the Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies proposed in the Notice of Proposed Rulemaking (NPRM). The Commission requests written public comments on the IRFA. Comments must

be identified as responses to the IRFA and must be filed by the deadlines for comments provided in the **DATES** section of this document. The Commission will send a copy of the *NPRM*, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

37. In the *NPRM*, the Commission explores the use of handset unlocking policies as a means to improve consumer choice and flexibility and to enhance competition across the mobile wireless marketplace. Over the past two decades, the Commission adopted handset unlocking requirements for particular providers in specific circumstances, finding that doing so will serve the public interest. In the *NPRM*, the Commission tentatively concludes that adopting a broadly-applicable set of handset unlocking requirements for all mobile wireless service providers would better serve the public interest and the Commission seeks comment on which specific requirements would best facilitate competition and consumer choice. In addition, the Commission specifically seeks comment on whether a 60-day unlocking rule would benefit small mobile wireless service providers because consumers could switch service providers without having to purchase a new handset.

B. Legal Basis

38. The proposed action is authorized pursuant to sections 1, 4(i), 4(j), 303, and 316 of the Communications Act of 1934, as amended; 47 U.S.C. 151, 154(i), 154(j), 303, and 316.

C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

39. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.” In addition, the term “small business” has the same meaning as the term “small-business concern” under the Small Business Act. A “small-business concern” is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

40. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, *according to* data from the Small Business Administration’s (SBA) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 33.2 million businesses.

41. Next, the type of small entity described as a “small organization” is generally “any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.” The Internal Revenue Service (IRS) uses a revenue benchmark of \$50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2020, there were approximately 447,689 small exempt organizations in the U.S. reporting revenues of \$50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

42. Finally, the small entity described as a “small governmental jurisdiction” is defined generally as “governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.” U.S. Census Bureau data from the 2017 Census of Governments indicate there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number, there were 36,931 general purpose governments (county, municipal, and town or township) with populations of less than 50,000 and 12,040 special purpose governments— independent school districts with enrollment populations of less than 50,000. Accordingly, based on the 2017 U.S. Census of Governments data, we estimate that at least 48,971 entities fall into the category of “small governmental jurisdictions.”

43. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services

using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 594 providers that reported they were engaged in the provision of wireless services. Of these providers, the Commission estimates that 511 providers have 1,500 or fewer employees. Consequently, using the SBA’s small business size standard, most of these providers can be considered small entities.

44. *Satellite Telecommunications.* This industry comprises firms “primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.” Satellite telecommunications service providers include satellite and earth station operators. The SBA small business size standard for this industry classifies a business with \$38.5 million or less in annual receipts as small. U.S. Census Bureau data for 2017 show that 275 firms in this industry operated for the entire year. Of this number, 242 firms had revenue of less than \$25 million. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 65 providers that reported they were engaged in the provision of satellite telecommunications services. Of these providers, the Commission estimates that approximately 42 providers have 1,500 or fewer employees. Consequently, using the SBA’s small business size standard, a little more than half of these providers can be considered small entities.

45. *Local Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Local Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and

reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 207 providers that reported they were engaged in the provision of local resale services. Of these providers, the Commission estimates that 202 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

46. *Toll Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Toll Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. MVNOs are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 457 providers that reported they were engaged in the provision of toll services. Of these providers, the Commission estimates that 438 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard,

most of these providers can be considered small entities.

47. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Providers of internet services (e.g., dial-up ISPs) or Voice over internet Protocol (VoIP) services, via client-supplied telecommunications connections are also included in this industry. The SBA small business size standard for this industry classifies firms with annual receipts of \$35 million or less as small. U.S. Census Bureau data for 2017 show that there were 1,079 firms in this industry that operated for the entire year. Of those firms, 1,039 had revenue of less than \$25 million. Based on this data, the Commission estimates that the majority of "All Other Telecommunications" firms can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

48. The *NPRM* explores the use of handset unlocking policies as a means to improve consumer choice and flexibility and to enhance competition across the mobile wireless marketplace. The *NPRM* tentatively concludes that adopting a broadly-applicable set of handset unlocking requirements for all mobile wireless service providers would serve the public interest and seeks comment on which specific requirements would best facilitate competition and consumer choice. The *NPRM* proposes to require all mobile wireless service providers to unlock handsets 60 days after a consumer's handset is activated with the provider. If the Commission were to require all service providers to unlock handsets after a set period of time, the *NPRM* seeks comment on an appropriate transition period and on any implementation issues the Commission should consider. This includes asking whether the Commission should allow a longer transition period for non-nationwide service providers, such as small and rural service providers, as compared to nationwide service providers.

49. If the Commission ultimately decides to adopt its proposed approach,

this could potentially result in additional costs, new or modified recordkeeping, reporting, or other compliance requirements for small and other providers. For example, new handset unlocking rules may require wireless service providers to unlock handsets 60 days after a consumer initiates service with the provider. New handset unlocking rules may also require that mobile wireless service providers provide automatic unlocking for those handsets that can be unlocked automatically and that they transition to being able to automatically unlock all handsets that they offer for sale to consumers. The *NPRM* seeks comment on the impact of the proposed rule on non-nationwide service providers, such as small and rural service providers, if the Commission adopts a generally applicable handset unlocking rule.

50. At present, the record does not include a detailed cost/benefit analysis that would allow us to quantify the costs of compliance for small entities, including whether it will be necessary for small entities to hire professionals to comply with any rules that may be adopted. Small and other entities are encouraged to quantify the costs and benefits of any reporting, recordkeeping, or compliance requirement that may be established in this proceeding. The Commission expects the comments it receives on its proposals, and the matters discussed in the *NPRM* to include information addressing costs, benefits, and other matters of concern for small entities, which should help the Commission identify and better evaluate compliance costs and relevant issues for small entities before adopting final rules.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

51. The RFA requires an agency to provide, "a description of the steps the agency has taken to minimize the significant economic impact on small entities . . . including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

52. The *NPRM* seeks comment on implementing a broadly applicable handset unlocking requirement across the mobile wireless industry and proposes to require all mobile wireless service providers to unlock handsets 60 days after a consumer's handset is activated with the provider. The *NPRM*

seeks comment on the economic impact or other burdens of such an approach, particularly for small and rural wireless service providers. The *NPRM* asks whether such a general unlocking requirement would affect small and rural wireless service providers and wireless resellers differently as compared to national service providers and, if so, how. If the Commission were to require all service providers to unlock handsets after a set period of time, the *NPRM* seeks comment on an appropriate transition period and on any implementation issues the Commission should consider, especially with regard to small and rural service providers.

53. The Commission expects to consider more fully the economic impact on small entities following its review of comments filed in response to the *NPRM*, including costs and benefits information. Alternative proposals and approaches from commenters could help the Commission further minimize the economic impact on small entities. The Commission's evaluation of the comments filed in this proceeding will shape the final conclusions it reaches, the final alternatives it considers, and the actions it ultimately takes to minimize any significant economic impact that may occur on small entities from the final rules.

F. Federal Rules That May Duplicate, Overlap, or Conflict With Proposed Rules

54. None.

V. Ordering Clauses

55. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 4(i), 4(j), 303(b),(g),(r), and 316(a), of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 303(b),(g),(r), 316(a), the Notice of Proposed Rulemaking is *adopted*.

56. *It is further ordered* that, pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on the Notice of Proposed Rulemaking on or before 30 days after publication in the **Federal Register**, and reply comments on or before 45 days after publication in the **Federal Register**.

57. *It is further ordered* that the Commission's Office of the Secretary shall send a copy of the Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2024–16642 Filed 8–7–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 24–224; RM–11988; DA 24–731; FR ID 235793]

Television Broadcasting Services Lubbock, Texas

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Video Division, Media Bureau (Bureau), has before it a Joint Petition for Rulemaking filed May 21, 2024, by Gray Television Licensee, LLC (Gray), the licensee of KCBD, Lubbock, Texas (KCBD), which is operating on channel 11 but previously held a construction permit for channel 36, and SagamoreHill of Lubbock, LLC (SagamoreHill), the licensee of KJTV–TV, channel 35, Lubbock, Texas (KJTV–TV). As discussed below, Gray and SagamoreHill request that the Bureau amend the Table of TV Allotments to permit the stations to “swap” channels and authorize KCBD to operate on channel 35 and KJTV–TV to operate on channel 11. Accordingly, we seek comment on substituting channel 11 for channel 35 and channel 35 for channel 36 at Lubbock, Texas (Lubbock).

DATES: Comments must be filed on or before September 9, 2024 and reply comments on or before September 23, 2024.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Joint Petitioner as follows: Joan Stewart, Esq., Wiley Rein, LLP, 2050 M Street NW, Washington, DC 20036 and Scott Woodworth, Esq., Edinger Associates PLLC, 1725 I Street, Ste. 300, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT:

Joyce Bernstein, Video Division, Media Bureau, (202) 418–1647, at Joyce.Bernstein@fcc.gov; Emily Harrison, Video Division, Media Bureau, (202) 418–1665, at Emily.Harrison@fcc.gov; or Mark Colombo, Video Division, Media Bureau, (202) 418–7611, at Mark.Colombo@fcc.gov.

SUPPLEMENTARY INFORMATION: In 2021, at Gray's request, the Bureau amended the Table of TV Allotments to substitute UHF channel 36 for VHF channel 11 at Lubbock. Accordingly, channel 11 is no longer allotted to Lubbock in the Table of TV Allotments. Gray requested and was granted a construction permit to modify KCBD's facility to operate on channel 36 at Lubbock, using the existing broadband antenna currently used by KJTV–TV that is mounted on a tower located 5.5 kilometers from the licensed KCBD channel 11 site. Gray did not construct the facility. The Joint Petitioners now propose to “swap” the licensed channels and equipment for KCBD (channel 11) and KJTV–TV (channel 35). In order to effectuate this proposal, the Bureau must: (1) amend the Table of TV Allotments to substitute channel 11 at Lubbock for channel 35 and (2) amend the Table of TV Allotments to substitute channel 35 at Lubbock for channel 36. Upon grant of the proposed channel substitutions, the Joint Petitioners must simultaneously implement their proposed channel substitutions.

According to the Joint Petitioners, this proposal will serve the public interest because it will allow SagamoreHill to replace KJTV–TV's failing equipment with the equipment currently used by KCBD on channel 11. Specifically, Joint Petitioners state that KJTV–TV's tube transmitter is failing, that replacement parts for tube transmitters are not available, and that the cost for SagamoreHill to replace the transmitter for KJTV–TV's 1000 kW facility is prohibitively expensive. KCBD's channel 11 equipment, however, “is in good operating condition.” According to the Joint Petitioners, because Gray had planned to invest in a new 1000 kW transmitter for KCBD on channel 36, it will be able to use the new transmitter to instead replace the failing channel 35 transmitter and operate KCBD on channel 35. In turn, Gray will provide SagamoreHill with its channel 11 equipment (*i.e.*, antenna, transmitter, etc.) that it had planned to decommission following its move to channel 36. With regard to the proposed channel substitutions, according to the Engineering Statement submitted with the Joint Petition, there would be no predicted loss area on channel 35 when compared to KCBD's previously-authorized channel 36 facility. There would in fact be a small gain of 191 persons. Further, the proposed channel 11 facility for KJTV–TV encompasses its currently licensed channel 35 facility, and thus would also not result in any viewer loss. In fact, moving KJTV–TV

from channel 35 to channel 11 would provide additional service to approximately 8,000 persons.

We believe that Joint Petitioners' proposal warrants consideration. We believe channel 11 can be substituted for channel 35 at Lubbock, as proposed, in compliance with the principal community coverage requirements of § 73.618(a) of the Commission's rules (Rules), at coordinates 33°–32'–29.9" N and 101°–50'–13.6" W. In addition, we find that this channel change meets the technical requirements set forth in § 73.622(a) of the Rules. Furthermore, the proposed channel substitution would not cause any loss of service to viewers of KJTV–TV, would increase the population served within KJTV–TV's NLSC, and would provide KJTV–TV with access to better and more functional equipment.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking*, MB Docket No. 24–224; RM–11988; DA 24–731, adopted July 29, 2024, and released July 29, 2024. The full text of this document is available for download at <https://www.fcc.gov/edocs>. To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to FCC504@fcc.gov or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a notice of proposed rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

Providing Accountability Through Transparency Act: The Providing Accountability Through Transparency Act, Public Law 118–9, requires each agency, in providing notice of a rulemaking, to post online a brief plain-

language summary of the proposed rule. The required summary of this notice of proposed rulemaking/further notice of proposed rulemaking is available at <https://www.fcc.gov/proposed-rulemakings>.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,
Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622, in the table in paragraph (j), under Texas, revise the entry for Lubbock to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *							
(j) * * *							
Community		Channel No.					
* * * * *							
Texas							
* * * * *							
Lubbock	11, 16,	* 25, 27,	31, 35.				
* * * * *							

[FR Doc. 2024–17426 Filed 8–7–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2021–0065; FXES1111090FEDR–245–FF09E21000]

RIN 1018–BH40

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Long Valley Speckled Dace

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Long Valley speckled dace (*Rhinichthys nevadensis caldera*), a fish native to California, as an endangered species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the Long Valley speckled dace. After a review of the best available scientific and commercial information, we find that listing the subspecies is warranted. Accordingly, we propose to list the Long Valley speckled dace as an endangered species under the Act. If we finalize this rule as proposed, it would add this subspecies to the List of Endangered and Threatened Wildlife and extend the Act's protections to the subspecies. We have determined that designation of critical habitat for the Long Valley speckled dace is not determinable at this time.

DATES: We will accept comments received or postmarked on or before October 7, 2024. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by September 23, 2024.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter FWS–R8–ES–2021–0065, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on “Comment.”

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2021–0065, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Supporting materials, such as the species status assessment report, are available at <https://www.regulations.gov> at Docket No. FWS–R8–ES–2021–0065.

FOR FURTHER INFORMATION CONTACT:

Justin Barrett, Deputy Field Supervisor, Reno Fish and Wildlife Office, U.S. Fish and Wildlife Service, 1340 Financial Boulevard, Suite 234, Reno, NV 89502; telephone 775–861–6338. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please see Docket No. FWS–R8–ES–2021–0065 on <https://www.regulations.gov> for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:**Executive Summary**

Why we need to publish a proposed rule. The Act (16 U.S.C. 1531 *et seq.*) defines the term “species” as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species’ critical habitat to the maximum extent prudent and determinable. We have determined that the Long Valley speckled dace meets the definition of an endangered species; therefore, we are proposing to list it as such. Listing a species as an endangered or threatened species can be completed only by issuing a proposed rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. We propose to list the Long Valley speckled dace as an endangered species under the Act.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors

affecting its continued existence. We have determined that the Long Valley speckled dace is endangered due to the following threats: disease; introduced species; grazing; recreation; a trout hatchery; geothermal development; climate change; and effects of small population size.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary), to the maximum extent prudent and determinable, concurrently with listing designate critical habitat for the species. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

We determined that designating critical habitat for the Long Valley speckled dace is prudent but not determinable at this time. We will coordinate with partners to obtain data sufficient to perform the required analysis of the impacts to inform our proposed critical habitat designation. When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Long Valley speckled dace’s biology, range, and population trends, including:

(a) Biological or ecological requirements of the subspecies, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns and the locations of any additional populations of this subspecies;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the subspecies, its habitat, or both.

(2) Threats and conservation actions affecting the subspecies, including:

(a) Factors that may be affecting the continued existence of the subspecies, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors;

(b) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this subspecies; and

(c) Existing regulations or conservation actions that may be addressing threats to this subspecies.

(3) Additional information concerning the historical and current status of this subspecies.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in

ADDRESSES. We request that you send comments only by the methods described in **ADDRESSES.**

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we

used in preparing this proposed rule, will be available for public inspection on <https://www.regulations.gov>.

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after this proposal. Based on the new information we receive (and, if relevant, any comments on that new information), we may conclude that the Long Valley speckled dace is threatened instead of endangered, or we may conclude that the subspecies does not warrant listing as either an endangered species or a threatened species. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On June 24, 2020, the Service received a petition, dated June 8, 2020, from the Center for Biological Diversity (CBD) requesting that the Long Valley speckled dace and two other speckled dace entities in the Death Valley region be listed as endangered or threatened species and critical habitat be designated under the Act. On September 29, 2021, we published in the **Federal Register** (86 FR 53937) a 90-day finding that the petition presented substantial scientific or commercial information indicating that listing the Long Valley speckled dace may be warranted.

Peer Review

A species status assessment (SSA) team prepared an SSA report for the Long Valley speckled dace (Service 2023, entire). The SSA team was composed of Service biologists, in consultation with other species experts.

The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review in listing and recovery actions under the Act, we solicited independent scientific review of the information contained in the Long Valley speckled dace SSA report. We sent the SSA report to four independent peer reviewers and received responses from all four reviewers. Results of this structured peer review process can be found at <https://www.regulations.gov>. In preparing this proposed rule, we incorporated the results of these reviews, as appropriate, into the SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed above in Peer Review, we received comments from four peer reviewers on the draft SSA report. We reviewed all comments for substantive issues and new information regarding the material contained in the SSA report. Reviewers generally provided additional references, clarifications, and suggestions for the SSA report. We updated the SSA report based on the information we received and worked with researchers to update the current and future condition analyses. Peer reviewer comments are addressed in the following summary, and information provided was incorporated into the SSA report as appropriate (Service 2023, entire).

Comment 1: A reviewer commented on cattails and other vegetation being a present threat at Whitmore Marsh and that removal of plants from selected areas may be beneficial for improving Long Valley speckled dace habitat.

Our Response: We added text to chapter 4.5.2.2 of the SSA report to describe the potential impacts of *Typha* spp. on the Long Valley speckled dace and its habitat.

Comment 2: A reviewer asked whether Lahontan cutthroat trout (*Oncorhynchus clarkii henshawi*) in the translocation site, O'Harrel Canyon Creek, would prey upon Long Valley speckled dace when migrating downstream in the winter.

Our Response: Lahontan cutthroat trout do have the potential to prey upon Long Valley speckled dace. We added text to chapter 3.1.5 of the SSA report

discussing the potential for Lahontan cutthroat trout to move downstream as potential predators.

Comment 3: A reviewer asked if the estimate of the refuge population was adults only or if juveniles were included. They expressed concern that the estimate may be overestimated if juveniles were included.

Our Response: We added the range of sizes of collected individuals to clarify the information presented in chapter 4.6 of the SSA report, where we describe the refuge population in greater detail.

Comment 4: A reviewer questioned what "relatively stable" meant in terms of survey results conducted by the California Department of Fish and Wildlife (CDFW) at Whitmore Marsh. The reviewer commented that a stable population with low abundance is still at risk of extirpation. They also questioned whether the negative effects of removing fish from Whitmore Marsh, a small population, were considered.

Our Response: We added text to chapter 4.3.7 of the SSA report to clarify that the CDFW characterized the population as relatively stable during their 2002 and 2009 surveys, although CDFW did not define the term "relatively stable" and no abundance data or estimates were generated in those surveys. All available information is provided in chapter 4.3.7 of the SSA report.

Comment 5: A reviewer requested clarification on how high snowpack prevents movement of Long Valley speckled dace.

Our Response: We added text to chapter 4.3.7 of the SSA report to clarify that cold temperatures from meltwater could have contributed to Long Valley speckled dace concentrating in the upper reaches of Whitmore Marsh near the spring source and the pool discharge.

Comment 6: Two reviewers questioned the genetic health of the Whitmore Marsh northeast pond refugium and questioned whether genetics were considered in the translocation of Long Valley speckled dace to O'Harrel Canyon Creek.

Our Response: Fin clips of Long Valley speckled dace at White Mountain Research Center (WMRC) were collected for genetic analyses in 2021, but we are not aware of any results or information on the genetic health of the population from this study. The O'Harrel Canyon Creek population was sourced from White Mountain Research Center and the White Mountain Research Center population was sourced from Whitmore Marsh; therefore, the genetics for all three populations are the same.

Comment 7: A reviewer commented that the text describing populations not being significantly influenced by grazing is not true. They mentioned historical grazing impacts have substantially altered stream habitat, water levels, and riparian areas. The commenter clarified that while current grazing may not be impacting populations, contemporary grazing likely limits the abilities of these streams to recover. They also commented that restoring stream habitat may help offset climate impacts in the near term.

Our Response: We made changes to the text in chapter 4.5.3 of the SSA report to clarify that while grazing appears to impact habitat, it may have less immediate impact to individuals and the local population when considered relative to other threats.

Comment 8: A reviewer commented that the Hot Creek Trout Hatchery is not hydrologically connected to Whitmore Marsh and mentioned it is unclear why the hatchery is being considered a threat to this population.

Our Response: We made changes to the text in the Executive Summary and in the body of the SSA report in sections discussing Hot Creek (Table 4) and Hot Creek Springs (section 4.3.1 and Table 4) historical locations: (1) to discuss how the trout hatchery has potentially played a role in the extirpation of historical populations of the Long Valley speckled dace at the Hot Creek and Hot Creek Springs historical locations; and (2) to remove associated text from the discussion of current threats to the subspecies at Whitmore Marsh.

Comment 9: A reviewer commented that while Long Valley speckled dace are currently found in geothermal waters, there is no evidence that this is a habitat requirement. The reviewer mentioned that Whitmore Marsh is extremely cold in the winter, emphasizing that Long Valley speckled dace habitat associations are linked more closely to the absence of nonnative trout.

Our Response: We made changes to the text in chapter 3.2.2 of the SSA report to remove the word “thermal” from “thermal spring systems,” although we do acknowledge there may be some geothermal influence on Whitmore Marsh, as its waters do not freeze even during extremely cold winters.

Comment 10: A reviewer commented that absence of nonnative trout seems to be the single most important factor for the survival of Long Valley speckled dace. They clarified that Long Valley speckled dace are broadly tolerant of a

range of water quality parameters, and this tolerance allows them to persist in marginal habitat where nonnative trout species cannot.

Our Response: We made changes to the text in chapter 3.2.2.1 of the SSA report to emphasize that the presence of nonnative species has a greater impact on the quality of habitat for Long Valley speckled dace than water quality does.

Comment 11: A reviewer questioned how the Hot Creek Trout Hatchery impacted Long Valley speckled dace populations given that other native minnows (tui chub (*Siphateles bicolor*)) persist in the spring brooks to this day. The reviewer noted that the spring brook habitat described by Sada (1989, p. 13) is still intact and not impacted by the hatchery.

Our Response: We made changes to the text in chapter 4.5.5 of the SSA report to emphasize that there is not concrete evidence that the hatchery led to the extirpation of Long Valley speckled dace populations but also to acknowledge that the hatchery may have had an impact on the subspecies’ habitat.

Comment 12: A reviewer commented that the status of the O’Harrel Canyon Creek population is unknown, and it should not be described as “established.”

Our Response: We removed the word “established” from the text in chapter 4.2 of the SSA report as a descriptor for the O’Harrel Canyon Creek population of Long Valley speckled dace.

Comment 13: A reviewer commented that there is no evidence to support the claim that the Hot Creek Trout Hatchery played a role in the extirpation of Long Valley speckled dace at previously occupied historical sites. They mentioned that the Owens tui chub (*Siphateles bicolor snyderi*) persisted in both spring brooks from which Long Valley speckled dace disappeared between 1933 and 1989. Long Valley speckled dace were also extirpated from that portion of Hot Creek away from the hatchery’s influence.

Our Response: We made changes to the text in chapter 4.5.5 of the SSA report, adding a citation from Sada (1989, p. 3) that corroborates the potential impacts the Hot Creek Trout Hatchery may have had on the Long Valley speckled dace’s habitat. In that discussion, we also removed the phrase “likely led to extirpation” and made other revisions to take the uncertainty into account.

Comment 14: One reviewer commented that the danger from fire caused by climate change is underrated in our analysis.

Our Response: We added a paragraph to chapter 4.5.7 of the SSA report addressing local fire risk and how precipitation may increase the risk of excessive sedimentation within local watersheds.

I. Proposed Listing Determination Background

A thorough review of the taxonomy, life history, and ecology of the Long Valley speckled dace is presented in the SSA report (Service 2023, pp. 6–8).

The Long Valley speckled dace is a small freshwater fish with one remaining historical population within the 700,000 year old Long Valley volcanic caldera and one refugium population in Mono County, California. The subspecies previously occupied habitat in the Owens Basin in California ranging from cold-water streams to hot springs with water temperatures typically below 29 degrees Celsius (°C) (84.2 degrees Fahrenheit (°F)) (Moyle et al. 2015, p. 3). This subspecies was found in 7 historical sites, including 6 spring sites and one small stream. While the stream population suggests the subspecies is capable of surviving in stream habitats, its disappearance from the historical stream location following development of a hydrologically-connected spring suggested the stream population relied on recruitment from spring-dwelling individuals (Sada 1989, p. 13). Population collapses in six historical sites that were modified and invaded by nonnative fish species indicates that the Long Valley speckled dace is highly susceptible to changes in its habitat. The remaining occupied habitat includes two populations: one native population at Whitmore Marsh and one translocated population at the three sites in O’Harrel Canyon Creek. The CDFW also maintains a refugium population in an artificial pond at the WMRC.

The Long Valley speckled dace is a small minnow that typically measures less than 8 centimeters (cm) but can reach 11 cm standard length. This subspecies is distinguished by its small downfacing mouth, a thick caudal peduncle, small scales, and a pointed snout. The snout typically has a small barbel on each end of the maxilla (jaw) and a small patch of skin connects the snout to the upper lip. Adults usually have eight rays in their dorsal fin, which originates behind the beginning of the pelvic fins, whereas the anal fin has six to eight rays. Distinctive dark spots on the sides and upper parts of the body, as well as a dark lateral band running to the snout, usually occur once the fish becomes larger than 3 cm. The body is

an olive to darkish yellow, with the stomach area paler in color. During the breeding season, both males and females have orange- or red-tipped fins, with males also exhibiting red snouts and lips. Males often develop tubercles on their head and pectoral fins (Moyle 2002, p. 160).

The Long Valley speckled dace is a minnow (family = *Leuciscidae*) in the genus *Rhinichthys*. In 1896, Jordan and Evermann divided *Rhinichthys osculus* into a complex of 10 species (Su et al. 2021, entire). Hubbs et al. (1974, entire) collapsed all of them into one species. In 2023, Moyle et al. (2023, entire) summarized the recent genomic findings and presented a revision of taxonomy for California dace populations. The new taxonomy consists of three species (Santa Ana speckled dace (*R. gabrielino*); desert speckled dace (*R. nevadensis*); and western speckled dace (*R. klamathensis*)) and six subspecies, including the Long Valley speckled dace (*R. n. caldera*).

There is little information regarding the biology and life history of Long Valley speckled dace; therefore, the following description is based primarily on information for general speckled dace (*Rhinichthys osculus*) and historical and current collections of Long Valley speckled dace. General speckled dace lifespan is coarsely correlated with maximum size, with dace under 80 millimeters fork length living for roughly 3 years. Typically, females grow faster than males. Under stressful environmental conditions, limited food, or high population densities, growth rates can decrease. General speckled dace reach sexual maturity by the end of their second summer. Females produce 190–800 eggs, depending on size and location, and release them underneath rocks or near gravel surfaces while males release sperm.

General speckled dace's subterminal mouth and tooth structure make it ideal for consumption of small aquatic invertebrates most common in riffles (hydropsychid caddisflies, baetid mayflies, and chironomid and simuliid midges). Invertebrates generally make up the bulk of their diet; however, they may also eat filamentous algae (Moyle et al. 2015, p. 2). Speckled dace forage opportunistically, which varies their diet of invertebrates depending on available food sources that may change during the seasons. Speckled dace can be active both in the day and at night, with water temperatures influencing their level of activity. Speckled dace are active year-round when stream temperatures stay above 4 °C (39.2 °F).

Long Valley speckled dace likely originated during the late Pleistocene pluvial period when they colonized the upper Owens Valley region from Mono Lake Basin water that spilled into the Adobe Valley. The Adobe Valley drained into the Owens River and fish presumably swam upstream to Long Valley. The Owens River eventually down-vaulted and formed steep waterfalls in the gorge around 100,000 years ago, ultimately isolating Long Valley from Owens Valley. Long Valley speckled dace currently have limited ability to disperse between populations, as many of the springs they occupied historically are not hydrologically connected to other lakes or streams in the broader Death Valley region or are separated by unsuitable habitat.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. On April 5, 2024, jointly with the National Marine Fisheries Service, we issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and what criteria we apply when designating listed species' critical habitat (89 FR 24300). On the same day, we published a final rule revising our protections for endangered species and threatened species at 50 CFR 17 (89 FR 23919). These final rules are now in effect and are incorporated into the current regulations.

The Act defines an "endangered species" as a species that is in danger of extinction throughout all or a significant portion of its range, and a "threatened species" as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an "endangered species" or a "threatened species" only after conducting this cumulative analysis and describing the expected effect on the species.

The Act does not define the term "foreseeable future," which appears in the statutory definition of "threatened species." Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis, which is further described in the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M-37021, January 16, 2009; "M-Opinion," available online at <https://www.doi.gov/eop/m-37021>).

www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf).

The foreseeable future extends as far into the future as the U.S. Fish and Wildlife Service and National Marine Fisheries Service (hereafter, the Services) can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat projection timeframes, and environmental variability. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies.

To assess the Long Valley speckled dace's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years); redundancy is the ability of the species to withstand catastrophic events (for example, droughts, large pollution events); and representation is the ability of the species to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogens). In general, species viability will increase with increases in resiliency, redundancy, and representation (Smith et al. 2018, p. 306). Using these principles, we identified the Long Valley speckled dace's ecological

requirements for survival and reproduction at the individual, population, and subspecies levels, and described the beneficial and risk factors influencing the subspecies' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual subspecies' life-history needs. The next stage involved an assessment of the historical and current condition of the subspecies' demographics and habitat characteristics, including an explanation of how the subspecies arrived at its current condition. The final stage of the SSA involved making predictions about the subspecies' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of the subspecies to sustain populations in the wild over time, which we then used to inform our regulatory decision.

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS-R8-ES-2021-0065 on <https://www.regulations.gov>.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the subspecies and its resources, and the threats that influence the subspecies' current and future condition, in order to assess the subspecies' overall viability and the risks to that viability.

Subspecies Needs

For Long Valley speckled dace to have high viability, the subspecies needs to maintain its representation (adaptive capacity) by having multiple, sufficiently resilient populations (redundancy). Long Valley speckled dace is a narrow endemic and inherently has low redundancy; however, it is still important that multiple, adequately resilient populations exist throughout its range. This allows the subspecies to retain some redundancy and representation, which help mitigate impacts from threats and stochastic events. Having multiple populations helps maintain genetic diversity and adaptive capacity, which is increasingly important due to the impacts of climate change.

To have high viability, the Long Valley speckled dace would need consistent clean cold water (water temperatures that stay below 29 °C (84.2 °F) in the summer months) with access to aquatic invertebrates as a food source. Fertilized eggs and larvae utilize

gravel substrates during development, and later larvae use rocks and emergent vegetation for cover. Adults typically inhabit springs but have also existed in creek systems. Populations need abundant individuals within habitat patches of adequate quality to maintain survival and reproduction despite disturbance. For Long Valley speckled dace, this revolves around having adequate aquifer-fed thermal spring systems or creeks that stay above 4 °C (39.2 °F). Having enough water in each spring or creek is important to allow dace within the population to disperse throughout the connected habitat during different seasons for reproductive purposes. Having multiple populations connected within the watershed is important to mitigate impacts from localized threats. Population size varies greatly based on the annual conditions of the habitat and will rebound in numbers when conditions are favorable.

The amount of habitat is mainly driven by snowmelt from the Sierra Nevada highlands on the western edge of the caldera (U.S. Geological Survey, undated). The subspecies inhabits a relatively small area, making adequate amounts of suitable habitat important for the resiliency of the subspecies. Quality of habitat revolves around water quality. For the subspecies, the water quality priorities are having water temperatures stay below 29 °C (84.2 °F) and limiting the amount of pollution and sedimentation in the waterways. Invasive species can also negatively impact habitat suitability directly by changing dissolved oxygen and pH levels of the water or by increasing predation and competition levels.

Capacity for population growth, particularly from low numbers, is important for the Long Valley speckled dace's resiliency. The Long Valley speckled dace currently occurs in low numbers, making it especially vulnerable to stochastic events. Having populations large enough to be self-sustaining and to be able to repopulate habitat in a highly variable and unpredictable environment is important for the Long Valley speckled dace's resiliency. In response to introduced species, disease, grazing, recreation, a trout hatchery, geothermal development, climate change, and small population size effects in the occupied habitat, Long Valley speckled dace populations must be resilient enough to repopulate habitat as environmental conditions change.

Although surveys have been completed at Whitmore Marsh as recently as 2023, the six extirpated historical sites have not been revisited as recently and assessed for current

habitat conditions because of previous surveys deeming them uninhabitable. An overall population estimate, and subsequent population trends, are unknown for the subspecies outside of the Whitmore Marsh population. O'Harrel Canyon Creek was surveyed in 2023 and 2024 (Buckmaster 2023, pers. comm.; Buckmaster 2024, pers. Comm.), with documented evidence of survival and reproduction. However, it is currently unknown how effectively translocated Long Valley speckled dace can establish in a wild environment. Robust monitoring would be needed to estimate population levels as the total number of Long Valley speckled dace fluctuates year-to-year based on habitat conditions.

Factors Influencing Subspecies Viability

The following discussion provides a summary of the primary factors that affect or may affect the current and future condition of the Long Valley speckled dace. For our analysis, we evaluated impacts from the following primary threats to the subspecies: (1) disease; (2) nonnative species; (3) grazing; (4) recreation; (5) water diversion; (6) geothermal development; (7) climate change; and (8) effects of small population size.

Disease

Growth and health status of fish may be negatively affected by parasites (Raissy and Ansari 2012, p. 74). In general, parasites may cause stress, reduced growth, increased risk of infection or secondary disease, and possibly death of individual fish (Hejna et al. 2023, entire). For example, in 1988, Long Valley speckled dace found in Whitmore Marsh were in poor condition due to a heavy parasite infestation of yellow grub (*Clinostomum marginatum*) (Bogan et al. 2002, p. 4). Because of the documented negative impacts to Long Valley speckled dace, and because there is only one historical population of Long Valley speckled dace remaining, we consider disease to pose a threat to the viability of the Long Valley speckled dace.

Nonnative Species

The introduction of nonnative species may stress indigenous fish populations via increased predation, competitive interactions, transmission of pathogens, or hybridization (Cucherousset and Olden 2011, pp. 216–221; Mills et al. 2004, pp. 719–720). Western mosquitofish are the most common nonnative fish species that have led to the extirpation of isolated general speckled dace populations. Nonnative Lahontan tui chub (*Gila bicolor*) are also

found in the range of the Long Valley speckled dace. Nonnative species can compete with or prey upon Long Valley speckled dace and may introduce parasites and disease into the freshwater ecosystems they inhabit (Stone et al. 2007, p. 131). Long Valley speckled dace have rarely been found in springs where other nonnative fish species are present, suggesting their ability to compete with or avoid predation from nonnatives is limited (Sada 1989, p. 10). For example, one Long Valley speckled dace population collapsed within a year of western mosquitofish and Lahontan tui chub (*Gila bicolor*) being recorded at the site, and the population is currently considered extirpated (Greene 2006, pers. comm., p. 4). Therefore, we consider nonnative species to pose a significant threat to the viability of Long Valley speckled dace populations.

Grazing

Cattle access is known to increase bank erosion, increasing turbidity and sedimentation in the springs. Long Valley speckled dace require clear water for their spawning and clean vegetation for egg laying. Sedimentation from cattle also has the potential to fill in spring pools and runs, reducing habitat area (American Fisheries Society, undated, entire). The increased turbidity and reduced riparian vegetation lead to increased water temperatures, which reduce dissolved oxygen levels and can stress Long Valley speckled dace and increase the competitive advantage for mosquitofish. Influxes of large amounts of cattle waste increase the amount of nutrients in the water and further reduce visibility, which can impact the spawning of Long Valley speckled dace. Higher levels of nutrients result in higher biological oxygen demand and reduce the dissolved oxygen levels in the water. Increased bacterial levels may also reduce egg viability and increase the risk of infection. Grazing has been occurring in Long Valley since before the discovery of Long Valley speckled dace, and historical grazing has altered stream habitat and riparian areas, such that it is less suitable habitat for the species. While historical grazing levels may have had detrimental impacts to Long Valley speckled dace habitat, the best available information indicates that while Whitmore Marsh and Little Alkali were historically heavily impacted by cattle grazing, both populations appeared to be stable at the time grazing impacts were observed (Sada, 1989, p. 12). Grazing still occurs at low levels around Whitmore Marsh and any impacts to habitat do not appear to be adversely affecting the population there. Thus, we do not consider grazing to be

a significant threat to Long Valley speckled dace populations.

Recreation

Recreation activities in general may impact water quality, substrate and vegetation, and free-flowing water. The spring source that supplies Whitmore Marsh also feeds a public swimming pool. Historically, the pool has discharged lightly chlorinated water into the marsh from May to September (Cox 2023, p. 1), however chlorinated water is no longer discharged into the marsh. While the effluent from the spring is undiminished by pool operations and has maintained sufficient flows to support this Long Valley speckled dace population, the potential for an accidental spill of chlorinated water into the spring still exists. There is also potential for structural damage to the pool to result in leaks because of the age of the pool or by events such as seismic activity. Because of the proximity of the swimming pool to Whitmore Marsh we consider recreation to be a significant threat to the viability of this population.

Water Diversion

Surface water diversions have the potential to affect fish survival directly or indirectly. Water diversions reduce the amount of water available to stream resources and return the remaining water far from the intake. Flow alterations directly impact fish by blocking migration routes (e.g., trapping fish in dewatered sections) and by disrupting breeding habits. Diversions indirectly affect fish by removing stream habitat, degrading water quality parameters, and introducing competing nonnative species (American Fisheries Society, undated, p. 2). For example, Long Valley speckled dace individuals disappeared from Hot Creek shortly following the development of the Hot Creek Trout Hatchery (a CDFW-owned facility) and associated water diversions in the 1960s.

Geothermal Development

Prior to geothermal development of a particular area, the flow path of water underneath the land surface is usually not known with sufficient detail to understand and prevent surface impacts that may be caused by such development (Sorey 2000, p. 705). Changes associated with surface expression of thermal waters from geothermal production are common and are expected. Typical changes seen in geothermal fields across the globe include, but are not limited to, changes in water temperature, flow, and quality (Bonte et al. 2011, pp. 4–8; Chen et al.

2020, pp. 2–6; Kaya et al. 2011, pp. 55–64; Sorey 2000, entire), which are all needs of Long Valley speckled dace.

Changes in surface-expressed water temperature and flow from geothermal production areas have been documented within the Long Valley Caldera at historical localities where Long Valley speckled dace previously occurred and near the remaining population of the subspecies (Sorey 2000, entire). Geothermal pumping between 1985–1998 at Casa Diablo Geothermal Plant, part of Ormat Technologies, Inc., Mammoth Geothermal Complex, resulted in flow ceasing at Colton Spring and declines in water level at Hot Bubbling Pool (Sorey 2000, p. 706), which are located roughly 6.4 kilometers (km) (4 miles (mi)) and 4.8 km (3 mi) from Whitmore Marsh, respectively. Based on historical operations of the Casa Diablo Geothermal Plant and surface water monitoring at Whitmore Marsh, the remaining historical population of Long Valley speckled dace is outside of the range where detectable changes in surface features have occurred. However, the Casa Diablo-IV power plant that was put into service in 2022 nearly doubles the capacity of the geothermal facility, and future impacts from the operation of the expanded plant may extend farther into the Long Valley speckled dace's range. The doubled capacity plant has only been in service since July 2022. Monitoring of spring flow, temperature, and stage is not taking place at Whitmore Marsh, so the data required for an analysis of the condition of, or possible effects from local geothermal development to, the springs and surface water there are currently not available. Additionally, if the operation does cause effects to the geothermally sourced springs at Whitmore Marsh, propagation and expression of those effects may take time. Therefore, the best available information used to consider the impacts of geothermal development does not indicate that it is currently a threat to the species; however, we recognize the potential for population-level impacts should the effects of groundwater and geothermal extraction be realized at Whitmore Marsh.

Climate Change

Changes in climate, such as increasing temperatures, shifts in precipitation patterns, drought, and increases in wildfire have already been observed in California where Long Valley speckled dace occur, and such changes are expected to continue. Current climate change forecasts for terrestrial areas in the Northern Hemisphere predict

warmer air temperatures, more intense precipitation events (both drought and flooding), and increased summer continental drying by the year 2100 (Intergovernmental Panel on Climate Change (IPCC) 2014, entire). Little is known about how and when spring flows may be affected by changes in climate. Direct hydrological connections have not been established in most cases, and for many areas, these connections remain difficult to make. Increased variations in temperature and precipitation in the range of the Long Valley speckled dace may result in effects on the life history of the subspecies. Thermal springs that comprise a major part of Long Valley are fed by aquifers dependent on snowmelt for recharge. Long Valley speckled dace are currently found in a hot-spring-fed marsh and a creek, with temperatures that stay below 29 °C (84.2 °F). Long Valley speckled dace are capable of withstanding elevated water temperatures (Moyle et al. 2015, p. 11), but the lethal upper temperature limit is unknown. Fish are generally more stressed at the upper extremes of their temperature range, and although they may be able to survive, elevated temperature is an example of a stressor that may affect them through reduced disease resistance (Moyle et al. 2015, p. 11). Average annual temperatures have increased almost 1.1 °C (1.9 °F) over the last century (Garfin et al. 2014, p. 464), and an additional increase of 1.9 to 5.3 °C (3.5 to 9.5 °F) is predicted to occur by the year 2100 (Walsh et al. 2014, p. 23). In recent decades, reductions in precipitation and winter snowpack have been observed, and this pattern is expected to continue (Garfin et al. 2014, p. 465). The frequency and intensity of these reductions have increased on a global scale (IPCC 2014, p. 77), and climate change is projected to reduce surface and groundwater resources in most subtropical deserts (IPCC 2014, p. 14).

Climate change is also predicted to increase fire frequency and severity. Whitmore Marsh, O'Harrel Canyon Creek, and certain historical sites (Little Alkali and Hot Creek Springs) are located within a moderate fire hazard severity zone. Other historical sites (Unnamed Spring and Sulfur Spring) are located within a high fire hazard severity zone. In the southern California mountains, debris flows can occur in both burned and unburned terrain. Wildfires greatly increase the likelihood of debris flows within the burned area by removing vegetation and temporarily elevating soil hydrophobicity (Staley et al. 2017, entire). Excess overland flow

from intense precipitation events caused by climate change may exacerbate the effects of debris flows in areas affected by wildfire. When debris flows occur, they can cause significant erosion to hillslopes and channels, resulting in large amounts of sediment being carried downstream. This excessive sediment can have profound negative impacts on local wildlife, including fish such as the Long Valley speckled dace. Wildfire also eliminates vegetation that shades the water and moderates water temperature and may further impact water transport, sediment transport, water quality, and flow regime. Burned uplands in the watersheds may affect Long Valley speckled dace habitat by producing silt-and-ash-laden runoff that can fill in pools and significantly increase turbidity of rivers. Large wildfires have caused local extirpations in isolated Long Valley speckled dace occurrences (Expert Working Group 2023, p. 23). Wildfire may impact the Long Valley speckled dace throughout its remaining range, although the location, frequency, and size of these events cannot be precisely predicted.

Increased frequency of snow drought induced by climate change may also affect the flow rates and temperatures of hydrologic features inhabited by the Long Valley speckled dace (Hatchett and McEvoy 2018, pp. 11–12). Particularly due to the historical impacts of wildfire on Long Valley speckled dace habitat, and the potential effects a single large fire could have on the remaining historical population at Whitmore Marsh, we consider climate change to pose a significant threat to the subspecies.

Effects of Small Population Size

Historically, Long Valley speckled dace mostly occurred in small, isolated populations throughout the subspecies' range. The subspecies currently consists of a single wild population at Whitmore Marsh. Small, isolated populations are vulnerable to a number of deleterious effects, including: (1) demographic fluctuation due to random variation in birth and death rates and sex ratio; (2) environmental fluctuation in resource or habitat availability, predation, competitive interactions, and catastrophes; (3) reduction in cooperative interactions and subsequent decline in fertility and survival (*i.e.*, Allee effects); (4) inbreeding depression reducing reproductive fitness; and (5) loss of genetic diversity reducing the ability to evolve and cope with environmental change (Traill et al. 2010, p. 29).

For example, small populations of Long Valley speckled dace are more

vulnerable to extirpation during environmental fluctuation, such as flooding (which can physically wash dace away), fire (and its subsequent impacts on Long Valley speckled dace habitat and water quality), or sustained drought (which can result in the loss or reduction of surface flows and concomitant increases in water temperature). Habitat fragmentation has subjected the small populations to genetic isolation, reduced space for rearing and reproduction, and reduced adaptive capabilities, and has increased the subspecies' likelihood of extinction. Isolation means that any remnant populations following these types of events caused by environmental fluctuation or habitat fragmentation are unlikely to benefit from demographic or genetic rescue, further elevating risks of inbreeding depression, loss of genetic diversity, and reductions in evolutionary potential that can contribute to population extirpation. These small population effects interact with other factors to pose a threat across the Long Valley speckled dace's current range. Thus, because the Long Valley speckled dace currently occurs in small, isolated populations, the magnitude of the threat posed by environmental stochasticity and inbreeding depression is elevated.

Conservation Efforts and Regulatory Mechanisms

At this time, Long Valley speckled dace is not listed under the California Endangered Species Act (CESA). Due to concerns over the future viability of the last remaining historical population of Long Valley speckled dace, CDFW staff deemed it necessary to establish a refugium population in an artificial pond at the White Mountain Research Center (WMRC) outside of the native range (Cox, 2021, p. 1). This population was sourced from individuals at Whitmore Marsh and a previous refuge population known as Becky's Pond, also sourced from Whitmore Marsh, which has since been extirpated. Although the refuge population appears stable, CDFW recommends continued monitoring for disease that may have been present in source individuals from Whitmore Marsh and management of water quality and water levels to maintain this population. Monitoring the genetic health of the refuge population will also be important for understanding and managing its long-term viability. The refugium population at WMRC represents a critical component of Long Valley speckled dace conservation and has already been used in translocation efforts.

Similar efforts to mitigate threats have also been initiated for the last remaining historical population. The public swimming pool operated by the town of Mammoth Lakes historically discharged chlorinated water into Whitmore Marsh, possibly contributing to the population decline occurring around 2017 (Cox, 2023, p. 1). The town has since made changes to the way the pool is managed and operated in order to limit the risk of introducing chlorinated water into the marsh in the future. A storage tank was constructed in 2022 to store discharged pool water until it can be transported off site to a sewage treatment plant (Cox, 2023, p. 2). This effort reduces the risk of chronic release events. In addition, the town of Mammoth Lakes has been coordinating with the Service to develop a management plan to implement response actions in the event of an accidental spill.

CDFW monitored the habitat at O'Harrel Canyon Creek in 2015–2016 and determined that drought did not have an effect on the creek despite the creek's size and watershed. These factors influenced CDFW to create a plan to translocate Long Valley speckled dace and create another wild population to supplement the Whitmore Marsh population. CDFW collected 413 Long Valley speckled dace from the Whitmore Marsh Complex Northeast pond refugium population on June 30, 2022. Collected Long Valley speckled dace were transported and released at three locations within O'Harrel Canyon Creek. Monitoring of these locations in 2023 and 2024 (Buckmaster 2023, pers. comm.; Buckmaster 2024, pers. comm.) indicated survival and reproduction; however, multiple years of monitoring will be needed to determine if this population successfully establishes.

Cumulative and Synergistic Effects

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have analyzed the cumulative effects of identified threats and conservation actions on the subspecies. To assess the current and future condition of the subspecies, we evaluate the effects of all the relevant factors that may be influencing the subspecies, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire subspecies, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

Current Condition

As mentioned previously, the Long Valley speckled dace is a narrow endemic subspecies known from seven historical sites within the Long Valley Caldera in Mono County, California. All but one of the seven historical sites are now thought to be extirpated (Moyle et al. 2015, p. 3). Because of the small spatial scale, few extant sites, limited survey data, and localized nature of the threats, we assessed the current conditions qualitatively by discussing rangewide factors affecting viability and by summarizing the available demographic and habitat information for each population. We then supplement the demographic and habitat quality data with a threats analysis for the extant wild population. We provide qualitative descriptions of the factors influencing viability and summarize these influences using a risk matrix approach to highlight major threats and their expected impacts.

Resiliency

Of seven known historical populations of Long Valley speckled dace, Whitmore Marsh is the sole remaining population and covers roughly 4,000–8,000 square meters (1–2 acres), based on accounts by Moyle et al. (2015, p. 3) and Geographic Information System calculations using satellite imagery of wetland vegetation over multiple years. In 2022, a population was translocated to O'Harrel Canyon Creek from the refuge population at White Mountain Research Center (Cox 2022, p. 2); however, it is uncertain whether this population will maintain viability over time.

The Long Valley speckled dace population in Whitmore Marsh was discovered in 1988 (Sada 1989, p. 10). Sada (1989, p. 11) visited this site four times between July 31 and December 12, 1988, to collect population size and habitat quality data. The habitat was supported by spring discharge that flowed through a chlorinated swimming pool owned and maintained by the Town of Mammoth Lakes on Los Angeles Department of Water and Power property. CDFW surveyed Whitmore Marsh again in 2002 and 2009, and found the population to be relatively stable. In 2011, Long Valley speckled dace were translocated from this site to a private pond ("Becky's Pond"), which was originally constructed in 2006. No population estimates were recorded at the time of the 2011 translocation. Individuals from Becky's Pond were later moved to a refuge population established at White Mountain Research Center. The Becky's Pond population

was supplemented with individuals from Whitmore Marsh in 2011 and then subsequently confirmed to be extirpated (Cox 2022, p. 2).

Low numbers at Whitmore Marsh over the past 7 years, including as few as two individuals being observed in 2021, have been attributed to a die-off that likely occurred in the spring of 2017. While the cause of the population crash is unknown, there are several threats in the area that may have led to the decline. One hypothesis is that an unusually heavy snowpack during the previous winter may have prevented the majority of Long Valley speckled dace from dispersing to colder reaches of the marsh. Long Valley speckled dace concentrating near the warm pool outlet stream could have also been exposed to chlorine from the public swimming pool upstream that historically discharged lightly chlorinated water into the marsh during the summer operating season. As mentioned previously, the swimming pool no longer discharges chlorinated water into the marsh. Other possible explanations for the population die-off include parasites, or unprecedented winter kill (Cox 2023, pp. 1–2). Although we do not have direct population estimates, such large decreases in the number of fish caught, suggest that the population has experienced dramatic declines that may limit its ability to persist.

O’Harrel Canyon Creek is a spring-fed creek situated at 2,083 meters (6,834 feet) of elevation in Mono County, California, near Benton Crossing. This creek originates in the Glass Mountains and terminates before reaching the Owens River. Introduced Lahontan cutthroat trout occupy the upper 0.8 km (0.5 mi) of the creek but are not found in the lower reaches that provide suitable habitat and water temperature for Long Valley speckled dace.

Monitoring efforts will be used to determine success of population establishment at O’Harrel Canyon Creek; however, heavy snowpack from the 2022/2023 winter season prevented staff members from accessing the site until later in 2023. Young of year were observed during that survey and surviving adults, including gravid females were observed in 2024. The initial success is encouraging, however more data across multiple years will be needed to determine if this population successfully establishes. Thus, the information available for these populations indicates that the overall resiliency for the Long Valley speckled dace is currently low.

Representation

Representation, or adaptive capacity, is maximized in a species with healthy populations distributed across the breadth of its evolutionary lineages and ecological niches that is capable of moving to new, suitable environments or capable of altering its physical or behavioral traits (phenotypes) to match changing environmental conditions through either plasticity or genetic change (Nicotra et al. 2015, p. 1270; Beever et al. 2016, p. 132). Although the general speckled dace complex appears to have inherent adaptive capacity, the Long Valley speckled dace’s limited range, lack of dispersal opportunities, and presumed small population size likely limit this capacity for the subspecies. The wild and translocated populations of Long Valley speckled dace are not connected hydrologically, limiting any potential for dispersal in response to localized threats, as well as any ability for recolonization following catastrophic events. In addition, the lack of genetic exchange is concerning given the population decline at Whitmore Marsh that occurred in 2017. Managing genetic diversity both within the wild population and the translocated population will be critical to conservation efforts for the Long Valley speckled dace and maintenance of the subspecies’ adaptive capacity.

Redundancy

The Long Valley speckled dace has lost roughly 83–99 percent of its historical extent of occurrence. Such a dramatic reduction in range for a narrowly distributed subspecies suggests that the Long Valley speckled dace currently has little if any redundancy to withstand the impact of the threats present within the Long Valley Caldera, which have led to extirpations of six historical populations.

Summary of Current Condition

The available data suggest that the remaining historical population has recently experienced a decline and may be persisting at extremely low densities relative to previous surveys. The declines observed at Whitmore Marsh are concerning because multiple threats exist on the landscape that are not part of the historical environmental variation experienced by this population. These are also the threats that likely caused impacts leading to the extirpation of six of seven historical populations of Long Valley speckled dace. The threats still posing a high risk to the subspecies’ overall viability include nonnative species, recreation, water diversion,

climate change, and small population size effects. Reduced abundance at the Whitmore Marsh may limit the ability of the population to withstand the synergistic effects of multiple threats and is a concern for the viability of the subspecies.

Any decrease in the resiliency of the Whitmore Marsh population places a large burden on the refuge population at the White Mountain Research Center for maintaining the viability of the subspecies. Although the population at the White Mountain Research Center appears to be currently stable, other populations in private/artificial ponds have failed (Cox 2022, p. 2), and maintaining the refuge population in more than one pond would decrease the chances of a catastrophic event affecting this entire population. Additionally, we do not know if the recently translocated population at O’Harrel Canyon Creek has survived and successfully reproduced. While translocation will likely be a key conservation action for this subspecies, evidence of successful reproduction would be required to meaningfully increase resiliency or redundancy across the subspecies’ range.

Future Condition

As part of the SSA, we also developed several future-condition scenarios to forecast the condition of the subspecies under different projections of threats. We used our existing assessment of current habitat as the starting point for our future scenarios. We then incorporated projections of factors likely to impact the viability of the Long Valley speckled dace into the future. Although there are several factors that may influence the condition of the subspecies in the future, we focused on (1) introduced species; (2) disease; (3) grazing; (4); water diversion; (5) recreation; (6) geothermal development; (7) climate change; and (8) effects of small population size as the threats most likely to impact the Long Valley speckled dace’s habitat and long-term viability. Because we determined that the current condition of the Long Valley speckled dace is consistent with an endangered species (see Determination of Long Valley Speckled Dace’s Status, below), we are not presenting the results of the future scenarios in this proposed rule. Please refer to the SSA report (Service 2023, pp. 38–43) for the full analysis of future scenarios.

Determination of Long Valley Speckled Dace’s Status

The Act defines the term “species” as including any subspecies of fish or wildlife or plants, and any distinct

population segment of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an “endangered species” as a species in danger of extinction throughout all or a significant portion of its range, and a “threatened species” as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

We have determined that the Long Valley speckled dace is likely extirpated in six of seven known historical populations, with recent declines in the only known extant population possibly caused by a number of factors, including: impacts associated with a recreational swimming pool (Factor E), parasites and disease (Factor C, or unprecedented winter kill (Factor E)). We anticipate that nonnative species will pose an additional threat to the persistence of the existing population (Factor C). Further, it is unknown whether the recently translocated population at O’Harrel Canyon Creek will establish and reproduce and be able to contribute to overall viability. Representation for the subspecies is low due to limited range, lack of dispersal opportunities between the remaining historic population and translocated population, and small population size. Redundancy for the Long Valley speckled dace is extremely low following the loss of historical populations.

After evaluating threats to the subspecies and assessing the cumulative effect of the threats under the Act’s section 4(a)(1) factors, the Long Valley speckled dace does not have sufficient resiliency, representation, and redundancy to sustain viability. Recent declines at the only known extant population at Whitmore Marsh likely

limit the ability of the subspecies to persist. A catastrophic event, such as a severe storm or wildfire, affecting one or both of the populations could result in the extinction of the subspecies. Other threats that may impact the sole remaining historical population, and uncertainty over the viability of the translocated population, place the subspecies at risk of extinction. Thus, after assessing the best available information, we determine that the Long Valley speckled dace is in danger of extinction throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. We have determined that the Long Valley speckled dace is in danger of extinction throughout all of its range and accordingly did not undertake an analysis of any significant portions of its range. Because the Long Valley speckled dace warrants listing as endangered throughout all of its range, our determination does not conflict with the decision in *Center for Biological Diversity v. Everson*, 435 F. Supp. 3d 69 (D.D.C. 2020), because that decision related to significant portion of the range analyses for species that warrant listing as threatened, not endangered, throughout all of their range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Long Valley speckled dace meets the Act’s definition of an endangered species. Therefore, we are proposing to list the Long Valley speckled dace as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition as a listed species, planning and implementation of recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, foreign governments, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies,

including the Service, and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

The recovery planning process begins with development of a recovery outline made available to the public soon after a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions while a recovery plan is being developed. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) may be established to develop and implement recovery plans. The recovery planning process involves the identification of actions that are necessary to halt and reverse the species’ decline by addressing the threats to its survival and recovery. The recovery plan identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (“downlisting”) or removal from protected status (“delisting”), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery outline, draft recovery plan, final recovery plan, and any revisions will be available on our website as they are completed (<https://www.fws.gov/program/endangered-species>), or from our Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and

outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their ranges may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If the Long Valley speckled dace is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of California would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Long Valley speckled dace. Information on our grant programs that are available to aid species recovery can be found at: <https://www.fws.gov/service/financial-assistance>.

Although the Long Valley speckled dace is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this subspecies. Additionally, we invite you to submit any new information on this subspecies whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7 of the Act is titled Interagency Cooperation, and it mandates all Federal action agencies to use their existing authorities to further the conservation purposes of the Act and to ensure that their actions are not likely to jeopardize the continued existence of listed species or adversely modify critical habitat. Regulations implementing section 7 are codified at 50 CFR part 402.

Section 7(a)(2) states that each Federal action agency shall, in consultation with the Secretary, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Each Federal agency shall review its action at the earliest possible time to determine whether it may affect listed species or critical habitat. If a determination is made that the action may affect listed species or critical habitat, formal consultation is required (50 CFR 402.14(a)), unless the Service concurs in writing that the action is not likely to adversely affect listed species or critical habitat. At the end of a formal consultation, the Service issues a biological opinion, containing its

determination of whether the Federal action is likely to result in jeopardy or adverse modification.

In contrast, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. Although the conference procedures are required only when an action is likely to result in jeopardy or adverse modification, action agencies may voluntarily confer with the Service on actions that may affect species proposed for listing or critical habitat proposed to be designated. In the event that the subject species is listed or the relevant critical habitat is designated, a conference opinion may be adopted as a biological opinion and serve as compliance with section 7(a)(2) of the Act.

Examples of discretionary actions for the Long Valley speckled dace that may be subject to conference and consultation procedures under section 7 of the Act are land management or other landscape-altering activities on Federal lands administered by the U.S. Forest Service and Bureau of Land Management, as well as actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation. Federal agencies should coordinate with the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**) with any specific questions on section 7 consultation and conference requirements.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or to cause to be committed any of the following acts with regard to

endangered wildlife: (1) import into, or export from, the United States; (2) take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct) within the United States, within the territorial sea of the United States, or on the high seas; (3) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such wildlife that has been taken illegally; (4) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or (5) sell or offer for sale in interstate or foreign commerce. Certain exceptions to these prohibitions apply to employees or agents of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits for endangered wildlife are codified at 50 CFR 17.22 and general Service permitting regulations are codified at 50 CFR part 13. With regard to endangered wildlife, a permit may be issued: for scientific purposes, for enhancing the propagation or survival of the species, or for take incidental to otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

II. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all

or part of the species' life cycle, even if not used on a regular basis (e.g., migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and translocation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that each Federal action agency ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect an area designated as critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal agency would have already been required to consult with the Service even absent the designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement "reasonable and prudent alternatives" to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over

time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Critical Habitat Determinability

Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

- (i) Data sufficient to perform required analyses are lacking, or
- (ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of "critical habitat."

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the Long Valley speckled dace and habitat characteristics where this subspecies is located. A careful assessment of the economic impacts that may occur due to a critical habitat designation is still ongoing, and we are in the process of acquiring the complex information needed to perform that assessment. Therefore, due to the current lack of data sufficient to perform

required analyses, we conclude that the designation of critical habitat for the Long Valley speckled dace is not determinable at this time.

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal

Governments; 59 FR 22951, May 4, 1994), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), the President's memorandum of November 30, 2022 (Uniform Standards for Tribal Consultation; 87 FR 74479, December 5, 2022), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes and Alaska Native Corporations (ANCs) on a government-to-government basis. In accordance with Secretary's Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We will continue to coordinate with Tribal entities throughout the rulemaking process to list the Long Valley speckled dace as an endangered species.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <https://www.regulations.gov> and upon request from the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Reno Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, FWS proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

- 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

- 2. In § 17.11, in paragraph (h), amend the List of Endangered and Threatened Wildlife by adding an entry for “Dace, Long Valley speckled” in alphabetical order under FISHES to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
FISHES				
*	*	*	*	*
Dace, Long Valley speckled.	<i>Rhinichthys nevadensis caldera</i> .	Wherever found	E	[Federal Register citation when published as a final rule].
*	*	*	*	*

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2024–17249 Filed 8–7–24; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 89, No. 153
Thursday, August 8, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

National Agricultural Library

Agricultural Research Service

Notice of Intent To Renew a Currently Approved Information Collection

AGENCY: National Agricultural Library, Agricultural Research Service, USDA.
ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, this notice announces the intention of the Agricultural Research Service (ARS) to request an extension of a currently approved information collection, Information Collection for Document Delivery Services at the National Agricultural Library (NAL), which expires January 31, 2025.

DATES: Comments must be submitted on or before October 7, 2024.

ADDRESSES: Send comments to: USDA, ARS–NAL, Digitization and Access Branch, 10301 Baltimore Avenue, Room 305–D, Beltsville, MD 20705–2351.

FOR FURTHER INFORMATION CONTACT: Manuel Jusino, Librarian, telephone: 202–690–4051; email: manuel.jusino@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Information Collection for Document Delivery Services.

OMB Number: 0518–0027.

Expiration Date of Approval: January 31, 2025.

Type of Request: To extend a currently approved information collection process.

Abstract: In its role as both a preeminent agricultural research library and a national library of the United States, NAL (part of the USDA’s ARS) provides loans and copies of materials from its collections to libraries and

other institutions and organizations. NAL follows applicable copyright laws and interlibrary loan guidelines, standards, codes, and practices when providing loans and copies and charges a fee, if applicable, for this service. To request a loan or copy, institutions must provide a formal request to NAL using either NAL’s web-based online request system or an interlibrary loan request system such as the Online Computer Library Center or the National Library of Medicine’s DOCLINE. Information in these requests includes the name, mailing address, email address, and telephone number of the party requesting the material. The requestor must also provide a statement acknowledging copyright compliance, bibliographic information for the material they are requesting, and the maximum dollar amount they are willing to pay for the material. The collected information is used to deliver the material to the requestor, monitor the return of loaned material to NAL, and identify and locate the requested material in NAL collections.

Estimate of Burden: Average 1.00 minute per response.

Description of Respondents: Respondents to the collection of information are those libraries, institutions, or organizations that request interlibrary loans or copies of material in the NAL collections. Each respondent must furnish the information for each loan or copying request.

Estimated Number of Respondents: 196.

Frequency of Responses: Average 9 per respondent.

Estimated Total Annual Burden on Respondents: 29 hours.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have a practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, such as through the use of appropriate automated, electronic, mechanical, or

other technological collection techniques. Comments may be sent to Manuel Jusino at the address listed above within 60 days of the date of publication. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Marlen Eve,
Acting Associate Administrator, Agricultural Research Service.
[FR Doc. 2024–17447 Filed 8–7–24; 8:45 am]
BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency’s estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 9, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency

informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Assessing Equity in Work Requirements and SNAP Employment and Training.

OMB Control Number: 0584–NEW.

Summary of Collection: Section 17 [7 U.S.C. 2026] (a)(1) of the Food and Nutrition Act of 2008, as amended, provides general legislative authority for the planned data collection. It authorizes the Secretary of Agriculture to enter into contracts with private institutions to undertake research that will help improve the administration and effectiveness of SNAP. FNS is conducting this study to identify data available from SNAP State agencies, their E&T provider partners, and other sources that can be used to develop measures to assess equity in the administration of SNAP work requirements and E&T services. The developed measures can be used to determine how and whether States are providing equitable access to SNAP through the administration of work requirements, achieving equitable participation in education and training opportunities through the SNAP E&T program, and adopting program option and discretionary policies and procedures that influence disparities.

Need and Use of the Information: FNS has identified four objectives for this study:

1. Identify areas in the administration of work requirements in SNAP and in SNAP E&T program administration and access where equity issues could occur.
2. Identify and describe the data that could be used to assess access and outcomes in the areas identified in Objective 1.
3. Describe how State agencies address equity in administering work requirements in their SNAP and SNAP E&T programs.
4. Develop recommendations on how FNS should assess and measure equity in the administration of work requirements in SNAP and in SNAP E&T program administration and access.

Description of Respondents: State, Local and Tribal Governments, Businesses, Individuals.

Number of Respondents: 296.

Frequency of Responses: Reporting: Once.

Total Burden Hours: 366.32.

Rachelle Ragland-Greene,
*Departmental Information Collection
Clearance Officer.*

[FR Doc. 2024–17584 Filed 8–7–24; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket#: RBS–24–BUSINESS–0011]

Notice of Solicitation of Applications for the Intermediary Relending Program for Fiscal Year 2025

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service (RBCS or Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), invites applications under the Intermediary Relending Program (IRP) for fiscal year (FY) 2025, subject to availability of funding. This Notice is being issued prior to passage of a FY 2025 appropriations act in order to allow applicants enough time to leverage financing, prepare and submit their applications, and give the Agency time to process program applications within FY 2025. Funding for FY 2024 was \$10,000,000, and the amount of funding appropriated for this program for FY 2025 will not be known until Congress passes the appropriations act for FY 2025. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. All applicant are responsible for any expenses incurred in developing their application whether or not funding is appropriated in FY 2025.

DATES: The deadlines for completed applications to be received in the USDA RD State Office for quarterly funding competitions is no later than 4:30 p.m. (local time) on: First Quarter—September 30, 2024, Second Quarter—December 31, 2024, Third Quarter—March 31, 2025, and Fourth Quarter—June 30, 2025.

ADDRESSES: Applications must be submitted to the USDA RD State Office for the state where the applicant is located. Applications may be submitted in paper or electronic format to the appropriate RD State Office and must be received by 4:30 p.m. local time on the deadline date(s) to compete for available funds in the fiscal quarter. Applicants are encouraged to contact their

respective RD State Office for an email contact to submit an electronic application prior to the submission deadline date(s). A list of the USDA RD State Office contacts can be found at: rd.usda.gov/about-rd/state-offices.

FOR FURTHER INFORMATION CONTACT: Lori Pittman, Program Management Division, Business Programs, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, MS 3226, Room 5160–S, Washington, DC 20250–3226, lori.pittman1@usda.gov, or call (202) 720–9815. For further information on this Notice, please contact the USDA RD State Office in the State in which the applicant's headquarters is located. A list of RD State Office contacts is provided at the following link: rd.usda.gov/about-rd/state-offices.

SUPPLEMENTARY INFORMATION:

Overview

Federal Awarding Agency Name: Rural Business-Cooperative Service (RBCS).

Funding Opportunity Title: Intermediary Relending Program (IRP).

Announcement Type: Notice of Solicitation of Application (NOSA).

Assistance Listing Number: 10.767.

Dates: The deadlines for completed applications to be received in the USDA RD State Office for quarterly funding competitions is no later than 4:30 p.m. (local time) on: First Quarter—September 30, 2024, Second Quarter—December 31, 2024, Third Quarter—March 31, 2025, and Fourth Quarter—June 30, 2025.

Rural Development Priorities: The Agency encourages applicants to consider projects that will advance the following key priorities (more details available at rd.usda.gov/priority-points):

- **Creating More and Better Markets:**

Assist rural communities to recover economically through more and better market opportunities and through improved infrastructure.

- **Addressing Climate Change and Environmental Justice:** Reduce climate pollution and increase resilience to the impacts of climate change through economic support for rural communities.

- **Advancing Racial Justice, Place-Based Equity, and Opportunity:** Ensure all rural residents have equitable access to RD programs and benefits from RD funded projects.

A. Program Description

1. *Purpose of the Program.* This program provides low-interest loans to local lenders (intermediaries) who then relend to businesses to help improve

economic conditions and create jobs in rural communities. This purpose is achieved through the loans made to intermediaries that establish a revolving loan fund for the purpose of providing loans to ultimate recipients to promote community development, establish new businesses, establish and support microlending programs, and create or retain employment opportunities in rural areas. All applicable program requirements in their entirety can be found at 7 CFR part 4274, subpart D.

2. *Statutory and Regulatory Authority.* This program is authorized under section 310H of the Consolidated Farm and Rural Development Act (7 U.S.C. 1936b) and is administered through regulations at 7 CFR part 4274, subpart D.

The Consolidated Appropriations Act, 2024, authorized set-aside funding to projects and intermediaries serving Federally recognized Indian Tribes, and for Mississippi Delta Region Counties (as determined in accordance with Pub. L. 118–42). Eligible applicants for the set-aside funds, assuming that similar set-aside funds are appropriated for Fiscal Year 2025, must demonstrate that at least 75 percent of the benefits of an approved loan in this program will assist ultimate recipients in the designated areas. Applications for any set-aside funds must be submitted to the RD State Office where the project is located by 4:30 p.m. (local time) on the following deadline dates. The deadline to submit completed applications for Federally recognized Indian Tribes and Mississippi Delta Region Counties' projects is May 31, 2025. It is possible that funds may also be appropriated by Congress for projects located in Rural Empowerment Zone/Enterprise Communities/Rural Economic Area Partnership areas. Completed applications for these projects, subject to available funding, must be submitted by July 15, 2025.

3. *Definitions.* The definitions applicable to this notice are published at 7 CFR 4274.302.

4. *Application of Awards.* The Agency will review, evaluate and score applications received in response to this Notice based on the provisions found in 7 CFR 4274.340 and as indicated in this Notice. Awards under the IRP will be made on a competitive basis using specific selection criteria contained in 7 CFR 4274.341(b). The Agency advises all interested parties that the applicant bears the full burden in preparing and submitting an application in response to this notice regardless of whether or not funding is appropriated for the IRP in FY 2025.

B. Federal Award Information

Type of Award: Loan.

Fiscal Year Funds: FY 2025.

Available Funds: Funding for the IRP program in FY 2025 will be determined in an appropriations act for FY 2025.

Award Amounts: The Agency anticipates a maximum award of \$1 million for eligible Intermediaries submitting a loan request.

Anticipated Award Dates—

(a) *Regular Funding:* First Quarter—December 1, 2024, Second Quarter—March 1, 2025, Third Quarter—June 1, 2025, Fourth Quarter—September 1, 2025.

(b) *Federally recognized Indian Tribes and Mississippi Delta Region Counties Funding:* June 15, 2025.

(c) *Empowerment Zones/Enterprise Communities/Rural Economic Area Partnership Funding:* August 1, 2025.

Performance Period: None.

Renewal or Supplemental Awards: None

Type of Assistance Instrument: Direct Loan.

C. Eligibility Information

1. *Eligible Applicants.* IRP loans may be made to a private non-profit corporation, a public agency, a Federally recognized Indian Tribe or one of its wholly owned arms and instrumentalities or a cooperative entity, identified as an eligible intermediary in accordance with 7 CFR 4274.310.

2. *Cost Share or Matching.* The IRP revolving fund share of the eligible project cost of an ultimate recipient's project funded under this Notice shall not exceed the lesser of (a) \$400,000; and (b) Fifty percent of the originally-approved Agency IRP loan amount to an intermediary. No more than 75 percent of the total cost of an ultimate recipient's project can be funded from Agency IRP loan funds. Points awarded for leveraging will be considered in accordance with the requirements specified in 7 CFR 4274.341(b)(4).

3. *Other.* Applications will only be accepted from eligible intermediaries that will establish, or have established, revolving loan programs for the purpose of providing loans to ultimate recipients for business purposes and community development in a rural area.

There are no responsiveness or threshold eligibility criteria for these loans. However, not more than one loan will be approved by the Agency for an intermediary in any single fiscal year unless the additional request is from this program's set-aside funding.

Applications will not be considered for funding if they do not provide enough information to determine

eligibility, are not suitable for evaluation, or are missing required elements as stated in 7 CFR 4274.340.

D. Application and Submission Information

1. *Address to Request Application Package.* For further information, entities wishing to apply for assistance should contact the USDA RD State Office where they are located, provided in the **ADDRESSES** section of this notice, to obtain copies of the application package. Applicants are also encouraged to contact their respective RD State Office for an email contact to submit an electronic application prior to the submission deadline date(s). Please note that applicants may locate the downloadable application package for this program by the Assistance Listing Number provided in the Overview Section above.

2. *Content and Form of Application Submission.* An application must contain all the required elements described in 7 CFR 4274.340, and each selection priority criterion outlined in 7 CFR 4274.341(b) must be addressed in the application. An original copy of the application must be filed with a RD State Office for the state where the Intermediary is located.

The applicant documentation and forms needed for a complete application are in 7 CFR 4274.340. There are no specific formats or limitations on the number of pages required for an application narrative, and applicants may request any Agency forms and addresses from the **ADDRESSES** section of this notice. Any form that requires an original signature, but is signed electronically in the application submission, must be signed in ink by the authorized person prior to the disbursement of funds.

3. *System for Award Management and Unique Entity Identifier.*

(a) At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25. To register in SAM, entities will be required to obtain a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at sam.gov/content/entity-registration.

(b) Applicants must maintain an active SAM registration, with current, accurate and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency.

(c) Applicants must ensure they complete the Financial Assistance

General Certifications and Representations in SAM.

(d) Applicants must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110.

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. *Submission Dates and Times.*

Applications, including applications for set-aside funding, must be received by the specified USDA RD State Office by the dates and times as indicated in the **DATES** section of this notice to compete for available funds. If the due date falls on a Saturday, Sunday or federal holiday, the application is due the next business day. The Agency will determine the application receipt date based on the actual date an application is received electronically, in person, or when a paper application is postmarked. The Agency will not solicit or consider new scoring or eligibility information that is submitted after the application deadline. RBCS also reserves the right to ask applicants for clarifying information and additional verification of assertions in the application.

5. *Intergovernmental Review.*

Executive Order (E.O.) 12372, Intergovernmental Review of Federal Programs, applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many states have established a Single Point of Contact (SPOC) to facilitate this consultation. For a list of States that maintain a SPOC, please see the White House website: [whitehouse.gov/omb/management/office-federal-financial-management/](https://www.whitehouse.gov/omb/management/office-federal-financial-management/). If your State has a SPOC, you may submit a copy of the application directly for review. Any comments obtained through the SPOC must be provided to your State Office for consideration as part of your application. If your state has not established a SPOC, you may submit your application directly to the Agency. Indian Tribes are exempt from this requirement.

6. *Funding Restrictions.* The intent of the IRP is identified above in section A.1 of this notice. There are no funding restrictions beyond that the loan proceeds be used for eligible type purposes stated in 7 CFR 4274.320.

Building construction is an eligible use of funds under the program and all projects must be located in a rural area of a State. Any administrative costs must be approved annually by the Agency.

7. *Other Submission Requirements.*

Please note that applicants may locate the downloadable application package for this program by the Assistance Listing Number provided in the Overview section of this notice.

E. Application Review Information

1. *Criteria.* All eligible and complete applications will be evaluated and scored based on the selection criteria and weights contained in 7 CFR 4274.341(b) and in this section of the notice. Failure to address any of the application criteria by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding.

(a) *Discretionary Points.* The Administrator may assign up to 10 discretionary points to an application when under their approval authority. Permissible justifications in accordance with 7 CFR 4274.341(b)(10) are geographic distribution of funds or special President/Secretary of Agriculture initiatives such as local foods, regional development, persistent poverty, energy-related, etc. The number of points to be awarded will be awarded for either or both items. Secretary of Agriculture initiatives include:

(1) Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure. Applicant would receive priority points if the project is located in or serving a rural community whose economic well-being ranks in the most distressed tier (distress score of 80 or higher) of the Distressed Communities Index using the Distressed Communities Look-Up Map available at rd.usda.gov/priority-points.

(2) Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects. Using the Social Vulnerability Index (SVI) Look-Up Map (available at rd.usda.gov/priority-points), an applicant would receive priority points if:

- The project is located in or serving a community with score 0.75 or above on the SVI;
- The applicant is a Federally recognized Indian Tribe, including Tribal instrumentalities and entities that are wholly owned by Tribes; or
- It is a project where at least 50 percent of the project beneficiaries are members of Federally recognized Indian Tribes and non-Tribal applicants

include a Tribal Resolution of Consent from the Tribe or Tribes that the applicant is proposing to serve.

- The application is from or benefits a Rural Partners Network's (RPN) community network. Currently RPN Networks exist in Alaska, Arizona, Georgia, Kentucky, Mississippi, Nevada, New Mexico, North Carolina, Puerto Rico, West Virginia and Wisconsin. Use the Community Look-Up map (available at www.rd.usda.gov/priority-points) to determine if your project qualifies for priority points.

(3) Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities. Using the Disadvantaged Community and Energy Community Look-Up Map (available at rd.usda.gov/priority-points), applicants will receive priority in three ways:

- If the project is located in or serves a Disadvantaged Community as defined by the Climate and Economic Justice Screening Tool (CEJST), from the White House Council on Environmental Quality (CEQ);
- If the project is located in or serves an Energy Community as defined by the Inflation Reduction Act of 2022 (Pub. L. 117-169) (IRA); and
- If applicants can demonstrate through a written narrative how the proposed climate-impact projects will improve the livelihoods of community residents and meet pollution mitigation or clean energy goals.

2. *Review and Selection Process.* The RD State Office will review applications to determine if they are eligible for assistance based on the requirements contained in 7 CFR part 4274, subpart D. If determined eligible, the application will be submitted to the National Office for funding competition with all eligible applications received by the quarterly application deadline or the deadline indicated for set-aside funding. The Agency Administrator reserves the right to award up to 10 discretionary points as identified under 7 CFR 4274.341(b)(10).

To distribute funds among the greatest number of projects possible during the respective funding periods, applications will be reviewed, organized and ranked in order from highest to lowest and funded up to the maximum funding available during each quarterly funding cycle in FY 2025.

F. Federal Award Administration Information

1. *Federal Award Notices.* Successful applicants will receive notification for funding from the USDA RD State Office. Applicants must comply with all applicable statutes and regulations

before the loan award will be obligated. An eligible application competing for regular IRP funds, but not selected, will be reconsidered in the three subsequent quarterly funding competitions, for a total of four competitions (and may be considered in a following fiscal year), provided the application and eligibility requirements have not changed. After competing in four consecutive quarterly competitions, any unsuccessful application for regular funds will receive written notification indicating that its application will no longer be considered for funding. Applicants competing for set-aside funding have only one application period per fiscal year to apply for set-aside funding. Unsuccessful applications for set-aside funding will receive written notification indicating that their application was not successful. An applicant with an unsuccessful application for set-aside funding may elect, in writing, to submit its project for IRP regular fund competitions commencing with the next quarterly application period.

2. Administrative and National Policy Requirements.

(a) *Build America, Buy America (BABAA)*. Awardees that are Non-Federal Entities, defined pursuant to 2 CFR 200.1 as any State, local government, Indian Tribe, Institution of Higher Education, or nonprofit organization, shall be governed by the requirements of Section 70914 of the Build America, Buy America Act (BABAA) within the Infrastructure Investment and Jobs Act (Pub. L. 117–58), and its implementing regulations at 2 CFR part 184. Any requests for waiver of these requirements must be submitted pursuant to USDA's guidance available online at usda.gov/ocfo/federal-financial-assistance-policy/USDABuyAmericaWaiver.

(b) *Geospatial Data*. Awardee, and any and all contracts entered into by the awardee with respect to the award, shall ensure that geospatial data required to be collected and provided to the agency, conforms with the requirements of USDA Department Regulation DR–3465–001 and the Geospatial Metadata Standards set forth in DM 3465–001, which can be obtained online at usda.gov/directives/dr-3465-001 and usda.gov/directives/dm-3465-001.

(c) Additional requirements that apply to intermediaries selected for this program can be found in 7 CFR part 4274, subpart D.

(d) All successful applicants will be notified by letter which will include a Letter of Conditions and a Letter of Intent to Meet Conditions, which are not approval determinations. The loan will

be considered approved when all conditions in the Letter of Conditions have been met and the Agency obligates the funding for the project.

3. *Reporting*. In addition, all recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive compensation (see 2 CFR part 170). Applicants will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b)), unless applicants are exempt under 2 CFR 170.110(b)).

Intermediaries must collect and maintain data provided by Ultimate Recipients on race, sex, and national origin and ensure that Ultimate Recipients collect and maintain this data. Race and ethnicity data will be collected in accordance with the Office of Management and Budget (OMB) **Federal Register** notice, Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (62 FR 58782), October 30, 1997. Sex data will be collected in accordance with Title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be made available upon request by the Agency.

The applicant and the Ultimate Recipients must comply with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Executive Order 12250, Executive Order 13166 Limited English Proficiency (LEP), and 7 CFR part 1901, subpart E.

G. Federal Awarding Agency Contact(s)

For General Questions About This Notice See the Point of Contact Provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

H. Other Information

1. *Paperwork Reduction Act*. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements associated with the programs, as covered in this notice, have been approved by Office of Management and Budget (OMB) under OMB Control Number 0570–0021.

2. *National Environmental Policy Act*: All recipients under this notice are subject to the requirements of 7 CFR part 1970 and must comply in accordance with 7 CFR 4274.305(b).

3. *Federal Funding Accountability and Transparency Act*. All applicants, in accordance with 2 CFR part 25, must be registered in SAM and have a UEI number as stated in Section D.3. of this notice. All recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170.

4. *Civil Rights Act*. All loans made under this notice are subject to Title VI of the Civil Rights Act of 1964 as required by USDA (7 CFR part 15, subpart A—Nondiscrimination in Federally-Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964) and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

5. Equal Opportunity for Religious Organizations.

(a) Faith-based organizations may apply for this award on the same basis as any other organization, as set forth at, and subject to the protections and requirements of, this part and any applicable constitutional and statutory requirements, including 42 U.S.C. 2000bb *et seq.* USDA will not, in the selection of recipients, discriminate for or against an organization on the basis of the organization's religious character, motives, or affiliation, or lack thereof, or on the basis of conduct that would not be considered grounds to favor or disfavor a similarly situated secular organization.

(b) A faith-based organization that participates in this program will retain its independence from the Government and may continue to carry out its mission consistent with religious freedom and conscience protections in Federal law. Religious accommodations may also be sought under many of these religious freedom and conscience protection laws.

(c) A faith-based organization may not use direct Federal financial assistance from USDA to support or engage in any explicitly religious activities except when consistent with the Establishment Clause of the First Amendment to the United States Constitution and any other applicable requirements. An organization receiving Federal financial assistance also may not, in providing services funded by USDA, or in their outreach activities related to such services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion, a

religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.

6. *Nondiscrimination Statement.* In accordance with Federal civil rights laws and USDA civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.*, Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office or the 711 Relay Service.

To file a program discrimination complaint, a complainant should complete a Form AD-3027, USDA Program Discrimination Complaint Form, which can be obtained online at usda.gov/sites/default/files/documents/ad-3027.pdf, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; or

(2) *Fax:* (833) 256-1665 or (202) 690-7442; or

(3) *Email:* program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Kathryn E. Dirksen Londrigan,
Administrator, Rural Business-Cooperative Service, USDA Rural Development.

[FR Doc. 2024-17480 Filed 8-7-24; 8:45 am]

BILLING CODE 3410-XY-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-42-2024]

Foreign-Trade Zone 163; Application for Subzone; Tallaboa PR, LLC; Peñuelas, Puerto Rico

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by CODEZOL, C.D., grantee of FTZ 163, requesting subzone status for the facility of Tallaboa PR, LLC, located in Peñuelas, Puerto Rico. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on August 5, 2024.

The proposed subzone (13.79 acres) is located at State Road 127 Int. 385, Penuelas, Puerto Rico. No authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is September 17, 2024. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to October 2, 2024.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Camille Evans at Camille.Evans@trade.gov.

Dated: August 5, 2024.

Camille R. Evans,
Acting Executive Secretary.

[FR Doc. 2024-17634 Filed 8-7-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-079]

Cast Iron Soil Pipe From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on cast iron soil pipe from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the "Final Results of Sunset Review" section of this notice.

DATES: Applicable August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2243.

SUPPLEMENTARY INFORMATION:

Background

On May 3, 2019, Commerce published the AD order on cast iron soil pipe from China.¹ On April 1, 2024, Commerce published the notice of initiation of the first sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).²

On April 16, 2024, Commerce received a notice of intent to participate in this review from the Cast Iron Soil Pipe Institute (CISPI) within the deadline specified in 19 CFR 351.218(d)(1)(i).³ CISPI claimed interested party status under section 771(9)(E) of the Act as a trade association whose members produce a domestic like product in the United States.⁴ On May 1, 2024, Commerce received an adequate substantive response from CISPI.⁵ We received no substantive responses from any other

¹ See *Cast Iron Soil Pipe from the People's Republic of China: Antidumping Duty Order*, 84 FR 19035 (May 3, 2019) (*Order*).

² See *Initiation of Five-Year (Sunset) Review*, 89 FR 22373 (April 1, 2024).

³ See CISPI's Letter, "Notice of Intent to Participate in the First Five-Year Review," dated April 16, 2024.

⁴ *Id.*

⁵ See CISPI's Letter, "Petitioner's Substantive Response to the Notice of Initiation," dated May 1, 2024.

interested parties, nor was a hearing requested.

On May 22, 2024, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.⁶ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

On July 22, 2024, Commerce tolled the deadline in this administrative proceeding by seven days.⁷ The deadline for the final results is now August 6, 2024.

Scope of the Order

The product covered by the *Order* is cast iron soil pipe from China. For a full description of the scope, see the Issues and Decision Memorandum.⁸

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review is contained in the accompanying Issues and Decision Memorandum.⁹ A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping and that the magnitude of the dumping likely to prevail are margins up to 235.93 percent.¹⁰

⁶ See Commerce's Letter, "Sunset Reviews for April 2024," dated May 22, 2024.

⁷ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁸ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Cast Iron Soil Pipe from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁹ See generally Issues and Decision Memorandum.

¹⁰ *Id.* at 8.

Administrative Protective Order (APO)

This notice serves as the only reminder to interested parties subject to an APO of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: August 5, 2024.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. History of the *Order*
- V. Legal Framework
- VI. Discussion of the Issues
 1. Likelihood of Continuation or Recurrence of Dumping
 2. Magnitude of the Margins Likely To Prevail
- VII. Final Results of Sunset Review
- VIII. Recommendation

[FR Doc. 2024–17627 Filed 8–7–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–823–815]

Oil Country Tubular Goods From Ukraine: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that oil country tubular goods (OCTG) from Ukraine were sold in the United States at less than normal value during the period of review (POR), July 1, 2022, through June 30, 2023. We

invite interested parties to comment on these preliminary results.

DATES: Applicable August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Toni Page, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1398.

SUPPLEMENTARY INFORMATION:

Background

On July 16, 2019, Commerce published the antidumping duty order on OCTG from Ukraine.¹ On July 3, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.² Pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b)(1), Commerce received timely requests to conduct an administrative review of the *Order* with respect to Interpipe from Borusan Mannesmann Pipe U.S., Inc. and Welded Tube USA, Inc (collectively, the domestic interested parties); and Interpipe.³ On September 11, 2023, Commerce initiated an administrative review of the *Order*.⁴ This review covers the sole mandatory respondent, Interpipe.⁵ On March 21, 2024, we extended the deadline for these preliminary results until no later than July 30, 2024.⁶ On July 22, 2024,

¹ See *Termination of the Suspension Agreement on Certain Oil Country Tubular Goods from Ukraine, Rescission of Administrative Review, and Issuance of Antidumping Duty Order*, 84 FR 33918 (July 16, 2019) (*Order*).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation: Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 88 FR 42693 (July 3, 2023).

³ See Domestic Interested Parties' Letter, "Request for Administrative Review," dated July 31, 2023; and Interpipe's Letter, "Request for Review—2022–2023," dated July 31, 2023.

⁴ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 87 FR 62323, 62333 (September 11, 2023).

⁵ The following companies are a single entity: Interpipe Europe S.A.; Interpipe Ukraine LLC; PJSC Interpipe Nizhnedneprovsky Tube Rolling Plant; LLC Interpipe Niko Tube (collectively, Interpipe). See *Oil Country Tubular Goods from Ukraine: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022*, 88 FR 51289 (August 3, 2023), and accompanying Preliminary Decision Memorandum unchanged in *Oil Country Tubular Goods from Ukraine: Final Results of Antidumping Duty Administrative Review; 2021–2022*, 88 FR 88362 (December 21, 2023), and accompanying Issues and Decision Memorandum.

⁶ See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated March 21, 2024.

Commerce tolled certain deadlines in this administrative proceeding by seven days.⁷ The deadline for these preliminary results is now August 6, 2024.

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.⁸ A list of topics discussed in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System

(ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Order⁹

The merchandise subject to the *Order* is certain OCTG from Ukraine. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the

Act. Constructed export price has been calculated in accordance with section 772 of the Act and normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists for the period July 1, 2022, through June 30, 2023:

Producer and/or exporter	Weighted-average dumping margin (percent)
Interpipe Europe S.A./Interpipe Ukraine LLC/PJSC Interpipe Nizhnedneprovsky Tube Rolling Plant/LLC Interpipe Niko Tube (collectively, Interpipe)	1.39

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis to parties in this review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹⁰ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; (2) a brief summary of the argument; and (3) a table of authorities.¹¹ Case and rebuttal briefs should be filed using ACCESS¹² and must be served on interested parties.¹³

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each

issue raised in their briefs.¹⁴ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁵

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within

30 days after the date of publication of this notice.

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.¹⁶ If the weighted-average dumping margin is not zero or *de minimis* (i.e., less than 0.5 percent), then Commerce will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of the review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. If Interpipe's weighted-average dumping margin is zero or *de minimis* in the final results of the review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews*, i.e., “[w]here the weighted-average margin of dumping for the exporter is

⁷ See Memorandum, “Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,” dated July 22, 2024.

⁸ See Memorandum, “Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Oil Country Tubular Goods from Ukraine; 2022–2023,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁹ See *Order*, 84 FR at 33919.

¹⁰ See 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹¹ See 19 CFR 351.309(c)(2) and (d)(2).

¹² *Id.*; *see also* 19 CFR 351.303 (for general filing requirements).

¹³ See 19 CFR 351.303(f).

¹⁴ We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁵ See *APO and Service Final Rule*.

¹⁶ See 19 CFR 351.212(b).

determined to be zero or *de minimis*, no antidumping duties will be assessed.”¹⁷

In accordance with Commerce’s “automatic assessment” practice, for entries of subject merchandise during the POR produced by Interpipe for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate (*i.e.*, 7.47 percent)¹⁸ if there is no rate for the intermediate company (or companies) involved in the transaction.¹⁹

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Interpipe will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the less-than-fair-value investigation (LTFV) but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding

¹⁷ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification*, 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

¹⁸ See *Order*, 84 FR at 33919.

¹⁹ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 7.47 percent, the rate established in the LTFV investigation of this proceeding.²⁰ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(2) and 351.221(b)(4).

Dated: August 5, 2024.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

[FR Doc. 2024–17636 Filed 8–7–24; 8:45 am]

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²⁰ See *Order*, 84 FR at 33919.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–080]

Cast Iron Soil Pipe From the People’s Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on cast iron soil pipe from the People’s Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the “Final Results of Review” section of this notice.

DATES: Applicable August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Robert Galantucci, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2923.

SUPPLEMENTARY INFORMATION:

Background

On May 3, 2019, Commerce published in the **Federal Register** the CVD order on cast iron soil pipe from China.¹ On April 1, 2024, Commerce published the notice of initiation of a sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).² On April 16, 2024, Commerce received a notice of intent to participate from the Cast Iron Soil Pipe Institute (CISPI) within the deadline specified in 19 CFR 351.218(d)(1)(i).³ The CISPI claimed interested party status under section 771(9)(F) of the Act as a trade or business association of which a majority of the members are producers of domestic like product.

Commerce received an adequate substantive response to the notice of initiation from the CISPI within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).⁴ We received no substantive responses from any respondent interested parties, including

¹ See *Cast Iron Soil Pipe from the People’s Republic of China: Countervailing Duty Order*, 84 FR 19039 (May 3, 2019) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 89 FR 22373 (April 1, 2024).

³ See CISPI’s Letter, “Notice of Intent to Participate in First Five-Year Review,” dated April 16, 2024.

⁴ See CISPI’s Letter, “Petitioner’s Substantive Response to the Notice of Initiation,” dated May 1, 2024.

the Government of China, nor was a hearing requested. On May 22, 2024, consistent with 19 CFR 351.218(e)(1)(ii)(B)(2) and (e)(1)(ii)(C)(2), Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.⁵ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.⁶ The deadline for the final results is now August 6, 2024.

Scope of the Order

The product covered by the *Order* is cast iron soil pipe. For a complete description of the scope of the *Order*, see the Issues and Decision Memorandum.⁷

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum.⁸ A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty

Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would likely lead to continuation or recurrence of countervailable subsidies at the rates below:

Company	Subsidy rate (percent <i>ad valorem</i>)
Kingway Pipe Co., Ltd	109.27
Yucheng Jiangxian Economic Development Zone HengTong Casting Co., Ltd	14.69
All Others	14.69

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: August 5, 2024.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. History of the *Order*

V. Legal Framework

VI. Discussion of the Issues

1. Likelihood of Continuation or Recurrence of Countervailable Subsidies
2. Net Countervailable Subsidy Rates That Are Likely To Prevail
3. Nature of the Subsidies

VII. Final Results of Sunset Review

VIII. Recommendation

[FR Doc. 2024–17628 Filed 8–7–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–428–848]

Forged Steel Fluid End Blocks From Germany: Final Results of the Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies were provided to BGH Edelstahl Siegen GmbH (BGH), a producer and exporter of forged steel fluid end blocks (fluid end blocks) from Germany. The period of review (POR) is

January 1, 2022, through December 31, 2022.

DATES: Applicable August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Rachel Accorsi or Bob Palmer, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3149 or (202) 482–9068, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 7, 2024, Commerce published the *Preliminary Results*.¹ For a detailed description of the events that occurred subsequent to the *Preliminary Results*, see the Issues and Decision Memorandum.² On May 1, 2024, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline for issuing the final results until July 26, 2024.³ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven

⁵ See Commerce's Letter, "Sunset Reviews for April 2024," dated May 22, 2024.

⁶ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁷ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Cast Iron Soil Pipe from the People's

Republic of China," dated concurrently with this notice (Issues and Decision Memorandum).

⁸ *Id.*

¹ See *Forged Steel Fluid End Blocks from the Federal Republic of Germany: Preliminary Results and Partial Recession of the Countervailing Duty Administrative Review; 2022*, 89 FR 8407 (February 7, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Forged Steel Fluid End Blocks from Germany; 2022," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ See Memorandum, "Extension of Deadline for the Final Results of Countervailing Duty Administrative Review; 2022," dated May 1, 2024.

days.⁴ The deadline for the final results is now August 2, 2024.

Scope of the Order ⁵

The products covered by the *Order* are fluid end blocks from Germany. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by interested parties in briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is provided in an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results*, we made certain revisions to the countervailable subsidy rate calculations for BGH Edelstahl Siegen GmbH (BGH).⁶ These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁷ The Issues and Decision Memorandum contains a full description of the methodology underlying Commerce's conclusions,

including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act.

Verification

As provided in section 782(i) of the Act, in May 2024, Commerce conducted verification of the subsidy information reported by BGH. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by the respondents.⁸

Final Results of Review

As a result of this review, we determine the following net countervailable subsidy rate for the POR January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent <i>ad valorem</i>)
BGH Edelstahl Siegen GmbH ⁹	2.75

Disclosure

We intend to disclose the calculations performed in connection with the final results of review to parties in this proceeding within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for BGH at the applicable *ad valorem* assessment rates listed for the POR (*i.e.*, January 1, 2022, to December 31, 2022). Commerce intends to issue assessment instructions to CBP for these companies no earlier than 35 days after the publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

⁸ See Memorandum, "Verification of the Questionnaire Responses of BGH Edelstahl Siegen GmbH," dated June 7, 2024.

⁹ Commerce found the following companies to be cross-owned with BGH Edelstahl Siegen GmbH: Boschgotthardshütte O. Breyer GmbH, BGH Edelstahlwerke GmbH, RPS Rohstoff-, Press- und Schneidbetrieb Siegen GmbH, and SRG Schrott und Recycling GmbH.

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the POR for BGH Siegen listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms subject to the *Order*, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of the final results of review, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(5).

Dated: August 2, 2024.

Ryan Majerus,
Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

- List of Topics Discussed in the Issues and Decision Memorandum**
- I. Summary
 - II. Background
 - III. Scope of the *Order*
 - IV. Subsidies Valuation
 - V. Analysis of Programs
 - VI. Discussion of the Issues
- Comment 1: Whether Commerce Erred by Deferring Analysis of the Reductions in Section 19 StromNEV Surcharge
- Comment 2: Whether Commerce Incorrectly Found the KfW 292 Energy Efficiency and 295 Energy and Resource

⁴ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

⁵ See *Forged Steel Fluid End Blocks from the People's Republic of China, the Federal Republic of Germany, India, and Italy: Countervailing Duty Orders, and Amended Final Affirmative Countervailing Duty Determination for the People's Republic of China*, 86 FR 7535 (January 29, 2021) (*Order*).

⁶ See Memorandum, "Final Results Calculations for BGH Edelstahl Siegen GmbH," dated concurrently with this notice.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Efficiency in Business Loan Programs To Be Countervailable

Comment 3: Whether Commerce Should Find the Changes to the 2018 Special Equalization Scheme—Reduced EEG Surcharge Program To Be an Additional Countervailable Subsidy

Comment 4: Whether Commerce Incorrectly Found the SES Reduced Surcharge Programs To Be Countervailable

Comment 5: Whether Commerce Incorrectly Found the Concession Fee Ordinance Relief Program To Be Countervailable

Comment 6: Whether Commerce Incorrectly Found the Electricity Tax Act and the Energy Tax Act Programs To Be Countervailable

Comment 7: Whether Commerce Incorrectly Found the EU ETS To Be Countervailable

Comment 8: Whether Commerce Incorrectly Found the EU ETS—Compensation of Indirect CO₂ Costs Program To Be Countervailable

VII. Recommendation

[FR Doc. 2024–17635 Filed 8–7–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–859]

Mattresses From Mexico: Final Affirmative Determination of Sales at Less-Than-Fair Value; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notice in the **Federal Register** on July 22, 2024, in which Commerce announced the final determination in the less-than-fair-value investigation of mattresses from Mexico. This notice failed to indicate the change in name for one of the individually examined companies.

FOR FURTHER INFORMATION CONTACT: Dakota Potts, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0223.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2024, Commerce published in the **Federal Register** the final determination in the less-than-fair-value investigation of mattresses from Mexico.¹ We listed an individually examined company under its correct name, *i.e.*, “Colchones Wendy S.A. de C.V.,” in the table indicating the final estimated dumping margins.² This is a change in the company name from that published in the *Preliminary Determination*, wherein the company was inadvertently listed as “Wendy Colchones S.A. de C.V.”³ However, the *Final Determination* did not include an explanation of the name change for this entity, and it should have explained that

the name change was to correct the name as published in the *Preliminary Determination*.

Correction

In the **Federal Register** on July 22, 2024, in FR Doc 2024–15986, on page 59063, in the “Final Determination” section, correct the company name “Colchones Wendy S.A. de C.V.” by adding a footnote which states “The name ‘Colchones Wendy S.A. de C.V.’ is the correct name for this entity and serves to correct the name of this entity in the *Preliminary Determination*, which read ‘Wendy Colchones S.A. de C.V.’” The corrected “Final Determination” section is attached as the appendix to this notice.

Notification to Interested Parties

This notice is issued and published in accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.210(c).

Dated: August 2, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

Final Determination

The final estimated dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Ureblock S.A. de C.V./Espumas de Oriente S.A. de C.V	37.59
GAIM Regiomontana S.A. de C.V	* 61.97
Colchones Wendy S.A. de C.V. ⁴	* 61.97
All Others	37.59

* Rate based on facts available with adverse inferences.

[FR Doc. 2024–17570 Filed 8–7–24; 8:45 am]

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¹ See *Mattresses from Mexico: Final Affirmative Determination of Sales at Less-Than-Fair Value*, 89 FR 59062 (July 22, 2024) (*Final Determination*).

² *Id.*, 89 FR at 59063.

³ See *Mattresses from Mexico: Preliminary Affirmative Determination of Sales at Less Than Fair Value*, 89 FR 15152, 15153 (March 1, 2024) (*Preliminary Determination*).

⁴ The name “Colchones Wendy S.A. de C.V.” is the correct name for this entity and serves to correct the name of this entity in the *Preliminary Determination*, which read “Wendy Colchones S.A. de C.V.”

DEPARTMENT OF COMMERCE**National Institute of Standards and Technology**

XRIN 0693–XC137

Request for Comments on the U.S. Artificial Intelligence Safety Institute's Draft Document: Managing Misuse Risk for Dual-Use Foundation Models

AGENCY: U.S. Artificial Intelligence Safety Institute (AIS), National Institute of Standards and Technology (NIST), U.S. Department of Commerce.

ACTION: Notice; request for comments.

SUMMARY: The U.S. Artificial Intelligence Safety Institute (AIS), housed within NIST at the Department of Commerce, requests comments on a draft document responsive to an Executive order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (AI) issued on October 30, 2023: NIST AI 800–1, Managing Misuse Risk for Dual-Use Foundation Models, found at <https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.800-1.ipd.pdf>.

DATES: Comments containing information in response to this notice must be received on or before September 9, 2024, at 11:59 p.m. eastern time. Submissions received after that date may not be considered.

ADDRESSES: The draft of NIST AI 800–1, Managing Misuse Risk for Dual-Use Foundation Models is available for review and comment on the U.S. AI Safety Institute website at <https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.800-1.ipd.pdf> and at www.regulations.gov under docket number 240802–0209.

Comments may be submitted:

By email:

• Comments on NIST AI 800–1 may be sent electronically to NISTAI800-1@nist.gov with “NIST AI 800–1, Managing the Risk of Misuse for Dual-Use Foundation Models” in the subject line. Electronic submissions may be sent as an attachment in any of the following unlocked formats: HTML; ASCII; Word; RTF; or PDF.

Via www.regulations.gov:

• To submit electronic public comments via the Federal eRulemaking Portal.

1. Go to www.regulations.gov and enter 240802–0209 in the search field,
2. Click the “Comment Now!” icon, complete the required fields, including the relevant document number and title in the subject field, and

3. Enter or attach your comments.

• Written comments may also be submitted by mail to Information

Technology Laboratory, ATTN: AI EO Document Comments, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8900, Gaithersburg, MD 20899–8900.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies of the referenced materials. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure.

AISI will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

All relevant comments received by the deadline will be posted at <https://www.regulations.gov> under docket number 240802–0209 and at <https://www.nist.gov/artificial-intelligence/executive-order-safe-secure-and-trustworthy-artificial-intelligence>. Attachments and other supporting materials may become part of the public record and may be subject to public disclosure.

FOR FURTHER INFORMATION CONTACT: For questions about this request for comments contact: christina.knight@nist.gov or Christina Knight, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC ((240) 961–8688). Direct media inquiries to NIST’s Office of Public Affairs at (301) 975–2762. Users of telecommunication devices for the deaf, or a text telephone may call the Federal Relay Service toll free at 1–800–877–8339. Accessible Format: NIST will make the request for comments available in alternate formats, such as Braille or large print, upon request by persons with disabilities.

SUPPLEMENTARY INFORMATION: AISI requests comments on the draft of Managing Misuse Risk for Dual-Use Foundation Models.

AISI welcomes input on all aspects of the draft guidance, such as modifications to the included objectives, practices, and recommendations; suggestions for additions or deletions; and areas where further empirical evidence is needed. The questions below are optional and intended to prompt feedback:

1. What practical challenges exist to meeting the objectives outlined in the guidance?

2. How can the guidance better address the ways in which misuse risks differ based on deployment (e.g., how a foundation model is released) and modality (text, image, audio, multimodal, and others)?

3. How can the guidance better reflect the important role for real-world monitoring in making risk assessments?

4. How can the guidance’s examples of documentation better support communication of practically useful information while adequately addressing confidentiality concerns, such as protecting proprietary information?

5. How can the guidance better enable collaboration among actors across the AI supply chain, such as addressing the role of both developers and their third-party partners in managing misuse risk?

Authority: Sections 4.1(a)(ii) and 4.1(a)(ii)(A) of Executive Order 14110 of Oct. 30, 2023; 15 U.S.C. 272.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–17614 Filed 8–7–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648–XE154]

Schedule for Atlantic Highly Migratory Species Outreach Workshops

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public outreach workshops.

SUMMARY: Three free Atlantic Highly Migratory Species (HMS) Outreach Workshops will be held from August 19, 2024 through August 21, 2024 in locations across Puerto Rico. These workshops are being offered to be responsive to stakeholder requests for additional outreach in Puerto Rico and U.S. Caribbean communities. The objectives of the HMS Outreach Workshops are to educate fishers, dealers, and the general public on HMS regulations, distribute outreach materials, and assist fishers in applying for HMS permits.

DATES: The HMS Outreach Workshops will be held August 19, 2024 through August 21, 2024. See the **SUPPLEMENTARY INFORMATION** section for the specific dates and times.

ADDRESSES: The HMS Outreach Workshops will be held in Cataño,

Guayama, and Fajardo, Puerto Rico. See the **SUPPLEMENTARY INFORMATION** section for the specific locations.

FOR FURTHER INFORMATION CONTACT: Delisse Ortiz, delisse.ortiz@noaa.gov, 301-427-8530.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries are managed under the 2006 Consolidated HMS Fishery Management Plan and its amendments pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635.

Atlantic Highly Migratory Species Outreach Workshop

In recent years, HMS fisheries stakeholders, including fishers, dealers, and the general public, have requested that NMFS prioritize HMS fisheries management education and outreach in the U.S. Caribbean, specifically in Puerto Rico. To be responsive to stakeholder needs in Puerto Rico, NMFS is carrying out free HMS Outreach Workshops across three locations in Puerto Rico. The workshops are designed to educate fishers, dealers, and the general public on HMS regulations, distribute outreach materials, and assist fishers and dealers in applying for HMS permits. The increased engagement, outreach, and education in the U.S. Caribbean as a result of the HMS Outreach Workshops will help meet NMFS's goal of promoting sustainable fisheries and address key shark management outreach requests by our stakeholders in that region. These workshops are also consistent with NMFS's effort to encourage the involvement of disadvantaged or underserved communities consistent with Executive Orders 14008, 12898, and 13895.

Workshop Dates, Times, and Locations

1. August 19, 2024, 5 p.m.–7 p.m.
AST, Villa Pesquera de Cataño, Centro Agropecuario, CVRF+QW4, Las Nereidas Ave., Cataño, PR 00962.

2. August 20, 2024, 4 p.m.–6 p.m.
AST, Club Náutico de Guayama, Carr. 7710 Final Bo Pozuelo, Guayama, PR 00784.

3. August 21, 2024, 5 p.m.–7 p.m.
AST, Centro de Usos Múltiples de Fajardo, Salon B, Calle Dr. Lopez, Estacionamiento Municipal (5to piso), Fajardo, PR 00738.

Additional free HMS Outreach Workshops could be conducted in 2025 and will be announced in a future notice.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 5, 2024.

Claudia Stephanie Womble,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-17618 Filed 8-7-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE179]

Endangered Species; File No. 20347

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for a permit modification.

SUMMARY: Notice is hereby given that the University of Maine, School of Marine Sciences, 5741 Libby Hall, Orono, ME 04469 (Gayle Zydlewski, Ph.D., Responsible Party), has requested a modification to scientific research Permit No. 20347-01.

DATES: Written comments must be received on or before September 9, 2024.

ADDRESSES: The modification request and related documents are available for review by selecting “Records Open for Public Comment” from the Features box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 20347 mod #9 from the list of available applications. These documents are also available upon written request via email to NMFS.Pr1Comments@noaa.gov.

Written comments on this application should be submitted via email to NMFS.Pr1Comments@noaa.gov. Please include File No. 20347 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to NMFS.Pr1Comments@noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Malcolm Mohead or Erin Markin, Ph.D., (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject modification to Permit No. 20347-01, issued on March 12, 2019 (84 FR 15595, April 16, 2019), is requested under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and

exporting of endangered and threatened species (50 CFR parts 222–226).

Permit 20347-01 authorizes research on Atlantic sturgeon and shortnose sturgeon occurring in the Gulf of Maine (GOM) and its tributaries, including the Penobscot, Kennebec, Saco and Merrimack Rivers. Adult, sub-adult, and juvenile sturgeon of each species are sampled with nets, trawls, and trotlines, annually, and then measured, weighed, passive integrated transponder tagged, tissue sampled, and photographed. A subset are acoustically tagged, apical scute and fin ray sampled for age analysis, gastric lavaged, borescoped, and blood sampled. Early life stages of both sturgeon species are also collected to document the occurrence of spawning in GOM tributaries. The permit holder requests to increase the number of adult shortnose sturgeon (from 15 to 30) that may be captured in the Merrimack River for implant of telemetry tags to document sturgeon coastal movement as well as provide evidence of sturgeon access to the Lawrence Dam project boundary. The permit is valid through March 31, 2027.

Dated: August 5, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024-17623 Filed 8-7-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE170]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (NEFMC) will host the Eighth National Meeting of the Scientific Coordination Subcommittee (SCS8) of the Council Coordination Committee. The meeting theme is “Applying Acceptable Biological Catch (ABC) Control Rules in a Changing Environment.” The objective of SCS8 is to provide actionable guidance on how to best support Councils in the management of fisheries, particularly on the use of ABC control rules, given the changing environment.

DATES: The meetings will be held from Monday, August 26 to Wednesday,

August 28, 2024. The times are as follows: August 26, 9 a.m.–5 p.m.; August 27, 8:30 a.m.–5 p.m.; August 28, 9 a.m.–12 p.m.

ADDRESSES:

Meeting address: This meeting will be held at the Seaport Hotel, Boston, MA, One Seaport Lane, Boston, MA 02210.

Webinar Registration information: https://nefmc-org.zoom.us/webinar/register/WN_7nZ9FuUnQUeycD2WcVDnig.

You can listen-only to the meeting online using a computer, tablet, or smart phone, or by phone only. Only the audio portion and presentations displayed on the screen at the SCS8 meeting will be broadcast.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:**Agenda**

The SCS8 objective will be met through a series of keynote and case study presentations, as well as, small-group and plenary discussions on the following topics: Current approaches to defining ABC control rules and challenges in their application; Advances in ecosystem science and assessment to inform ABC control rules in a dynamic environment; Application of social science to achieve management goals under dynamic conditions; Adaptation of reference points, control rules, and rebuilding plans to a changing environment. The agenda is subject to change, and the latest version will be posted at: <https://www.nefmc.org/calendar/aug-26-28-2024-eighth-national-scs-workshop-2024>.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 5, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–17633 Filed 8–7–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648–XE166]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of application; 13 permit renewals, 2 permit modifications, and 6 new permits.

SUMMARY: Notice is hereby given that NMFS has received 21 scientific research permit application requests relating to Pacific salmon, steelhead, green sturgeon, rockfish, and eulachon. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts.

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on September 9, 2024.

ADDRESSES: All written comments on the applications should be sent by email to nmfs.wcr-apps@noaa.gov (please include the permit number in the subject line of the email).

The applications may be viewed online at: https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.

FOR FURTHER INFORMATION CONTACT: Diana Dishman, Portland, OR (ph.: 503–736–4466), email: Diana.Dishman@noaa.gov. Permit application instructions are available from the address above, or online at <https://apps.nmfs.noaa.gov>.

SUPPLEMENTARY INFORMATION:**Species Covered in This Notice**

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened Puget Sound (PS); threatened Snake River (SnkR) fall-run; threatened SnkR spring/summer-run; endangered Upper Columbia River (UCR) spring-run; threatened Upper Willamette River (UWR); threatened Lower Columbia River (LCR); endangered Sacramento River (SacR) winter-run; threatened California Coastal (CC).

Steelhead (*O. mykiss*): Threatened Middle Columbia River (MCR); threatened PS; threatened SnkR Basin; threatened UCR; threatened UWR; threatened Central California Coast (CCC); threatened California Central Valley (CCV); threatened Northern California (NC); threatened LCR.

Chum salmon (*O. keta*): Threatened Hood Canal summer-run (HCS); threatened Columbia River (CR).

Coho salmon (*O. kisutch*): threatened Southern Oregon/Northern California Coast (SONCC); endangered Central California Coast (CCC); threatened LCR.

Sockeye salmon (*O. nerka*): Endangered SnkR; Threatened Ozette Lake (OL).

Eulachon (*Thaleichthys pacificus*): Threatened southern (S).

Rockfish: Endangered Puget Sound/Georgia Basin (PS/GB) Boccacio (*Sebastes paucispinis*) Distinct Population Segment (DPS); threatened PS/GB Yelloweye (*Sebastes ruberrimus*) DPS.

Green sturgeon (*Acipenser medirostris*): Threatened southern Distinct Population Segment (SDPS).

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR 222–226). NMFS issues permits based on findings that such permits: (1) are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Applications Received

Permit 1386–11M

Under permit 1386–11M, the Washington Department of Ecology (WDOE) is seeking to modify a permit that would authorize them to continue taking adult and juvenile PS Chinook salmon, PS steelhead, HCS chum salmon, OL sockeye salmon, UCR spring-run Chinook salmon, UCR steelhead, MCR steelhead, SnkR spring/summer-run Chinook salmon, SnkR fall-run Chinook salmon, SnkR steelhead, LCR Chinook salmon, LCR coho salmon, LCR steelhead, and CR chum salmon. in order to characterize toxic contaminants in resident freshwater fish across Washington.

The WDOE conducts this research in order to meet Federal and State regulatory requirements. This research would benefit listed species by identifying toxic contaminants in resident and prey fish and thereby inform pollution control actions. The WDOE proposes to capture fish using various methods including backpack and boat electrofishing, beach seining, block, fyke, and gill netting, and angling. All captured salmon and steelhead would either be released immediately or held temporarily in an aerated live well to help them recover before release. The researchers do not propose to kill any fish but a small number may die as an unintended result of research activities.

Permit 1484–8R

Under permit 1484–8R, the Washington Department of Natural Resources (WA DNR), Pacific Cascade Region, is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile MCR steelhead, LCR Chinook salmon, LCR coho salmon, LCR steelhead, and CR chum salmon in order to identify fish-bearing streams on WA DNR land in Southwest Washington. Most streams are typed as fish or non-fish bearing based on the physical characteristics of average width and gradient, and connectivity to established fish-bearing waters. This activity will occur on WA DNR land in Lewis, Pacific, Grays Harbor, Wahkiakum, Clark, Cowlitz, Skamania, and Klickitat counties in the state of Washington.

Juveniles would be collected via backpack electrofishing, and would be captured, handled (weighed, measured, and checked for marks or tags), and released. The captured fish would be identified and released back to the waters from which they came. In some cases, the researchers may not actually capture any fish but would merely note

their presence, however electrofishing where listed species are observed would still be reported as take. The researchers are not proposing to kill any of the listed fish being taken, but a small number may be killed as an inadvertent result of these activities. The information gathered would be used to determine salmonid presence and distribution and thereby inform land management decisions on WA DNR holdings. This information would benefit listed species by helping WDNR identify existing man-made fish barriers, and ensuring fish-bearing streams receive adequate riparian buffers.

Permit 1523–5R

Under permit 1523–5R, the National Council for Air and Stream Improvements (NCASI) is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile and adult UWR Chinook salmon in order to study water quality and biological conditions in rivers receiving paper and pulp mill discharges from their facilities. This work would take place in the upper Willamette and McKenzie Rivers in Oregon.

Adult and juvenile fish would be collected via backpack electrofishing or boat electrofishing. Juvenile and adult fish may be captured, handled (weighed, measured, and checked for marks or tags), and released. In some cases, the researchers may not actually capture any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The goal of the project is to identify changes in physical, chemical, and biological conditions in discharge watersheds, including biological assessments of periphyton, macroinvertebrate, and resident fish communities. Monitoring natural variability as well as changes resulting from pulp and paper mill discharges will allow researchers to identify where key sources of fish stress from impaired water quality are in the context of the larger watershed, and to rank the magnitude of those stressors. This study focuses on resident fish rather than migratory species such as ESA-listed salmon and steelhead, however, we expect that identifying areas with impaired water quality or habitat will benefit recovery planning for listed as well.

Permit 15205–5R

Under permit 15205–5R, Kwiáht the (Center for the Historical Ecology of the Salish Sea) is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile PS Chinook salmon in order to understand long term changes in the food web that supports Salish Sea Chinook salmon populations. This work would take place on Lopez Island, Waldron Island, and Decatur Island in San Juan County, Washington.

Juveniles would be collected via beach seine. Juvenile fish identified as hatchery-origin would be captured, and may be handled (measured, weighed, and checked for marks or tags) prior to release. Captured natural-origin juveniles would be anesthetized, checked for marks and tags, lavaged for stomach contents, and tissue sampled prior to release. Scales shed during handling would also be retained. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to characterize the food web supporting rearing juvenile Chinook salmon in the nearshore habitats of the San Juan Islands, and is expected to benefit ESA-listed PS Chinook salmon by identifying factors that may be limiting the growth and survival of outmigrating juveniles. A regime shift in regional weather patterns starting in 2014–2015 may have de-synchronized the relationship between outmigrating juvenile Chinook salmon and availability of prey, and this work aims to evaluate whether naturally-produced Chinook salmon can adapt to changes in key prey resources.

Permit 15230–4R

Under permit 15230–4R, the West Fork Environmental, Inc. is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile PS Chinook salmon and PS steelhead in order to better understand the seasonal use of various reaches of the Tolt River by juvenile summer steelhead prior to their outmigration as smolts. These activities would take place in King County, Washington.

Juveniles would be collected via backpack electrofishing and hook and line angling. Juvenile Chinook salmon would be captured, handled (weighed, measured, checked for marks and tags), and released. Captured juvenile steelhead would be anesthetized, tissue sampled and PIT-tagged prior to release. A subset of steelhead will also have scale samples collected. The researchers are not proposing to kill any of the

listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this study is to understand the reach-specific characteristics of juvenile summer steelhead rearing in the Tolt River across seasons, including information about timing of movement, size at age, and growth of juvenile steelhead in the upper reach. This work will also provide a better understanding of juvenile and adult summer steelhead movement across seasons, and the relative contribution of hatchery-origin fish to the summer steelhead population. This work is expected to benefit ESA-listed PS steelhead by informing managers about factors that may be limiting steelhead production within the Tolt River basin.

Permit 16298–5R

Under permit 16298–5R, the Shoshone-Bannock Tribes Fisheries Department is seeking to renew for 5 years a permit that would authorize them to continue taking adult SnkR spring/summer-run Chinook salmon and SnkR Basin steelhead in order to measure adult and juvenile Chinook salmon abundance and other salmon population viability parameters in Bear Valley Creek, Idaho.

Juveniles would be collected via screw trap, and the majority would be captured, handled (weighed, measured, and checked for marks and tags), and released. A subsample of captured juveniles would be anesthetized, tissue sampled, PIT-tagged, and may also have scale samples collected prior to release. Adults would be observed via a temporary fish counting station comprising a fish funneling weir, fish counting chamber, video surveillance system, and PIT tag antenna. Spawning ground surveys and creel surveys would also be conducted to enumerate spawning adults. No adult capture, handling, sampling, or tagging is proposed, but fish may be unintentionally injured or killed if impinged on or entangled in the weir. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to continue maintaining a long-term dataset for Chinook salmon in Bear Valley Creek that includes information on abundance, productivity, spatial structure, run-timing, proportion of hatchery-origin contribution to the population, and genetic diversity. This work is expected to benefit ESA-listed SnkR Chinook salmon and steelhead by assisting fishery resource managers in

identifying key factors that are preventing recovery in this basin.

Permit 17062–7R

Under permit 17062–7R, the NMFS Northwest Fisheries Science Center (NWFSC) is seeking to renew a permit that would authorize them to continue taking juvenile and adult PS Chinook salmon, PS steelhead, PS/Georgia Basin DPS bocaccio, PS/Georgia Basin DPS yelloweye rockfish, HCS chum salmon, and adult Southern DPS eulachon in order to collect demographic information and genetic samples from rockfish in Puget Sound. This work would take place across the main basins of Puget Sound, Hood Canal, and the San Juan Islands and other coastal areas in northern Puget Sound and the Strait of Juan de Fuca in the state of Washington.

Juveniles would be collected via minnow trap, moored mesh bags, hand or dip nets, and hook and line angling. Any Chinook salmon, steelhead, or chum collected would be handled (weighed, measured, checked for marks and tags) and released. Adult eulachon may also be unintentionally captured via these methods and would be released. Juvenile rockfish would be intentionally lethally sacrificed for genetic, tissue, and otolith analysis, and a small number may be from ESA-listed bocaccio or yelloweye rockfish DPSs. Adult salmon, steelhead, and rockfish would be collected via hook and line angling. Adult salmon and steelhead would be released without bringing them on board research vessels. Adult rockfish would be handled (weighed, measured, checked for marks and tags), tissue sampled, and floy-tagged prior to release at depth using a rapid descending device. The researchers are proposing to kill a small number of listed juvenile rockfish, and a small number of additional juvenile and adult fish may be killed as an inadvertent result of these activities.

The goal of this work is to collect biological, genetic, physiological and habitat information to evaluate bocaccio DPS structure and investigate how rocky reef, kelp forest, and eelgrass habitat characteristics affect the relative quality of these areas as nursery habitat for rockfishes in Puget Sound. This work is expected to benefit ESA-listed rockfish by providing more information on the structure of the endangered bocaccio DPS, and on juvenile rearing habitat quality and trophic relationships of rockfish relevant to managing yelloweye rockfish and bocaccio for recovery.

This study falls within the scope of the NWFSC research program that we previously analyzed in Biological

Opinion WCRO–2023–01601. In that opinion, we concluded that the NWFSC research program would not jeopardize the continued existence of any ESA-listed species or destroy or adversely modify their critical habitats. In reaching our conclusion, we also considered activities related to permitting or authorizing individual studies under that research program for up to 10 years. Therefore, neither this study nor subsequently issuing a section 10(a)(1)(A) permit requires further consultation under the ESA.

Permit 17761–3R

Under permit 17761–3R, the East Bay Municipal Utility District is seeking to renew a permit that would authorize them to take adult and juvenile CCV steelhead in order to conduct monitoring and research of anadromous and resident fishes in the lower Mokelumne River. This work would take place in the San Joaquin Valley, in California.

Juveniles would be collected via backpack electrofishing, boat electrofishing, hook and line angling, beach seine, incline plane trap, screw trap, fish ladder, fyke trap, bypass trap, snorkel survey, and midwater trawl. All juvenile steelhead captured would be handled (weighed, measured, checked for marks and tags), and may be anesthetized as needed to collect accurate measurements, prior to release. A subsample of captured juveniles would be anesthetized, tissue sampled, and may be marked with photonic dye, elastomer tags, coded-wire tags, PIT-tags, acoustic tags, or floy tags prior to release. A subset of captured juvenile steelhead would also be gastric lavaged for stomach contents. A batch of hatchery-reared juvenile steelhead may also be implanted with acoustic tags prior to release.

Adults would be collected via fish weir, boat electrofishing, fish ladder, hook and line angling, incline plane trap, screw trap, fyke trap, and midwater trawl. Adults would be captured, handled (anesthetized, weighed, measured, and checked for marks or tags), and released. A subsample of captured adults would be anesthetized, tissue sampled and may be marked with photonic dye, elastomer tags, coded-wire tags, PIT-tags, acoustic tags, or floy tags prior to release. A subset of captured adult steelhead would also be gastric lavaged for stomach contents. Spawning adults or post-spawn carcasses would be enumerated via spawning surveys. Juvenile and adult fish would also be observed during snorkel surveys and video monitoring in the fish ladder. The

researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The goals of this project are to measure the success of the Lower Mokelumne River Restoration Program and determine if the modifications of the Lower Mokelumne River Project are appropriate for conserving fish and wildlife resources in the lower Mokelumne River. This project is expected to benefit ESA-listed species by providing scientific data to the Central Valley Project Improvement Act (CVPIA) Comprehensive Assessment and Monitoring Program (CAMP) to evaluate the relative effectiveness of CVPIA actions in restoring anadromous fish production.

Permit 18852-3R

Under permit 18852-3R, the U.S. Fish and Wildlife Service (USFWS) Mid-Columbia Fish and Wildlife Conservation Office is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile and adult UCR spring-run Chinook salmon, UCR steelhead, and MCR steelhead in order to define the distribution and status of Pacific Lamprey, Bull Trout, and other native fish species. This work would take place in the Yakima, Wenatchee, Entiat, Methow, and Okanogan watersheds in the state of Washington.

Juveniles would be collected via backpack electrofishing, hand or dip net, fish ladders and weirs, minnow traps, and fyke nets. Most juvenile Chinook salmon and steelhead would not be targeted and, if captured, would be handled and immediately released. A subsample of captured juveniles may be anesthetized to identify species, obtain weights and measurements, and scanned for PIT tags before being released. Juvenile MCR steelhead trout captured in the Yakima Basin may be PIT-tagged and tissue sampled as well. Adults would be collected at dams and other structures and in traps, and may be caught by hook and line angling. Adult Chinook salmon or steelhead would be captured, handled (anesthetized, weighed, measured, and checked for marks or tags), and released, and may be anesthetized to identify species, obtain weights and measurements, and scanned for PIT tags before being allowed to recover and released. Spawning adults or post-spawn carcasses would be enumerated via spawning surveys. Juvenile and adult fish would also be observed during snorkel surveys. The researchers are not proposing to kill any of the listed fish being captured, but a small number of

fish may be killed as an inadvertent result of these activities.

The purpose of this project is to assess recovery actions including capture and transport of Bull Trout to upstream of barriers, assessing fish utilization of restored habitat, and assessing Pacific Lamprey passage at existing structures and at lamprey-passage-engineered structures. This work is expected to benefit ESA-listed fish under the jurisdiction of the USFWS, and also provide information on passage barriers and habitat use relevant to managing listed Chinook salmon and steelhead in the UCR and MCR.

Permit 18921-3R

Under permit 18921-3R, the Samish Indian Nation is seeking to renew a permit that would authorize them to continue taking juvenile PS Chinook salmon and PS steelhead, and adult southern DPS eulachon in order to monitor the presence of fish species within and around the Cypress Island Secret Harbor restoration site. This work would take place on Cypress Island in Skagit County, Washington.

Juvenile PS Chinook salmon and steelhead and adult eulachon would be collected via beach seine. Captured fish would be handled (weighed, measured, and checked for marks or tags), and released. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to assess the effectiveness of the Cypress Island Secret Harbor restoration project over 10 years after it was completed; particularly forage fish and salmonid habitat use within the site. Effective restoration at this site is expected to increase the amount of high quality estuarine habitat available to rearing PS Chinook salmon and steelhead juveniles, and this monitoring will provide managers information about whether the intended benefit has been realized.

Permit 19263-3R

Under permit 19263-3R, the Idaho Department of Fish and Game (IDFG) is seeking to renew for 5 years a permit that would authorize them to continue taking juvenile SnkR spring/summer-run Chinook salmon, SnkR Basin steelhead, and SnkR sockeye salmon in order to determine the distribution and abundance of various fish species in the Salmon River basin. This work would take place throughout the Salmon River basin in Idaho.

Juveniles would be collected via boat electrofishing. Juveniles of all three

ESA-listed species may be anesthetized during capture and handling, however any SnkR sockeye juveniles will be released without tagging. A subsample of captured juvenile Chinook salmon and steelhead may be anesthetized, tissue sampled and PIT-tagged prior to release. In some cases, the researchers may not actually capture any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this project is to address various IDFG priority fisheries management and research issues relevant to their mandates, and to evaluate completed habitat restoration activities and prioritize future restoration actions. Both ESA-listed and resident fish are expected to benefit from research that will help inform decisions about how and where to protect and improve habitat conditions throughout the upper Salmon River basin.

Permit 22944-2R

Under permit 22944-2R, the NMFS NWFSC is seeking to renew a permit that would authorize them to continue taking juvenile UCR spring-run Chinook salmon, UCR steelhead, MCR steelhead, SnkR spring/summer-run Chinook salmon, SnkR fall-run Chinook salmon, SnkR Basin steelhead, SnkR sockeye salmon, LCR Chinook salmon, LCR coho salmon, LCR steelhead, CR chum salmon, Upper Willamette River Chinook salmon, and Upper Willamette River steelhead in order to document patterns of habitat occurrence, diet, and health indicators in juvenile salmon and steelhead in the Lower Columbia River. This work would take place in nearshore areas of the Lower Columbia River in Washington and Oregon, and in the Lower Willamette River in Oregon.

Juvenile salmon and steelhead would be collected via beach seine. Juvenile fish would be captured, handled (weighed, measured, and checked for marks and tags), and may be anesthetized to obtain measurements prior to release. A subsample of captured Chinook salmon juveniles would be anesthetized and further tissue sampled and PIT-tagged prior to release, and a small number would also be intentionally lethally sacrificed to determine their lipid content, conduct otolith analysis for health and growth assessment, do stomach content diet analyses, and take tissue samples for genetic stock identification. The

researchers are proposing to kill a small number of listed fish, and a small number of fish may also be killed as an inadvertent result of these activities.

The objectives of the study are to better understand how juvenile salmonids utilize tidal freshwater habitats in the Columbia, to assess the quality of representative habitats in the lower river, to provide baseline data to guide habitat restoration and remediation activities, and to monitor the success of such activities at selected sites. The study is expected to benefit ESA-listed fish species by providing relevant information on (a) how habitat degradation may be affecting listed stocks that migrate through the Lower Columbia River and (b) what steps that can be taken to improve habitat quality.

This study falls within the scope of the NWFSC research program that we previously analyzed in Biological Opinion WCRO-2023-01601. In that opinion, we concluded that the NWFSC research program would not jeopardize the continued existence of any ESA-listed species or destroy or adversely modify their critical habitats. In reaching our conclusion, we also considered activities related to permitting or authorizing individual studies under that research program for up to 10 years. Therefore, neither this study nor subsequently issuing a section 10(a)(1)(A) permit requires further consultation under the ESA.

Permit 23629-2R

Under permit 23629-2R, the U.S. Geological Survey (USGS) is seeking to renew for 5 years a permit that would authorize them to continue taking adult UWR Chinook salmon and SONCC coho salmon in order to evaluate contaminant exposure, bioaccumulation, and effects in aquatic ecosystems and aquatic-dependent wildlife by assessing a wide range of contaminants (e.g., mercury, lead, copper, selenium, pesticides, organochlorines, PDBEs, and other emerging contaminants) in various fish and inland aquatic invertebrate species over a range of habitats and locations. This work would take place in the Willamette and Rogue River basins in the state of Oregon.

Juvenile and adult salmon would be collected via backpack electrofishing, boat electrofishing, hook and line angling, gill net, beach seine, and minnow trap. This contaminant study targets resident fish species and does not target ESA-listed salmon and steelhead, therefore listed fish would be captured, handled (weighed, measured, and checked for marks or tags), and swiftly released. In some cases, the researchers may not actually capture

any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to evaluate contaminant risks in aquatic ecosystems of the Pacific Northwest and assess the factors that influence contaminant exposure and effects in aquatic wildlife. This work is expected to benefit ESA-listed salmon by providing greater understanding on where and why contaminant threats exist, what impacts they may have on ecological function, and how management efforts can be targeted to minimize potential risk and thereby help recovery planning for these species.

Permit 23843-2R

Under permit 23843-2R the Skagit River System Cooperative is seeking to renew a permit that would authorize them to take juvenile PS Chinook salmon and PS steelhead in order to measure changes in fish densities, smolt production, and habitat attributable to restoration activities to continue the assessment of restoration efforts within the Skagit River and its floodplain. This work will take place in multiple locations across the Skagit River Basin in the State of Washington.

Juveniles PS Chinook salmon and steelhead would be collected via weir, backpack electrofishing, boat electrofishing, or beach seining. Juvenile fish would be captured, handled (weighed, measured, and checked for marks or tags), and released. A subsample of captured juveniles would be marked with a caudal fin clip or dye prior to release. In some cases, the researchers may not actually capture any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. Spawning adults or post-spawn carcasses would be enumerated via spawning surveys. Juvenile and adult fish would also be observed during snorkel surveys. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The goals of this project are to conduct traditional restoration effectiveness monitoring following restoration projects in the Skagit River Basin, and also contribute to development of a fish and habitat association model to inform restoration design. This work is expected to benefit

ESA-listed fish by informing adaptive management of one restoration site specifically (Barnaby Slough) to increase the likelihood it will provide the expected habitat benefits for PS Chinook salmon and steelhead, and more broadly, improved fish and habitat association models that incorporate hydrodynamics will inform future restoration design.

Permit 26776

Under permit 26776, Anchor QEA is seeking a new permit that would authorize them to take juvenile PS Chinook salmon and PS steelhead in order to conduct stream typing and evaluate culverts as potential barriers to fish passage in support of Pierce County. This work would be conducted in locations across Pierce County, Washington.

Juvenile PS Chinook salmon and steelhead would be collected via hand or dip netting and backpack electrofishing. Captured fish would be handled (weighed, measured, and checked for marks or tags) prior to release. In some cases, the researchers may not actually capture any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. The researchers will only deploy electrofishing if attempts to visually observe and identify fish from the bank and to sample fish by dip nets are unsuccessful. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to confirm the upper extent of fish presence in potentially fish-bearing streams, and support the prioritization of fish passage structures to establish access to suitable habitat in the upstream extent of fish-bearing habitat. This work is expected to benefit ESA-listed species by informing the planning of restoration and enhancement efforts to improve salmonid habitat, and salmonid access upstream of anthropogenic barriers in Pierce County.

Permit 27091-2M

Under permit 27091-2M, the Port of Seattle is seeking to modify a permit that would authorize them to take additional juvenile PS Chinook salmon and PS steelhead in order to assess juvenile salmonid habitat use and the presence of key invertebrate prey resources in the Lower Duwamish Waterway T-117 restoration site. This work would be conducted solely within the Lower Duwamish River in King County, Washington.

Juveniles would be collected via fyke net. Juvenile salmon and steelhead would be anesthetized, tissue sampled and PIT-tagged prior to release. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this project is to characterize salmonid use of the restoration site during individual tidal cycles and monitor the physical and biological characteristics of the site to measure whether the restoration project is meeting its stated objectives. The restoration of the T-117 site is expected to benefit PS Chinook salmon and steelhead by increasing the area and functional value of riparian, estuarine marsh, exposed intertidal substrate, and shallow subtidal habitats used by salmonids, and this monitoring work will increase the likelihood the restoration will be managed to provide the expected habitat benefits.

Permit 27824

Under permit 27824, the USGS is seeking a new permit that would authorize them to take juvenile SacR winter-run Chinook salmon in order to conduct egg incubation studies and mark-recapture monitoring programs to address juvenile production of winter-run Chinook salmon. This work will be conducted in Battle Creek and the Sacramento River below Shasta Dam, in the California Central Valley.

Juveniles would be collected via screw traps, and captured juveniles would be anesthetized, tissue sampled and PIT-tagged prior to release. Released juveniles may be recaptured using beach seines or backpack electrofishing, and handled (weighed, measured, checked for marks and tags) prior to release. Fertilized eggs from Livingston Stone National Fish Hatchery would be placed in egg boxes and set in designated redd locations along the Sacramento River. The egg boxes would be enclosed in mesh and visually observed from fertilization through emergence, and surviving alevins or fry will be released into the Sacramento River. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this project is to estimate tributary-level survival, somatic growth, and movement patterns of Chinook salmon, focusing on winter-run eggs and juveniles. These studies will help characterize influences of environmental conditions on salmon productivity, and are expected to benefit SacR winter-run Chinook salmon by addressing important data gaps for

managers and informing habitat restoration efforts.

Permit 28055

Under permit 28055 the Gold Ridge Resource Conservation District (GRCD) is seeking a new permit that would authorize them to take juvenile and adult CC Chinook salmon, CCC coho salmon, and CCC steelhead in order to document the status and trends of salmonid populations in watersheds of the Sonoma Coast. This work will be conducted in the Bodega Bay and Russian River basins in coastal California.

Juveniles would be collected via backpack electrofishing, hook and line angling, hand or dip net, beach seine, minnow trap, and funnel or pipe trap. Juvenile fish would be captured, handled (anesthetized, weighed, measured, and checked for marks or tags), and released. A subsample of captured juveniles would also be tissue sampled and PIT-tagged prior to release. Adults are not being targeted during this work, but some may be unintentionally collected via funnel or pipe trap or encountered during electrofishing. Captured adults would be handled (weighed, measured, and checked for marks or tags), and released. Spawned adults or post-spawn carcasses would be enumerated via spawning surveys, and tissues may be collected from carcasses encountered during spawning surveys. Adult and juvenile fish would be observed during snorkel surveys. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The goals of the restoration projects conducted by the GRCD are collectively to improve watershed health and resiliency for the benefit of salmonids, and these studies are intended to improve understanding of restoration needs by addressing information gaps about the current status of salmonid species in the targeted watersheds. This work is expected to benefit ESA-listed salmon and steelhead by providing information on the status and trends of their populations, and their contributions to broader ESUs, which can be used to better inform ESA-listed species management and restoration efforts.

Permit 28158

Under permit 28158 the Northwest Straits Foundation is seeking a new permit that would authorize them to take juvenile PS Chinook salmon and PS steelhead and adult southern DPS eulachon in order to evaluate the impact of shoreline armoring removal, beach

nourishment, vegetation enhancement and toxic cleanup restoration efforts on nearshore fish habitat use. This work would take place in Bowman Bay, Cornet Bay, and Fidalgo Bay in Skagit County and Island County in the state of Washington.

Juvenile salmon and steelhead and adult eulachon would be collected via beach seining. Fish would be captured, handled (identified, weighed, measured, and checked for marks or tags), and released. The researchers are not proposing to kill any of the listed fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of the restoration projects managed by the Northwest Straits Foundation is to restore and enhance habitat for nearshore wildlife, including migrating salmon and their prey species. These restoration efforts are expected to benefit rearing PS Chinook and steelhead, and this pre- and post-construction monitoring work will increase the likelihood the restoration projects will be designed and managed to provide the expected habitat benefits.

Permit 28199

Under permit 28199 the California State Polytechnic University Humboldt (Cal Poly Humboldt) is seeking a new permit that would authorize them to take adult SONCC coho salmon, NC steelhead, CC Chinook salmon, and SDPS green sturgeon in order to assess the presence, distribution, migration, habitat preferences, and movement patterns of sub-adult and adult green sturgeon. This work would take place in Humboldt Bay, Arcata Bay, Mad River Slough and Mad River Estuary in Humboldt and Del Norte Counties, in California.

Adults of all fish species would be collected via hook and line angling. This study is not targeting salmon or steelhead, so any CCC coho salmon, CC Chinook salmon, or NC steelhead captured would be immediately released. Captured adult green sturgeon would be handled (weighed, measured, and checked for marks or tags), tissue sampled and tagged with pop-up satellite archival tags prior to release. Adults would also be visually observed through vessel surveys and aerial surveys, including the use of cameras attached to aerial drones. The researchers are not proposing to kill any of the listed fish being captured, and do not anticipate any will be killed as an inadvertent result of these activities.

The purpose of this study is to assess the presence, distribution, and migration patterns of sub-adult and

adult SDPS green sturgeon in Humboldt and Del Norte County, describe the habitat preferences, identify potential congregation sites, and evaluate individual movement patterns and their correlation with environmental variables. This work is expected to benefit ESA-listed SDPS green sturgeon by addressing current data gaps about distribution and habitat use, providing managers information necessary to evaluate how the species may be affected by future actions that would impact these bay and estuary habitats.

Permit 28292

Under permit 28292, the City of Portland is seeking a permit that would authorize them to take adult LCR Chinook salmon, LCR coho salmon, LCR steelhead, UWR Chinook salmon, and UWR steelhead while conducting a study to determine the levels of contamination in resident fish tissue and to continue documenting how tissue contamination levels are changing over the long term in the Columbia Slough. This work will be conducted within the lower Willamette River in Multnomah County, Oregon.

Juveniles and adults may be collected via boat electrofishing, and would be captured, handled, and released. ESA-listed fish are not being targeted for this study, but some may be unintentionally captured while targeting resident fish. In some cases, the researchers may not actually capture any fish but would merely note their presence, however electrofishing where listed species are observed would still be reported as take. The researchers are not proposing to kill any listed fish, but a small number of fish may be killed as an inadvertent result of these activities.

The purpose of this work is to assess whether or not upland source control actions are reducing toxic loads in fish tissue over time. This study is expected to benefit ESA-listed salmon and steelhead by providing data that will guide programmatic and risk management decisions in contaminated urban waterways and thereby reduce contaminant exposure and uptake in resident and migrating fish in the lower Willamette River over time.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: August 1, 2024.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–17410 Filed 8–7–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE148]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Management Team (CPSMT) and Coastal Pelagic Species Advisory Subpanel (CPSAS) will hold public meetings.

DATES: The CPSMT meeting will be held Wednesday, September 4, 2024, from 1 p.m. to 4 p.m., Pacific Time or until business for the day has been completed.

The CPSAS meeting will be held Friday, September 6, 2024, from 1 p.m. to 4 p.m., Pacific Time or until business for the day has been completed.

ADDRESSES: These meetings will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Jessi Doeringhaus, Staff Officer, Pacific Council; telephone: (503) 820–2415.

SUPPLEMENTARY INFORMATION: The primary purpose of the CPSMT and CPSAS online meetings are to discuss and develop work products and recommendations for the Pacific Council's September 2024 meeting. Topics will include marine planning, membership appointments, and workload planning for future meetings. Projects funded by the Inflation Reduction Act (IRA) will also be

discussed. Other items on the Pacific Council's September agenda may be discussed. The CPSMT may also discuss the development of the Stock Assessment Fishery Evaluation document. The meeting agendas will be available on the Pacific Council's website in advance of the meetings. No management actions will be decided by the CPSMT or CPSAS. CPSMT and CPSAS recommendations will be considered by the Pacific Council at their September Council meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820–2412) at least ten days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 2, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–17513 Filed 8–7–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE159]

New England Fishery Management Council; Public Meeting; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of correction of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Joint Herring Committee and Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will

be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, August 22, 2024, at 9:30 a.m.

ADDRESSES: Webinar registration URL information:

<https://nefmc-org.zoom.us/join/register/tJUlde2hqj0rE9S93wF9at0Dq8m3tUI-2n9d>.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: The original notice published in the **Federal Register** on August 5, 2024 (89 FR 63414). The original notice stated that the webinar meeting would be held on Thursday, August 22, 2024, at 1 p.m. This notice corrects the time of the meeting to 9:30 a.m. All other previously-published information remains unchanged.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 5, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-17599 Filed 8-7-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE146]

Fisheries of the Gulf of Mexico and South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 96 Recreational Landings Topical Working Group Webinar I for Southeast (SE) Yellowtail Snapper.

SUMMARY: The SEDAR 96 assessment for SE yellowtail snapper will consist of a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 96 Recreational Landings Topical Working Group Webinar I will be held August 29, 2024, from 10 a.m. to 12 p.m., Eastern.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open

to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571-4366; email: Julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and State and Federal agencies.

The items of discussion in the webinar are as follows:

Participants will discuss what recreational landings streams, including the SRFPS (State of Florida's State Reef Fish Survey) data, that is available for

use in the assessment of SE yellowtail snapper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 2, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-17512 Filed 8-7-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 22-0P]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Neil Hedlund at neil.g.hedlund.civ@mail.mil or (703) 697-9214.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22-0P.

Dated: August 5, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

November 2, 2022

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 22-0P. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 21-61 of October 8, 2021.

Sincerely,

James A. Hursch
Director

Enclosures:

1. Transmittal

Transmittal No. 22-0P

**REPORT OF ENHANCEMENT OR
UPGRADE OF SENSITIVITY OF
TECHNOLOGY OR CAPABILITY (SEC.
36(B)(5)(C), AECA)**

(i) *Purchaser:* Government of
Australia

(ii) *Sec. 36(b)(1), AECA Transmittal
No.:* 21-61

Date: October 8, 2021

Military Department: Navy

(iii) *Description:* On October 8, 2021, Congress was notified by Congressional certification transmittal number 21-61, of the possible sale, under Section 36(b)(1) of the Arms Export Control Act, of twelve (12) MH-60R Multi-Mission helicopters; thirty (30) T-700-GE-401C engines (24 installed, 6 spares); twelve (12) APS-153(V) Multi-Mode Radars (installed); twelve (12) AN/AAS-44C(V) Multi-Spectral Targeting Systems

(installed); thirty-four (34) Embedded Global Positioning System/Precise Positioning Service (GPS/PPS)/Inertial Navigation Systems (EGI) with Selective Availability/Anti-Spoofing Module (SAASM) (24 installed, 10 spares); twenty (20) Link 16 Multifunctional Information Distribution Systems (MIDS)—Joint Tactical Radio System (JTRS) (12 installed, 8 spares); twelve (12) GAU-61 Digital Rocket Launchers (aircraft provisions only); twelve (12) Airborne Low Frequency Sonars (ALFS) (aircraft provisions only); eighteen (18) AN/AAR-47 Missile Warning Systems (12 installed, 6 spares); eighteen (18) AN/ALE-47 Chaff and Flare Dispenser, Electronic Countermeasures (12 installed, 6 spares); twelve (12) AN/ALQ-210 Electronic Support Measures (ESM) Systems (installed); twenty-four (24) M299 Missile Launchers; twelve (12) GAU-21 Crew Served Guns aircraft

provisions (installed, includes aircraft adapter, ammunition bin, and other accessories); twelve (12) M240D Crew Served Gun Cradles (installed); and eighteen (18) AN/ARQ-59 Hawklink Radio Terminals (12 installed, 6 spares). Also included were AN/ARC-210 RT-2036 UHF/VHF radios with Communications Security (COMSEC); AN/APX-123 Identification Friend or Foe (IFF) transponders; KIV-78; KIV-6; KOV-21; KGV-135A; Advanced Data Transfer Systems (ADTS); Airborne Low Frequency Sonars (ALFS) Training Simulators/Operational Machine Interface Assistants (ATS OMIA); spare engine containers; trade studies with industry to determine the feasibility and cost of implementing provisions for additional passenger seating and modifications to achieve enhanced crew survivability; defense services; spare and repair parts; support and test

equipment; communication equipment; ferry support; publications and technical documentation; personnel training and training equipment; United States (U.S.) Government and contractor engineering, technical, and logistics support services; obsolescence engineering, integration, and test activities required to ensure readiness for the production of the Australian MH-60R helicopters; and other related elements of programmatic, technical and logistics support. The estimated total cost was \$985 million. Major Defense Equipment (MDE) constituted \$665 million of this total.

This transmittal notifies the addition of the following MDE items: one (1) MH-60R Multi-Mission helicopter; two (2) T-700-GE-401C engines (installed); two (2) Embedded Global Positioning System/Precise Positioning Service (GPS/PPS)/Inertial Navigation Systems (EGI) with Selective Availability/Anti-Spoofing Module (SAASM) (installed); and one (1) Link 16 Multifunctional Information Distribution Systems (MIDS)—Joint Tactical Radio System (JTRS) (installed). Also included is non-MDE APS-153(V) multi-mode radar; AN/AAS-44C(V) Multi-Spectral Targeting System; AN/AAR-47 Missile Warning System; AN/ALE-47 Chaff and Flare Dispenser, Electronic Countermeasures; AN/ALQ-210 Electronic Support Measures (ESM) System; and AN/ARQ-59 Hawklink

radio terminal. The estimated total value of these items is \$49.21 million, but will not cause an increase in the total estimated program cost. The total estimated case value will remain \$985 million with MDE remaining \$665 million of this total.

(iv) *Significance*: The proposed sale will improve Australia's capability to perform anti-surface and antisubmarine warfare missions along with the ability to perform secondary missions including vertical replenishment, search and rescue, and communications relay. Australia will use the enhanced capability as a deterrent to regional threats and to strengthen its homeland defense.

(v) *Justification*: This proposed sale will support the foreign policy and national security objectives of the United States. Australia is one of our most important allies in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

(vi) *Sensitivity of Technology*: The Sensitivity of Technology Statement contained in the original notification applies to items reported here.

(vii) *Date Report Delivered to Congress*: November 2, 2022

[FR Doc. 2024-17588 Filed 8-7-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 22-57]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Neil Hedlund at neil.g.hedlund.civ@mail.mil or (703) 697-9214.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22-57 and Policy Justification.

Dated: August 5, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
 2800 Defense Pentagon
 Washington, DC 20301-2800

October 19, 2022

The Honorable Nancy Pelosi
 Speaker of the House
 U.S. House of Representatives
 H-209, The Capitol
 Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 22-57, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Australia for defense articles and services estimated to cost \$162 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

James A. Hursch
 Director

Enclosures:

1. Transmittal
2. Policy Justification

Transmittal No. 22-57

Notice of Proposed Issuance of Letter of Offer

Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Australia

(ii) *Total Estimated Value:*
 Major Defense Equipment * \$ 0 million

Other \$162 million
 TOTAL \$162 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* Foreign

Military Sales (FMS) case AT-P-KOB was below congressional notification threshold at \$89.8 million for non-MDE MH-60R sustainment. The Government of Australia has requested the case be amended to include additional non-MDE MH-60R sustainment items and services. This case amendment will increase the total case value above the non-MDE notification threshold and thus require notification of the entirety of the FMS case.

Major Defense Equipment (MDE):

None

Non-MDE:

Included are MH-60R aircraft sustainment consumables and spare and

repair parts; and other related elements of logistical and program support.

(iv) *Military Department:* Navy (AT-P-KOB)

(v) *Prior Related Cases, if any:* AT-P-KOA

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None known at this time

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:*

None

(viii) *Date Report Delivered to Congress:* October 19, 2022

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION*Australia—MH-60R Sustainment*

The Government of Australia has requested to buy additional non-MDE MH-60R sustainment items and services that will be added to a previously implemented case. The original FMS case, valued at \$89.8 million, included MH-60R sustainment. The estimated total cost is \$162 million.

This proposed sale will support the foreign policy and national security objectives of the United States. Australia is one of our most important allies in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

The proposed sale will continue Australia's capability to interoperate with U.S. forces by maintaining alignment with the U.S. Navy's MH-60R program and maintain mission readiness to deter regional threats and strengthen its homeland defense.

Australia will have no difficulty absorbing this equipment and services into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin, Owego, NY. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2024-17593 Filed 8-7-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Transmittal No. 22-0Q]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Neil Hedlund at neil.g.hedlund.civ@mail.mil or (703) 697-9214.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22-0Q.

Dated: August 5, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY

2800 Defense Pentagon
Washington, DC 20301-2800

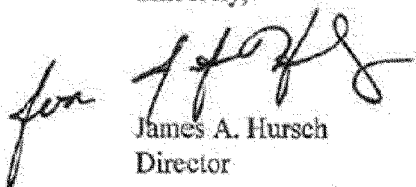
November 2, 2022

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 22-0Q. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 20-09 of March 4, 2020.

Sincerely,



James A. Hursch
Director

Enclosures:

1. Transmittal

Transmittal No. 22-0Q

*REPORT OF ENHANCEMENT OR
UPGRADE OF SENSITIVITY OF
TECHNOLOGY OR CAPABILITY (SEC.
36(B)(5)(C), AECA)*

(i) *Purchaser:* Republic of Poland
(ii) *Sec. 36(b)(1), AECA Transmittal*
No.: 20-09
Date: March 4, 2020
Military Department: Army
Funding Source: National Funds
(iii) *Description:* On March 4, 2020,
Congress was notified by Congressional
certification transmittal number 20-09,
of the possible sale, under Section

36(b)(1) of the Arms Export Control Act,
of one hundred eighty (180) Javelin
missiles and seventy-nine (79) Javelin
Command Launch Units (CLUs). Also
included were Basic Skill Trainers
(BST), Missile Simulation Rounds
(MSR), Battery Coolant Units (BCU),
tool kits, modified 2-level maintenance
parts, training, U.S. Government and
contractor technical assistance,
transportation and other related
elements of logistics support. The
estimated total cost was \$100 million.
Major Defense Equipment (MDE)
constituted \$75 million of this total.

This transmittal notifies the inclusion
of an additional four hundred ninety
(490) Javelin missiles; and fifty (50)
Javelin Light Weight Command Launch
Units (LWCLU) (MDE). These non-MDE
items are also included: Javelin LWCLU
Basic Skills Trainers; Javelin Outdoor
Trainers; Missile Simulation Rounds;
System Integration and Check out;
Javelin Restricted Interactive Electronic
Technical Manual (IETM); Javelin
Operator Manual, and Technical
Assistance (TAGM); tools; Javelin
Gunner Training; Ammunition
Technical Officer Training (ATO); and

Javelin Maintenance Training. The estimated value of the additional MDE items is \$125 million, and the estimated value of the additional non-MDE items is \$25 million. The revised total estimated MDE value is \$200 million, and the revised total case value is \$250 million.

(iv) *Significance*: This proposed sale of additional Javelin systems will help Poland build its long-term defense capacity to defend its sovereignty and territorial integrity in order to meet its national defense requirements and improve its interoperability with U.S. and NATO forces.

(v) *Justification*: This proposed sale will support the foreign policy and national security of the United States by improving the security of a NATO ally and partner nation, which is an important force for peace, political

stability, and economic progress in Eastern Europe.

(vi) *Sensitivity of Technology*: The Sensitivity of Technology Statement contained in the original notification applies to items reported here.

(vii) *Date Report Delivered to Congress*: November 2, 2022

[FR Doc. 2024–17589 Filed 8–7–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 22–61]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Neil Hedlund at neil.g.hedlund.civ@mail.mil or (703) 697–9214.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22–61, Sensitivity of Technology, and Policy Justification.

Dated: August 5, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY

2800 Defense Pentagon
Washington, DC 20301-2800

November 2, 2022

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 22-61, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Finland for defense articles and services estimated to cost \$535 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for 
James A. Hursch
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 22-;61

Notice of Proposed Issuance of Letter of Offer

Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Finland

(ii) *Total Estimated Value:*
Major Defense Equipment * \$512 million

Other \$23 million

TOTAL \$535 million

Funding Source: National Funds

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

One hundred fifty (150) M30A1 Guided Multiple Launch Rocket System (GMLRS) Alternative Warhead (AW) (Steel Case), or M30A2 Guided Multiple Launch Rocket System (GMLRS) Alternative Warhead (AW) Missile Pods with Insensitive Munitions Propulsion System (IMPS), or a combination of both

Two hundred fifty (250) M31A1 GMLRS Unitary (GMLRS-U) Warhead (Steel Case), or M31A2 GMLRS-U IMPS, or a combination of both

Non-MDE:

Also included is a Quality Assurance Team (QAT); transportation services;

and other related elements of program and logistics support.

(iv) *Military Department:* Army (FI-B-VBE)

(v) *Prior Related Cases, if any:* FI-B-VBB

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* November 2, 2022

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION***Finland—Guided Multiple Launch Rocket Systems (GMLRS)***

The Government of Finland has requested to buy one hundred fifty (150) M30A1 Guided Multiple Launch Rocket System (GMLRS) Alternative Warhead (AW) (Steel Case), or M30A2 Guided Multiple Launch Rocket System (GMLRS) Alternative Warhead (AW) Missile Pods with Insensitive Munitions Propulsion System (IMPS), or a combination of both; and two hundred fifty (250) M31A1 GMLRS Unitary (GMLRS-U) Warhead (Steel Case), or M31A2 GMLRS-U IMPS, or a combination of both. Also included is a Quality Assurance Team (QAT); transportation services; and other related elements of program and logistics support. The total estimated cost is \$535 million.

This proposed sale will support the foreign policy and national security of the United States by improving the security of a trusted partner, which is an important force for political stability and economic progress in Europe. It is vital to the U.S. national interest to assist Finland in developing and maintaining a strong and ready self-defense capability.

Finland intends to use these defense articles and services to increase its national stock, bolstering the land and air defense capabilities in Europe's northern flank. The increased national stock is critical to Finland's defense and deterrence due to the deteriorated security situation in Europe. Finland will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors will be Lockheed Martin Corp, Missile and Fire Control, Grand Prairie, TX. There are no known offset agreements in connection with this potential sale. There is a request pending for diversion of 50% of this procurement from U.S. stock. That final decision will determine which version GMLRS could potentially be procured.

Implementation of this proposed sale will not require the assignment of U.S. Government or contractor representatives to Finland.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 22–61

Notice of Proposed Issuance of Letter of Offer

Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The M30A2 GMLRS-Alternative Warhead (AW) is a Department of Defense Cluster Munitions Policy compliant area suppression munition. The AW carries a 200-pound fragmentation assembly filled with high explosives which, upon detonation, accelerates two layers of preformed penetrators optimized for effectiveness against large area and imprecisely located targets. The M30A2 is a material change to the M30A1 GMLRS AW, incorporating the Insensitive Munition Propulsion System (IMPS) complaint motor. The IMPS motor minimizes the probability of inadvertent initiation and severity of collateral damage when subjected to damage, enhances survivability of launch systems and reduces risk of injury to personnel. The M30A2 shares a greater than 90% commonality with the M30A1. Commonalities include the Global Positioning System/Precise Positioning Service (GPS/PPS) aided inertial guidance and control systems, fuzing mechanisms, and multi-option height of burst fuze capability. They have an identical range of 70km + and a minimum range of 15km.

2. The M31A2 GMLRS Unitary Warhead is the Army's primary munition for the M142 HIMARS and M270A1/M270A2 Multiple Launcher Rocket System (MLRS) Launchers. The M31A2 Unitary is a material change to the M31A1 Unitary incorporating the Insensitive Munition Propulsion System (IMPS) complaint motor. The IMPS motor minimizes the probability of inadvertent initiation and severity of collateral damage when subjected to damage, enhances survivability of launch systems and reduces risk of injury to personnel. The M31A2 shares the same Global Positioning System/Precise Positioning Service (GPS/PPS) aided inertial guidance and control systems, fuzing mechanisms, and multi-mode fuzing capability. They have an identical range of 70km + and a minimum range of 15km.

3. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that Finland can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Finland.

[FR Doc. 2024–17596 Filed 8–7–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE
Office of the Secretary

[Transmittal No. 22–59]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Neil Hedlund at neil.g.hedlund.civ@mail.mil or (703) 697–9214.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22–59, Policy Justification, and Sensitivity of Technology.

Dated: August 5, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
 2800 Defense Pentagon
 Washington, DC 20301-2800

October 20, 2022

The Honorable Nancy Pelosi
 Speaker of the House
 U.S. House of Representatives
 H-209, The Capitol
 Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 22-59, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Japan for defense articles and services estimated to cost \$450 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

James A. Hursch
 Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 22-59

Notice of Proposed Issuance of Letter of Offer

Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Japan

(ii) *Total Estimated Value:*
 Major Defense Equipment * \$200 million

Other \$250 million
 TOTAL \$450 million
 (iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):
 Up to thirty-two (32) Standard Missile 6 (SM-6) Block I Missiles (in two tranches of 16)

Non-MDE:

Also included are MK 21 Vertical Launch System (VLS) canisters; obsolescence engineering, integration and test activity; canister handling equipment, spares, training and training equipment/aids; technical publications/data; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support.

(iv) *Military Department:* Navy (JA-P-AUQ)

(v) *Prior Related Cases, if any:* JA-P-ASZ

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or*

Defense Services Proposed to be Sold:
 See Attached Annex

(viii) *Date Report Delivered to Congress:* October 20, 2022

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Japan—Standard Missile 6 Block I (SM-6 Blk I) Missiles

The Government of Japan has requested to buy up to thirty-two (32) Standard Missile 6 (SM-6) Block I missiles (in two tranches of 16). Also included are MK 21 Vertical Launch System (VLS) canisters; obsolescence engineering, integration and test activity; canister handling equipment, spares, training and training equipment/

aids; technical publications/data; U.S. Government and contractor engineering, technical and logistical support services; and other related elements of logistical and program support. The estimated total program cost is \$450 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a major ally that is a force for political stability and economic progress in the Asia-Pacific region.

The proposed sale will improve Japan's Air Defense and Ballistic Missile Defense capabilities against potential adversaries in the region. It will also provide the U.S.-Japan Security Alliance with the latest and most advanced capabilities, reducing Japan's reliance on U.S. Forces for the defense of Japan and further improving U.S.-Japan military interoperability. Japan will have no difficulty absorbing these missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Missiles and Defense (RMD), Tucson, AZ. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require U.S. Government and contractor personnel to visit Japan on a temporary basis in conjunction with program technical oversight and support requirements, including program and technical reviews, as well as to provide training and maintenance support in Japan.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 22-59

Notice of Proposed Issuance of Letter of Offer

Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Standard Missile-6 (SM-6) is a surface Navy Anti-Air Warfare missile that provides area and ship self-defense. The missile is intended to project power and contribute to raid annihilation by destroying manned fixed and rotary wing aircraft, Unmanned Aerial Vehicles (UAV), Land Attack Cruise Missiles, and Anti-Ship Cruise Missiles in flight. It was designed to fulfill the need for a vertically launched, extended range missile compatible with the

AEGIS Weapon System to be used against extended range threats at-sea, near land, and over land. The SM-6 combines the tested legacy of STANDARD Missile-2 (SM-2) propulsion and ordnance with an active Radio Frequency seeker allowing for over-the-horizon engagements, enhanced capability at extended ranges, and increased firepower.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Japan can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Japan.

[FR Doc. 2024-17594 Filed 8-7-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Withdrawal of Notice of Intent (NOI) To Prepare a Draft Environmental Impact Statement for the Amite River and Tributaries-East of the Mississippi River, Louisiana, Flood Risk Management Feasibility Study

AGENCY: Corps of Engineers, Department of the Army, Department of Defense.

ACTION: Notice of intent; withdrawal.

SUMMARY: The U.S. Army Corps of Engineers (USACE) is issuing this notice to advise Federal, State, and local governmental agencies and the public that USACE is withdrawing the notice of intent for the preparation of the Draft Environmental Impact Statement (DEIS) for the Amite River and Tributaries-East of the Mississippi River, Louisiana, Flood Risk Management Feasibility Study, which was published in the **Federal Register** on April 2, 2019. Since publication of the NOI, the USACE released a Draft Integrated Feasibility

Report and Environmental Impact Statement (DIFR/EIS) associated with this study on November 26, 2019 for concurrent public, technical, legal, and policy review. The USACE, after further evaluation of potential impacts, determined the revised (and current) TSP is not likely to result in significant impacts requiring the preparation of an EIS. The USACE therefore prepared the Supplemental Second Draft Integrated Feasibility Report with Environmental Assessment #600 (SSDIFR/EA) that was made available for a 45-day public review starting on December 15, 2023.

DATES: The notice of intent to prepare an EIS published in the **Federal Register** on April 4, 2019 (84 FR 12602), is withdrawn as of August 8, 2024.

ADDRESSES: Department of the Army, U.S. Army Corps of Engineers, New Orleans District, 7400 Leake Avenue New Orleans, LA 70118-3651.

FOR FURTHER INFORMATION CONTACT:

Questions about the withdrawal of the Notice of Intent can be directed to Jordan Logarbo, at (504) 862-1158 or Jordan.r.logarbo@usace.army.mil.

SUPPLEMENTARY INFORMATION: The study's purpose is to investigate flood risk reduction alternatives to reduce flood damages from rainfall in the Amite River Basin (ARB). The study is authorized by the Resolution of the Committee on Public Works of the United States Senate, adopted on April 14, 1967. The report is funded through Public Law 115-123 (the Bipartisan Budget Act of 2018).

A DIFR/EIS for this study was released on November 26, 2019, for concurrent public, technical, legal, and policy review. It evaluated four alternatives as a part of its final array, which included two dams, and a nonstructural plan in its final array. The TSP of the 2019 DIFR/EIS was an estimated \$2.3 billion-dollar new large-scale dry dam with a nonstructural component to address residual risk over a 2200 mi² study area. During review, the TSP was identified to have extensive technical and policy concerns, which found the dam was constrained by site conditions that made it in-feasible as designed and potentially increased life safety risk.

Due to these concerns the USACE re-evaluated critical tasks to inform the decision on the revised tentatively selected plan, a nonstructural-only plan for voluntary elevation of eligible residential structures and floodproofing of eligible nonresidential structures. The USACE does not anticipate that this revised TSP would have impacts requiring the preparation of an EIS. This was documented in the SSDIFR/EA. The

SSDIFR/EA was made available on the Amite River and Tributaries Feasibility Study website (<https://www.mvn.usace.army.mil/Amite-River-and-Tributaries/>) for a 45-day public review and comment period beginning on December 15, 2023 and ending on January 29, 2024.

James A. Bodron,

Programs Director, Mississippi Valley Division.

[FR Doc. 2024–17632 Filed 8–7–24; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0074]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Center for College Students With Disabilities (NCCSD) Database of Disability Services and Activities in Higher Education

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before September 9, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Shedita Alston, 202–453–7090.

SUPPLEMENTARY INFORMATION: The Department is especially interested in

public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: National Center for College Students with Disabilities (NCCSD) Database of Disability Services and Activities in Higher Education.

OMB Control Number: 1840–0841.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 5,916.

Total Estimated Number of Annual Burden Hours: 17,748.

Abstract: The National Center for College Students with Disabilities (NCCSD) at the University of Minnesota and originated by the Association on Higher Education and Disability (AHEAD) is authorized by Congress in the Higher Education Opportunity Act of 2008 (777.4) and was established in 2016. The NCCSD College Disability Resource Database is designed to address a gap in information about services and accessibility for college students with disabilities, who make up 19.5% of the undergraduate population. Existing general information about colleges is available in the Department of Education’s online College Navigator and College Affordability and Transparency Center, but the only information about students with disabilities in these databases is the percentage of students registered with campus disability services offices. At this time, this is the only database that provide systematic collection of information about campus-level disability-related services, access, and activities at colleges and universities in the United States. The NCCSD survey asks all U.S. campuses to provide basic information about disability services, accessibility of campus, and disability-related activities that may affect inclusion and the campus climate. The data is available to the public in an accessible and searchable database to help prospective college students and their families make informed decisions during the college search process.

Because the database is public, researchers and policymakers are able to utilize the data to gather information about disability and higher education in systematic ways.

The Department is requesting a revision of the survey for the following reasons: to add non-degree-granting institutions of higher education to the respondent universe; to change the timeframe for and revise one question; to revise the possible responses to one question; and to add three new questions regarding faculty/instructor disability training.

Dated: August 5, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–17616 Filed 8–7–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0075]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Providing Reading Interventions for Students in Middle School Toolkit Evaluation

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before September 9, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting

documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Anousheh Shayestehpour, (202) 987–1148.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Providing Reading Interventions for Students in Middle School Toolkit Evaluation.

OMB Control Number: 1850–NEW.

Type of Review: New ICR.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 2,647.

Total Estimated Number of Annual Burden Hours: 851.

Abstract: The current authorization for the Regional Educational Laboratories (REL) program is under the Education Sciences Reform Act of 2002, Part D, Section 174, (20 U.S.C. 9564), administered by the Department of Education, Institute of Education Sciences (IES), National Center for Education Evaluation and Regional Assistance (NCEE). The central mission and primary function of the RELs is to support applied research and provide technical assistance to state and local education agencies within their region (ESRA, Part D, section 174[f]). The REL program’s goal is to partner with educators and policymakers to conduct work that is change-oriented and supports meaningful local, regional, or state decisions about education policies, programs, and practices to improve outcomes for students.

Grades 6–8 mark an extended and crucial period in which students are expected to master increasingly complex literacy skills (Biancarosa & Snow, 2006; Hagaman et al., 2016). By the middle school grades, reading instruction typically shifts from a focus on fundamental literacy skills, such as decoding and phonemic awareness, to genre-specific textual conventions,

comprehension strategies, and learning curricular content from texts (Chall, 1983; Goldman & Snow, 2015). For students without the fundamental skills to read fluently, decode accurately, and comprehend text, the more advanced literacy practices needed for secondary content acquisition and text reading can be out of reach. Students who struggle with reading at the middle school level often have limited ability to access curricular content aligned to grade-level standards in English language arts and other subject areas (Torgesen et al., 2007) and may experience adverse educational outcomes with respect to attendance (Fisher & Frey, 2014), graduation rates (Daniel et al., 2006), and mental health (Daniel et al., 2006; Mugnaini et al., 2009).

The purpose of this evaluation is to test the efficacy of the Providing Reading Interventions for Students in Middle School Toolkit, or the PRISMS Toolkit. This toolkit supports the application of evidence-based recommendations from the What Works Clearinghouse (WWC) Providing Reading Interventions for Students in Grades 4–9 Educator’s Practice Guide (hereafter, practice guide; Vaughn et al., 2022) through a suite of professional development activities. We anticipate that the toolkit will impact teacher knowledge, self-efficacy, and instructional practice. These changes in teacher knowledge, beliefs, and practice, in turn, will positively impact student outcomes, including student engagement, as measured by student engagement in reading and school attendance, and reading proficiency.

The evaluation team plans to conduct an independent evaluation using a school-level, cluster randomized control trial design to assess the program’s impact on teachers’ practices and beliefs and students’ engagement and literacy outcomes. The evaluation will also assess the implementation of the toolkit and how it may be effectively scaled. The evaluation will take place in 52 schools across an estimated 10 districts in Texas and will focus on teachers and students in grade 6–8. The evaluation will produce a report and presentations to study participants, practitioners, policymakers, and researchers, and infographics and blog posts for a wider audience of educators and policymakers. These will be designed to inform district and school leaders and teachers about reading interventions that could be beneficial for all students in grade 6–8, but particularly those who are reading below grade level expectations.

Dated: August 5, 2024.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–17624 Filed 8–7–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–496–000]

Rover Pipeline LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on July 18, 2024, Rover Pipeline LLC (Rover), 8111 Westchester Drive, Suite 600, Dallas, Texas 75225, filed an application under section 7(c) of the Natural Gas Act (NGA), and part 157 of the Commission’s regulations requesting authorization for its Rover-Berne Meter Station Expansion Project (Project). The Project will consist of the replacement of the existing filter separator with a new, larger filter separator, within the existing Rover-Berne Meter Station located at Milepost 0.0 on Rover’s Berne Lateral in Monroe County, Ohio. The new, larger filter separator will allow Rover to increase the meter station receipt capacity from 350,000 dekatherms per day (Dth/d) to 400,000 Dth/d. Rover estimates the total cost of the Project to be \$950,000, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission’s Home Page (<http://www.ferc.gov>). From the Commission’s Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission’s website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the

Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.reference.room@ferc.gov.

Any questions regarding the proposed project should be directed to Blair Lichtenwalter, Senior Director of Regulatory Affairs, Rover Pipeline LLC, 1300 Main Street, Houston, Texas 77002, by phone at (713) 989–2605 or by email at blair.lichtenwalter@energytransfer.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,¹ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on August 22, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)² and 385.211³ of the Commission's regulations under the NGA, any person⁴ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁵ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before August 22, 2024.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–496–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–496–000).

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

² 18 CFR 157.10(a)(4).

³ 18 CFR 385.211.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 385.2001.

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁶ has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁷ and the regulations under the NGA⁸ by the intervention deadline for the project, which is August 22, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

There are two ways to submit your motion to intervene. In both instances,

⁶ 18 CFR 385.102(d).

⁷ 18 CFR 385.214.

⁸ 18 CFR 157.10.

¹ 18 CFR (Code of Federal Regulations) 157.9.

please reference the Project docket number CP24–496–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–496–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Blair Lichtenwalter, Senior Director of Regulatory Affairs, Rover Pipeline LLC, 1300 Main Street, Houston, Texas 77002 or by email at blair.lichtenwalter@energytransfer.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the

Commission's Rules and Regulations.¹¹ A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on August 22, 2024.

Dated: August 1, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17495 Filed 8–7–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–473]

Grand River Dam Authority; Notice Dismissing Request for Clarification

On July 2, 2024, the City of Miami, Oklahoma (City), filed a request for clarification of Commission staff's June 3, 2024 order¹ granting Grand River Dam Authority (GRDA), licensee of the Pensacola Project No. 1494, an extension of time to complete its flooding and property rights report required by the Commission's January 18, 2024 Order on Remand (Order on Remand).² The City requests that the Commission clarify the intended scope

of analysis of the flooding and property rights report required by the Order on Remand.³

On July 17, 2024, GRDA filed an answer to the City's request for clarification asserting that the Commission should reject the City's request because no clarification is needed, it is time barred under section 313(a) of the FPA, and it is relitigating issues that the Commission has previously rejected.⁴

The City's request for clarification concerns the scope of the flooding and property rights report required by the Commission's Order on Remand and discussed in GRDA's request for an extension of time to file its report. Rule 213 of the Commission's regulations allows for an answer to a motion for an extension of time within five days after the motion is filed.⁵ Here, the deadline to file an answer to GRDA's extension of time request was May 21, 2024. The City filed its request for clarification on July 2, 2024, well beyond the date allowed under the Commission's regulations. Therefore, the City's request for clarification is dismissed.

Dated: August 1, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17488 Filed 8–7–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–503–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 24, 2024, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.213 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA), and Columbia's blanket certificate issued in Docket No. CP83–76–000, for authorization to convert one existing injection/withdrawal well to observation status and to abandon or replace associated storage lines and appurtenant facilities located at the Laurel Storage Field in

¹¹ 18 CFR 385.214(b)(3) and (d).

¹ Commission staff June 3, 2024 Order Granting Extension of Time to File Flooding and Property Rights Report.

² *Grand River Dam Auth.*, 186 FERC ¶61,045 (Order on Remand), *order on reh'g*, 187 FERC ¶61,211 (2024).

³ City of Miami, Oklahoma, July 2, 2024 Request for Clarification at 2.

⁴ *Grand River Dam Auth.*, July 17, 2024 Answer at 1.

⁵ 18 CFR 385.213(d)(i) (2023).

⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

Hocking County, Ohio (Laurel Well Conversion Project). The estimated cost for the project is \$225,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

Any questions concerning this request should be directed to David A. Alonzo, Manager, Project Authorizations, 700 Louisiana Street, Suite 1300, Houston, Texas 77002-2700, by phone at (832)-320-5477, or by email at david_alonzo@tcenergy.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on September 30, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for

rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is September 30, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁴ and the regulations under the NGA⁵ by the intervention deadline for the project, which is September 30, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 385.214.

⁵ 18 CFR 157.10.

www.ferc.gov/resources/guides/how-to-intervene.asp.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before September 30, 2024. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24-503-000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing"; or⁶

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24-503-000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy

⁶ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: David A. Alonzo, Manager, Project Authorizations, 700 Louisiana Street, Suite 1300, Houston, Texas 77002-2700, or by email at david.alonzo@tcenergy.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17494 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24-2653-000]

69SV 8me LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of 69SV 8me LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17493 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24-107-000.

Applicants: Split Rail Solar Energy LLC, Union Electric Company d/b/a Ameren Missouri.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Split Rail Solar Energy LLC, et al.

Filed Date: 7/30/24.

Accession Number: 20240730-5191.

Comment Date: 5 p.m. ET 8/20/24.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24-248-000.

Applicants: Blue Bird Solar, LLC.

Description: Blue Bird Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 7/31/24.
Accession Number: 20240731–5255.
Comment Date: 5 p.m. ET 8/21/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2437–021.
Applicants: Arizona Public Service Company.

Description: Notice of Change in Status of Arizona Public Service Company.

Filed Date: 7/30/24.
Accession Number: 20240730–5199.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER11–2375–003.
Applicants: Consolidated Edison Company of New York, Inc.

Description: Notice of Non-Material Change in Status of Consolidated Edison Company of New York, Inc.

Filed Date: 7/30/24.
Accession Number: 20240730–5193.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER11–2376–004.
Applicants: Orange and Rockland Utilities, Inc.

Description: Notice of Non-Material Change in Status of Orange and Rockland Utilities, Inc.

Filed Date: 7/30/24.
Accession Number: 20240730–5194.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER16–1720–029.
Applicants: Invenergy Energy Management LLC.

Description: Notice of Change in Status of Invenergy Energy Management LLC.

Filed Date: 7/31/24.
Accession Number: 20240731–5263.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER21–1755–010;
 ER23–1642–007; ER14–2498–018;
 ER14–2500–018.

Applicants: Newark Energy Center, LLC, EIF Newark, LLC, Stored Solar J&WE, LLC, Hartree Partners, LP.

Description: Notice of Change in Status of Hartree Partners, LP, et al.

Filed Date: 7/30/24.
Accession Number: 20240730–5197.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER21–2137–013.
Applicants: IR Energy Management LLC.

Description: Notice of Change in Status of IR Energy Management LLC.

Filed Date: 7/31/24.
Accession Number: 20240731–5261.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER22–2091–007.
Applicants: Calhoun Solar Energy LLC.

Description: Notice of Change in Status of Calhoun Solar Energy LLC.

Filed Date: 7/31/24.

Accession Number: 20240731–5265.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER23–1582–004.
Applicants: Crooked Lake Solar, LLC.
Description: Notice of Change in Status of Crooked Lake Solar, LLC.

Filed Date: 7/30/24.
Accession Number: 20240730–5204.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER23–2746–003.
Applicants: El Sol Storage LLC.
Description: Notice of Change in Status of El Sol Energy Storage LLC.

Filed Date: 7/31/24.
Accession Number: 20240731–5266.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–266–002.
Applicants: Solar of Alamosa LLC.
Description: Notice of Non-Material Change in Status of Solar of Alamosa LLC.

Filed Date: 7/31/24.
Accession Number: 20240731–5264.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–343–002.
Applicants: Nestlewood Solar I LLC.
Description: Notice of Non-Material Change in Status of Nestlewood Solar I LLC.

Filed Date: 7/30/24.
Accession Number: 20240730–5190.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER24–1958–001.
Applicants: Union Electric Company, Huck Finn Solar, LLC.
Description: Tariff Amendment: Huck Finn Solar, LLC submits tariff filing per 35.17(b); Huck Finn Deficiency Response, Req. for Exp. Action & Shortened Comment Period to be effective 12/31/9998.

Filed Date: 8/1/24.
Accession Number: 20240801–5178.
Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–1990–001.
Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Response to July 5, 2024 Deficiency Notice re SA No. 7226 in ER24–1990 to be effective 4/11/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5209.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2653–000.
Applicants: 69SV 8me LLC.
Description: Baseline eTariff Filing: 69SV 8me LLC MBR Tariff to be effective 9/30/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5204.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2654–000.
Applicants: Morgan Stanley Capital Group Inc.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5205.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2655–000.
Applicants: Morgan Stanley Energy Structuring, L.L.C.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5207.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2656–000.
Applicants: Energy Prepay II, LLC.
Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5205.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2655–000.
Applicants: Morgan Stanley Energy Structuring, L.L.C.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5207.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2656–000.
Applicants: Energy Prepay II, LLC.
Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5212.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2657–000.
Applicants: Blue Bird Solar, LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 9/11/2024.

Filed Date: 7/31/24.
Accession Number: 20240731–5217.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2658–000.
Applicants: Midcontinent Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2024–08–01_SA 4312 OTP-Red Lake County Community Hybrid LLC GIA (R121) to be effective 8/25/2024.

Filed Date: 8/1/24.
Accession Number: 20240801–5029.
Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2659–000.
Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original WMPA, Service Agreement No. 7313; AG1–282 to be effective 7/2/2024.

Filed Date: 8/1/24.
Accession Number: 20240801–5030.
Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2660–000.
Applicants: Midcontinent Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2024–08–01_SA 4315 ITC Midwest-Kinsella Energy GIA (J1444) to be effective 7/23/2024.

Filed Date: 8/1/24.
Accession Number: 20240801–5032.
Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2661–000.
Applicants: Rpower, LLC.

Description: Baseline eTariff Filing: RPower, LLC Application For Market Based Rate Authority to be effective 10/1/2024.

Filed Date: 8/1/24.
Accession Number: 20240801–5078.
Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2662–000.

Applicants: Duane Arnold Solar II, LLC.

Description: Baseline eTariff Filing: Duane Arnold Solar II—Application for Market-Based Rate Authorization to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5095.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2663–000.

Applicants: Anticline Wind, LLC.
Description: Baseline eTariff Filing: Anticline Wind, LLC Application for Market-Based Rate Authorization to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5097.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2664–000.

Applicants: Cedar Springs Wind IV, LLC.

Description: Baseline eTariff Filing: Cedar Springs Wind IV, LLC Application for Market-Based Rate Authorization to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5100.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2665–000.

Applicants: UGI Utilities, Inc., PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: UGI Utilities, Inc. submits tariff filing per 35.13(a)(2)(iii); UGIU submits revisions to OATT Attachment H–8C to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5106.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2666–000.

Applicants: 68SF 8me LLC.

Description: 205(d) Rate Filing: 68SF 8me LLC Shared Facilities Agreement to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5111.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2667–000.

Applicants: 68SF 8me LLC.

Description: 205(d) Rate Filing: 68SF 8me LGIA Co-Tenancy Agreement to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5112.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2668–000.

Applicants: LS Power Grid California, LLC.

Description: 205(d) Rate Filing: LS Power Grid California eTariff Filing to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5113.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2669–000.

Applicants: CleanChoice Power Solutions, LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 9/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5154.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2670–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: 205(d) Rate Filing: Initial Filing of Rate Schedule FERC Nos. 377 Through 386 to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5160.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2671–000.

Applicants: California Independent System Operator Corporation.

Description: 205(d) Rate Filing: 2024–08–01 Interconnection Process Enhancements 2023 Initiative—Track 2 to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5172.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2672–000.

Applicants: Puget Sound Energy, Inc.

Description: 205(d) Rate Filing: Glendive Wind Project to be effective 6/18/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5173.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2673–000.

Applicants: Puget Sound Energy, Inc.

Description: 205(d) Rate Filing: Glendive Wind 2 Project to be effective 6/17/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5174.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2674–000.

Applicants: 69SV 8me LLC.

Description: 205(d) Rate Filing: 69SV 8me LLC Shared Facilities Agreement to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5186.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2675–000.

Applicants: 69SV 8me LLC.

Description: 205(d) Rate Filing: 69SV 8me LLC LGIA Co-Tenancy Agreement to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5189.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2676–000.

Applicants: Cedar River Transmission, LLC.

Description: 205(d) Rate Filing: Cedar River Transmission, LLC, et al.'s Shared Facilities Agreement to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5192.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2677–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original WMPA Service Agreement No. 7314, AG1–532 to be effective 7/2/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5218.

Comment Date: 5 p.m. ET 8/22/24.

Docket Numbers: ER24–2678–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to ISA and CSA, SA Nos. 6527 and 6515; Queue No. AC1–053 to be effective 10/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5220.

Comment Date: 5 p.m. ET 8/22/24.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES24–52–000; ES24–53–000; ES24–54–000; ES24–55–000.

Applicants: Evergy Missouri West, Inc., Evergy Metro, Inc., Evergy Kansas South, Inc., Evergy Kansas Central, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Evergy Kansas Central, Inc., et al.

Filed Date: 7/30/24.

Accession Number: 20240730–5202.

Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ES24–56–000.

Applicants: Evergy Missouri West, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Evergy Missouri West, Inc.

Filed Date: 7/30/24.

Accession Number: 20240730–5205.

Comment Date: 5 p.m. ET 8/20/24.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17497 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24-2657-000]

Blue Bird Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Blue Bird Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2024.

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eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17492 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Privacy Act of 1974; System of Records

AGENCY: Federal Energy Regulatory Commission (FERC), DOE.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, all agencies are required to publish in the **Federal Register** a notice of their systems of records. Notice is hereby given that the Federal Energy Regulatory Commission (FERC) is publishing a notice of modifications to an existing FERC system of records titled "*Department of Energy (DOE) Inspector General Investigative Records Relating to the Federal Energy Regulatory Commission (FERC-48)*".

DATES: Comments on this modified system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by FERC, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If FERC receives public comments, FERC shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted in writing to Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, or electronically to privacy@ferc.gov. Comments should indicate that they are submitted in response to "Department of Energy (DOE) Inspector General Investigative Records Relating to the Federal Energy Regulatory Commission (FERC-48)".

FOR FURTHER INFORMATION CONTACT: Mittal Desai, Chief Information Officer & Senior Agency Official for Privacy, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502-6432.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, and to comply with the Office of Management and Budget (OMB) Memorandum M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information*, January 3, 2017, this notice has nineteen (19) routine uses, including twelve new

routine uses, two of which will permit FERC to disclose information as necessary in response to an actual or suspected breach that pertains to a breach of its own records or to assist another agency in its efforts to respond to a breach that was previously published separately at 87 FR 35543 (June 10, 2022).

The following sections have been updated to reflect changes made since the publication of the last notice in the **Federal Register**: dates; addresses; for further contact information; system location; system manager; authority for maintenance of the system; purpose of the system; categories of individuals covered by the system; categories of records in the system; record source categories; routine uses of records maintained in the system, including categories of users and the purpose of such; policies and practices for storage of records; policies and practices for retrieval of records; policies and practices for retention and disposal of records; administrative, technical, physical safeguards; records access procedures; contesting records procedures; notification procedures; and history.

SYSTEM NAME AND NUMBER:

Department of Energy (DOE) Inspector General Investigative Records Relating to the Federal Energy Regulatory Commission (FERC-48).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Federal Energy Regulatory Commission, Chief Security Officer Directorate, Office of the Executive Director, 888 First Street NE, Washington, DC 20426.

SYSTEM MANAGER(S):

Security Specialist, Chief Security Officer Directorate, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 95-452, as amended; 5 U.S.C. 401-424.

PURPOSE(S) OF THE SYSTEM:

The system is used to collect and maintain records concerning FERC investigations and documentation on investigations conducted by the DOE Inspector General. FERC uses the system to manage referrals to and from DOE Inspector General; and to provide authorized assistance to lawful administrative, civil,

counterintelligence, and criminal investigations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following categories of individuals are covered by this system: present and former FERC employees, contractors, assignees, interns, visitors, and guests. In addition, persons who report concerns, witnesses, relatives, or parties who have been identified by DOE Inspector General for further investigation, and individuals with other relevant personal associations with FERC insider are covered by the system of records notice.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include: full name, title, office, type of violation, laptop assignment number, IP address, case name, time and attendance records, building access logs, contact information, correspondence relevant to the investigation; internal staff correspondence, subpoenas issued during the investigation, affidavits, statements from witnesses, transcripts of testimony taken in the course of the investigation and accompanying exhibits; documents and records or copies obtained during the investigation; working papers of the staff and other documents and records relating to the investigation; opening reports, progress reports and closing reports; and any other information gathered in the course of or relating to an inquiry, review, inspection, or investigation of a criminal, civil, or administrative nature.

RECORD SOURCE CATEGORIES:

Records are obtained from (1) software that monitors FERC's user's activity on U.S. Government computer networks; (2) information supplied by individuals to FERC or by the individual's employer; (3) information provided to FERC to gain access to FERC facilities, information, equipment, networks, or systems; (4) publicly available information obtained from open source platforms, including publicly available social media; (5) any departmental records for which the individual has been granted authorized access to; (6) any federal, state, tribal, local government, or private sector records for which the individual has been given authorized access to; (7) individuals who are the subject of the investigation or inquiry, employer, law enforcement organizations, and detention facilities; (8) individuals including, where practicable, those to whom the information relates; (9) witnesses, corporations and other

entities; (10) records of individuals and of the Commission; (11) records of other entities; (12) Federal, foreign, state or local bodies and law enforcement agencies; (13) documents, correspondence relating to litigation, and transcripts of testimony; and (14) miscellaneous other sources. FERC also receives tips and leads by other means, such as email or telephone.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, information maintained in this system may be disclosed to authorized entities outside FERC for purposes determined to be relevant and necessary as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) FERC suspects or has confirmed that there has been a breach of the system of records; (2) FERC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when FERC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

3. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

4. To the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation.

5. To the Federal Labor Relations Authority or its General Counsel when

requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

6. To disclose information to another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, when the Government is a party to the judicial or administrative proceeding. In those cases where the Government is not a party to the proceeding, records may be disclosed if a subpoena has been signed by a judge.

7. To the Department of Justice (DOJ) for its use in providing legal advice to FERC or in representing FERC in a proceeding before a court, adjudicative body, or other administrative body, where the use of such information by the DOJ is deemed by FERC to be relevant and necessary to the advice or proceeding, and such proceeding names as a party in interest: (a) FERC; (b) any employee of FERC in his or her official capacity; (c) any employee of FERC in his or her individual capacity where DOJ has agreed to represent the employee; or (d) the United States, where FERC determines that litigation is likely to affect FERC or any of its components.

8. To non-Federal Personnel, such as contractors, agents, or other authorized individuals performing work on a contract, service, cooperative agreement, job, or other activity on behalf of FERC or Federal Government and who have a need to access the information in the performance of their duties or activities.

9. To the National Archives and Records Administration in records management inspections and its role as Archivist.

10. To the Merit Systems Protection Board or the Board's Office of the Special Counsel, when relevant information is requested in connection with appeals, special studies of the civil service and other merit systems, review of OPM rules and regulations, and investigations of alleged or possible prohibited personnel practices.

11. To appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, if the information may be relevant to a potential violation of civil or criminal law, rule, regulation, order.

12. To appropriate agencies, entities, and person(s) that are a party to a dispute, when FERC determines that information from this system of records is reasonably necessary for the recipient to assist with the resolution of the dispute; the name, address, telephone number, email address, and affiliation;

of the agency, entity, and/or person(s) seeking and/or participating in dispute resolution services, where appropriate.

13. Where there is an indication of a violation or a potential violation of law, whether civil, criminal or regulatory in nature, whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether federal, foreign, state, or local, charged with enforcing or implementing the statute, or rule, regulation or order.

14. To Federal, foreign, state, or local authorities in order to obtain information or records relevant to an Inspector General investigation.

15. To Federal, foreign, state, or local governmental authorities maintaining civil, criminal, or other relevant enforcement information or other pertinent information to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

16. To Federal, foreign, state, or local governmental authorities in response to their request in connection with the hiring or retention of an employee, discriminatory or other administrative action concerning an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

17. To non-governmental parties where those parties may have information the Inspector General seeks to obtain in connection with an investigation.

18. To independent auditors or other private firms with which the Inspector General has contracted to carry out an independent audit, or to collate, aggregate or otherwise refine data collected in the system of records.

19. To respond to subpoenas in any litigation or other proceeding.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in electronic and paper format. Electronic records are stored on a restricted shared drive, and some records are in the individual's human resources file. Paper records are stored in lockable file room. Access to electronic records is controlled by the organizations Single Sign-On and Multi-Factor Authentication solution. Agency

buildings and Data center buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures.

Access to electronic and hard copy files is restricted to those individuals whose official duties require access.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name and log number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with the schedule approved under the Department of Energy Administration Records Schedule 22: Audit/Investigative Records (October 2021, Rev. 4) available at <https://www.energy.gov/sites/default/files/2023-01/ADM%2022%20Rev%204%20Oct%202021.pdf>; and General Records Schedule 5.6: Security Management Records (March 2022), item 210–240 available at <https://www.archives.gov/files/records-mgmt/grs/grs05-6.pdf>.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

See Policies and Practices for Storage of Records.

RECORD ACCESS PROCEDURES:

Individuals requesting access to the contents of records must submit a request through the Freedom of Information Act (FOIA) office. The FOIA website is located at: <https://www.ferc.gov/foia>. Requests may be submitted through the following portal: <https://www.ferc.gov/enforcement-legal/foia/electronic-foia-privacy-act-request-form>. Written requests for access to records should be directed to: Director, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures.

NOTIFICATION PROCEDURE:

Generalized notice is provided by the publication of this notice. For specific notice, see Records Access Procedure, above system.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

65 FR 21759 (April 24, 2000).

Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–17490 Filed 8–7–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. IC24–26–000]

Commission Information Collection Activities (FERC–585); Comment Request; Extension**AGENCY:** Federal Energy Regulatory Commission, DOE.**ACTION:** Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–585 (Reporting of Electric Energy Shortages and Contingency Plans Under PURPA Section 206).

DATES: Comments on the collection of information are due October 7, 2024.

ADDRESSES: You may submit copies of your comments (identified by Docket No. IC24–26–000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by other delivery methods:

- *Mail via U.S. Postal Service Only:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *All other delivery services:* Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this

docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT: Jean Sonneman may be reached by email at DataClearance@FERC.gov, telephone at (202) 502–6362.

SUPPLEMENTARY INFORMATION:

Title: FERC–585 (Reporting of Electric Energy Shortages and Contingency Plans Under PURPA ¹ Section 206).

OMB Control No.: 1902–0138.

Type of Request: Three-year extension of the FERC–585 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses the information collected under the requirements of FERC–585 to implement the statutory provisions of Section 206 of PURPA. Section 206 of PURPA amended the Federal Power Act (FPA) by adding a new subsection (g) to section 202, under which the Commission, by rule, was to require each public utility to report to the Commission and any appropriate state regulatory authority:

- any anticipated shortages of electric energy or capacity which would affect the utility's capability to serve its wholesale customers; and
- a contingency plan that would outline what circumstances might give rise to such occurrences.

- In Order No. 575,² the Commission modified the reporting requirements in 18 CFR 294.101(b) to provide that, if a public utility includes in its rates schedule, provisions that during electric energy and capacity shortages:

- it will treat firm power wholesale customers without undue discrimination or preference; and
 - it will report any modifications to its contingency plan for accommodating shortages within 15 days to the appropriate state regulatory agency and to the affected wholesale customers, then the utility need not file with the Commission an additional statement of contingency plan for accommodating such shortages.

¹ PURPA = Public Utility Regulatory Policies Act of 1979 (Pub. L. 95–617, 92 Stat. 3117), enacted 11/9/1978.

² Final Rule in Docket RM92–12–000, issued on 1/13/1995.

This revision changed the reporting mechanism, specifically the public utility's contingency plan would be in its filed rate rather than in a separate document. In Order No. 659,³ the Commission modified the reporting requirements in 18 CFR 294.101(e) to provide that public utilities must comply with the requirements to report shortages and anticipated shortages by submitting this information electronically using the Office of Electric Reliability's alert system at emergency@ferc.gov in lieu of submitting an original and two copies to the Secretary of the Commission. The Commission uses the information to evaluate and formulate an appropriate option for action in the event an unanticipated shortage is reported and/or materializes. Without this information, the Commission and State agencies would be unable to:

- examine and approve or modify utility actions;
- prepare a response to anticipated disruptions in electric energy; and/or
- ensure equitable treatment of all public utility customers under the shortage situation.

The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR part 294.101.

Type of Respondents: Public Utilities.

*Estimate of Annual Burden:*⁴ The Commission estimates the annual public reporting burden for the information collection as:

³ Final Rule in Docket RM05–19–000, issued on 5/27/2005.

⁴ “Burden” is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

FERC–585

[Reporting of electric shortages and contingency plans under PURPA Section 206]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ⁵	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Contingency Plan	1	1	1	1 hrs.; \$100.00	1 hrs.; \$100.00	\$100.00
Capacity Shortage	1	1	1	1 hrs.; \$100.00	1 hrs.; \$100.00	100.00
Total					2 hrs.; \$200.00	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: August 1, 2024.
Debbie-Anne A. Reese,
Acting Secretary.
[FR Doc. 2024–17491 Filed 8–7–24; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[Project No. 1494–405]

Grand River Dam Authority; Notice of
Effectiveness of Withdrawal of
Application for Amendment of License

On May 24, 2018, Grand River Dam Authority, licensee for the Pensacola Hydroelectric Project No. 1494, filed an application for a non-capacity amendment for the Coal Creek Wildlife Management Area in compliance with the requirements of Article 411 of the Pensacola Project license ¹ and the 2003 Fish and Waterfowl Habitat

⁵ The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * 100.00 per Hour = Average Cost per Response. This is Based upon FERC’s 2024 FTE average salary plus benefits. Commission staff believes that any industry effort applied to FERC–585 would be compensated similarly to FERC’s average salary.

¹ *Grand River Dam Auth.*, 59 FERC ¶ 62,073 (1992) (License Order). Article 411 was added in a 1996 amendment order. *See Grand River Dam Auth.*, 77 FERC ¶ 61,251 (1996).

Management Plan for the project.² On July 15, 2024, the licensee filed a notice withdrawing the amendment application.

No motion in opposition to the notice of withdrawal has been filed, and the Commission has taken no action to disallow it. Accordingly, pursuant to Rule 216(b) of the Commission’s Rules of Practice and Procedure,³ the withdrawal of the application became effective on July 30, 2024.

Dated: August 1, 2024.
Debbie-Anne A. Reese,
Acting Secretary.
[FR Doc. 2024–17538 Filed 8–7–24; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory
Commission

[Docket No. PF23–2–000]

Sabine Pass Liquefaction, LLC, Sabine
Pass Liquefaction Stage V, LLC,
Sabine Crossing, LLC; Notice of
Scoping Period Requesting Comments
on Environmental Issues for the
Planned Sabine Pass Stage 5
Expansion Project, and Notice of
Public Scoping Session

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Sabine Pass Stage 5 Expansion Project involving construction and operation of facilities by Sabine Pass Liquefaction, LLC and Sabine Pass Liquefaction Stage V, LLC (collectively, Sabine Pass), and Sabine Crossing, LLC (Sabine Crossing) in Cameron Parish, Louisiana, and Liberty, Jefferson, and Chambers Counties, Texas. The Commission will use this environmental document in its decision-making process to determine whether the

² *Grand River Dam Auth.*, 103 FERC ¶ 62,102 (2003).

³ 18 CFR 385.216(b) (2023).

planned pipeline project is in the public convenience and necessity and if the planned liquid natural gas facility expansion is in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity and authorization. This gathering of public input is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission’s NEPA process is described below in the NEPA Process and Environmental Document section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on September 3, 2024. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the Public Participation section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written or oral comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on February 22,

2023, you will need to file those comments in Docket No. PF23–2–000 to ensure they are considered.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this planned project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with State law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the

Commission has no jurisdiction over these matters.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (www.ferc.gov) under the Natural Gas, Landowner Topics link.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or FercOnlineSupport@ferc.gov.

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling

feature, which is located on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; a comment on a particular project is considered a "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (PF23–2–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

(4) In lieu of sending written comments, the Commission invites you to attend the public scoping session its staff will conduct in the project area, scheduled as follows:

Date and time	Location
Wednesday, August 28, 2024, 5:00–7:00 p.m. CDT	Huddleston Community Building, 924 State Highway 124, Winnie, TX 77665, (409) 296–8250.

The primary goal of this scoping session is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. Individual oral comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of oral comments in a convenient way during the timeframe allotted.

The scoping session is scheduled from 5:00 p.m. to 7:00 p.m. Central Daylight Time. You may arrive at any time after 5:00 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 7:00 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 6:30 p.m. Please see appendix 1 for additional

information on the session format and conduct.¹

Your scoping comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see the last page of this notice for instructions on using eLibrary). If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit may be implemented for each commentator.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a scoping session.

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary". For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at FercOnlineSupport@ferc.gov or call toll free, (866) 208–3676 or TTY (202) 502–8659.

Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. Representatives from Sabine Crossing will also be present to answer project-specific questions.

Additionally, the Commission offers a free service called eSubscription, which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and

others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or *OPP@ferc.gov*.

Summary of the Planned Project

Sabine Pass and Sabine Crossing plan to expand existing liquefied natural gas (LNG) facilities and construct a new natural gas pipeline to provide a feed supply to the LNG terminal. The Sabine Pass Stage 5 Expansion Project (Project) would be located in Cameron Parish, Louisiana and Liberty, Chambers, and Jefferson Counties, Texas and would consist of constructing the following facilities:

- two natural gas liquefaction trains;
- two aboveground LNG storage tanks;
- boil off gas re-liquefaction unit;
- operations and maintenance building;
- a new 57.6-mile, 48-inch-diameter natural gas pipeline;
- one new compressor station;
- two pig traps; and
- four mainline valves and one tap valve.

Sabine Pass also proposes modifications to existing ship-loading facilities.

The general location of the project facilities is shown in appendix 2.

Land Requirements for Construction

Construction of the planned facilities would disturb about 1,013.4 acres of land for the LNG facilities and the pipeline. Following construction, Sabine Pass and Sabine Crossing would maintain about 884.1 acres for permanent operation of the Project's facilities; the remaining acreage would be restored and could revert to former uses. About 60 percent of the planned pipeline route parallels existing pipeline, utility, or road rights-of-way.

NEPA Process and the Environmental Document

Any environmental document issued by Commission staff will discuss impacts that could occur as a result of the construction and operation of the planned project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- environmental justice;

- air quality and noise;
- reliability and safety; and
- climate change.

Commission staff have already identified several issues that deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Sabine Pass and Sabine Crossing. This preliminary list of issues may change based on your comments and our analysis:

- permanent wetland impacts;
- flooding and storm surge;
- cumulative impacts; and
- alternative routes.

Commission staff will also evaluate reasonable alternatives to the planned project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Although no formal application has been filed, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact Federal and State agencies to discuss their involvement in the scoping process and the preparation of the environmental document.

If a formal application is filed, Commission staff will then determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the environmental issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its determination on the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued once an application is filed, which will open an additional public comment period. Staff will then prepare a draft EIS that will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS, and

revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary² and the Commission's natural gas environmental documents web page (<https://www.ferc.gov/industries-data/natural-gas/environmental-environmental-documents>). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this project to formally cooperate in the preparation of the environmental document.³ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, the U.S. Army Corps of Engineers Galveston District, the Department of Energy, and the National Marine Fisheries Service have expressed their intention to participate as cooperating agencies in the preparation of the environmental document.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁴ The environmental document for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials;

² For instructions on connecting to eLibrary, refer to the last page of this notice.

³ The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at title 40, Code of Federal Regulations, part 1501.8.

⁴ The Advisory Council on Historic Preservation regulations are at title 36, Code of Federal Regulations, part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to GasProjectAddressChange@ferc.gov stating your request. You must include the docket number PF23-2-000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached "Mailing List Update Form" (appendix 3).

Becoming an Intervenor

Once Sabine Crossing files its application with the Commission, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Only intervenors have the right to seek rehearing of the Commission's decision and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at <https://www.ferc.gov/how-intervene>. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the project, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number in the "Docket Number" field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at <https://www.ferc.gov/news-events/events> along with other related information.

Dated: August 1, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17486 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24-934-000.
Applicants: Northern Natural Gas Company.

Description: 4(d) Rate Filing: 20240731 Negotiated Rate to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5121.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-935-000.

Applicants: Ruby Pipeline, L.L.C.

Description: 4(d) Rate Filing: RP 2024-07-31 FL&U and EPC Rate Adjustment to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5125.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-936-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco Aug 2024) to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5153.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-937-000.

Applicants: Sabine Pipe Line LLC.

Description: 4(d) Rate Filing: Normal filing July 2024-7.26-4.9 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5167.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-938-000.

Applicants: Sierrita Gas Pipeline LLC.

Description: 4(d) Rate Filing: 2024 Jul Quarterly FL&U Filing to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5202.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-939-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal Aug-Oct 2024) to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5220.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-940-000.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: 4(d) Rate Filing: Limited Section 4 to Adjust Fuel Gas and L&U Retention Factors 2024 to be effective 9/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801-5001.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24-941-000.

Applicants: Mountain Valley Pipeline, LLC.

Description: 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements-8/1/2024 to be effective 8/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801-5014.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24-942-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: 4(d) Rate Filing: Negotiated Rates-Various Releases eff 8-1-24 to be effective 8/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801-5031.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24-943-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: 4(d) Rate Filing: AGT Name Change Filing August 2024 to be effective 9/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801-5036.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24-944-000.

Applicants: ANR Pipeline Company.
Description: 4(d) Rate Filing; NR NC and Misc Housekeeping to be effective 9/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5039.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24–945–000.

Applicants: NEXUS Gas

Transmission, LLC.

Description: 4(d) Rate Filing; Negotiated Rates—Various Releases eff 8–1–2024 and 8–31–2024 to be effective 8/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5053.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24–946–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: 4(d) Rate Filing; Negotiated Rates—Various Releases eff 8–1–24 to be effective 8/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5054.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24–947–000.

Applicants: Rover Pipeline LLC.

Description: 4(d) Rate Filing; Summary of Negotiated Rate Capacity Release Agreements 8–1–2024 to be effective 8/1/2024.

Filed Date: 8/1/24.

Accession Number: 20240801–5102.

Comment Date: 5 p.m. ET 8/13/24.

Docket Numbers: RP24–948–000.

Applicants: UGI Storage Company.

Description: Annual Report of Operational Sales and Purchases of UGI Storage Company.

Filed Date: 8/1/24.

Accession Number: 20240801–5140.

Comment Date: 5 p.m. ET 8/13/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP22–1222–005.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: Compliance filing; NGPL Fuel Transparency Report Informational Filing 2024 to be effective N/A.

Filed Date: 8/1/24.

Accession Number: 20240801–5000.

Comment Date: 5 p.m. ET 8/13/24.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the

Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: August 1, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17496 Filed 8–7–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15324–001]

Scott D. Sanicki; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption from Licensing.

b. *Project No.:* 15324–001.

c. *Date Filed:* July 22, 2024.

d. *Applicant:* Scott D. Sanicki.

e. *Name of Project:* Quiet Woods Water Wheel Project.

f. *Location:* On the Pocotopaug Creek, near the town of East Hampton, Middlesex County, Connecticut.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708, amended by the Hydropower Regulatory Efficiency Act of 2013, Public Law 113–23, 127 Stat. 493 (2013).

h. *Applicant Contact:* Scott D. Sanicki, 102 Quiet Woods Road, East Hampton, CT; sdsanicki@gmail.com.

i. *FERC Contact:* John Baummer at (202) 502–6837; or email at john.baummer@ferc.gov.

j. *Cooperating agencies:* Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* September 20, 2024.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/FERCOOnline.aspx>. For assistance, please contact FERC Online Support at FERCOOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Quiet Woods Water Wheel Project (P–15324–001).

m. This application is not ready for environmental analysis at this time.

n. *The proposed project would consist of:* (1) a new 6-foot-diameter undershot poncelet water wheel and 3-kilowatt generator cantilevered to a 6-foot-wide,

6-foot-long, 3-foot-deep concrete support pad on the creek bank; (2) a new 350-foot-long underground transmission line connecting to a dwelling structure; and (3) appurtenant facilities. The project is estimated to generate an average of 8,800 kilowatt-hours annually.

The proposed project does not include a dam or impoundment. The applicant proposes to manually operate the project in a run-of-river mode.

o. Copies of the application may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document (P-15324). For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or call tollfree, (866) 208-3676 or (202) 502-8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/ferconline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

p. With this notice, we are initiating consultation with the Connecticut State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. Procedural schedule: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate (e.g., if there are no deficiencies or a need for additional information, the schedule would be shortened).

Issue Deficiency Letter (if necessary).	October 2024.
Request Additional Information ..	October 2024.
Issue Acceptance Letter	January 2025.
Issue Scoping Document 1 for comments.	February 2025.
Request Additional Information (if necessary).	April 2025.
Issue Scoping Document 2	May 2025.

Dated: August 1, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-17487 Filed 8-7-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0520; FRL-11518-02-OCSPP]

Final Modifications to the Safer Choice Standard and a Provision for a Safer Choice Cleaning Service Certification Program; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is announcing the availability of the final, updated Safer Choice and Design for the Environment (DfE) Standard ("the Standard"). This update includes a name change to the title of the Standard, a revision to the packaging criteria, a new certification for cleaning service providers, a new provision allowing for preterm partnership termination under exceptional circumstances, and the addition of several product and functional use class requirements. Safer Choice helps consumers, businesses, and purchasers find products that perform and contain ingredients that are safer for human health and the environment. DfE is a similar program used by EPA for the purpose of helping consumers and commercial buyers identify antimicrobial products that meet the health and safety standards of the normal pesticide registration process required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as well as other EPA DfE criteria (as described in the Standard).

DATES: The Standard is effective August 8, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0520, is available online at <https://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Melanie Adams, Safer Choice Program (7406M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1201 Constitution Ave. NW, Washington DC 20004; telephone number: (202) 564-1843; email address: adams.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you participate in or apply for certification under the Safer Choice or DfE programs and use or hope to use the programs' label or logo, respectively, on your products. Also potentially affected are consumers, institutional purchasers, retailers, and distributors of Safer Choice- or DfE-certified products who use the label or logo to identify products that have met the Agency's safer-product criteria. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Affected entities may include:

- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180);
- All Other Basic Organic Chemical Manufacturing (Primary) (NAICS code 325199);
- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 325320);
- Paint and Coating Manufacturing (NAICS code 325510);
- Adhesive Manufacturing (NAICS code 325520);
- Soap and Other Detergent Manufacturing (NAICS code 325611);
- Polish and Other Sanitation Good Manufacturing (NAICS code 325612);
- Surface Active Agent Manufacturing (Primary) (NAICS code 325613);
- Toilet Preparation Manufacturing (NAICS code 325620);
- Photographic Film, Paper, Plate, and Chemical Manufacturing (NAICS code 325992);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998);
- Service Establishment Equipment and Supplies Merchant Wholesalers (Primary) (NAICS code 423850);
- Other Chemical and Allied Products Merchant Wholesalers (Primary) (NAICS code 424690);
- Supermarkets and Other Grocery (except Convenience) Stores (Primary) (NAICS code 445110);
- All Other Specialty Food Stores (NAICS code 445299);
- Pharmacies and Drug Stores (NAICS code 446110);
- Office Supplies and Stationery Stores (NAICS code 453210);
- All Other Miscellaneous Store Retailers (except Tobacco Stores) (Primary) (NAICS code 453998);

- Electronic Shopping and Mail-Order Houses (NAICS code 454110);
- Research and Development in Biotechnology (except Nanobiotechnology) (Primary) (NAICS code 541714);
- Facilities Support Services (NAICS code 561210). Janitorial Services (NAICS code 561720);
- Carpet and Upholstery Cleaning Services (NAICS code 561740);
- Elementary and Secondary Schools (NAICS code 611110);
- Colleges, Universities, and Professional Schools (NAICS code 611310);
- Promoters of Performing Arts, Sports, and Similar Events with Facilities (NAICS code 711310);
- Drycleaning and Laundry Services (NAICS code 8123);
- Civic and Social Organizations (Primary) (NAICS code 813410);
- Business Associations (Primary) (NAICS code 813910);
- Other General Government Support (NAICS code 921190); and
- Administration of Air and Water Resource and Solid Waste Management Programs (Primary) (NAICS code 924110).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

In 2023, EPA announced the availability of and sought public comment on several proposed changes to the existing Standard (88 FR 78017, November 14, 2023 (FRL-11518-01)) and held a public webinar on December 19, 2023, to present the Agency's proposed plans. EPA received 90 comments, representing 131 organizations or individuals. The Response to Comments document, which is available in the docket, is a compilation of the public comments received and EPA's responses. EPA's responses do not address each comment individually. EPA considered each comment and organized responses by section of the Standard.

After considering the public comments, EPA is issuing the final, updated Standard, which is available in the docket and on the Safer Choice website at <https://www.epa.gov/saferchoice/standard>. Revisions to the Standard serve, in part, to add clarity and transparency. Notable changes include an update to packaging requirements to respond to an increased stakeholder interest in more sustainable packaging and a certification for

cleaning service providers that use Safer Choice-certified products for cleaning and DfE-certified products for disinfecting.

II. Background

A. What is the Safer Choice program?

As part of its environmental mission, the Safer Choice program partners with businesses to help consumers and commercial buyers identify products with safer chemical ingredients, without sacrificing quality or performance. The Safer Choice program certifies products containing ingredients that have met the program's specific and rigorous human health and environmental toxicological criteria. The Safer Choice program allows companies to use its label on certified products that contain safer ingredients and perform, as determined by expert evaluation. The Safer Choice program certification represents a high level of achievement in formulating products that are safer for people and the environment. For more information on the Safer Choice program, please see: <https://www.epa.gov/saferchoice>.

B. What is the DfE program?

The DfE program is a similar program currently used by EPA for the purpose of helping consumers and commercial buyers identify antimicrobial products that meet the health and safety standards of the normal pesticide registration process required by FIFRA as well as meeting the DfE certification criteria (as described in the Standard). For more information on the DfE program, please see: <https://www.epa.gov/pesticide-labels/learn-about-design-environment-dfe-certification>.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 31, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024-17606 Filed 8-7-24; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OGC-2024-0319; FRL-12102-01-OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act),

notice is given of a proposed consent decree to address a lawsuit filed by Center for Biological Diversity, Sierra Club, and Center for Environmental Health (collectively, Plaintiffs) in the United States District Court for the Northern District of California: *Center for Biological Diversity, et al. v. Michael S. Regan, in his official capacity the Administrator of the United States Environmental Protection Agency*, No. 3:23-cv-04979-RFL (N.D. Cal.). Plaintiffs filed a complaint alleging that the Environmental Protection Agency (EPA) failed to perform a non-discretionary duty under the Act to complete a review of the air quality criteria and the primary National Ambient Air Quality Standards (NAAQS) for oxides of nitrogen. EPA is providing notice of this proposed consent decree, which would resolve all claims in the case by establishing deadlines for EPA to take certain actions in its review of the air quality criteria and NAAQS for oxides of nitrogen, as specified in the decree.

DATES: Written comments on the proposed consent decree must be received by September 9, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OGC-2024-0319, online at <https://www.regulations.gov> (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the "Additional Information about Commenting on the Proposed Consent Decree" heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Melina Williams, Air and Radiation Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone (202) 564-3406; email address williams.melina@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA-HQ-OGC-2024-0319) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West,

Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the OEI Docket is (202) 566-1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through <https://www.regulations.gov>. You may use <https://www.regulations.gov> to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search."

II. Additional Information About the Proposed Consent Decree

The proposed consent decree would establish deadlines for EPA to take certain actions pursuant to CAA sections 108 and 109 to complete a review of the air quality criteria and the primary NAAQS for oxides of nitrogen. The proposed consent decree would require EPA to: issue a final Integrated Science Assessment, a document containing the air quality criteria, addressing human health effects of oxides of nitrogen no later than September 30, 2026; sign a notice setting forth its proposed decision concerning its review of the primary NAAQS for oxides of nitrogen no later than January 17, 2028; sign a notice setting forth its final decision concerning its review of the primary NAAQS for oxides of nitrogen no later than November 10, 2028; and, within 15 business days of issuance of the final Integrated Science Assessment, signature of the proposed decision, and signature of the final decision, respectively, send a notice to the Office of Federal Register for review and publication.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA-HQ-OGC-2024-0319, via <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the <https://www.regulations.gov> website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket

system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

Gautam Srinivasan,
Associate General Counsel.

[FR Doc. 2024-17580 Filed 8-7-24; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL RESERVE SYSTEM

Solicitation of Statements of Interest for Membership on the Insurance Policy Advisory Committee

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Notice.

SUMMARY: The Economic Growth, Regulatory Relief, and Consumer Protection Act established at the Board an Insurance Policy Advisory Committee (IPAC). This Notice advises individuals who wish to serve as IPAC members of the annual opportunity to be considered for the IPAC.

DATES: Individuals who submit a Statement of Interest that is received by the Board from the first Monday in August through the first Monday in October of each year will be considered for appointments to the IPAC announced in the fourth calendar quarter of the same year. Statements of Interest received outside the period from the first Monday in August through the first Monday in October generally will not be considered.

ADDRESSES: Individuals seeking an appointment to the IPAC may send a Statement of Interest by email to IPAC@frb.gov. The Statement of Interest contains only contact information. Candidates also may choose to provide additional information. Candidates may send this information by email to IPAC@frb.gov. The Privacy Act Statement for IPAC Member Selection, which describes the purposes, authority, effects of nondisclosure, and uses of this information, can be found at <https://www.federalreserve.gov/aboutthefed/ipac-privacy.htm>.

Individuals also may mail Statements of Interest and any additional information to the Board of Governors of the Federal Reserve System, Attn: Insurance Policy Advisory Committee,

20th Street and Constitution Ave. NW, Washington, DC 20551.

FOR FURTHER INFORMATION CONTACT: Lara Lylozian, Deputy Associate Director and Chief Accountant, (202) 475-6656; Matt Walker, Manager, Insurance Supervision & Regulation, (202) 872-4971; or Joan Sullivan, Senior Insurance Policy Analyst, (202) 579-4987; Division of Supervision and Regulation; or *IPAC@frb.gov*. For users of TDD-TYY, please call 711 from any telephone, anywhere in the United States.

SUPPLEMENTARY INFORMATION: The Economic Growth, Regulatory Relief, and Consumer Protection Act established at the Board an Insurance Policy Advisory Committee (IPAC) to advise the Board on international capital standards and other insurance matters. This notice advises individuals of the opportunity to be considered for appointment to the IPAC. To assist with the appointment of IPAC members, the Board considers information submitted by the candidate, public information, and any other relevant information the Board determines to consider.

Council Size and Terms

The IPAC has at most 21 members. IPAC members serve staggered three-year terms. Members are appointed to three-year terms unless the Board appoints a member to fill a vacant unexpired term. A member that is appointed to serve a three-year term begins his or her service on the first January 1 occurring after his or her appointment. A member appointed to fill a vacant unexpired term serves for the remainder of the term. The Board provides a nominal honorarium and reimburses members only for their actual travel expenses, subject to Board policy.

Statement of Interest

A Statement of Interest must contain the following information:

- Full name;
- Address;
- Phone number; and
- Email address.

At their option, candidates may provide additional information for consideration.

Qualifications

IPAC candidates should be insurance experts. The Board provides equal appointment opportunity to all persons without regard to race, color, religion, sex (including sexual orientation, gender identity, and pregnancy), national origin, age, disability, genetic information, or military service. In addition, the Board is committed to a diverse committee and seeks a diverse

set of expert perspectives from the various sectors of the U.S. insurance industry including life insurance, property and casualty insurance and reinsurance, agents and brokers, academics, consumer advocates, and experts on issues facing underserved insurance communities and consumers. The Board also seeks relevant actuarial, legal, regulatory, and accounting expertise, as well as expertise on lines of business underwritten by its currently supervised population of insurance institutions.

Members must be willing and able to participate in conference calls and prepare for and attend meetings in person. Membership and attendance is not delegable.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Supervision and Regulation under delegated authority.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2024-17615 Filed 8-7-24; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-E-3201]

Determination of Regulatory Review Period for Purposes of Patent Extension; REZLIDHIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for REZLIDHIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 7, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by

February 4, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-E-3201 for “Determination of Regulatory Review Period for Purposes of Patent Extension; REZLIDHIA.” Received comments, those filed in a

timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic

Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, REZLIDHIA (olutasidenib). REZLIDHIA is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test. Subsequent to this approval, the USPTO received a patent term restoration application for REZLIDHIA (U.S. Patent No. 9,834,539) from Forma Therapeutics, Inc., and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated February 6, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of REZLIDHIA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for REZLIDHIA is 2,563 days. Of this time, 2,273 days occurred during the testing

phase of the regulatory review period, while 290 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 27, 2015. The applicant claims November 29, 2015, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 27, 2015, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* February 15, 2022. FDA has verified the applicant’s claim that the new drug application (NDA) for REZLIDHIA (NDA 215814) was initially submitted on February 15, 2022.

3. *The date the application was approved:* December 1, 2022. FDA has verified the applicant’s claim that NDA 215814 was approved on December 1, 2022.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 440 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the

Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17511 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-E-5281]

Determination of Regulatory Review Period for Purposes of Patent Extension; XOFLUZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for XOFLUZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 7, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 4, 2025. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-E-5281 for "Determination of Regulatory Review Period for Purposes of Patent Extension; XOFLUZA." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical

investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, XOFLUZA (baloxavir marboxil). XOFLUZA is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Subsequent to this approval, the USPTO received a patent term restoration application for XOFLUZA (U.S. Patent No. 8,987,441) from Shionogi & Co., Ltd., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XOFLUZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for XOFLUZA is 985 days. Of this time, 801 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* February 14, 2016. The applicant claims March 2, 2016, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 14, 2016, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 24, 2018. FDA has verified the applicant's claim that

the new drug application (NDA) for XOFLUZA (NDA 210854) was initially submitted on April 24, 2018.

3. *The date the application was approved:* October 24, 2018. FDA has verified the applicant's claim that NDA 210854 was approved on October 24, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 399 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17648 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3510]

Determination That CIPRO (Ciprofloxacin Hydrochloride) Tablet, Equivalent to 100 Milligrams Base, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CIPRO (ciprofloxacin hydrochloride (HCl)) tablet, equivalent to (EQ) 100 milligrams (mg) base, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for ciprofloxacin HCl tablet, EQ 100 mg base.

FOR FURTHER INFORMATION CONTACT:

Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993-0002, 240-402-4191, Ayako.sato@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

On October 22, 1987, FDA approved NDA 019537 for CIPRO (ciprofloxacin HCl) tablet, EQ 250 mg base, 500 mg base, and 750 mg base. On April 8, 1996, FDA approved a supplement to NDA 019537 to add the tablet, EQ 100 mg base, to treat acute uncomplicated cystitis in adult females to be supplied as a cystitis pack containing six 100 mg oral tablets with a dosing regimen of 100 mg twice daily for 3 days.

On May 18, 2005, FDA approved labeling revisions for NDA 019537, including updates to reflect that the 100 mg tablet drug product was no longer being marketed. CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, was moved from the “Prescription Drug Product List” to the “Discontinued Drug Product List” section of the Orange Book. Subsequently, the Agency made a safety and effectiveness determination that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, was not discontinued for reasons of safety or effectiveness, which was later published in the **Federal Register** on October 1, 2019 (84 FR 52113). Since the Agency’s initial safety and effectiveness determination, new information related to the safe and effective use of ciprofloxacin HCl tablet, EQ 100 mg base, for its indication has become available.

The resistance of *Escherichia coli* (*E. coli*), the main causative pathogen for acute uncomplicated cystitis, to ciprofloxacin has been increasing since CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis was removed from the labeling in 2005. The effectiveness of CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, and ciprofloxacin HCl tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis is not supported by the current ciprofloxacin susceptibility test interpretive criteria (STIC) (also known as break points),¹ established by the Clinical and Laboratory Standards Institute and

recognized by FDA on June 10, 2019.² Recent pharmacokinetic/pharmacodynamic analyses conducted by FDA indicated that the dosage regimen of ciprofloxacin HCl tablet, 100 mg twice daily for 3 days may not be effective for the treatment of acute uncomplicated cystitis. A review of published literature also showed that more contemporary studies of the treatment of acute uncomplicated cystitis with ciprofloxacin were conducted with the dosage of 250 mg tablet twice daily or 500 mg extended-release tablet daily. A literature search produced no studies comparing the efficacy of ciprofloxacin 100 mg tablet twice daily versus ciprofloxacin 250 mg tablet twice daily or 500 mg extended-release tablet daily in treatment of acute uncomplicated cystitis. Finally, significant adverse reactions associated with the use of fluoroquinolones, including ciprofloxacin HCl, have been identified.³

On June 16, 2023, the Agency notified Bayer HealthCare Pharmaceuticals Inc. (Bayer) that it believed the potential problems associated with the drug product are sufficiently serious that the EQ 100 mg base strength product should be removed from the market pursuant to § 314.150(d) (21 CFR 314.150(d)). Bayer requested in a letter dated July 7, 2023, that FDA withdraw approval of the EQ 100 mg base strength product in NDA 019537 under § 314.150(d) and waived its opportunity for a hearing. FDA also notified application holders for ANDAs 075593, 075817, 075939, and 076794 on June 16, 2023, and for ANDA 076912 on June 21, 2023. FDA asked the ANDA holders to request withdrawal of approval under § 314.150(d) of the generic versions of ciprofloxacin HCl tablet, EQ 100 mg base, and to waive their opportunity for a hearing.

Consistent with requests from the relevant application holders, in the **Federal Register** of December 8, 2023 (88 FR 85636), FDA announced that it was withdrawing approval of the EQ 100 mg base strength product from NDA 019537 and ANDAs 075593, 075817, 075939, 076794, and 076912 for the treatment of acute uncomplicated cystitis, effective December 8, 2023. The Agency further noted that the withdrawal of approval is limited to

CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, and ciprofloxacin HCl tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis and that other products approved in NDA 019537 for CIPRO (ciprofloxacin HCl) tablet or related ANDAs for ciprofloxacin HCl tablet (e.g., the EQ 250 mg base, 500 mg base, or 750 mg base strength products) remain approved. Accordingly, the Agency has withdrawn approval of the EQ 100 mg strength product from NDA 019537 and ANDAs 075593, 075817, 075939, 076794, and 076912 for the treatment of acute uncomplicated cystitis.⁴

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis from sale. We have also independently evaluated relevant literature and data. We have reviewed the available evidence. Given that the safe and effective use of ciprofloxacin HCl tablet, 100 mg twice daily for 3 days for the treatment of acute uncomplicated cystitis is not supported by its current STIC and considering the risks of serious adverse reactions along with the increased resistance of *E. coli* to ciprofloxacin, we have determined that CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, would not be considered safe and effective if it were introduced to the market today in the absence of new clinical studies to address relevant effectiveness concerns identified during our review.

Accordingly, under § 314.162 the Agency will remove Bayer’s NDA 019537 for CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base, for the treatment of acute uncomplicated cystitis from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product. Likewise, the Agency will

⁴ Previously, a decade earlier, in a letter dated June 10, 2013, Plivia Inc., subsidiary of Teva Pharmaceuticals USA Inc., notified FDA that ciprofloxacin HCl tablet, EQ 100 mg base, EQ 250 mg base, EQ 500 mg base, and EQ 750 mg base, the subject of ANDA 076426, was being voluntarily withdrawn from the market and FDA moved the drug products to the “Discontinued Drug Product List” section of the Orange Book. In the **Federal Register** of October 4, 2016, FDA announced it was withdrawing from approval ANDA 076426, held by Plivia Inc., under § 314.150(c), effective November 3, 2016 (81 FR 68427).

¹ See Ciprofloxacin Oral, Injection products, available at <https://www.fda.gov/drugs/development-resources/ciprofloxacin-oral-injection-products>. Note *E. coli* is within the order of Enterobacterales.

² 21st Century Cures Act: Annual Compilation of Notices of Updates from the Susceptibility Test Interpretive Criteria web page; Request for Comments (85 FR 67353 at 67354 to 67355, October 22, 2020), recognizing on June 10, 2019, updated standard STIC for ciprofloxacin.

³ Fluoroquinolone Antimicrobial Drugs Information, available at <https://www.fda.gov/drugs/information-drug-class/fluoroquinolone-antimicrobial-drugs-information>.

remove from the list of drug products published in the Orange Book, those drug products in ANDAs that used NDA 019537 CIPRO (ciprofloxacin HCl) tablet, EQ 100 mg base as their reference listed drug; these are Amneal Pharmaceuticals, LLC's ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075939; Dr. Reddy's Laboratories' ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075593; Watson Laboratories, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076794; Rising Pharma Holdings, Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 075817; Taro Pharmaceutical Industries Ltd.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076912; and Pliva Inc.'s ciprofloxacin HCl tablet, EQ 100 mg base, in ANDA 076426.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17650 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2603]

Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with a proposed study entitled "Healthcare Provider Survey of Topics Related to Prescription Drug Promotion."

DATES: Either electronic or written comments on the collection of information must be submitted by October 7, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be

considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-2603 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Provider Survey of Topics Related to Prescription Drug Promotion." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

The draft survey instrument is available upon request from DTCresearch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Healthcare Provider Survey of Topics Related to Prescription Drug Promotion
OMB Control Number 0910—NEW

I. Background

This information collection request supports Agency research authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) and section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)).

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options.

OPDP’s research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area: advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research>, which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

This current project will be a survey with a selection of prescribers examining a variety of topics of interest to OPDP. The prescriber sample will be primary care physicians (PCPs) (in family practice, general practice, or internal medicine), nurse practitioners

and physician assistants (NP/PAs), and specialists (cardiology, dermatology, endocrinology, neurology, obstetrics/gynecology, oncology, ophthalmology, psychiatry, rheumatology, and urology). Topics we plan to assess include, but are not limited to, awareness and use of the Bad Ad program (Refs. 1 and 2), understanding of quantitative data displays that may appear in prescription drug promotion (Refs. 3 and 4), perceptions of trust in FDA, perceptions of medical misinformation (Refs. 5 and 6), and attitudes about prescription drug promotion on social media (Refs. 7 and 8). These topics were selected to extend previous FDA work on healthcare provider understanding of quantitative data displays, provide an updated snapshot of social media attitudes and Bad Ad program awareness, and help inform FDA’s role in addressing medical misinformation (Ref. 9).

We estimate that participation in the survey will take approximately 20 minutes. Our target respondents are adult voluntary participants who are PCPs, NP/PAs, or specialists engaging in patient care at least half time, with a range of gender, race and ethnicity, and ages that reflects the composition of the American Medical Association. Participants will be recruited by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. We will exclude individuals who are employees of the Department of Health and Human Services and individuals who work for a marketing, advertising, or pharmaceutical firm.

The target sample size for the survey is 2,410 respondents. Before conducting the survey, we will conduct up to two pretests. If the first pretest wave reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest wave will be conducted with revised materials. The target sample size for Pretest 1 is 75 respondents and for Pretest 2 is 50 respondents.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response ²	Total hours
Pretest 1 Screener ³	150	1	150	0.08 (5 minutes)	12
Pretest 1	75	1	75	0.33 (20 minutes)	25
Pretest 2 Screener ^{3,4}	100	1	100	0.08 (5 minutes)	8
Pretest 2 ⁴	50	1	50	0.33 (20 minutes)	17
Survey Screener ³	4,820	1	4,820	0.08 (5 minutes)	386
Survey ⁵	2,410	1	2,410	0.33 (20 minutes)	795

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response ²	Total hours
Total	5,070				1,243

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

³ Number of screener respondents assumes a 50 percent eligibility rate with targeted recruitment.

⁴ Pretest 2 will be conducted only if changes to study materials are made in response to the findings of Pretest 1.

⁵ Sample size is based on power analysis and designed to accommodate a within-survey test of recruitment language.

II. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, et al., "Awareness of the Food and Drug Administration's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings," *Journal of Health Communication*, vol. 20, issue 11, pp. 1330–1336, 2015, doi:10.1080/10810730.2015.1018649.

2. Betts, K.R., A.C. O'Donoghue, M. Johnson, et al., "Detecting and Reporting Deceptive Prescription Drug Promotion: Differences Across Consumer and Physician Audiences and by Number and Type of Deceptive Claims and Tactics," *Health Communication*, vol. 37, issue 13, pp. 1609–1621, 2022, doi:10.1080/10410236.2021.1909264.

3. Thompson, J., M. Lynch, H.W. Sullivan, et al., "Complexity of Data Displays in Prescription Drug Advertisements for Healthcare Providers," *Therapeutic Innovation & Regulatory Science*, vol. 57, issue 4, pp. 712–716, 2023, doi:10.1007/s43441-023-00523-3.

4. Thompson, J., R.C. Wines, M. Brewington, et al., "Healthcare Providers' Understanding of Data Displays of Clinical Trial Information: A Scoping Review of the Literature," *Journal of Communication in Healthcare*, vol. 16, issue 3, pp. 260–267, 2023, doi:10.1080/17538068.2022.2150236.

5. Goldwire, M.A., S.T. Johnson, M. Abdalla, et al., "Medical Misinformation: A Primer and Recommendations for Pharmacists," *Journal of the American College of Clinical Pharmacy*, vol. 6, issue 5, pp. 497–511, 2023, doi:10.1002/jac5.1760.

6. Boudewyns, V., B.G. Southwell, K.R. Betts, et al., "Awareness of Misinformation in Health-Related Advertising: A Narrative Review of the Literature," *Misinformation and Mass Audiences*, edited by B.G. Southwell, E.A. Thorson, and L. Sheble, University of Texas Press, 2018.

7. Campbell, B.C. and C.M. Craig, "Social Media and Health: Current and Future Healthcare Provider Perspectives," *Journal of Contemporary Medical Education*, vol. 2, issue 2, pp. 128–133, 2014, doi:10.5455/jcme.20140515123200.

8. Betts, K.R., A.C. O'Donoghue, K.J. Aikin, et al., "Professional Online Community Membership and Participation Among Healthcare Providers: An Extension to Nurse Practitioners and Physician Assistants," *Journal of the American Association of Nurse Practitioners*, vol. 28, issue 12, pp. 639–645, 2016, doi:10.1002/2327-6924.12383.

9. Califf, R.M., "Speech by Commissioner Robert M. Califf to the House of Medicine," June 16, 2023, <https://www.fda.gov/news-events/speeches-fda-officials/speech-commissioner-robert-m-califf-house-medicine-06162023>.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17646 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificate Application Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 9, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written

comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910–0793. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Revision

This information collection helps support implementation of statutory and regulatory authorities governing the export of certain FDA-regulated products found in section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), and in 21 CFR part 1, subpart E—Imports and Exports, of Agency regulations. Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a "certificate." In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that

the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

Consistent with this authority, interested persons may request human food and cosmetic export certificates electronically via the Export Certification Application and Tracking System (eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting FDA for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. All information is currently submitted electronically using Forms FDA 3613d, 3613e, and 3613k. The eCATS Module is Form 3613k, where 3613e is the Certificate of Free Sale (<https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>). All “forms” are electronic and part of the eCATS or CAP portal accessed via <https://www.access.fda.gov>. To view representations of the forms, instructions must be downloaded and are accessible through the following links: <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

While a burden associated with information collection activities for

export certificates issued for other FDA regulated products is accounted for and approved under OMB control number 0910–0498, this collection specifically supports information collection activity attributable to export certificates issued for human food and cosmetic products. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact FDA directly by email (CFSANExportCertification@fda.hhs.gov) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and instructions for requesting export certificates for food (Forms FDA 3613e and Form 3613k) are available online at <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

We are revising the information collection to include a web-based inquiry form, Form FDA 5077, entitled “U.S. Department of Health and Human Services Food and Drug Administration Export Certification Inquiry,” intended to facilitate processing by cross-referencing the request with existing Agency data. A mockup of the proposed electronic form is posted to the docket to solicit public comment. For food

products, respondents may identify facilities using their Food Facility Registration number, FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for applications that include multiple products.

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

In the **Federal Register** of May 15, 2024 (89 FR 42472), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, neither appeared to be responsive to the information collection topics solicited in the notice, nor suggested FDA modify its burden estimates.

We therefore estimate the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of certificate	Form No. ²	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cosmetics	FDA 3613d	66	3	198	0.5 (30 minutes)	99
Food	FDA 3613e, 3613k	454	10	4,540	0.5 (30 minutes)	2,270
Export Certification Inquiry	FDA 5077	520	18	9,360	0.25 (15 minutes) ...	2,340
Total						4,709

¹ There are no operating and maintenance costs associated with this collection of information.
² All forms are submitted electronically via FDA Industry Systems.

Since our last review of the information collection, we have adjusted our estimate of the number of respondents downward. At the same time, we have increased the number of responses per respondent and added new Form FDA 5077. Cumulatively these activities result in an estimated burden increase of 2,433 hours and 9,547 responses annually.

Dated: August 5, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–17641 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3538]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 213972 for Sulopenem Etzadroxil/Probenecid Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 9, 2024, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: The public may attend the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31

Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-3538. The docket will close on September 6, 2024. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before August 29, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-3538 for "Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 213972 for Sulopenem Etzadroxil/Probenecid Tablets." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as "confidential." Any information marked

as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-2855, email: AMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Committee will discuss new drug application 213972, for oral sulopenem etzadroxil/probenecid tablets consisting of 500 milligrams (mg) sulopenem etzadroxil and 500 mg probenecid, submitted by Iterum Therapeutics US Ltd., for the proposed indication of treatment of uncomplicated urinary tract infections caused by designated susceptible bacteria in adult women 18 years of age and older.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference

meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before August 29, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately between 1:45 p.m. to 2:45 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before August 21, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by August 22, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17642 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3531]

Determination That DELATESTRYL (Testosterone Enanthate) Injection, 200 Milligrams/Milliliter, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to

these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 009165	DELATESTRYL	Testosterone Enanthate	200 Milligrams (mg)/Milliliter (mL).	Injectable; Injection	Endo Pharmaceuticals Inc.
NDA 011145	DIURIL	Chlorothiazide Sodium	Equivalent to (EQ) 500 mg base/Vial.	Injectable; Injection	Rising Pharma Holdings Inc.
NDA 013217	SKELAXIN	Metaxalone	800 mg	Tablet; Oral	King Pharmaceuticals Research and Development LLC, a subsidiary of Pfizer Inc.
NDA 017710	NALFON	Fenoprofen Calcium	EQ 600 mg Base	Tablet; Oral	Dista Products Co., a division of Eli Lilly and Co.
NDA 018716	TRANDATE	Labetalol Hydrochloride	100 mg; 200 mg; 300 mg	Tablet; Oral	Alvogen Inc.
NDA 018827	LOTRISONE	Betamethasone Dipropionate; Clotrimazole.	EQ 0.05% Base; 1%	Cream; Topical	Organon LLC, a subsidiary of Organon and Co.
NDA 020080	IMITREX	Sumatriptan Succinate	EQ 6 mg Base/0.5 mL (EQ 12 mg Base/mL).	Injectable; Subcutaneous.	GlaxoSmithKline.
NDA 020617	PYTEST KIT	Urea, C-14	1 mCi	Capsule; Oral	Avent Inc.
NDA 020763	AMERGE	Naratriptan Hydrochloride	EQ 1 mg Base; EQ 2.5 mg Base.	Tablet; Oral	GlaxoSmithKline.
NDA 020897	DITROPAN XL	Oxybutynin Chloride	5 mg; 10 mg	Tablet, Extended Release; Oral.	Janssen Pharmaceuticals Inc.
NDA 020918	GLUCAGEN	Glucagon Hydrochloride	EQ 1 mg Base/Vial	Injectable; Injection	Novo Nordisk Pharmaceuticals Inc.
NDA 020928	GLUCAGON	Glucagon	1 mg/Vial	Injectable; Injection	Eli Lilly and Co.
NDA 021615	RAZADYNE ER	Galantamine Hydrobromide	EQ 8 mg Base; EQ 16 mg Base; EQ 24 mg Base.	Capsule, Extended Release; Oral.	Janssen Pharmaceuticals Inc.
NDA 021627	NAMENDA	Memantine Hydrochloride	2 mg/mL	Solution; Oral	Allergan Sales LLC.
NDA 021652	EPZICOM	Abacavir Sulfate; Lamivudine	EQ 600 mg Base, 300 mg	Tablet; Oral	ViiV Healthcare Co.
NDA 021743	TARCEVA	Erlotinib Hydrochloride	EQ 25 mg Base; EQ 100 mg Base; EQ 150 mg Base.	Tablet; Oral	OSI Pharmaceuticals LLC.
NDA 021892	OSMOPREP	Sodium Phosphate, Dibasic, Anhydrous; Sodium Phosphate, Monobasic, Monohydrate.	0.398 grams (g)m; 1.102 (g)	Tablet; Oral	Salix Pharmaceuticals Inc.
NDA 022013	OLUX E	Clobetasol Propionate	0.05%	Aerosol, Foam; Topical Gel; Transdermal	Mylan Pharmaceuticals Inc.
NDA 022204	GELNIQUE	Oxybutynin Chloride	10% (100 mg/Package)	Capsule, Extended Release; Oral.	Abbvie Inc.
NDA 022525	NAMENDA XR	Memantine Hydrochloride	7 mg	Capsule, Extended Release; Oral.	Abbvie Inc.
NDA 050168	CORTISPORIN	Bacitracin Zinc; Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate.	400 units/g 1%, EQ 3.5 mg Base/g, 5,000 units/g.	Ointment; Topical	Monarch Pharmaceuticals LLC.
NDA 050218	CORTISPORIN	Hydrocortisone Acetate; Neomycin Sulfate; Polymyxin B Sulfate.	0.5%, EQ 3.5 mg Base/g, 10,000 units/g.	Cream; Topical	Monarch Pharmaceuticals LLC.
NDA 050278	ACHROMYCIN V	Tetracycline Hydrochloride	250 mg; 500 mg	Capsule; Oral	Avet Pharmaceuticals Inc.
NDA 050578	FORTAZ	Ceftazidime	500 mg/Vial; 1 g/Vial; 2 g/Vial; 6 g/Vial.	Injectable; Injection	PAI Holdings LLC DBA Pharmaceutical Associates Inc.
NDA 050679	MAXIPIME	Cefepime Hydrochloride	EQ 500 mg Base/Vial; EQ 1 g Base/Vial; EQ 2 g Base/Vial.	Injectable; Injection	Hospira Inc.
NDA 202543	LEVETIRACETAM IN SODIUM CHLORIDE.	Levetiracetam	250 mg/50 mL (5 mg/mL)	Injectable; Intravenous	HQ Specialty Pharma Corp.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the

products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17649 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2422]

Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Reopening the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is reopening the comment period for the proposed administrative order (proposed order) entitled “Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use”, announced in the **Federal Register** of June 14, 2024. We are taking this action due to technical difficulties with the OTC Monographs@FDA portal. Because comments cannot be submitted to the OTC Monographs@FDA portal at this time, submit comments on proposed order (OTC000035) to the Federal eRulemaking portal (Docket No. FDA–2024–N–2422).

DATES: FDA is reopening the comment period on proposed order (OTC000035) announced in the **Federal Register** of June 14, 2024 (89 FR 50593). Electronic comments or written comments must be submitted by September 27, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 27, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Other than using the Federal eRulemaking Portal to submit comments (instead of the OTC Monographs@FDA portal), follow the instructions for submitting comments on the proposed order (OTC000035) available in the OTC Monographs@FDA portal at <https://dps.fda.gov/omuf>.

FOR FURTHER INFORMATION CONTACT:

Helen Lee, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0138.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2024 (89 FR 50593), FDA announced the availability of proposed order (OTC000035) entitled “Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use.” The proposed administrative order (proposed order), if finalized, will amend the requirements for internal analgesic, antipyretic, and

antirheumatic drug products for over-the-counter (OTC) human use, as currently described in Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (OTC Monograph M013).¹

Interested persons were originally given until July 29, 2024, to comment on the proposed order (OTC000035) via the OTC Monographs@FDA portal. However, as of June 14, 2024, technical difficulties prevented the electronic submission of comments through the OTC Monographs@FDA portal. Therefore, we are reopening the comment period for the proposed order (OTC000035) and are instead accepting comments through the Federal eRulemaking Portal. Accordingly, submit comments on the proposed order (OTC000035) electronically using Docket No. FDA–2024–N–2422 in the Federal eRulemaking Portal at <https://www.regulations.gov>. The reopened comment period will close on September 27, 2024.

The proposed order (OTC000035) remains available in the OTC Monographs@FDA portal at <https://dps.fda.gov/omuf>. Other than using the Federal eRulemaking Portal to submit comments (instead of the OTC Monographs@FDA portal), follow the instructions for submitting comments on the proposed order (OTC000035) available in the OTC Monographs@FDA portal at <https://dps.fda.gov/omuf>. The proposed order contains general instructions for commenting, which otherwise remain applicable.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17645 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

¹ OTC Monograph M013 is currently set forth in the Final Administrative Order OTC000027. We note that at 89 FR 50593 at 50594, the notice of availability for the proposed order to amend OTC Monograph M013 erroneously referred to “Final Administrative Order OTC000027” as “Final Administrative Order OTC000035.”

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2026, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–731–3544, Christina.Vert@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA’s research program, which provides the scientific support for regulating these agents.

The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends

classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum

when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than most of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/blood-products-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: August 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17518 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-0164, FDA-2024-E-0165, FDA-2024-E-0166, FDA-2024-E-0167, and FDA-2024-E-0168]

Determination of Regulatory Review Period for Purposes of Patent Extension; VANFLYTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VANFLYTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the

submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 7, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 4, 2025. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket Nos. FDA-2024-E-0164, FDA-2024-E-0165, FDA-2024-E-0166, FDA-2024-E-0167, and FDA-2024-E-0168 for

“Determination of Regulatory Review Period for Purposes of Patent Extension; VANFLYTA.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://>

www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, VANFLYTA (quizartinib). VANFLYTA is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3 internal tandem duplication-

positive as detected by an FDA-approved test. Subsequent to this approval, the USPTO received patent term restoration applications for VANFLYTA (U.S. Patent Nos. 7,820,657; 8,129,374; 8,357,690; 8,557,810; and 8,836,218) from Ambit Biosciences Corporation, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated January 24, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VANFLYTA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VANFLYTA is 6,110 days. Of this time, 5,779 days occurred during the testing phase of the regulatory review period, while 331 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 29, 2006. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on October 29, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* August 24, 2022. FDA has verified the applicant’s claim that the new drug application (NDA) for VANFLYTA (NDA 216993) was initially submitted on August 24, 2022.

3. *The date the application was approved:* July 20, 2023. FDA has verified the applicant’s claim that NDA 216993 was approved on July 20, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,781 days or 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17510 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5282]

Determination of Regulatory Review Period for Purposes of Patent Extension; TALZENNA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TALZENNA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 7, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for

extension acted with due diligence during the regulatory review period by February 4, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–E–5282 for “Determination of Regulatory Review Period for Purposes

of Patent Extension; TALZENNA.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, TALZENNA (talazoparib tosylate). TALZENNA is indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated HER2-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA. Subsequent to this approval, the USPTO received a patent term restoration application for TALZENNA (U.S. Patent No. 8,012,976) from Medivation Technologies LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TALZENNA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO

requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TALZENNA is 2,869 days. Of this time, 2,675 days occurred during the testing phase of the regulatory review period, while 194 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 10, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 10, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 6, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for TALZENNA (NDA 211651) was initially submitted on April 6, 2018.

3. *The date the application was approved:* October 16, 2018. FDA has verified the applicant's claim that NDA 211651 was approved on October 16, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,093 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17643 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0129 and FDA–2024–E–0130]

Determination of Regulatory Review Period for Purposes of Patent Extension; INPEFA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for INPEFA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 7, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 4, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 7, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2024-E-0129 and FDA-2024-E-0130, for "Determination of Regulatory Review Period for Purposes of Patent Extension; INPEFA." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, INPEFA (sotagliflozin). INPEFA is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors. Subsequent to this approval, the USPTO received patent term restoration applications for INPEFA (U.S. Patent No. 7,781,577 and 8,217,156) from Lexicon Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of INPEFA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for INPEFA is 5,268 days. Of this time, 4,903 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 24, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 27, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for INPEFA (NDA 216203) was initially submitted on May 27, 2022.

3. *The date the application was approved:* May 26, 2023. FDA has verified the applicant's claim that NDA 216203 was approved on May 26, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17639 Filed 8–7–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3271]

Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of two abbreviated new drug applications (ANDAs) and is announcing an opportunity for the ANDA holder to request a hearing on this proposal. The basis for the proposal is that the ANDA holder has repeatedly failed to file required annual reports for those ANDAs.

DATES: The ANDA holder may submit a request for a hearing by September 9, 2024. Submit all data, information, and analyses upon which the request for a hearing relies October 7, 2024. Submit electronic or written comments by October 7, 2024.

ADDRESSES: The request for a hearing may be submitted by the ANDA holder by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to <https://www.regulations.gov>, including any attachments to the request for a hearing, will be posted to the docket unchanged.

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. The request

for a hearing must include the Docket No. FDA–2024–N–3271 for “Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two Abbreviated New Drug Applications; Opportunity for a Hearing.” The request for a hearing will be placed in the docket and publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. The ANDA holder may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- *Confidential Submissions—*To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov> or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2024-N-3271 for “Flamingo Pharmaceuticals Ltd.; Proposal To Withdraw Approval of Two Abbreviated New Drug Applications; Opportunity for a Hearing.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting

of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved ANDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved ANDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holder of the approved ANDAs listed in table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency’s request for submission of the reports.

TABLE 1—APPROVED ANDAs FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	Holder
ANDA 207309	Metronidazole tablet, 250 milligrams (mg) and 500 mg	Flamingo Pharmaceuticals Ltd., U.S. Agent for Flamingo Pharmaceuticals Ltd., 1125 Gaither Rd., Rockville, MD 20850.
ANDA 207938	Piroxicam capsule, 10 mg and 20 mg	Do.

Therefore, under 21 CFR 314.150(b)(1) and § 314.200 (21 CFR 314.200), notice is given to the holder of the approved ANDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the ANDAs and all amendments and supplements thereto on the grounds that the ANDA holder has failed to submit reports required under §§ 314.81 and 314.98.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the ANDA holder is hereby provided an opportunity for a hearing to show why the approval of the ANDAs listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all

issues relating to the legal status of the drug products covered by these ANDAs.

An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER’s proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that

there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: August 2, 2024.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2024-17515 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3449]

Office of Pharmaceutical Quality Experiential Learning Site Visit Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Fiscal Year 2025 CDER Office of Pharmaceutical Quality (OPQ) Experiential Learning Site Visit Program (ELSVP). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

DATES: Starting October 1, 2024, FDA will accept requests to participate in the ELSVP program.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic proposal to CDEROPQSiteVisits@fda.hhs.gov or a written proposal to Lyle Canida (see **FOR FURTHER INFORMATION CONTACT**). See the "III. Site Selection" and "IV. Proposals for Participation" sections of this document for potential priorities onsite

selection criteria and how to submit a proposal to participate in the program.

FOR FURTHER INFORMATION CONTACT: Lyle Canida, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. M4522, Silver Spring, MD 20993-0002, 301-796-6825, email: CDEROPQSiteVisits@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A critical part of the commitment by CDER to assure safe and effective high-quality drugs are available to the American public is gaining an understanding of all aspects of a drug's development and commercial lifecycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs, including the FY2025 OPQ ELSVP. This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as the challenges that may impact a drug's developmental program and commercial life cycle. The goal of these visits is to enhance OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities, including manufacturing and laboratory operations, is an integral part of the experience.

II. The Experiential Learning Site Visit Program (ELSVP)

In this site visit program, groups on average of no more than 15 OPQ staff—who have experience in a variety of educational backgrounds, supporting pharmaceutical quality assessment—will observe operations or important aspects of commercial manufacturing, pilot plants (if applicable), and testing over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development, manufacturing, and testing may be included.

CDER encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond.

OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures. Participating sites will have an opportunity to showcase their technologies and their actual manufacturing and testing facilities.

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, the following list identifies a number of areas of particular interest to its staff. The list is not intended to be exhaustive, mutually exclusive, or to limit industry response:

- Drug products:
 - Solutions, suspensions, emulsions, semisolids, and solids
 - Modified- and immediate-release formulations
 - Drug-device combination products regulated by CDER (e.g., inhalation products, transdermal systems, implants intended for drug delivery, and pre-filled syringes)
- Active pharmaceutical ingredients manufactured by:
 - Chemical synthesis
 - Fermentation
 - Biotechnology
- Design, development, manufacturing, and controls:
 - Engineering controls for aseptic processes
 - Novel delivery technologies
 - Hot melt extrusion
 - Soft-gel encapsulation
 - Lyophilization
 - Blow-Fill-Seal packaging
 - Isolators
 - Spray-drying
 - Process analytical technology, measurement systems, and real-time release testing
- Advanced manufacturing technologies:
 - Continuous manufacturing
 - 3-dimensional printing
 - Nanotechnology
- Terminal sterilization:
 - Gamma irradiation
 - PET drug manufacturing and controls
 - Medical gas manufacturing and controls

III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of CDER Offices; therefore, the number of sites selected will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site

visit program should respond by submitting a proposal directly to Lyle Canida at CDEROPQSiteVisits@fda.hhs.gov (see the **FOR FURTHER INFORMATION CONTACT** sections of this document for more information). To aid in OPQ's site selection and planning, your proposal should include the information below:

- A contact person,
- Site visit location(s),
- Facility Establishment Identifier and D-U-N-S numbers, as applicable,
- Maximum number of FDA staff that can be accommodated during a site visit (maximum of 15, on average),
- A proposed agenda outlining the learning objectives and associated activities for the site visit,
- Maximum number of site visits your site would be willing to host by the close of the Government fiscal year, September 30, 2025, and
- Proposed time frames for each site visit (*i.e.*, month or quarter).

Please note that the requested proposed agenda will be reviewed to determine the educational benefit to OPQ in conducting the visit, and selected sites may be asked to refine the agenda to maximize the educational benefit. After a site is selected, OPQ will communicate with the contact person for the site to determine the actual dates for the visit.

Proposals submitted without this minimum information will not be considered. Based on response rate and type of responses, OPQ may consider alternative pathways to meeting our training goals.

Dated: August 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-17640 Filed 8-7-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all

proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8W-25A, Rockville, Maryland 20857; (301) 443-6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**." Set forth below is a list of petitions received by HRSA on

June 1, 2024, through June 30, 2024. This list provides the name of the petitioner, city, and state of vaccination (if unknown then the city and state of the person or attorney filing the claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

a. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by" one of the vaccines referred to in the Table, or

b. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

In accordance with section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Health Systems Bureau, 5600 Fishers Lane, 8W-25A, Rockville, Maryland 20857. The Court's caption (*Petitioner's Name v. Secretary of HHS*) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of Title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Carole Johnson,
Administrator.

List of Petitions Filed

1. Patrick Wey, Portland, Oregon, Court of Federal Claims No: 24-0851V

2. Rebecca Drone, Milton, Florida, Court of Federal Claims No: 24–0854V
3. Marie Moray, Scarsdale, New York, Court of Federal Claims No: 24–0855V
4. Richard Bieber, Centennial, Colorado, Court of Federal Claims No: 24–0856V
5. Amber Hendzel, Monroe, Michigan, Court of Federal Claims No: 24–0862V
6. Chloe Wurth, Remsen, Iowa, Court of Federal Claims No: 24–0864V
7. Ida Rothschild, Portland, Maine, Court of Federal Claims No: 24–0865V
8. Serah G. Starcher on behalf of G.S., Kaneohe, Hawaii, Court of Federal Claims No: 24–0866V
9. Sidney Wells, Grand Junction, Colorado, Court of Federal Claims No: 24–0870V
10. Mary Ellen Maurer, Racine, Wisconsin, Court of Federal Claims No: 24–0876V
11. Lee Ann Mason, Parkersburg, West Virginia, Court of Federal Claims No: 24–0879V
12. Charles Wolle, Windom, Minnesota, Court of Federal Claims No: 24–0880V
13. Joshua Kasabian, Ashburn, Virginia, Court of Federal Claims No: 24–0881V
14. Helen Gant-Farley, Oak Lawn, Illinois, Court of Federal Claims No: 24–0885V
15. Andrea Adams, Quakertown, Pennsylvania, Court of Federal Claims No: 24–0888V
16. Gina Brigner, Lancaster, Ohio, Court of Federal Claims No: 24–0889V
17. Terin Ronson, St. Augustine, Florida, Court of Federal Claims No: 24–0895V
18. Sherri Berry on behalf of A.B., Plaquemine, Louisiana, Court of Federal Claims No: 24–0896V
19. Terry Bryant, Seminole, Florida, Court of Federal Claims No: 24–0897V
20. Dianne Huerta, Boston, Massachusetts, Court of Federal Claims No: 24–0900V
21. Linda C. Culliton, Rochester, New York, Court of Federal Claims No: 24–0901V
22. Rodney Lyon, Fresno, California, Court of Federal Claims No: 24–0902V
23. Kindra Nounou, Tacoma, Washington, Court of Federal Claims No: 24–0903V
24. Teresa Rowe, Boston, Massachusetts, Court of Federal Claims No: 24–0904V
25. Timothy Hake, Milford, Delaware, Court of Federal Claims No: 24–0905V
26. Lynn Louise Torreso on behalf of Kent Torreso, Deceased, Boston, Massachusetts, Court of Federal Claims No: 24–0906V
27. Katie Strickland, Houston, Texas, Court of Federal Claims No: 24–0912V
28. Dorian Sandlin, Franklin, Indiana, Court of Federal Claims No: 24–0915V
29. Oscar Arana on behalf of S.A., Orlando, Florida, Court of Federal Claims No: 24–0918V
30. Tina Rogers, Louisville, Kentucky, Court of Federal Claims No: 24–0920V
31. Autumn Hockaday, Houston, Texas, Court of Federal Claims No: 24–0921V
32. Kenneth Ault, Eureka, Missouri, Court of Federal Claims No: 24–0925V
33. Eva Santiago, Mount Juliet, Tennessee, Court of Federal Claims No: 24–0930V
34. Alyna Zimmerman, New York, New York, Court of Federal Claims No: 24–0932V
35. Matthew Dean, Wichita Falls, Texas, Court of Federal Claims No: 24–0934V
36. Christina Carter, Athens, Tennessee, Court of Federal Claims No: 24–0936V
37. Devin Hight, Bloomington, Minnesota, Court of Federal Claims No: 24–0937V
38. Sonya Hayes, Dadeville, Alabama, Court of Federal Claims No: 24–0938V
39. Barbara Respo Montgomery, Alabama, Court of Federal Claims No: 24–0939V
40. Bonnie Jayne on behalf of H.H., Los Angeles, California, Court of Federal Claims No: 24–0941V
41. Raul Octavio Heredia, Los Angeles, California, Court of Federal Claims No: 24–0942V
42. Margaret Brown, Sarasota, Florida, Court of Federal Claims No: 24–0944V
43. Lori Christopherson, Plattsburgh, New York, Court of Federal Claims No: 24–0945V
44. Anubhav Bhatia and Khushbu Thakkar on behalf of S. B., Phoenix, Arizona, Court of Federal Claims No: 24–0946V
45. Genevieve Rathburn, Erie, Pennsylvania, Court of Federal Claims No: 24–0952V
46. Michael Nickels, San Diego, California, Court of Federal Claims No: 24–0953V
47. Shelby Friend, Newton, Mississippi, Court of Federal Claims No: 24–0959V
48. Janet Zimet, Clarksville, Tennessee, Court of Federal Claims No: 24–0961V
49. John Oliver, Folsom, Pennsylvania, Court of Federal Claims No: 24–0962V
50. Rebecca Brown, Lexington, Kentucky, Court of Federal Claims No: 24–0964V
51. Jessica Mora, San Diego, California, Court of Federal Claims No: 24–0965V
52. Kristi Strobel, Columbus, Ohio, Court of Federal Claims No: 24–0966V
53. Emily Gross, St. Clair Shores, Michigan, Court of Federal Claims No: 24–0967V
54. Heather Hurd, Saint Paul, Minnesota, Court of Federal Claims No: 24–0969V
55. Sheena Fluker, Little Rock, Arkansas, Court of Federal Claims No: 24–0971V
56. Marylou April Gracia, Storm Lake, Iowa, Court of Federal Claims No: 24–0972V
57. Ardeshir Adhami, San Francisco, California, Court of Federal Claims No: 24–0973V
58. Margarita Loukachkina, Baltimore, Maryland, Court of Federal Claims No: 24–0975V
59. Jeffrey Clements, Buckingham, Pennsylvania, Court of Federal Claims No: 24–0977V
60. Ellie Hopkins, St. Louis, Missouri, Court of Federal Claims No: 24–0978V
61. Timothy Rhoades, Boston, Massachusetts, Court of Federal Claims No: 24–0980V
62. Zenaida Viste, Bakersfield, California, Court of Federal Claims No: 24–0983V
63. Huetta Mateen-Pierce, Greenville, North Carolina, Court of Federal Claims No: 24–0984V
64. Korey Gruba, Rapid City, South Dakota, Court of Federal Claims No: 24–0985V
65. Erin C. McKee, Muscatine, Iowa, Court of Federal Claims No: 24–0987V
66. Vanessa L. Mobley-Knox, Las Cruces, New Mexico, Court of Federal Claims No: 24–0988V
67. Holly Riggs, Huntsville, Alabama, Court of Federal Claims No: 24–0989V
68. Linda Kerr, Roseville, California, Court of Federal Claims No: 24–0990V
69. Leah Z. Roberts, Brainerd, Minnesota, Court of Federal Claims No: 24–0992V
70. Julie Munafo, Middletown, Rhode Island, Court of Federal Claims No: 24–0993V
71. Anna Martin, Boston, Massachusetts, Court of Federal Claims No: 24–0998V
72. Elaine Stevens, Columbus, Ohio, Court of Federal Claims No: 24–0999V
73. Howard A. Laster, Souderton, Pennsylvania, Court of Federal Claims No: 24–1000V
74. John Hurst, Wood River, Illinois, Court of Federal Claims No: 24–1002V

[FR Doc. 2024–17601 Filed 8–7–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Alliance for Innovation on Maternal Health—Community Care Initiative (AIM CCI)/Non-Competitive Supplement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of non-competitive supplemental funding.

SUMMARY: HRSA is providing non-competitive supplemental funds in

fiscal year (FY) 2024 to pilot test community-based methods and/or maternal safety bundles to address hypertension during pregnancy and the postpartum period to improve maternal health.

FOR FURTHER INFORMATION CONTACT: India Hinton, Public Health Analyst, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, at IHinton@hrsa.gov and via phone at (301) 945-5235.

SUPPLEMENTARY INFORMATION: *Intended Recipient(s) of the Award:* Funding for the AIM CCI program recipient through a Non-Competitive Supplement to extend the project period by 12 months to pilot test community-based methods and/or maternal safety bundles targeting hypertension during pregnancy and the postpartum period to improve maternal health.

Amount of Competitive or Non-Competitive Award(s): One award up to \$1,800,000.

Project Period: September 30, 2019–September 29, 2025.

Assistance Listing (CFDA) Number: 93.100.

Award Instrument: Non-competitive supplement to a cooperative agreement.

Authority: 42 U.S.C. 701(a)(2) (Social Security Act, title V, sec. 501(a)(2)).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, State	Award amount
U7BMC33635	National Healthy Start Association	Washington, DC	Up to \$1,800,000.

Justification: The majority of pregnancy-related deaths occur following delivery. Improving health care outside of the labor and delivery setting is an important strategy for reducing pregnancy-related deaths. The planned supplemental award is within the scope of the most recent funding opportunity (HRSA-19-109) program purpose, which aims to: (1) support the development and implementation of non-hospital focused maternal safety bundles within community-based organizations and outpatient clinical settings across the United States and (2) build upon the foundational work of AIM by addressing preventable maternal mortality and severe maternal morbidity among pregnant and postpartum women outside of hospital and birthing facility settings.

HRSA will award a non-competitive supplement not to exceed \$1.8 million to support the implementation of community-based activities, to include maternal safety bundles and supporting resources, with a focus on hypertension during pregnancy and the postpartum period. Lessons learned from the pilot

will be used to strengthen and inform community-based approaches targeting hypertension in pregnant and postpartum people.

Carole Johnson,

Administrator.

[FR Doc. 2024-17576 Filed 8-7-24; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, Health Center Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA will provide a performance period extension with supplemental funds to one Health Center Program award recipient with a period of performance ending in fiscal year 2025. The supplemental funding

will extend their current period of performance by 12 months to prevent interruptions in access to critical primary health care services in the community.

FOR FURTHER INFORMATION CONTACT:

Erica Clift, HSRA, at EClift@hrsa.gov and 301-594-4300.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Bronx Community Health Network (BCHN), which serves the Bronx, NY service area, which is a community that is vulnerable to a lapse in access to comprehensive primary health care services.

Amount of Competitive or Non-Competitive Award: One award for \$9,369,314.

Project Period: February 1, 2022 to January 31, 2026.

Assistance Listing (CFDA) Number: 93.224.

Award Instrument: Grant for Health Services.

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, State	Award amount
H80CS00626	Bronx Community Health Network	Bronx, NY	\$9,369,314

Justification: BCHN is a current Health Center Program award recipient, and the supplemental funding will permit BCHN to continue operations from February 1, 2025, through January 31, 2026, before submitting a competitive Service Area Competition application by the end of the 12-month extension period. The award recipient will continue activities with this supplemental funding that are within

the scope of its current Health Center Program project. This action is necessary to ensure continued access to comprehensive primary health care services for the surrounding community. HRSA has determined that it is in the best interests of the Health Center Program and the residents in the service area to extend the period of performance for the current Health Center Program awardee to ensure the

uninterrupted availability of and access to high-quality, comprehensive primary health care services to individuals throughout the service area and target population, regardless of the ability to pay.

Carole Johnson,

Administrator.

[FR Doc. 2024-17582 Filed 8-7-24; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group Health, Behavior, and Context Study Section.

Date: October 28, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimberly L. Houston, M.D., Scientific Review Officer, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2137C, Bethesda, MD 20892, (301) 827-4902, kimberly.houston@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 2, 2024.
Lauren A. Fleck,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2024-17516 Filed 8-7-24; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Project: Medications for the Treatment of Opioid Use Disorder—42 CFR Part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that opioid treatment programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid use disorder treatment under the federal opioid use disorder treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the

regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the *Application for Certification to Use Medications for the Treatment of Opioid Use Disorder in a Treatment Program Under 42 CFR 8.11* (Form SMA-162); the *Application for Approval as Accreditation Body Under 42 CFR 8.3(b)* (Form SMA-163); and the *Exception Request and Record of Justification Under 42 CFR 8.11(h)* (Form SMA-168), which may be used on a voluntary basis by OTP practitioners when there is a patient care situation in which the OTP practitioner must make a treatment decision that falls outside of the standards delineated in the regulation. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: a patient's medical examination when admitted to treatment, a patient's medical history, a care plan, any prenatal support provided the patient if applicable, the medical rationale for initial starting doses above 50mg, the medical rationale for a patient's dosage schedule, and care decisions made as a result of follow-up medical examinations.

The table that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are minor changes to these forms to improve data collection, remove unnecessary questions, and align terms with the final 42 CFR part 8 rule released February 2, 2024.

Form	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
Estimated Annual Reporting Requirement Burden for Accreditation Bodies					
SMA-163	54	26.055	1,407	0.28	394
Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs					
SMA-162	751.33	17.976	13,506	0.08	1,081
SMA-168	1,302.67	17.977	23,418	0.08	1,873
Subtotal	2,054	17.977	36,925	0.08	2,954
Total			38,332		3,348

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Alicia Broadus,
Public Health Advisor.

[FR Doc. 2024–17647 Filed 8–7–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4774–DR; Docket ID FEMA–2024–0001]

Kansas; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA–4774–DR), dated April 28, 2024, and related determinations.

DATES: This change occurred on July 10, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Andrew P. Meyer, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of DuWayne Tewes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—

Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,
Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17544 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4796–DR; Docket ID FEMA–2024–0001]

Iowa; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4796–DR), dated June 24, 2024, and related determinations.

DATES: This amendment was issued July 9, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 24, 2024.

Woodbury County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,
Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17556 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4796–DR; Docket ID FEMA–2024–0001]

Iowa; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4796–DR), dated June 24, 2024, and related determinations.

DATES: This amendment was issued July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 24, 2024.

Buena Vista and O’Brien Counties for Individual Assistance (already designated for debris removal and emergency protective measures (Categories A and B), including direct Federal assistance, under the Public Assistance program).

Cherokee County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17555 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4774–DR; Docket ID FEMA–2024–0001]

Kansas; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA–4774–DR), dated April 28, 2024, and related determinations.

DATES: This amendment was issued June 27, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Kansas is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 28, 2024.

Marion County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17543 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4781–DR; Docket ID FEMA–2024–0001]

Texas; Amendment No. 14 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4781–DR), dated May 17, 2024, and related determinations.

DATES: This amendment was issued July 8, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 17, 2024.

Anderson, Panola, and Rusk Counties for Individual Assistance (already designated for Public Assistance).

Nacogdoches and Sabine Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17547 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4794–DR; Docket ID FEMA–2024–0001]

Florida; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA–4794–DR), dated June 17, 2024, and related determinations.

DATES: This amendment was issued July 16, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 17, 2024.

Columbia County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17553 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4781-
DR; Docket ID FEMA-2024-0001]

**Texas; Amendment No. 15 to Notice of
a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA-4781-DR), dated May 17, 2024, and related determinations.

DATES: This amendment was issued July 15, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 17, 2024.

Blanco, Cass, Cherokee, Gonzales, Hopkins, McCulloch, Morris, Rains, and Titus Counties for Public Assistance. Dallas and Sabine Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,
*Administrator, Federal Emergency
Management Agency.*

[FR Doc. 2024-17548 Filed 8-7-24; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4798-
DR; Docket ID FEMA-2024-0001]

**Texas; Amendment No. 1 to Notice of
a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA-4798-DR), dated July 9, 2024, and related determinations.

DATES: This amendment was issued July 12, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include Individual Assistance for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 9, 2024.

Brazoria, Chambers, Galveston, Harris, Jackson, Jasper, Jefferson, Liberty, Matagorda, Montgomery, Orange, Polk, San Jacinto, Walker, and Wharton Counties for Individual Assistance (already designated for debris removal and emergency protective measures (Categories A and B), including direct Federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,
*Administrator, Federal Emergency
Management Agency.*

[FR Doc. 2024-17558 Filed 8-7-24; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4780-
DR; Docket ID FEMA-2024-0001]

**Massachusetts; Amendment No. 1 to
Notice of a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Massachusetts (FEMA-4780-DR), dated May 15, 2024, and related determinations.

DATES: This amendment was issued July 1, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Massachusetts is hereby amended to include Disaster Legal Services for the areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 15, 2024.

Bristol and Worcester Counties for Disaster Legal Services.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,
*Administrator, Federal Emergency
Management Agency.*

[FR Doc. 2024-17545 Filed 8-7-24; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4794-
DR; Docket ID FEMA-2024-0001]

**Florida; Amendment No. 1 to Notice of
a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Florida (FEMA-4794-DR), dated June 17, 2024, and related determinations.

DATES: This amendment was issued June 27, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Florida is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 17, 2024.

Jefferson and Santa Rosa Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

*Administrator, Federal Emergency
Management Agency.*

[FR Doc. 2024-17552 Filed 8-7-24; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4787-
DR; Docket ID FEMA-2024-0001]

**West Virginia; Amendment No. 1 to
Notice of a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA-4787-DR), dated May 24, 2024, and related determinations.

DATES: This amendment was issued July 3, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of West Virginia is hereby amended to include the Individual Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 24, 2024.

Hancock, Marshall, Ohio, and Wetzel Counties for Individual Assistance (already designated for Public Assistance).

Kanawha, Roane, and Wood Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

*Administrator, Federal Emergency
Management Agency.*

[FR Doc. 2024-17550 Filed 8-7-24; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND
SECURITY****Federal Emergency Management
Agency**

[Internal Agency Docket No. FEMA-4781-
DR; Docket ID FEMA-2024-0001]

**Texas; Amendment No. 13 to Notice of
a Major Disaster Declaration**

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA-4781-DR), dated May 17, 2024, and related determinations.

DATES: This amendment was issued July 1, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 17, 2024.

Anderson, Baylor, Cochran, Delta, Milam, Rockwall, and Rusk Counties for Public Assistance.

Henderson, Kaufmann, and Van Zandt Counties for Public Assistance (already designated for Individual Assistance).

Ellis, Guadalupe, and Smith Counties for emergency protective measures (Category B), limited to direct federal assistance under the Public Assistance program (already designated for Individual Assistance).

Hays and Hill Counties for emergency protective measures (Category B), limited to direct federal assistance under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17546 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4791–DR; Docket ID FEMA–2024–0001]

Oklahoma; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Oklahoma (FEMA–4791–DR), dated June 14, 2024, and related determinations.

DATES: This amendment was issued July 16, 2024.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Oklahoma is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 14, 2024.

Caddo, Custer, and Jackson Counties for Public Assistance (already designated for Individual Assistance).

Roger Mills and Woods Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17551 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4784–DR; Docket ID FEMA–2024–0001]

Iowa; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4784–DR), dated May 24, 2024, and related determinations.

DATES: This amendment was issued June 27, 2024.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 24, 2024.

Adair County for permanent work [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures under the Public Assistance program).

Adams, Cedar, Jasper, Montgomery, Polk, and Story Counties for Public Assistance (already designated for Individual Assistance).

Buena Vista, Butler, Calhoun, Cherokee, Clay, Dallas, Franklin, Hamilton, Hancock, Harrison, Humboldt, Iowa, Jackson, Kossuth, Marshall, Mitchell, Muscatine, Pottawattamie, Poweshiek, Shelby, Tama, and Wright Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially

Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17549 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4798–DR; Docket ID FEMA–2024–0001]

Texas; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4798–DR), dated July 9, 2024, and related determinations.

DATES: This amendment was issued July 13, 2024.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 9, 2024.

Fort Bend and Nacagdoches Counties for Individual Assistance (already designated for debris removal and emergency protective measures (Categories A and B), including direct Federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially

Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17559 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4797–DR; Docket ID FEMA–2024–0001]

Minnesota; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Minnesota (FEMA–4797–DR), dated June 28, 2024, and related determinations.

DATES: This amendment was issued July 11, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 4, 2024.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17557 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4795–DR; Docket ID FEMA–2024–0001]

New Mexico; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Mexico (FEMA–4795–DR), dated June 20, 2024, and related determinations.

DATES: This amendment was issued July 11, 2024.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Mexico is hereby amended to include the following areas among the areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 20, 2024.

Lincoln and Otero Counties, including the Mescalero Apache Tribe for permanent work [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Rio Arriba and San Juan Counties for Individual Assistance.

Rio Arriba and San Juan Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2024–17554 Filed 8–7–24; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2024–0126; FXES11140800000–245–FF08EVEN00]

Endangered and Threatened Wildlife and Plants; Two Draft Habitat Conservation Plans and Associated Draft Categorical Exclusions for School Improvement Projects in San Benito and Monterey Counties, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received two applications for incidental take permits (ITPs) for the federally threatened Central California Distinct Population Segment (DPS) of the California tiger salamander and California red-legged frog under the Endangered Species Act of 1973, as amended. Each of the two applicants submitted a permit application which, if issued, would authorize take of the California tiger salamander and California red-legged frog incidental to activities associated with the development and improvement of school facilities in the cities of San Juan Bautista and Salinas in San Benito and Monterey Counties, respectively, in California. As part of the application for an ITP, each applicant submitted a draft habitat conservation plan for their respective project. For each project, the Service prepared a draft screening form in accordance with the National Environmental Policy Act (NEPA) to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to each applicant for their project. We invite the public and local, State, Tribal, and Federal agencies to comment on the draft screening forms and on the Service's preliminary determination that the proposed permitting actions may be eligible for categorical exclusions pursuant to the Council on Environmental Quality's NEPA regulations, the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual.

DATES: Written comments should be received on or before September 9, 2024.

ADDRESSES:

Obtaining Documents: The documents this notice announces, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–

R8-ES-2024-0126 at <https://www.regulations.gov>.

Submitting Written Comments: Please send us your written comments using one of the following methods:

- **Online:** <https://www.regulations.gov>.

Follow the instructions for submitting comments on Docket No. FWS-R8-ES-2024-0126.

- **U.S. Mail:** Public Comments

Processing; Attn: FWS-R8-ES-2024-0126; U.S. Fish and Wildlife Service; MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041-3803.

FOR FURTHER INFORMATION CONTACT:

Karen Sinclair, Fish and Wildlife Biologist, by email at fw8venturaitp@fws.gov or via phone at (805) 644-1766. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received two applications for incidental take permits (ITPs) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicants have developed draft habitat conservation plans (HCPs) for the respective projects that include measures to minimize and mitigate impacts to the federally threatened Central California DPS of the California tiger salamander (*Ambystoma californiense*) and California red-legged frog (*Rana draytonii*). Each of the permits, if granted, would authorize take of the California tiger salamander and California red-legged frog incidental to otherwise lawful activities associated with the development and improvement of school facilities in the cities of San Juan Bautista and Salinas in San Benito and Monterey Counties, respectively, in California. We invite public comment on the applications, which include the applicants' HCPs, and on the Service's preliminary determination that both proposed ITPs qualify as low effect, and may qualify for categorical exclusions pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations (40 CFR 1501.4), the Department of the Interior's (DOI) NEPA regulations (43 CFR 46), and the DOI's Departmental Manual (516 DM 8.5(C)(2)). To make these preliminary determinations, we prepared draft low-effect screening forms, which are also available for public review.

Background

The Service listed the Central California DPS of the California tiger salamander as threatened on August 4, 2004 (69 FR 47212), and listed the California red-legged frog as threatened on May 23, 1996 (61 FR 25813). Section 9 of the ESA prohibits "take" of fish and wildlife species listed as endangered (16 U.S.C. 1538), where take is defined to include the following activities: "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532). The take prohibitions of section 9 are extended to species listed as threatened at the discretion of the Secretary of the Department of the Interior; in this case, they were extended to both species; however, this was done with exceptions for the California tiger salamander.

Under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize take of listed fish and wildlife species that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species are in the Code of Federal Regulations (CFR) at 50 CFR 17.22 and 17.32, respectively. Issuance of an ITP also must not jeopardize the existence of federally listed fish, wildlife, or plant species, pursuant to section 7 of the ESA and 50 CFR 402.02. The permittee would receive assurances under our "No Surprises" regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

Proposed Activities

Each applicant has applied for a permit for incidental take of the California tiger salamander and California red-legged frog. The take would occur in association with development and improvement activities of school facilities.

The respective HCPs include minimization measures for the California tiger salamander and California red-legged frog and mitigation for unavoidable take and loss of suitable habitat for these species. As mitigation for take and loss of suitable habitat, the applicants propose mitigation that will support the recovery goals of the species such as restoration and protection of habitat through the purchase of credits at a conservation bank.

Our Preliminary Determination

The Service has made a preliminary determination that the applicants' proposed projects, and proposed mitigation and minimization measures, would individually and cumulatively

have a minor effect on the species and the human environment. Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) permits would be low-effect ITPs that individually or cumulatively would have a minor effect on the species and may qualify for application of categorical exclusions pursuant to the Council on Environmental Quality's NEPA regulations, DOI's NEPA regulations, and the DOI Departmental Manual. A low-effect ITP is one that would result in (1) minor or nonsignificant effects on species covered in the HCP; (2) nonsignificant effects on the human environment; and (3) impacts that, when added together with the impacts of other past, present, and reasonably foreseeable actions, would not result in significant cumulative effects to the human environment.

Next Steps

The Service will evaluate the applications and the comments received to determine whether to issue the requested ITPs. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed covered activities on the Central California DPS of the California tiger salamander and California red-legged frog. After considering the preceding and other matters, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue one or both ITPs.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10(c) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and

its implementing regulations (40 CFR 1500–1508 and 43 CFR 46).

Stephen P. Henry,
*Field Supervisor, Ventura Fish and Wildlife
Office, Ventura, California.*

[FR Doc. 2024–17577 Filed 8–7–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO4500180777]

Call for Nominations to the Western Montana Resource Advisory Council

AGENCY: Bureau of Land Management,
Interior.

ACTION: Notice of call for nominations.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management's (BLM) Western Montana Resource Advisory Council (RAC) to fill existing vacancies, as well as for member terms that are scheduled to expire. The RAC provides advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within the Western Montana District.

DATES: All nominations must be received no later than September 9, 2024.

ADDRESSES: Nominations and completed applications should be sent to the BLM office listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: Ann Boucher, BLM Montana/Dakotas State Office, 5001 Southgate Drive, Billings, MT 59101; telephone: (406) 896–5255; email: aboucher@blm.gov.

Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior (Secretary) to involve the public in planning and issues related to the management of lands administered by the BLM. Section 309 of FLPMA (43 U.S.C. 1739) directs the Secretary to establish 10- to 15-member citizen-based advisory councils that are consistent with the Federal Advisory

Committee Act (FACA). As required by FACA, RAC membership must be balanced, and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR part 1780 and include the following three membership categories:

Category One—Holders of Federal grazing permits or leases within the area for which the RAC is organized; represent interests associated with transportation or rights-of-way; represent developed outdoor recreation, off-highway vehicle users, or commercial recreation activities; represent the commercial timber industry; or represent energy and mineral development.

Category Two—Representatives of nationally or regionally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups.

Category Three—Hold State, county, or local elected office; are employed by a State agency responsible for the management of natural resources, land, or water; represent Indian Tribes within or adjacent to the area for which the RAC is organized; are employed as academicians in natural resource management or the natural sciences; or represent the affected public-at-large.

Individuals may nominate themselves or others. Nominees must be residents of the State of Montana. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

- A completed RAC application, which can either be obtained through the nominee's BLM office or online at: https://www.blm.gov/sites/default/files/docs/2022-05/BLM-Form-1120-19_RAC-Application.pdf.
- Letters of reference from represented interests or organizations; and
- Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, the BLM Montana/Dakotas office will issue an online announcement providing additional information for submitting nominations.

(Authority: 43 CFR 1784.4–1)

Carrie H. Cecil,
*Acting Western Montana BLM District
Manager.*

[FR Doc. 2024–17610 Filed 8–7–24; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO4500180832]

Public Meeting of the Missouri Basin Resource Advisory Council

AGENCY: Bureau of Land Management,
Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Missouri Basin Resource Advisory Council (RAC) will meet as follows.

DATES: The Missouri Basin RAC will meet on September 11, 2024, from 12 p.m. to 5 p.m. Mountain Time.

ADDRESSES: The meeting will be held at the Glasgow City-County Library, 408 3rd Avenue South, Glasgow, MT 59230. A virtual participation option will also be available. Individuals who wish to participate virtually must register with the contact person listed below at least 7 business days prior to the meeting date.

FOR FURTHER INFORMATION CONTACT: Gina Baltrusch, Missouri Basin RAC Coordinator, BLM North Central Montana District, 1220 38th Street North, Great Falls, MT 59405; telephone: 406–308–9387; email: rbaltrusch@blm.gov.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please make requests in advance for sign language interpreter services, language translation services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed above at least 14 business days prior to the meeting to give the BLM sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Central and Eastern Montana, and North and South Dakota. Agenda topics will include North-Central Montana and Eastern Montana/Dakotas districts' reports, Field Office manager reports, a public comment period, and other topics the council may wish to cover. A final agenda will be posted on the RAC's web page at <https://www.blm.gov/get-involved/resourceadvisory-council/near-you/montanadakotas/missouri-basin-rac> two weeks in advance of the meeting. The meeting is open to the public, with a public comment period offered at 4 p.m. Written comments to the RAC can be emailed in advance to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment, including your personally identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1784.4–2).

Wendy Warren,

Eastern Montana/Dakotas District Manager and Missouri Basin RAC Designated Federal Official.

[FR Doc. 2024–17591 Filed 8–7–24; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_CA_FRN_MO4500180553]

Notice of Public Meetings of the Central California Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Central California

Resource Advisory Council (RAC) will meet as follows.

DATES: The Central California RAC will hold virtual public meetings on Wednesday, September 11, 2024, from 8:30 a.m. to 2:15 p.m. Pacific Time (PT), with a public comment period scheduled for 1:45 p.m. PT; and on Wednesday, February 5, 2025, from 8:30 a.m. to 12:30 p.m. PT, with a public comment period scheduled for 12:00 p.m. PT; and an in-person meeting on Wednesday, May 8, 2025, from 8:30 a.m. to 2:15 p.m. PT, with a public comment period scheduled for 1:45 p.m. PT. A field tour will be held on May 7, 2025, from 12:30 p.m. to 5 p.m. PT. The meetings and field tour are open to the public.

ADDRESSES: Meeting links, final agendas, and participation instructions will be made available to the public via social media, the BLM Central California RAC's website at <https://go.usa.gov/xH9ya>, and through personal contacts 2 weeks prior to the meetings. The May 7, 2025, field tour will commence and conclude, and the May 8, 2025, in-person meeting will be held, at the BLM Bakersfield Field Office, 35126 McMurtrey Avenue, Bakersfield, CA 93308.

FOR FURTHER INFORMATION CONTACT: Public Affairs Officer, Philip Oviatt, email: poviatt@blm.gov or telephone: (661) 432–4252. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. For sign language interpretation services, language translation services, assistive listening devices, or other reasonable accommodations, please contact the individual listed above at least 14 business days before the meeting to ensure there is sufficient time to process the request. The Department of the Interior manages accommodation requests on a case-by-case basis.

SUPPLEMENTARY INFORMATION: The chartered 12-member Central California RAC advises the Secretary of the Interior, through the BLM California State Director, on planning and management of public land resources located within the jurisdictional boundaries of the RAC. Agenda topics for the September 11, 2024, meeting include a briefing on Alabama Hills Management Plan implementation as well as an update on the Bi-State Sage

Grouse program. The RAC will also hear reports from the district and field offices. In addition, the RAC will hear a fee proposal from the United States Department of Agriculture (USDA) Forest Service for sites in the Inyo National Forest. Agenda topics for the February 5, 2025, meeting include a briefing on habitat and watershed restoration projects in the Mother Lode Field Office. The RAC will also be briefed on fuels reduction projects as well as briefings from the district and field offices, including a wildland fire update.

On May 7, 2025, the RAC will tour the Diablo Canyon Fuels Reduction Project with partners in San Luis Obispo County. Members of the public are welcome to participate in the field tour but must provide their own transportation and meals. Agenda topics for the May 8, 2025, meeting include the Bakersfield Fuels Reduction Program, and the RAC will receive an update on the Bakersfield Oil and Gas Program. The RAC will also hear reports from the district and field offices. In addition, the RAC will hear a fee proposal from the USDA Forest Service for a site in the Los Padres National Forest. Members of the public who wish to participate in the field tour must provide their own transportation and meals.

Each formal RAC meeting will have time allocated for public comments. Depending on the number of persons wishing to speak and the time available, the amount of time for oral comments may be limited. Written public comments may be sent to the BLM Central California District Office listed in the **ADDRESSES** section of this notice. All comments received will be provided to the RAC.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Detailed minutes for the RAC meetings will be maintained in the BLM Central California District Office. Minutes will also be posted to the BLM California RAC web page.

Authority: 43 CFR 1784.4–2.

Christopher Rocker Heppe,
Central California District Manager.

[FR Doc. 2024–17604 Filed 8–7–24; 8:45 am]

BILLING CODE 4331–15–P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement**

[S1D1S SS08011000 SX064A000
245S180110; S2D2S SS08011000
SX064A000 24XS501520; OMB Control
Number 1029–0111]

Agency Information Collection Activities; Areas Designated by Act of Congress

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 9, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 1544–MIB, Washington, DC 20240, or by email to mgehlhar@osmre.gov. Please reference OMB Control Number 1029–0111 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at mgehlhar@osmre.gov, or by telephone at (202) 208–2716. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to

comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on March 5, 2024 (89 FR 15894). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: OSMRE and State regulatory authorities use the information collected for 30 CFR part 761 to ensure that persons planning to conduct surface coal mining operations on the lands protected by section 522(e) of the Surface Mining Control and Reclamation Act of 1977 have the right to do so under one of the exemptions or

waivers provided by this section of the Act.

Title of Collection: Areas Designated by Act of Congress.

OMB Control Number: 1029–0111.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public:

Businesses and State governments.

Total Estimated Number of Annual Respondents: 53.

Total Estimated Number of Annual Responses: 129.

Estimated Completion Time per Response: Varies from 1 hour to 40 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 1,458.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: \$8,220.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Office of Surface Mining Reclamation and Enforcement.*

[FR Doc. 2024–17631 Filed 8–7–24; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION**Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Pre-Stretched Synthetic Braiding Hair and Packaging Therefor, DN 3764*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant’s filing pursuant to the Commission’s Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be

accessed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of JBS Hair, Inc. on August 2, 2024. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain certain pre-stretched synthetic braiding hair and packaging therefor. The complaint names as respondents: Sun Taiyang Co., Ltd. (d/b/a Outre®) of Moonachie, NJ; Beauty Elements Corporation (d/b/a Bijouz®) of Miami Gardens, FL; Hair Zone, Inc. (d/b/a Sensationnel®) of Moonachie, NJ; Beauty Essence, Inc. (d/b/a Supreme™ Hair US) of Moonachie, NJ; SLI Production Corp. (d/b/a It's a Wig!) of Moonachie, NJ; Royal Imex, Inc. (d/b/a Zury® Hollywood) of Santa Fe Springs, CA; GS Imports, Inc. (d/b/a Golden State Imports, Inc.) of Paramount, CA; Eve Hair, Inc. of Lakewood, CA; Kum Kang Trading USA, Inc. (d/b/a BNGHAIR) of Paramount, CA; Midway International, Inc. (d/b/a BOBBI BOSS) of Cerritos, CA; Mayde Beauty Inc. of Port Washington, NY; Hair Plus Trading Co., Inc. (d/b/a Femi Collection) of Suwanee, GA; Optimum Solution Group LLC (d/b/a Oh Yes Hair) of Duluth, GA; Choix International, Inc. of Norcross, GA; Twin Peak International, Inc. (d/b/a Dejavu Hair) of Atlanta, GA; Loc N Products, LLC of Atlanta, GA; Crown Pacific Group Inc. of Doraville, GA; Vivace, Inc. (d/b/a Dae Do Inc.) of Levittown, NY; A-Hair Import Inc. of Norcross, GA; Chade Fashions, Inc. of Niles, IL; Mink Hair, Ltd. (d/b/a Sensual® Collection) of Wayne, NJ; Mane Concept Inc. of Moonachie, NJ; Oradell International Corp. (d/b/a MOTOWN TRESS) of Manalapan, NJ;

Beauty Plus Trading Co., Inc. (d/b/a Janet Collection™) of Moonachie, NJ; Model Model Hair Fashion, Inc. of Port Washington, NY; New Jigu Trading Corp. (d/b/a Harlem 125®) of Port Washington, NY; Shake N Go Fashion, Inc. of Port Washington, NY; Amekor Industries, Inc. (d/b/a Vivica A. Fox® Hair Collection) of Conshohocken, PA; I & I Hair Corp. of Dallas, TX; and Zugoo Import Inc. of Norcross, GA. The complainant requests that the Commission issue a general exclusion order, limited exclusion orders, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, members of the public, and interested government agencies are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial

determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3764") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDIS3Help@usitc.gov.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S.

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

Government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission’s Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.
Issued: August 5, 2024.

Lisa Barton,
Secretary to the Commission.
[FR Doc. 2024–17638 Filed 8–7–24; 8:45 am]
BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration
[Docket No. DEA–1404]

Importer of Controlled Substances
Application: Experic LLC

AGENCY: Drug Enforcement Administration, Justice.
ACTION: Notice of application.

SUMMARY: Experic LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2024. Such persons may also file a written request for a hearing on the application on or before September 9, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If

² All contract personnel will sign appropriate nondisclosure agreements.
³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 10, 2024, Experic LLC, 2 Clarke Drive, Cranbury, New Jersey 08512–3619, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to import drug code Tetrahydrocannabinols (7370) for clinical trial purposes. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,
Acting Deputy Assistant Administrator.
[FR Doc. 2024–17621 Filed 8–7–24; 8:45 am]
BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration
[Docket No. DEA–1405]

Importer of Controlled Substances
Application: Cambrex High Point, Inc.

AGENCY: Drug Enforcement Administration, Justice.
ACTION: Notice of application.

SUMMARY: Cambrex High Point, Inc., has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2024. Such persons may also file a written request for a hearing on the application on or before September 9, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 25, 2024, Cambrex High Point, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265–8017, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Poppy Straw Concentrate.	9670	II

The company plans to import the listed controlled substances for research and development purposes. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-

approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–17626 Filed 8–7–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1403]

Bulk Manufacturer of Controlled Substances Application: AMPAC Fine Chemicals, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AMPAC Fine Chemicals, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 7, 2024. Such persons may also file a written request for a hearing on the application on or before October 7, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 29, 2024, AMPAC Fine Chemicals, LLC, Highway 50 & Hazel Avenue, Rancho Cordova, California 95670, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Norlevorphanol	9634	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Levomethorphan	9210	II
Levorphanol	9220	II
Thebaine	9333	II
Remifentanyl	9739	II
Tapentadol	9780	II

The company plans to bulk manufacture the listed controlled substances for distribution to its customers. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–17612 Filed 8–7–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1402]

Bulk Manufacturer of Controlled Substances Application: Cambrex Charles City

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cambrex Charles City has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 7, 2024. Such persons may also file a written request for a hearing on the application on or before October 7, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If

you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on June 18, 2024, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616–3466, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Tetrahydrocannabinols	7370	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
ANPP (4-Anilino-N-phenethyl-4-piperidine).	8333	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for conversion to other controlled substances and sales to its customers for dosage form development, clinical trials and use in stability qualification studies.

In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–17613 Filed 8–7–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1406]

Importer of Controlled Substances Application: Catalent Greenville, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent Greenville, Inc., has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2024. Such persons may also file a written request for a hearing on the application on or before September 9, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 12, 2024, Catalent Greenville, Inc., 1240 Sugg Parkway, Greenville, North Carolina 27834-9006, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Lysergic Acid Diethylamide	7315	I

The company plans to import the listed controlled substances for the development of bulk dosage formulations for research and clinical studies. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,
Acting Deputy Assistant Administrator.
[FR Doc. 2024-17630 Filed 8-7-24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1399]

Importer of Controlled Substances Application: Benuvia Operations, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations, LLC., has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2024. Such persons may also file a written request for a hearing on the application on or before September 9, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal

Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 14, 2024, Benuvia Operations, LLC., 3950 North Mays Steet, Round Rock, Texas 78665-2729, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to import the listed controlled substances for clinical trial manufacturing and analytical purposes. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,
Acting Deputy Assistant Administrator.
[FR Doc. 2024-17597 Filed 8-7-24; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1400]

Bulk Manufacturer of Controlled Substances Application: VICI Health Sciences, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: VICI Health Sciences, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before October 7, 2024. Such

persons may also file a written request for a hearing on the application on or before October 7, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 15, 2024, VICI Health Sciences, LLC, 6655 Amberton Drive, Suite O, Elkridge, Maryland 21075, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Fentanyl related substances as defined in 21 CFR 1308.11(h).	9850	I

The company plans to bulk manufacture the listed controlled substance for sale to its customers. No other activity for this drug code is authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024-17607 Filed 8-7-24; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1397]

Importer of Controlled Substances Application: Cerilliant Corporation

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cerilliant Corporation has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 9, 2024. Such persons may also file a written request for a hearing on the application on or before September 9, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all

comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 21, 2024, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665-2402, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
3-Fluoro-N-methylcathinone (3-FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4-FMC)	1238	I
Pentedrone (α -methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4-MEC)	1249	I
Naphyrone	1258	I
N-Ethylamphetamine	1475	I
N,N-Dimethylamphetamine	1480	I
Fenethylamine	1503	I
Methaqualone	2565	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
5-Fluoro-UR-144 and XLR11 [1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I
AB-FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	7012	I
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	7019	I
AB-PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7023	I
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	7024	I
AB-CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	7031	I
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	7035	I
APINACA and AKB48 (N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	7048	I
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I
UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I

Controlled substance	Drug code	Schedule
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I
AM2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
PB-22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate)	7222	I
5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate)	7225	I
Alpha-ethyltryptamine	7249	I
Ibogaine	7260	I
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7297	I
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol)	7298	I
Lysergic acid diethylamide	7315	I
2C-T-7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine)	7348	I
Marihuana	7360	I
Parahexyl	7374	I
Mescaline	7381	I
2C-T-2 (2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine)	7385	I
3,4,5-Trimethoxyamphetamine	7390	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
2,5-Dimethoxyamphetamine	7396	I
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
3,4-Methylenedioxyamphetamine	7400	I
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I
4-Methoxyamphetamine	7411	I
5-Methoxy-N,N-dimethyltryptamine	7431	I
Alpha-methyltryptamine	7432	I
Bufotenine	7433	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
N-Ethyl-1-phenylcyclohexylamine	7455	I
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I
N-Benzylpiperazine	7493	I
4-MePPP (4-Methyl-alpha-pyrrolidinopropiophenone)	7498	I
2C-D (2-(2,5-Dimethoxy-4-methylphenyl) ethanamine)	7508	I
2C-E (2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine)	7509	I
2C-H 2-(2,5-Dimethoxyphenyl) ethanamine)	7517	I
2C-I 2-(4-iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I
2C-C 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine)	7519	I
2C-N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I
2C-P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I
2C-T-4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine)	7532	I
MDPV (3,4-Methylenedioxypropylvalerone)	7535	I
25B-NBOMe (2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7536	I
25C-NBOMe (2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7537	I
25I-NBOMe (2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine)	7538	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
alpha-pyrrolidinopentiophenone (α -PVP)	7545	I
alpha-pyrrolidinobutiophenone (α -PBP)	7546	I
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I
Desomorphine	9055	I
Etorphine (except HCl)	9056	I
Codeine methylbromide	9070	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Pholcodine	9314	I
U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)	9547	I
AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Betacetylmethadol	9607	I

Controlled substance	Drug code	Schedule
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I
Dextromoramide	9613	I
Dipipanone	9622	I
Hydroxypethidine	9627	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Racemoramide	9645	I
Trimeperidine	9646	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
Tilidine	9750	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Thiofentanyl	9835	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
Methamphetamine	1105	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Dihydrocodeine	9120	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levomethorphan	9210	II
Levorphanol	9220	II
Meperidine	9230	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Levo-alphacetylmethadol	9648	II
Noroxymorphone	9668	II
Racemethorphan	9732	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II

The company plans to import the listed controlled substances for the manufacturing of analytical reference standards and distribution to their research and forensic customers. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-

approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024-17595 Filed 8-7-24; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Steel Erection Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before September 9, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202-693-0213, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Standard on Steel Erection requires that workers exposed to fall hazards receive specified training in the recognition and control of these hazards and that they are notified that building materials, components, steel structures, and fall protection equipment are safe for specific uses. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 22, 2024 (89 FR 45017).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL-OSHA.

Title of Collection: Steel Erection Standard.

OMB Control Number: 1218-0241.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 15,383.

Total Estimated Number of Responses: 84,650.

Total Estimated Annual Time Burden: 28,454 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024-17590 Filed 8-7-24; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request, National Worker Survey, New Collection

AGENCY: Chief Evaluation Office, Office of the Assistant Secretary for Policy, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data for the National Worker Survey. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before October 7, 2024.

ADDRESSES: You may submit comments by either one of the following methods:

Email: ChiefEvaluationOffice@dol.gov; *Mail or Courier:* Kacie Chang, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S-2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must

include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT:

Kacie Chang by email at ChiefEvaluationOffice@dol.gov or by phone at (202) 693-5992.

SUPPLEMENTARY INFORMATION: I.

Background: The Chief Evaluation Office (CEO) of the U.S. Department of Labor (DOL) intends to study the prevalence and severity of violations to the Fair Labor Standards Act (FLSA) which requires that workers who are covered by the act and not specifically exempt from its provisions be paid at least the Federal minimum wage and 1.5 times their regular rate of pay for hours worked over 40 in a workweek. The act also regulates the employment of youth under the age of 18 and establishes recordkeeping requirements for employers, among other provisions.

Violations of the FLSA are not uncommon. In a survey of 4,387 workers in low-wage industries in Chicago, Los Angeles, and New York City, two-thirds experienced at least one pay-related violation in any given week (Bernhardt, A., Milkman, R. and Theodore, N. 2009. Broken laws, unprotected workers: Violations of employment and labor laws in America's cities. National Employment Law Project, New York, NY). The actual extent of violations is unknown and must be estimated through surveys. Existing national surveys do a poor job of including workers who are at the highest risk of violations and are generally able to measure only minimum wage violations due to the way questions are asked. Given DOL's limited resources to investigate individual complaints, it is important to have nationally representative data on prevalence across industries and worker subpopulations to prioritize enforcement. The current study will build on the work of previous surveys by designing a nationally representative survey of workers with oversamples of workers in low-wage industries where violations are most likely to occur. The study will provide DOL with information it needs to promote compliance with the FLSA as well as outreach and education to raise awareness among vulnerable workers about the types of pay practices and other actions used by employers who violate the FLSA.

This **Federal Register** Notice provides the opportunity to comment on proposed data collection instrument that will be used in the National Worker Survey. The instrument will contain approximately 25 questions and is expected to take up to 25 minutes to complete (not every participant will be expected to answer every question).

II. Desired Focus of Comments:

Currently, the Department of Labor is soliciting comments concerning the above data collection for the National Worker Survey. DOL is particularly interested in comments that do the following:

- evaluate whether the proposed collection of information is necessary

for the proper performance functions of the agency, including whether the information will have practical utility;

- evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology—

for example, permitting electronic submissions of responses.

III. Current Actions: At this time, the Department of Labor is requesting clearance for the survey instrument.

Type of Review: New information collection request.

OMB Control Number: 1290–0NEW

Affected Public: Individuals or households

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument (form/activity)	Number of respondents	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
Address-based sample screener only	6,000	1	6,000	.08	480
Address-based sample screener and survey	4,000	1	4,000	.5	2,000
Respondent-driven sample screener only	1,000	1	1,000	.08	80
Respondent-driven sample screener and survey	4,000	1	4,000	.5	2,000
Total	15,000		15,000		4,560

Upeksha Savi Swick,

*Director of Research, Chief Evaluation Office,
U.S. Department of Labor.*

[FR Doc. 2024–17587 Filed 8–7–24; 8:45 am]

BILLING CODE 4510–HX–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request, Reemployment Services and Eligibility Assessment (RESEA) Evidence Building Portfolio Project, New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden

(time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data about the Reemployment Services and Eligibility Assessment (RESEA) Evidence Building Portfolio Project. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before October 7, 2024.

ADDRESSES: You may submit comments by either one of the following methods:

Email: ChiefEvaluationOffice@dol.gov; *Mail or Courier:* Megan Lizik, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized

and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT:

Megan Lizik by email at ChiefEvaluationOffice@dol.gov or by phone at (202) 430–1255.

SUPPLEMENTARY INFORMATION:

I. Background: DOL funds RESEA programs across all 50 states, DC, Puerto Rico, and the Virgin Islands. States and territories use these funds to address the reemployment services needs of Unemployment Insurance (UI) claimants and to prevent and detect UI improper payments (Unemployment Insurance Program Letter 08–24). The Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123) contains requirements to “establish and expand the use of evidence-based interventions” in states’ RESEA programs. To help meet this requirement and build evidence about RESEA, DOL is funding several studies including the RESEA Component Impact Study, the RESEA Behavioral Impact Study and the RESEA Cost Study. The RESEA Impact Studies will help participating states meet the RESEA evaluation requirement under the BBA while simultaneously building casual evidence on program components that are of interest to states for RESEA program improvement. The RESEA Cost Study will help DOL and

states better understand how costs of implementing RESEA programs vary by program and place.

This **Federal Register** Notice provides the opportunity to comment on several new proposed information collection activities that will be used for the studies across this contract.

1. *Semi-structured program stakeholder interview protocols.* Site visits for the RESEA Impact Study (Component Impact Study) will occur in the Spring of 2025 and Summer of 2026 in approximately six states. Site visits or virtual interviews for the RESEA Impact Study (Behavioral Study) will occur in the Summer of 2025 in approximately two states. These visits will last 3 days each. During these site visits, we will conduct one-on-one or small-group semi-structured interviews with managers and staff at up to three American Job Centers (AJCs) or local Workforce Development Boards (WDBs), as appropriate. We will also observe program activities for both the Component Impact Study and Behavioral Study to help us describe key program components, assess the quality of program delivery, and understand participant needs. The observations will not involve additional burden. Site visits for the RESEA Cost Study will take place in Summer of 2025 in three states, with staff interviews at the central State Workforce Agency and approximately 4 AJCs per state. The combined site visits

will last 5 days in each state. During these site visits, we will conduct one-on-one or small-group semi-structured interviews with staff including approximately 4 program staff at each of the 3 central offices and 6 staff at each of the 4 AJCs per state.

2. *Participant focus group protocols.* During the site visits for both the RESEA Component Impact Study and RESEA Cost Study, we will also conduct focus groups at each site. For the RESEA Component Impact Study, we will conduct one focus group per site with approximately four to six claimants participating in the study. For the RESEA Cost Study, we will conduct 90-minute focus groups at up to 12 AJCs to understand the costs claimants' experience when participating in the RESEA program.

3. *Participant interview protocols.* For the RESEA Behavioral Impact Study, we will conduct 9 participant interviews per State, for a total of 18 interviews.

II. *Desired Focus of Comments:* Currently, the Department of Labor is soliciting comments concerning the above data collection for the Reemployment Services and Eligibility Assessment (RESEA) Evidence Building Portfolio Project. DOL is particularly interested in comments that do the following:

○ evaluate whether the proposed collection of information is necessary for the proper performance functions of

the agency, including whether the information will have practical utility;

○ evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions;

○ enhance the quality, utility, and clarity of the information to be collected; and

○ minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology—for example, permitting electronic submissions of responses.

III. *Current Actions:* At this time, the Department of Labor is requesting clearance for the semi-structured program stakeholder interview protocols, participant interview protocols, and participant focus group protocols.

Type of Review: New information collection request.

OMB Control Number: 1290–0NEW.

Affected Public: State, Local, and Tribal Government; Individuals or Households.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument (form/activity)	Number of respondents	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
RESEA Impact Study: Component					
Semi-structured program manager interview protocol	1 ¹ 18	1	18	1	18
Semi-structured program staff interview protocol	2 ² 54	1	54	1	54
Participant interview protocol	3 ³ 54	1	54	0.5	27
RESEA Impact Study: Behavioral					
Semi-structured program manager interview protocol	4 ² 2	1	2	1	2
Semi-structured program staff interview protocol	5 ⁶ 6	1	6	1	6
Participant interview protocol	6 ⁸ 8	1	8	1	8
RESEA Cost Study					
Semi-structured program stakeholder interview protocol	7 ²⁸	1	28	1.5	42
Participant focus group protocol	8 ³²	1	32	1.5	48
Total					
Total	202		202		205

¹ Assumes 3 site visits × 6 states, each including approximately 3, 1-hr semi-structured manager interviews for a total of 54 program managers and 54 hours over the three-year clearance period; an average of 18 respondents and 18 hours per year.

² Assumes 3 site visits × 6 states, each including approximately 9, 1-hr semi-structured staff interviews for a total of 162 program staff members and 162 hours over the three-year clearance period; an average of 54 respondents and 54 hours per year.

³ Assumes 3 site visits × 6 states, each including approximately 9, 0.5-hr semi-structured participant interviews for a total of 162 program participants and 81 hours over the three-year clearance period; an average of 54 respondents and 27 hours per year.

⁴ Assumes 1 site visits × 2 states, each including approximately 3, 1-hr semi-structured management interviews for a total of 6 program managers and 6 hours over the three-year clearance period; an average of 2 respondents and 2 hours per year.

⁵ Assumes 1 site visits × 2 states, each including approximately 9, 1-hr semi-structured staff interviews for a total of 18 program staff members and 18 hours over the three-year clearance period; an average of 6 respondents and 6 hours per year.

⁶ Assumes 1 site visits × 2 states, each including approximately 12, 1-hr semi-structured participant interviews for a total of 24 program participants and 24 hours over the three-year clearance period; an average of 8 respondents and 8 hours per year.

⁷ Assumes 1 site visit × 3 states, each including 28, 1.5-hr staff interviews for a total of 84 respondents and 126 hours over the three-year clearance period; an average of 28 respondents and 42 hours per year.

⁸ Assume 1 site visit × 3 states, each including 4, 1.5-hr focus groups with approximately 8 program participants in each group for a total of 96 participants and 144 hours over the three-year clearance period; an average of 32 participants and 48 hours per year.

Upeksha Savi Swick,

*Director of Research, Chief Evaluation Office,
U.S. Department of Labor.*

[FR Doc. 2024–17585 Filed 8–7–24; 8:45 am]

BILLING CODE 4510–HX–P

**MORRIS K. UDALL AND STEWART L.
UDALL FOUNDATION**

Sunshine Act Meetings

TIME AND DATE: 1:00 p.m. to 1:15 p.m.
(MST–AZ), Monday, August 19, 2024.

PLACE: Virtual Special Board of Trustees
Meeting via Microsoft Teams.

STATUS: This virtual special meeting of
the Board of Trustees will be open to the
public. Members of the public who
would like to observe this meeting may
request remote access by contacting Sara
Moeller at moeller@udall.gov prior to
August 19, 2024, to obtain the
teleconference connection information.

MATTERS TO BE CONSIDERED: (1) Call to
Order and Chair's Remarks and (2)
Program Eligibility.

CONTACT PERSON FOR MORE INFORMATION:
Sara Moeller, Administrative Officer,
434 E University Blvd., Suite 300,
Tucson, AZ 85705, (520) 901–8568.

Dated: August 6, 2024.

David P. Brown

*Executive Director, Morris K. Udall and
Stewart L. Udall Foundation.*

[FR Doc. 2024–17796 Filed 8–6–24; 4:15 pm]

BILLING CODE 6820–FN–P

**NEIGHBORHOOD REINVESTMENT
CORPORATION**

Sunshine Act Meetings

TIME AND DATE: 3:00 p.m., Tuesday,
August 13, 2024.

PLACE: via ZOOM.

STATUS: Parts of this meeting will be
open to the public. The rest of the
meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Audit
Committee of the Board of Directors
meeting.

The General Counsel of the
Corporation has certified that in her
opinion, one or more of the exemptions
set forth in the Government in the

Sunshine Act, 5 U.S.C. 552b(c)(2)
permit closure of the following
portion(s) of this meeting:

- Executive (Closed) Session

Agenda

- I. Call to Order
- II. Sunshine Act Approval of Executive
(Closed) Session
- III. Executive Session: GAO Workplan
Update
- IV. Executive Session: Ethics Officer
Report
- V. Executive Session: Chief Audit
Executive Report
- VI. Discussion Item: Internal Audit
Status Report
 - a. Internal Audit Performance
Scorecard
 - b. Implementation of Internal Audit
Recommendations
 - c. Internal Audit FY24 Project Status
 - d. Quality Assurance Improvement
Program
- VII. Management Reports
 - a. Network Watchlist Report

Portions Open to the Public:
Everything except the Executive
(Closed) Session.

Portions Closed to the Public:
Executive (Closed) Session.

CONTACT PERSON FOR MORE INFORMATION:
Jenna Sylvester, Paralegal, (202) 568–
2560; jsylvester@nw.org.

Jenna Sylvester,
Paralegal.

[FR Doc. 2024–17667 Filed 8–6–24; 11:15 am]

BILLING CODE 7570–01–P

**NEIGHBORHOOD REINVESTMENT
CORPORATION**

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m., Thursday,
August 15, 2024.

PLACE: via ZOOM.

STATUS: Parts of this meeting will be
open to the public. The rest of the
meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Regular
Board of Directors meeting.

The General Counsel of the
Corporation has certified that in her
opinion, one or more of the exemptions
set forth in the Government in the
Sunshine Act, 5 U.S.C. 552b(c)(2)

permit closure of the following
portion(s) of this meeting:

- Executive (Closed) Session

Agenda

- I. Call to Order
- II. Sunshine Act Approval of Executive
(Closed) Session
- III. Executive Session: Special Topic
- IV. Executive Session: CEO Report
- V. Executive Session: CFO Report
- VI. Executive Session: General Counsel
Report
- VII. Executive Session: CIO Report
- VIII. Action Item: Approval of Meeting
Minutes from June 24, 2024 Regular
Board of Directors Meeting and June
28, 2024 Special Audit Committee
Meeting
- IX. Action Item: Approval of Revised
Whistleblower Policy
- X. Action Item: Approval of Revised
Code of Ethical Conduct
- XI. Action Item: FY2025 Preliminary
Spend Plan
- XII. Discussion Item: Audit Committee
Report—June 28, 2024 Special
Meeting; August 13, 2024 Regular
Meeting
- XIII. Management Reports
 - a. 2024 Board Calendar
 - b. 2024 Board Agenda Planner
 - c. CFO Report
 - i. Financials Through May 31, 2024
 - ii. Single Voice Approvals \$100K and
Over
 - iii. Vendor Payments \$350K and Over
 - d. Exceptions
 - e. Programs Dashboard
 - f. Housing Stability Counseling
Program (HSCP)
 - g. Strategic Plan Scorecard—FY2024
Q2 (With Q2 Production)

Portions Open to the Public:
Everything except the Executive
(Closed) Session.

Portions Closed to the Public:
Executive (Closed) Session.

CONTACT PERSON FOR MORE INFORMATION:
Jenna Sylvester, Paralegal, (202) 568–
2560; jsylvester@nw.org.

Jenna Sylvester,
Paralegal.

[FR Doc. 2024–17785 Filed 8–6–24; 4:15 pm]

BILLING CODE 7570–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-0320; NRC-2024-0099]

TMI-2SOLUTIONS, LLC; Three Mile Island Nuclear Station, Unit No. 2; Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a final environmental assessment (EA) and finding of no significant impact (FONSI) for a proposed amendment of NRC Possession Only License (POL) DPR-73 for the Three Mile Island Nuclear Station, Unit No. 2 (TMI-2), located in Londonderry Township, Dauphin County, Pennsylvania. The proposed amendment would ensure that TMI-2 Energy Solutions (TMI-2Solutions, the licensee) can continue decommissioning the facility in accordance with NRC regulations. TMI-2Solutions will be engaging in certain major decommissioning activities, including the physical demolition of buildings previously deemed eligible for the National Register of Historic Places (NRHP). The EA, "Environmental Assessment for Specific Decommissioning Activities at Three Mile Island, Unit 2 in Dauphin County, Pennsylvania," documents the NRC staff's environmental review of the license amendment application.

DATES: The EA and FONSI referenced in this document are available on August 8, 2024.

ADDRESSES: Please refer to Docket ID NRC-2024-0099 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0099. Address questions about Docket IDs to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For

problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- **Project Website:** Information related to the TMI-2 project can be accessed on NRC's TMI-2 public website at <https://www.nrc.gov/info-finder/decommissioning/power-reactor/three-mile-island-unit-2.html>.

FOR FURTHER INFORMATION CONTACT: Jean Trefethen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0867; email: Jean.Trefethen@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Three Mile Island Nuclear Station (TMINS) is approximately 16 kilometers (10 miles) southeast of Harrisburg, Pennsylvania. The TMINS site includes Three Mile Island Nuclear Station, Unit 1 and TMI-2. It encompasses approximately 178 hectares (440 acres), including the adjacent islands on the north end, a strip of land on the mainland along the eastern shore of the river, and an area on the eastern shore of Shelley Island. The TMINS site has significance in U.S. history because it is the site of the nation's most serious commercial nuclear power plant accident, occurring at TMI-2. On March 28, 1979, TMI-2 experienced an accident initiated by interruption of secondary feedwater flow which led to a core heat up that caused fuel damage. The partial meltdown of the reactor core led to a very small offsite release of radioactivity. In response to this accident many changes occurred at nuclear power plants including emergency response planning, reactor operator training, human factors engineering, radiation protection and heightened NRC regulatory oversight.

II. Discussion

By letter dated February 22, 2023 (ADAMS Accession No. ML23058A064), TMI-2Solutions requested an

amendment to POL No. DPR-73. TMI-2Solutions will be engaging in certain major decommissioning activities, including the physical demolition of buildings previously deemed eligible for the NRHP. Because the impacts on the historic properties from these decommissioning activities have not been previously evaluated and are not bounded by the impact's discussion in NUREG-0586, "Final Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities," TMI-2Solutions requested an amendment that would require evaluation of the impacts of the decommissioning activities on the NRHP-eligible properties, in compliance with paragraph 50.82(a)(6)(ii) of title 10 of the *Code of Federal Regulations* (10 CFR).

Pursuant to 36 CFR 800.8, the NRC used its National Environmental Policy Act process for developing the EA to facilitate consultation pursuant to section 106 of the National Historic Preservation Act (NHPA).

Adverse effects to historic properties would result from decommissioning activities at TMI-2. Therefore, the NRC and consulting parties proceeded with development of a programmatic agreement (PA) to resolve adverse effects. The draft PA was issued for public comment through a **Federal Register** notice dated March 6, 2024 (89 FR 16037). One comment was received and considered before finalizing the PA. The PA addresses the potential direct and indirect adverse effects from the decommissioning activities and ensures that appropriate mitigation measures are implemented. The NRC's EA references the final PA and, therefore, conclude NHPA section 106 consultation.

In accordance with NRC's regulations in 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," that implement the National Environment Protection Agency (NEPA), the NRC staff has prepared an EA documenting its environmental review of the license amendment application. Based on the environmental review, the NRC has made a determination that the proposed action will not significantly affect the quality of the human environment and that a FONSI is therefore appropriate.

III. Summary of Environmental Assessment

The EA is publicly available in ADAMS under Accession No. ML24197A005. A summary description of the proposed action and expected environmental impacts is provided as follows.

Description of the Proposed Action

The proposed action is to amend POL No. DPR-73 so that TMI-2 *Solutions* can continue with certain major decommissioning activities planned under Phase 2 of its decommissioning schedule. Phase 2 decommissioning activities include the removal of any radioactive components in preparation for demolition of structures, decommissioning and dismantlement of the TMI-2 site to a level that permits the release of the site, except for an area potentially to be set aside for storage of fuel-bearing material (small quantities of spent nuclear fuel, damaged core material, and high-level waste) on the independent spent fuel storage installation, backfilling of the site, license termination plan submittal and implementation, and site restoration activities. In order to comply with 10 CFR 50.82(a)(6)(ii), TMI-2 *Solutions* requested that NRC evaluate the impacts of certain major decommissioning activities on historic and cultural resources and NRHP-eligible properties. The definition of major decommissioning activity is in 10 CFR 50.2, which states “major decommissioning activity means, for a nuclear power reactor facility, any activity that results in permanent removal of major radioactive components, permanently modifies the structure of the containment, or results in dismantling components for shipment containing greater than class C waste in accordance with § 61.55 of this chapter.” Due to radioactive contamination, the TMI-2 structures must be demolished and removed during decommissioning.

Environmental Impacts of the Proposed Action

In the EA, the staff assessed the potential environmental impacts from the proposed license amendment to the following resource areas: land use; visual and scenic resources; the geologic environment; surface and groundwater resources; ecological resources; air quality; noise; historic and cultural resources; socioeconomic conditions; environmental justice; public and occupational health; transportation; and waste generation and management. The NRC staff also considered the cumulative impacts from past, present, and reasonably foreseeable actions when combined with the proposed action. The TMI-2 Historic District would be adversely affected by the TMI-2 decommissioning, and adverse effects cannot be avoided. The mitigation of adverse effects to the TMI-2 Historic District will be completed in

accordance with the TMI-2 Demolition and Decommissioning Programmatic Agreement (NRC 2024a).

As part of the NRC’s consultation under section 7 of the Endangered Species Act, NRC staff determined that the proposed action may affect but is not likely to adversely affect the Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), tricolored bat (*Perimyotis subflavus*), monarch butterfly (*Danaus plexippus*), northeastern bulrush (*Scirpus ancistrochaetus*), or green floater (*Lasmigona subviridis*). The NRC staff transmitted a letter to the U.S. Fish and Wildlife Service (FWS) for its review and concurrence on May 24, 2024 (ADAMS Accession No. ML24120A324). The FWS concurred with the NRC’s findings on July 15, 2024 (ADAMS Accession No. ML24199A062).

All other potential impacts from the proposed action were determined to be not significant, as described in the EA. The NRC staff found that there would be no significant negative cumulative impact to any resource area from the proposed action when added to other past, present, and reasonably foreseeable actions.

Environmental Impacts of the Alternative to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.*, the “no-action” alternative). Under the no-action alternative, the NRC would deny the licensee’s request to allow for the continuation of major decommissioning activities under Phase 2. In this case, the NRC staff would not review the historic and cultural resource impacts of the major decommissioning activities as defined in 10 CFR 50.2 and would therefore disallow the removal of NRHP-eligible structures and any impacts to historic and cultural resources. However, due to the presence of radioactive contamination, TMI-2 structures, including the NRHP-eligible structures, must be removed during the decommissioning process. Therefore, the NRC staff concludes that denying the amendment request is not a reasonable alternative.

IV. Finding of No Significant Impact

In accordance with the NEPA and 10 CFR part 51, the NRC staff has conducted an environmental review of a request for an amendment to POL No. DPR-73. The proposed amendment would revise the POL to allow the licensee to conduct decommissioning at TMI-2 covering activities that were not previously addressed in the staff’s environmental assessments (site-specific

historical and cultural resources). Based on its environmental review of the proposed action, the NRC staff has made a finding of no significant impact in the EA. Therefore, the NRC staff has determined, pursuant to 10 CFR 51.31, that preparation of an environmental impact statement is not required for the proposed action and a FONSI is appropriate.

Dated: August 2, 2024.

For the Nuclear Regulatory Commission.

Christopher M. Regan,

Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024-17521 Filed 8-7-24; 8:45 am]

BILLING CODE 7590-01-P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Qualified Domestic Relations Orders Submitted to PBGC

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval, with modifications.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget extend its approval (with modifications), under the Paperwork Reduction Act of 1995, of the information collection related to PBGC’s booklet, Qualified Domestic Relations Orders & PBGC. This notice informs the public of PBGC’s intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before October 7, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* paperwork.comments@pbgc.gov. Refer to OMB control number 1212-0054 in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20245-2101.

Commenters are strongly encouraged to submit public comments electronically. Commenters who submit comments on paper by mail should allow sufficient time for mailed

comments to be received before the close of the comment period.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212-0054. All comments received will be posted without change to PBGC's website www.pbgc.gov, including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

Copies of the collection of information may be obtained without charge by writing to the Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101, or calling 202-229-4040 during business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT:

Karen Levin (levin.karen@pbgc.gov), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024-2101; 202-229-3559. If you are deaf or hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: A defined benefit pension plan that does not have enough money to pay benefits may be terminated if the employer responsible for the plan faces severe financial difficulty, such as bankruptcy, and is unable to maintain the plan. In such an event, PBGC becomes trustee of the plan and pays benefits, subject to legal limits, to plan participants and beneficiaries.

The benefits of a pension plan participant generally may not be assigned or alienated. Title I of ERISA provides an exception for domestic relations orders (DRO) that relate to child support, alimony payments, or marital property rights of an alternate payee (a spouse, former spouse, child, or other dependent of a plan participant). The exception applies only if the DRO meets specific legal requirements that make it a qualified domestic relations order (QDRO).

When PBGC is trustee of a plan, it reviews submitted domestic relations orders to determine whether the order is qualified before paying benefits to an alternate payee. The requirements for submitting a domestic relations order and the contents of such orders are established by statute. The models and the guidance provided by PBGC assist parties by making it easier for them to comply with ERISA's QDRO

requirements in plans trustee by PBGC; they do not create any additional requirements and result in a reduction of the statutory burden.

The Office of Management and Budget (OMB) has approved the collection of information in PBGC's booklet, *Qualified Domestic Relations Orders & PBGC* under control number 1212-0054 through January 31, 2025. PBGC intends to request that OMB extend approval of the collection of information with modifications for 3 years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC is adding one term and is making clarifying changes to other terms in the Glossary. PBGC is making other editorial and clarifying changes to the QDRO booklet.

PBGC estimates that it will receive approximately 253 DROs each year. PBGC further estimates that the total average annual burden of this collection of information will be approximately 190 hours and \$177,100.

PBGC is soliciting public comments to—

- evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2024-17609 Filed 8-7-24; 8:45 am]

BILLING CODE 7709-02-P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2024-15; MC2024-471 and CP2024-478; MC2024-472 and CP2024-479; MC2024-475 and CP2024-482; MC2024-476 and CP2024-483]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 12, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of

the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s)*: CP2024–15; *Filing Title*: USPS Notice of Amendment to Priority Mail, USPS Ground Advantage, Parcel Select & Parcel Return Service Contract 1 Filed Under Seal; *Filing Acceptance Date*: August 2, 2024; *Filing Authority*: 39 CFR 3035.105; *Public Representative*: Alain Brou; *Comments Due*: August 12, 2024.

2. *Docket No(s)*: MC2024–471 and CP2024–478; *Filing Title*: USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 42 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: August 2, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Katalin K. Clendenin; *Comments Due*: August 12, 2024.

3. *Docket No(s)*: MC2024–472 and CP2024–479; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 193 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: August 2, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Christopher C. Mohr; *Comments Due*: August 12, 2024.

4. *Docket No(s)*: MC2024–475 and CP2024–482; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 295 to Competitive Product List and Notice of Filing

Materials Under Seal; *Filing Acceptance Date*: August 2, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Christopher C. Mohr; *Comments Due*: August 12, 2024.

5. *Docket No(s)*: MC2024–476 and CP2024–483; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 196 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: August 2, 2024; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Alain Brou; *Comments Due*: August 12, 2024.

This Notice will be published in the **Federal Register**.

Kimberly R. Banks,

Secondary Certifying Official.

[FR Doc. 2024–17600 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice*: August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 31, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 190 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–465, CP2024–472.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–17530 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice*: August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 191 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–469, CP2024–476.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–17531 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice*: August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 186 to Competitive Product List*. Documents

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

are available at www.prc.gov, Docket Nos. MC2024–461, CP2024–468.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17526 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 184 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–458, CP2024–465.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17524 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 5, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 197 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–477, CP2024–484.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17542 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 192 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–470, CP2024–477.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17532 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a

domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:
Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 185 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–460, CP2024–467.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17525 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:
Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 31, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 294 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–467, CP2024–474.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17537 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE**Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 2, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 195 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-474, CP2024-481.

Sean C. Robinson,*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2024-17535 Filed 8-7-24; 8:45 am]

BILLING CODE 7710-12-P**POSTAL SERVICE****Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 31, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 293 to Competitive Product List*. Documents

are available at www.prc.gov, Docket Nos. MC2024-466, CP2024-473.

Sean Robinson,*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2024-17536 Filed 8-7-24; 8:45 am]

BILLING CODE 7710-12-P**POSTAL SERVICE****Product Change—Parcel Select Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Parcel Select Contract 60 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-468, CP2024-475.

Sean Robinson,*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2024-17522 Filed 8-7-24; 8:45 am]

BILLING CODE 7710-12-P**POSTAL SERVICE****Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 2, 2024,

it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 196 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-476, CP2024-483.

Sean C. Robinson,*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2024-17541 Filed 8-7-24; 8:45 am]

BILLING CODE 7710-12-P**POSTAL SERVICE****Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT:

Sean C. Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 31, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 189 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-464, CP2024-471.

Sean C. Robinson,*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2024-17529 Filed 8-7-24; 8:45 am]

BILLING CODE 7710-12-P**POSTAL SERVICE****Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement****AGENCY:** Postal Service™.**ACTION:** Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 29, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 183 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–457, CP2024–464.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17523 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 2, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 194 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–473, CP2024–480.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17534 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 188 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–463, CP2024–470.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17528 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 30, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 187 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–462, CP2024–469.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17527 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 2, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 294 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–475, CP2024–482.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2024–17540 Filed 8–7–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 8, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 2, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 193 to Competitive Product List*. Documents

are available at www.prc.gov, Docket Nos. MC2024–472, CP2024–479.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–17533 Filed 8–7–24; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100646; File No. SR–Phlx–2024–36]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 19, 2024, Nasdaq PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/phlx/rules>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, section 1, to \$151.50 per hour.

General 8, section 1 includes the Exchange’s fees that relate to co-location services, including “Remote Hands Services.” The term “Remote Hands Services” refers to the use of Exchange engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to the Exchange of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange’s Remote Hands Services fee is the same as that which the Exchange expressed when it increased the fee by 5.5% earlier this year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR–Phlx–2024–08). On April 29, 2024, the Exchange withdrew that filing and submitted SR–Phlx–2024–019. On June 27, 2024, the Exchange withdrew and replaced that filing with SR–Phlx–2024–27.

to SR–Phlx–2024–27, the Exchange had not increased its Remote Hands fee since 2010.⁴ However, since 2010, there has been notable inflation. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index (“PPI”) for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings (“AHE”) growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

⁴ See Securities Exchange Act Release No. 34–62395 (June 28, 2010), 75 FR 38584 (July 2, 2010) (SR–Phlx–2010–18).

⁵ See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

⁷ See <https://www.bls.gov/web/empsit/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/ceseeb8a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,¹⁰ in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service, as fees for the service in question has been static in nominal terms, and

therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR-Phlx-2024-27, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2010. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.¹² Moreover, a more specific and pertinent gauge of inflation—the PPI for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.¹³ An even more specific gauge of inflation—AHE growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as

it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBXX-2024-021).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

¹² See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

¹⁴ See <https://www.bls.gov/web/empsit/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/ceseeb8a.htm> (Last updated July 5, 2024).

things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.¹⁵ No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁶ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. "If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior."¹⁷ Accordingly, "the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonable or unfairly discriminatory."¹⁸ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms

and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-Phlx-2024-36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-Phlx-2024-36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number

¹⁵ See Choe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at https://www.cboe.com/us/equities/market_statistics/.

¹⁶ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁷ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR-NYSEArca-2006-21).

¹⁸ *Id.*

¹⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

SR-Phlx-2024-36 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17508 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100643; File No. SR-NYSE-2024-42]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

August 2, 2024.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b-4 thereunder, ³ notice is hereby given that on July 26, 2024, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to (1) revise the requirements for market at-the-close (“MOC”) and limit at the close (“LOC”) orders on MOC/LOC Tier 1 and Tier 2; (2) modify the requirements and charges for D Orders at the close based on time of entry or last modification; and (3) introduce incremental per share credits for orders entered and executed by a Floor broker that add liquidity to the Exchange and for D Orders at the close. The Exchange proposes to implement the fee changes effective July 26, 2024. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to (1) revise the requirements for MOC and LOC orders on MOC/LOC Tier 1 and Tier 2; (2) modify the requirements and charges for D Orders at the close based on time of entry or last modification; and (3) introduce incremental per share credits for orders entered and executed by a Floor broker that add liquidity to the Exchange and for D Orders at the close.

The proposed change responds to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders and closing price orders by revising the requirements and offering additional incentives for member organizations to send liquidity to the Exchange, especially during the Closing Auction. The purpose of the proposed rule change is also to encourage efficient usage of Exchange systems by member organizations by continuing to encourage all member organizations to enter or modify D Orders as early as possible, which the Exchange believes is in the best interests of all member organizations and investors who access the Exchange.

The Exchange proposes to implement the fee changes effective July 26, 2024.⁴

Background

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices,

products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”⁵

While Regulation NMS has enhanced competition, it has also fostered a “fragmented” market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that “such competition can lead to the fragmentation of order flow in that stock.”⁶ Indeed, cash equity trading is currently dispersed across 16 exchanges,⁷ numerous alternative trading systems,⁸ and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 20% market share.⁹ Therefore, no exchange possesses significant pricing power in the execution of cash equity order flow. More specifically, the Exchange’s share of executed volume of equity trades in Tapes A, B and C securities is less than 12%.¹⁰ It should also be noted that, in the currently highly competitive national market system, numerous exchanges and other order execution venues compete for order flow at the close, and competition for closing orders is robust.¹¹

⁵ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7-10-04) (Final Rule) (“Regulation NMS”).

⁶ See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7-02-10) (Concept Release on Equity Market Structure).

⁷ See Cboe U.S. Equities Market Volume Summary, available at https://markets.cboe.com/us/equities/market_share. See generally <https://www.sec.gov/fast-answers/divisionsmarketregmrexchangeshtml>.

⁸ See FINRA ATS Transparency Data, available at <https://otctransparency.finra.org/otctransparency/AtsIssueData>. A list of alternative trading systems registered with the Commission is available at <https://www.sec.gov/foia/docs/atslist.htm>.

⁹ See Cboe Global Markets U.S. Equities Market Volume Summary, available at https://markets.cboe.com/us/equities/market_share/.

¹⁰ See *id.*

¹¹ There are at least seven broker-dealer sponsored products competing for volume at the close, including Credit Suisse’s CLOSEX; Instinet’s Market-on-Close Cross; Morgan Stanley’s Market-on-Close Aggregator (MOCHA); Bank of America’s Instinct X® and Global Conditional Cross; JP Morgan’s JPB-X; Piper Sandler’s On-Close Match Book; and Goldman Sachs’ One Delta Close Facility (ODCF). Moreover, the percentage of volume at the NYSE closing price in NYSE-listed securities

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ The Exchange originally filed to amend the Price List on June 3, 2024 (SR-NYSE-2024-34). SR-NYSE-2024-34 was withdrawn on July 26, 2024 and replaced by this filing.

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm's reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which the firm routes order flow. Accordingly, competitive forces compel the Exchange to use exchange transaction fees and credits because market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

In response to this competitive environment, the Exchange has established incentives for member organizations who submit orders on the Exchange. The proposed fee change is designed to provide incentives to member organizations to submit additional such liquidity to the Exchange, including during closing auctions.

Proposed Rule Change

MOC/LOC Tiers 1 and 2

Currently, for MOC/LOC Tier 1, the Exchange charges \$0.0007 per share for MOC orders and \$0.0007 per share for LOC orders from any member organization in the prior three billing months executing (1) an average daily trading volume ("ADV") of MOC activity on the NYSE of at least 0.45% of NYSE consolidated ADV ("CADV"),¹² (2) an ADV of total close activity (MOC/LOC and executions at the close) on the NYSE of at least 0.7% of NYSE CADV, and (3) whose MOC activity comprised at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close). Similarly, for MOC/LOC Tier 2, the Exchange charges \$0.0008 per share for MOC orders and \$0.0008 per share for LOC orders from any member organization in the prior three billing months executing (1) an ADV of MOC

activity on the NYSE of at least 0.35% of NYSE CADV,¹³ (2) an ADV of total close activity (MOC/LOC and executions at the close) on the NYSE of at least 0.525% of NYSE CADV, and (3) whose MOC activity comprised at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close).

The Exchange proposes to eliminate the third requirement from both tiers.

As proposed for MOC/LOC Tier 1, the Exchange would charge \$0.0007 per share for MOC orders and \$0.0007 per share for LOC orders from any member organization in the prior three billing months executing an (1) ADV of MOC activity on the NYSE of at least 0.45% of NYSE CADV, and (2) ADV of total close activity (MOC/LOC and executions at the close) on the NYSE of at least 0.7% of NYSE CADV. The current rates would remain the same.

As proposed for MOC/LOC Tier 2, the Exchange would charge \$0.0008 per share for MOC orders and \$0.0008 per share for LOC orders from any member organization in the prior three billing months executing an (1) an ADV of MOC activity on the NYSE of at least 0.35% of NYSE CADV, and (2) an ADV of total close activity (MOC/LOC and executions at the close) on the NYSE of at least 0.525% of NYSE CADV. The current rates would also remain the same.

The proposed change responds to the current competitive environment where order flow providers have a choice of where to direct orders in NYSE-listed securities, including at the close, by modifying requirements in order to facilitate member organizations qualifying for a MOC/LOC tier and encourage additional liquidity to the Exchange. Higher volumes of MOC and LOC orders contribute to the quality of the Exchange's closing auction and provide market participants whose orders are executed at the close with a greater opportunity for execution, which benefits all market participants.

D Orders

Currently, the Exchange does not charge member organizations for the first 750,000 ADV of the aggregate of executions at the close for D Orders, Floor broker executions swept into the close, and executions at the close, excluding MOC Orders, LOC Orders and Closing Offset ("CO") Orders. Further, the Exchange currently charges certain fees differentiated by time of entry (or

last modification) for D Orders at the close after the first 750,000 ADV of aggregate of executions at the close by a member organization.

The Exchange proposes to no longer exclude the first 750,000 ADV of the aggregate of executions at the close by member organizations for D Orders, Floor broker executions swept into the close, and executions at the close, excluding MOC Orders, LOC Orders and CO Orders. As discussed below, the Exchange would waive fees for member organizations with an ADV of at least 10,000 shares entered and executed by its Floor broker up to specific monthly ADV levels based on time of entry (or last modification) in an effort to encourage additional liquidity on the trading floor of a national securities exchange.

The Exchange also proposes to modify the time of entry (or last modification) for D Order fee determination in order to encourage member organizations to enter D Orders earlier in the trading day, thereby increasing transparency in the Closing Auction and reducing member organization's operational risk. Consistent with this purpose, the current rates for D Orders would not change with the exception of D Orders entered in the final minute of trading, which the Exchange proposes to label as "Late D Orders."

The Exchange would modify the current requirements and charges for D Orders as follows:

- The Exchange currently charges \$0.0003 per share for executed D Orders last modified¹⁴ by the member organization earlier than 25 minutes before the scheduled close of trading. The Exchange proposes to charge the current rate to D Orders last modified earlier than 10 minutes before the scheduled close of trading. The Exchange would define these orders as "Early D Orders."

- The Exchange currently charges \$0.0007 per share for executed D Orders last modified by the member organization from 25 minutes up to but not including 3 minutes before the scheduled close of trading. The Exchange proposes to charge the current rate to D Orders last modified from 10 minutes up to but not including 1 minute before the scheduled close of trading. The Exchange would define these orders as "Mid D Orders."

- For D Orders last modified in the last 3 minutes before the scheduled

executed off-exchange has been steadily increasing since before the pandemic. In 2018, the percentage of volume at the NYSE closing price in NYSE-listed securities executed off-exchange was 21.3%. In 2019, the percentage increased to 23.5%. After dipping briefly to 22.1% in 2020, the percentage resumed its upward trend and increased to 25.2% in 2021. The percentage was 24.1% and 23.8% in 2022 and 2023, respectively, and has increased again in 2024 to 26.1% through May 31.

¹² ADV and CADV are defined in footnote * of the Price List. The Exchange would delete "[Tape A]" between NYSE and CADV in one place in the tier as redundant. The Exchange would also add "and an" between the remaining requirements to qualify for the tier.

¹³ The Exchange would similarly delete "[Tape A]" between NYSE and CADV in two places in the tier as redundant and add "and an" between the remaining requirements to qualify for this tier as proposed for Tier 1.

¹⁴ As set forth in footnote 10 to the Price List, as used in the Price List, the phrase "last modified" means the later of the order's entry time or the final modification or cancellation time for any D Order designated for the close with the same broker badge, entering firm mnemonic, symbol, and side.

close of trading, the Exchange charges three different fees. The Exchange proposes to charge these fees, as modified, for D Orders last modified by the member organization in the last 1 minute before the scheduled close of trading, which the Exchange would define as "Late D Orders."

- The Exchange currently charges \$0.0008 per share for executed D Orders last modified in the last 3 minutes before the scheduled close of trading for member organizations in MOC/LOC Tiers 1 and 2, both with Adding ADV of at least 0.50% of Tape A CADV or MOC/LOC Tiers 1, 2 or 3 with Adding ADV of at least 1.05% of Tape A CADV. The Exchange would eliminate the limitation to member organizations in MOC/LOC Tiers 1 and 2 and would charge \$0.0011 per share for executed D Orders last modified in the last 1 minute before the scheduled close of trading for member organizations with Adding ADV of at least 0.50% of Tape A CADV (unchanged from the current requirement) and total close activity of at least 1.75% of Tape A CADV.

- The Exchange currently charges \$0.0009 per share for executed D Orders last modified in the last 3 minutes before the scheduled close of trading for member organizations in MOC/LOC Tiers 1, 2 and 3 with Adding ADV of at least 0.65% of Tape A CADV. The Exchange would eliminate this fee.

- The Exchange currently charges \$0.0010 per share for executed D Orders last modified in the last 3 minutes before the scheduled close of trading for all other member organizations. The Exchange proposes to charge all other member organizations \$0.0012 per share for executed D Orders last modified one minute before the scheduled close of trading.

- For member organizations with an ADV of at least 10,000 shares entered and executed by its Floor broker, the Exchange proposes that Early, Mid- and Late D Orders up to specific monthly ADV levels would be free.¹⁵ Qualifying member organizations would be charged the previously described rates for all volume for each D Order type above the proposed thresholds.

As proposed, qualifying member organizations would not be charged for the first 500,000 shares of Early D Orders, with the above rates for Early D Orders applicable to all volume above that threshold.

For Mid D Orders, qualifying member organizations would not be charged for

the first 750,000 shares, with the above rates for Mid D Orders applicable to all volume above that threshold.

Finally, for Late D Orders, qualifying member organizations would not be charged for the first 250,000 shares, with the above rates for Late D Orders applicable to all volume above that threshold.

- Orders from continuous trading swept into the close would continue to be charged the current rate of \$0.0008.

The purpose of these changes is to continue to encourage additional liquidity on the Exchange. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. Since the proposal not to charge Early, Mid- and Late D Orders up to specific monthly ADV levels for member organizations with a minimum ADV entered and executed by its Floor broker would be new, the Exchange does not know how many member organizations could qualify based on their current trading profile and if they choose to direct order flow to the Exchange. Based on the profile of member organizations and their liquidity provision, the Exchange believes that additional member organizations could qualify for the discounts if they choose to direct order flow to the Exchange. However, without having a view of member organization's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization directing orders to the Exchange in order to qualify for the discounts.

The Exchange believes that it is reasonable to not charge member organizations for Early, Mid- and Late D Orders up to specific monthly ADV levels if the member organization has an ADV of at least 10,000 shares executed by its Floor broker. The Exchange notes that other marketplaces offer various incentives to only certain members based on ADV and/or heightened quoting requirements. For instance, marketplaces offer incremental credits to members that are lead market makers ("LMM") registered in a minimum number of securities and that add a specified percentage of displayed liquidity¹⁶ as well as discounted remove fees for market makers meeting certain heightened quoting requirements that also meet specific trading

obligations.¹⁷ Moreover, the proposed ADV of at least 10,000 shares executed by its Floor broker requirement is low relative to these other markets' requirements for market maker-only incentives.¹⁸ The Exchange further believes that eligibility for the proposed fee waiver for member organizations that have a Floor broker plus an adding volume requirement is not unfairly discriminatory because member organizations that do not operate a Floor brokerage business can still qualify for the fee waiver by choosing to add a Floor broker on the Exchange. Indeed, to the extent that member organizations add Floor brokers to qualify for the proposed fee waiver for D Orders, the proposal would have the added benefit of potentially attracting new Floor brokers to the Exchange.

Incremental Floor Broker Credits

As part of what the Exchange proposes to call the "Floor Broker Incentive and Rebate Program," the Exchange proposes an incremental per share credit for orders executed by a Floor broker in addition to the preceding fees and credits specified in the Price List. Specifically, the Exchange proposes that orders executed by a member organization's Floor broker would receive an additional \$0.0002 per share for orders that add liquidity to the Exchange, other than MPL and Non-Displayed Limit Orders, and/or (2) an additional \$0.000025 per share for the proposed Early, Mid- and Late D Orders where the member organization has (1) an ADV of at least 10,000 shares entered and executed by its Floor broker, and (2) an ADV comprised of at least 50% Floor broker ADV of the member organization's total ADV, excluding routing.

For example, assume that Member Organization A enters and executes 2 million shares that add liquidity on the trading Floor through its Floor broker. Further assume that a second member

¹⁷ Nasdaq offers discounted remove fees in Tape A and Tape B securities for market makers meeting the requirements to qualify as Qualified Market Makers (QMMs) in addition to QMM rebate incentives if they execute shares of liquidity representing 1.00% or more of Consolidated Volume during the month for shares executed (in securities priced at or greater than \$1). See Nasdaq Price List, available at <https://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2#~:text=Qualified%20Market%20Makers,certain%20quoting%20requirements%20each%20month.>

¹⁸ For instance, Nasdaq's discounted remove fees in Tape A and Tape B securities for QMMs in addition to QMM rebate incentives are available if they execute shares of liquidity representing 1.00% or more of Consolidated Volume during the month for shares executed (in securities priced at or greater than \$1), which is a much higher bar than the proposed ADV requirement for Floor brokers. See generally *id.*

¹⁵ For the avoidance of doubt, the member organization eligible for the proposed fee waiver for D Orders up to the specific monthly ADV levels would be the same legal entity as the member organization operating the Floor broker.

¹⁶ Cboe BZX offers a higher tiered rebate based on a lower adding requirement if the member is enrolled in a minimum number of LMM securities. See Cboe BZX Equities Fee Schedule, available at https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.

organization, Member Organization B, enters 10 million shares that add liquidity and routes it flow to Member Organization A for execution on the trading Floor through Member Organization A's Floor broker. Both member organizations receive the current rate for adding liquidity on the trading Floor of at least \$0.0019 per share for their shares entered as the entering firm, unless a better current tiered rate applies. Under the proposed pricing, Member Organization A would also receive an additional credit of \$0.0002 for executing the 10 million shares for adding liquidity on the trading Floor on behalf of Member Organization B.

The purpose of the proposed incremental Floor broker credits is to continue to encourage member organizations to send orders to trading Floor for execution, thereby contributing to robust levels of liquidity, especially for adding liquidity and during the Closing Auction, which benefits all market participants. Members and member organizations benefit from the substantial amounts of liquidity present on the Exchange during the close. The Exchange believes the proposed change would also thereby promote price discovery and transparency, and enhance order execution opportunities for member organizations from the substantial amounts of liquidity that are present on the Exchange both intraday and during the close.

Since the proposed incremental credits are new, the Exchange does not know how many member organizations could qualify for the new discounts based on their current trading profile and if they choose to direct order flow to the Exchange. Based on the profile of liquidity-adding firms generally, the Exchange believes that a number of member organizations could qualify for the credits if they choose to direct order flow to the Exchange. However, without having a view of member organization's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization directing orders to the Exchange in order to qualify for the discounts.

The proposed changes are not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

Section 6(b) of the Act,¹⁹ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,²⁰ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."²¹ While Regulation NMS has enhanced competition, it has also fostered a "fragmented" market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that "such competition can lead to the fragmentation of order flow in that stock."²²

The Proposed Change Is Reasonable

In light of the competitive environment in which the Exchange currently operates, the proposed rule change is a reasonable attempt to increase liquidity to the Exchange, especially during the Closing Auction, and improve the Exchange's market share relative to its competitors. The Exchange believes the proposed change is also reasonable because it is designed to attract higher volumes of orders transacted on the Exchange by member organizations, which would benefit all market participants by offering greater price discovery and an increased opportunities to trade on the Exchange, both intraday and during the Closing Auction. The proposed rule change also represents a reasonable attempt to encourage efficient usage of Exchange systems by member organizations by

continuing to encourage all member organizations to enter or modify D Orders as early as possible, which the Exchange believes is in the best interests of all member organizations and investors who access the Exchange.

MOC/LOC Tiers 1 and 2

The Exchange believes that eliminating the requirement that a member organization's MOC activity comprise at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close) in order to qualify for to qualify for MOC/LOC Tier 1 and Tier 2 is a reasonable way to encourage greater participation which leads to greater marketable and other liquidity at the Closing Auction. MOC and LOC orders contribute meaningfully to the price and size discovery, which is the hallmark of the closing auction process. Higher volumes of MOC orders contribute to the quality of the Exchange's Closing Auction and provide market participants whose orders are executed at the close with a greater opportunity for execution, which benefits all market participants. Further, as noted above, in the currently highly competitive national market system, competition for closing orders among exchanges, ATSS and other market execution venues is robust.

D Orders

The Exchange believes that its proposal would encourage additional liquidity on the Exchange from multiple sources, which helps to maintain the quality of the Exchange's Closing Auction for the benefit of all market participants.

Specifically, the Exchange believes that no longer exempting the first 750,000 ADV of the aggregate of executions at the close from fees is reasonable as it has not operated as originally intended. Member organizations that currently reach the 750,000 ADV threshold are generally larger member organizations that would continue to derive a substantial benefit from the high volume of closing executions on the Exchange and the Exchange believes would continue to send orders to the Exchange. While the Exchange is removing the first 750,000 ADV exemption, it notes that it is introducing a new exemption for qualifying member organizations with a Floor broker, which totals 1.5 million shares across Early-, Mid- and Late D Orders. Further, the Exchange believes that not charging Early, Mid- and Late D Orders up to specific monthly ADV levels for member organizations with a minimum

¹⁹ 15 U.S.C. 78f(b).

²⁰ 15 U.S.C. 78f(b)(4) & (5).

²¹ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7-10-04) (Final Rule) ("Regulation NMS").

²² See Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7-02-10) (Concept Release on Equity Market Structure).

ADV entered and executed by its Floor broker would encourage additional liquidity for execution on the trading Floor in the Closing Auction, thereby contributing to robust levels of liquidity on the Floor and at the close, which benefits all market participants. Moreover, the proposed fee waiver for Early, Mid- and Late D Orders would incentivize qualifying member organizations to enter or modify D Orders as early as possible in order to avoid fees for Early, Mid-, and Late D Orders up to the proposed thresholds for each.

Similarly, the Exchange believes that modifying the time of entry for last modification for member organizations to qualify for the existing fees for Early, Mid- and Late D Orders encourages all member organizations to enter or modify D Orders as early as possible, beginning with as early as up to 10 minutes before the close of trading, in order to build up liquidity going into the Closing Auction. Member organizations are waiting until later in the trading day to enter and/or modify D Orders than the current 25 minutes. By expanding the time period to enter Early D Orders to up to 10 minutes before the close, the Exchange hopes to encourage member organizations to send D Orders earlier in order to qualify for lower fees. Moreover, the Exchange hopes thereby to incentivize more member organizations to send adding liquidity to the Exchange, which in turn supports the quality of price discovery on the Exchange. In addition, charging member organizations higher rates for entering or modifying their interest in the final minute of regular trading hours reflects a risk premium for delaying entry or modification until nearly the end of trading, while reducing the time entry which results in fewer trades qualifying for these higher fees. Further, it is reasonable to charge member organizations a lower rate based on a higher percentage of Adding ADV of Tape A CADV and total close activity of Tape A CADV for entering or modifying their interest in the final minute of regular trading hours because such interest most benefits from the flexibility afforded the order type. The Exchange notes that while the proposed fee for Late D-Orders is higher than the current fee, the proposed increase in time of order entry or last modified to qualify for Early- and Mid D Orders, which have lower rates than Late D Orders, will result in lower overall fees for member organizations, and incentivize greater liquidity in the Closing Auction, which benefits all market participants.

Incremental Floor Broker Credits

The Exchange believes that the proposed additional credits for orders executed by a Floor broker for representation on the Exchange is a reasonable way to encourage additional liquidity, including D Orders, on the Exchange both during intraday and in Closing Auction because member organizations benefit from the substantial amounts of liquidity that are present on the Exchange during such times. The Exchange believes the proposed change would encourage member organizations to send orders to the trading Floor for execution, thereby contributing to robust levels of liquidity on the trading Floor both intraday and during the Closing Auction, which benefits all market participants. The proposed fee would also encourage the submission of additional liquidity to a national securities exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations from the substantial amounts of liquidity that are present on the Exchange during the closing. The proposed change would also encourage the execution of such transactions on a public exchange, thereby promoting price discovery and transparency. Moreover, the Exchange believes that requiring an ADV comprised of at least 50% Floor broker ADV of the member organization's total ADV is reasonable because it would encourage member organizations that make a substantial contribution to trading Floor liquidity without excluding smaller member organizations.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposal equitably allocates fees and credits among market participants because all member organizations that participate on the Exchange may qualify for the proposed credits and fees on an equal basis. The Exchange believes its proposal equitably allocates its fees and credits among its market participants by fostering liquidity provision and stability in the marketplace.

MOC/LOC Tiers 1 and 2

The Exchange believes that the proposed elimination of the requirement that a member organization's MOC activity comprise at least 35% of the member organization's total close activity (MOC/LOC and other executions at the close) in order to qualify for to qualify for MOC/LOC Tier 1 and Tier 2 will incentivize member organizations to send additional

liquidity to achieve lower fees and encourage greater marketable and other liquidity at the closing auction. Higher volumes of MOC and LOC orders contribute to the quality of the Exchange's Closing Auction and provide market participants whose orders are executed in the close with a greater opportunity for execution of orders on the Exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities and improving overall liquidity on a public exchange. The Exchange also believes that the proposed change is equitable because it would apply to all similarly situated member organizations that utilize MOC and LOC orders on the Exchange on an equal basis.

D Orders

The Exchange believes that the proposed changes to D Orders are an equitable allocation of fees because the proposed changes, taken together, will incentivize member organizations to enter or modify D Orders as early as possible, beginning with as early as up to 10 minutes before the close of trading, in order to build up liquidity going into the closing auction. The Exchange's closing auction is a recognized industry benchmark,²³ and member organizations receive a substantial benefit from the Exchange in obtaining high levels of executions at the Exchange's closing price on a daily basis. The Exchange also believes that it is equitable to charge member organizations a higher rate for entering or modifying their interest in the final minute of regular trading hours because such interest most benefits from the flexibility afforded the order type. Moreover, the proposed fees are equitable because all similarly situated member organizations will be subject to the same fee structure that would be available on an equal basis to all similarly situated member organizations that utilize D Orders on the Exchange. In this regard, the proposed changes are equitable because any member organization can choose to send D Orders earlier than 10 minutes or 1 minute prior to the close in order to qualify for lower fees, and any member organization can choose to have a Floor broker in order to qualify for the lower fee for Late D Orders or to exclude volume from fees up to the proposed specified thresholds for Early, Mid- and Late D Orders. Similarly, the proposal to waive fees for Early, Mid- and Late D

²³ For example, the pricing and valuation of certain indices, funds, and derivative products require primary market prints.

Orders for member organizations that have a Floor broker plus an adding volume requirement is equitable because a member organization that would not qualify for the fee waiver because the member organization does not operate a Floor brokerage business can still qualify for the fee waiver by adding a Floor broker. Indeed, to the extent that member organizations bring on Floor brokers to qualify for the fee waiver, the proposal would have the added benefit of potentially attracting new Floor brokers to the Exchange.

Incremental Floor Broker Credits

The proposed incremental credits for orders executed by a member organization's Floor broker that add liquidity to the Exchange and D Orders during the close, are equitable because the incremental fees would be available on an equal basis to all similarly situated member organizations that operate a Floor brokerage business. In this regard, the proposed discounts and requirements are equitable because any member organization can choose to increase their adding volume entered and executed by its Floor broker, excluding routing, in order to qualify for the proposed incremental credits and any member organization can choose to operate as a Floor broker in order to qualify for the additional credits on an equal basis. The Exchange notes that the current Incremental Discounts on MOC Orders utilize similar requirements.²⁴

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

MOC/LOC Tiers 1 and 2

The proposed streamlined requirements for MOC orders to qualify for MOC/LOC Tiers 1 and 2 are not unfairly discriminatory because the requirements would be applied to all similarly situated member organizations and other market participants, who would all be subject to the same fees, requirements and discounts on a full and equal basis. For the same reason, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. Accordingly, no member

organization already operating on the Exchange would be disadvantaged by this allocation of fees. Finally, the submission of orders to the Exchange is optional for member organizations in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

D Orders

The Exchange believes that the proposed changes to D Orders to modify the time periods by which such orders are considered early, mid-or late is not unfairly discriminatory because the proposed changes will incentivize member organizations to enter or modify D Orders as early as possible, beginning with as early as up to 10 minutes before the close of trading, in order to build up liquidity going into the closing auction. The Exchange also believes that it is not unfairly discriminatory to charge member organizations a higher rate for entering or modifying their interest in the final minute of regular trading hours because all member organizations can utilize D Orders and all have an equal choice as to when to submit those orders to benefit most from the flexibility afforded the order type. The Exchange believes that the proposal is not unfairly discriminatory because all similarly situated member organizations that submit D Orders last modified in the last 10 minutes and less before the scheduled close of trading will be subject to the same fee structure based on time of entry (or last modification). In addition, the Exchange believes that waiving fees for Early, Mid- and Late D Orders for member organizations with a Floor broker plus an adding volume requirement is equitable because the proposed fee waiver would apply equally to all similarly situated member organizations. Moreover, the proposed fee waiver is not unfairly discriminatory because member organizations that do not operate a Floor brokerage business can still qualify for the fee waiver by choosing to add a Floor broker on the Exchange. Indeed, to the extent that member organizations add Floor brokers to qualify for the proposed fee waiver for D Orders, the proposal would have the added benefit of potentially attracting new Floor brokers to the Exchange. In addition, the Exchange believes that it is reasonable to not charge member organizations for Early, Mid- and Late D Orders up to specific monthly ADV levels if the member organization has an ADV of at least 10,000 shares executed by a Floor broker. As noted, other marketplaces offer various incentives to only certain

members based on ADV and/or heightened quoting requirements.²⁵

Incremental Floor Broker Credits

The proposed incremental Floor broker credits are not unfairly discriminatory because the proposed fees would be applied to all similarly situated member organizations and other market participants operating a Floor brokerage business, who would all be subject to the same fees, requirements, and discounts on an equal basis. For the same reason, the proposal neither targets nor will it have a disparate impact on any particular category of market participant. Accordingly, no member organization already operating on the Exchange would be disadvantaged by this allocation of fees. Further, the Exchange believes the proposal would incentivize member organizations to send more orders to the Floor in order to qualify for incremental credits. Finally, the submission of orders to the Exchange is optional for member organizations in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,²⁶ the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."²⁷

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed changes would continue to incentivize market participants to direct

²⁴ See NYSE Price List at p. 4, available at https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf.

²⁵ See notes 16 & 17, *supra*.

²⁶ 15 U.S.C. 78f(b)(8).

²⁷ See Regulation NMS, 70 FR at 37498–99.

order flow to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. The proposed credits would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the changes on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) ²⁸ of the Act and paragraph (f) thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2024-42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSE-2024-42. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSE-2024-42 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17505 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100645; File No. SR-NASDAQ-2024-041]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 19, 2024, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

²⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

²⁸ 15 U.S.C. 78s(b)(3)(A).

places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, section 1, to \$151.50 per hour.

General 8, section 1 includes the Exchange's fees that relate to co-location services, including "Remote Hands Services." The term "Remote Hands Services" refers to the use of Nasdaq engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to Nasdaq of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange's Remote Hands Services fee is the same as that which the Exchange expressed when it increased the fee by 5.5% earlier this year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior

to SR-NASDAQ-2024-032, the Exchange had not increased its Remote Hands fee since 2010.⁴ However, since 2010, there has been notable inflation. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index ("PPI") for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings ("AHE") growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

⁴ See Securities Exchange Act Release No. 34-62397 (June 28, 2010), 75 FR 38860 (July 6, 2010) (SR-NASDAQ-2010-019).

⁵ See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

⁷ See <https://www.bls.gov/web/empsit/cese3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese3a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,¹⁰ in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service, as fees for the service in question has been static in nominal terms, and

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBYX-2024-021).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR-NASDAQ-2024-008). On April 29, 2024, the Exchange withdrew that filing and submitted SR-NASDAQ-2024-020. On June 27, 2024, the Exchange withdrew and replaced that filing with SR-NASDAQ-2024-032.

therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR–NASDAQ–2024–032, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2010. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.¹² Moreover, a more specific and pertinent gauge of inflation—the PPI for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.¹³ An even more specific gauge of inflation—AHE growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as

it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other

things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.¹⁵ No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁶ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. "If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior."¹⁷ Accordingly, "the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory."¹⁸ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms

¹² See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

¹⁴ See <https://www.bls.gov/web/empsit/cese3eb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese3eb8a.htm> (Last updated July 5, 2024).

¹⁵ See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at https://www.cboe.com/us/equities/market_statistics/.

¹⁶ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁷ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

¹⁸ *Id.*

and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NASDAQ-2024-041 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-NASDAQ-2024-041. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number

SR-NASDAQ-2024-041 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17507 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100644; File No. SR-BX-2024-026]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 19, 2024, Nasdaq BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/bx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, Section 1, to \$151.50 per hour.

General 8, Section 1 includes the Exchange's fees that relate to co-location services, including "Remote Hands Services." The term "Remote Hands Services" refers to the use of Exchange engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to the Exchange of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange's Remote Hands Services fee is the same as that which the Exchange expressed when it increased the fee by 5.5% earlier this

year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior to SR-BX-2024-020, the Exchange had not increased its Remote Hands fee since 2010.⁴ However, since 2010, there has been notable inflation. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index ("PPI") for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings ("AHE") growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above,

and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service,

⁴ See Securities Exchange Act Release No. 34-62396 (June 28, 2010), 75 FR 38585 (July 2, 2010) (SR-BX-2010-012).

⁵ See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

⁷ See <https://www.bls.gov/web/empsit/cese33a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese38a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBYX-2024-021).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR-BX-2024-008). On April 29, 2024, the Exchange withdrew that filing and submitted SR-BX-2024-014. On June 27, 2024, the Exchange withdrew and replaced that filing with SR-BX-2024-020.

as fees for the service in question has been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR-BX-2024-020, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2010. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2010 and 2024, the dollar had an average inflation rate of 2.64% per year, producing a cumulative price increase of 44.03%.¹² Moreover, a more specific and pertinent gauge of inflation—the PPI for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 17.8% from 2010 to 2024.¹³ An even more specific gauge of inflation—AHE growth for Computing Infrastructure—increased 77% for non-managers and 81% for all employees from 2010 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2010. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month

rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2010. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and

services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.¹⁵ No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁶ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. "If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior."¹⁷ Accordingly, "the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory."¹⁸ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable

¹⁵ See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at https://www.cboe.com/us/equities/market_statistics/.

¹⁶ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁷ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR-NYSEArca-2006-21).

¹⁸ *Id.*

¹² See <https://www.officialdata.org/us/inflation/2010?amount=1> (Last updated July 8, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated July 7, 2024).

¹⁴ See <https://www.bls.gov/web/empsit/cese3b3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese3b8a.htm> (Last updated July 5, 2024).

dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-BX-2024-026 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-BX-2024-026. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or

subject to copyright protection. All submissions should refer to file number SR-BX-2024-026 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17506 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100641; File No. SR-GEMX-2024-25]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 19, 2024, Nasdaq GEMX, LLC ("GEMX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/gemx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, section 1, to \$151.50 per hour.

General 8, section 1 includes the Exchange's fees that relate to co-location services, including "Remote Hands Services." The term "Remote Hands Services" refers to the use of Exchange engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to the Exchange of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange's Remote Hands Services fee is the same as that which

the Exchange expressed when it increased the fee by 5.5% earlier this year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior to SR-GEMX-2024-15, the Exchange had not increased its Remote Hands fee since 2017.⁴ However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index ("PPI") for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings ("AHE") growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees from 2017 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1%

increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,¹⁰ in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair

⁴ In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Remote Hands Service. See Securities Exchange Act Release No. 34-81902 (October 19, 2017), 82 FR 49453 (October 25, 2017) (SR-GEMX-2017-48).

⁵ See <https://www officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

⁷ See <https://www.bls.gov/web/empst/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empst/ceseeb8a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBYX-2024-021).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR-GEMX-2024-05). On April 29, 2024, the Exchange withdrew that filing and submitted SR-GEMX-2024-09. On June 27, 2024, the Exchange withdrew and replaced that filing with SR-GEMX-2024-15.

discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service, as fees for the service in question has been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR-GEMX-2024-15, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2017. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.¹² Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index (“PPI”) for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.¹³ An even more specific gauge of inflation—average hourly earnings (“AHE”) growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees from 2017 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that

customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange’s costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange’s existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange’s competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is

unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁵ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange’s services. “If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.”¹⁶ Accordingly, “the existence of significant competition provides a substantial basis for finding that the terms of an exchange’s fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.”¹⁷ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading

¹² See <https://www.officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

¹⁴ See <https://www.bls.gov/web/empsit/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/ceseeb8a.htm> (Last updated July 5, 2024).

¹⁵ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁶ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR-NYSEArca-2006-21).

¹⁷ *Id.*

venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in

the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-GEMX-2024-25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-GEMX-2024-25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number

SR-GEMX-2024-25 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17503 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100639; File No. SR-MRX-2024-28]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 19, 2024, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/mrx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, Section 1, to \$151.50 per hour.

General 8, Section 1 includes the Exchange's fees that relate to co-location services, including "Remote Hands Services." The term "Remote Hands Services" refers to the use of Exchange engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to the Exchange of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange's Remote Hands Services fee is the same as that which the Exchange expressed when it increased the fee by 5.5% earlier this

year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior to SR-MRX-2024-18, the Exchange had not increased its Remote Hands fee since 2017.⁴ However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index ("PPI") for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings ("AHE") growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees from 2017 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange

believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁰ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBXX-2024-021).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

⁴ In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Remote Hands Service. See Securities Exchange Act Release No. 34-81907 (October 19, 2017), 82 FR 49447 (October 25, 2017) (SR-MRX-2017-21).

⁵ See <https://www.officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

⁷ See <https://www.bls.gov/web/empsit/cese33a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese33a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR-MRX-2024-04). On April 29, 2024, the Exchange withdrew that filing and submitted SR-MRX-2024-10. On June 27, 2024, the Exchange withdrew and replaced that filing with SR-MRX-2024-18.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service, as fees for the service in question has been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR-MRX-2024-18, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2017. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.¹² Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index (“PPI”) for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.¹³ An even more specific gauge of inflation—average hourly earnings (“AHE”) growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees from 2017 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the

Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange’s costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange’s existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange’s competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered

broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁵ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange’s services. “If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.”¹⁶ Accordingly, “the existence of significant competition provides a substantial basis for finding that the terms of an exchange’s fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.”¹⁷ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and

¹² See <https://www.officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

¹⁴ See <https://www.bls.gov/web/empsit/cese3b3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/cese3b8a.htm> (Last updated July 5, 2024).

¹⁵ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁶ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR-NYSEArca-2006-21).

¹⁷ *Id.*

trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection

of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MRX-2024-28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-MRX-2024-28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MRX-2024-28 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17501 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100642; File No. SR-SAPPHIRE-2024-05]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 531, Reports and Market Data Products, To Adopt the "Liquidity Taker Event Report—Complex Orders" and the "Liquidity Taker Event Report—Resting Simple Orders"

August 2, 2024.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 24, 2024, MIAX Sapphire, LLC ("MIAX Sapphire" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 531, Reports and Market Data Products, to: (1) adopt rule text for the "Liquidity Taker Event Report—Complex Orders"; (2) adopt rule text for the "Liquidity Taker Event Report—Resting Simple Orders"; and (3) make non-substantive, clarifying changes to current Exchange Rules 531(a) and (b).

The text of the proposed rule change is available on the Exchange's website at <https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings>, at the Exchange's principal office, and at the Commission's Public Reference Room.

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange currently offers the Liquidity Taker Event Report (referred to herein as the "Simple Order Report"), which is a Member³-specific report and helps Members to better understand by how much time a particular order missed executing against a specific order resting on the Exchange's Simple Order Book.⁴ The current Liquidity Taker Event Report is described under Exchange Rule 531(a).⁵ The Exchange now proposes to: (1) amend Exchange Rule 531(b)⁶ to provide for the new "Liquidity Taker Event Report—Complex Orders" (referred to herein as the "Complex Order Report");⁷ (2) adopt new Exchange Rule 531(c) to

provide for the new "Liquidity Taker Event Report—Resting Simple Orders" (referred to herein as the "Resting Simple Order Report");⁸ (3) make corresponding changes to current Exchange Rule 531(a) to specify that it is for the Simple Order Report; and (4) renumber current Exchange Rule 531(b), Market Data Products, to Exchange Rule 531(d).

Complex Order Report

The proposed Complex Order Report would be substantially similar to the existing Simple Order Report, but would include data concerning a Member's complex orders.⁹ The Exchange also proposes to amend the name of the existing Liquidity Taker Event Report in Exchange Rule 531(a) to now be titled the "Liquidity Taker Event Report—Simple Orders" and amend references in Exchange Rule 531(a) accordingly.

The Simple Order Report includes information about incoming orders seeking to remove resting orders from the Simple Order Book. The proposed Complex Order Report would include the same information about incoming complex orders that seek to remove complex orders resting on the Strategy Book.¹⁰ Two other differences between the proposed Complex Order Report and the Simple Order Report are that the proposed Complex Order Report will include the Complex SBBO¹¹ in place

of the SBBO and Complex ABBO¹² in place of the ABBO, as described further below. These are minor differences designed to provide the SBBO and ABBO that are relevant to trading complex orders. Otherwise, the content and dissemination of the proposed Complex Order Report set forth under amended Exchange Rule 531(b) will be identical to that of the Simple Order Report under Exchange Rule 531(a). Other than the difference set forth above, the Exchange represents that there are no other differences between simple orders and complex orders that would necessitate any other changes to the proposed Complex Order Report or render the effects or use of the proposed Complex Order Report as different from the Simple Order Report.

Like the Simple Order Report, the proposed Complex Order Report is an optional product¹³ available to Members. Currently, the Exchange provides real-time prices and analytics in the marketplace. The Exchange believes the additional data points from the matching engine outlined below may help Members gain a better understanding about their complex order interactions with the Exchange. The Exchange believes the proposed Complex Order Report will provide Members with an opportunity to learn more about better opportunities to access liquidity and receive better execution rates when trading complex orders. The proposed Complex Order Report will increase transparency and democratize information so that all firms that subscribe to the proposed Complex Order Report have access to the same information on an equal basis, even for firms that do not have the

bid or offer for that complex strategy. The icSBBO is calculated using the best price from the Simple Order Book for each component of a complex strategy including displayed and non-displayed trading interest. For stock-option orders, the icSBBO for a complex strategy is calculated using the best price (whether displayed or non-displayed) on the Simple Order Book in the individual option component(s), and the NBBO in the stock component. See Exchange Rule 518(a). The term "NBBO" means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. See Exchange Rule 100.

¹² The term "ABBO" or "Away Best Bid or Offer" means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Exchange Rule 1400(g)) and calculated by the Exchange based on market information received by the Exchange from the Options Price Reporting Authority ("OPRA"). See Exchange Rule 100. The Complex ABBO is calculated using the ABBO for each component of a complex strategy to establish the away markets' best net bid or offer for a complex strategy.

¹³ The Exchange intends to submit a separate filing with the Commission pursuant to section 19(b)(1) to propose fees for the Simple Order Report, proposed Complex Order Report, and proposed Resting Simple Order Report.

³ The term "Member" means an individual or organization that is registered with the Exchange pursuant to Chapter II of MIAX Sapphire Rules for purposes of trading on the Exchange as an "Electronic Exchange Member" or "Market Maker." Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

⁴ The "Simple Order Book" is the Exchange's regular electronic book of orders and quotes. See Exchange Rule 100.

⁵ See Exchange Rule 531(a) and Securities Exchange Act Release No. 100539 (July 15, 2024) (In the Matter of the Application of MIAX Sapphire, LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission).

⁶ Currently, Exchange Rule 531(b) is titled "Market Data Products" and provides the rule text for the Open-Close Report. See current Exchange Rule 531(b). Pursuant to this proposal, the Exchange proposes to move the rule text for Market Data Products to now be renumbered as Exchange Rule 531(d). Proposed Exchange Rule 531(c) will be for the Resting Simple Order Report, described below. The Exchange does not propose to amend any of the rule text for Market Data Products as currently stated in Exchange Rule 531.

⁷ The proposed rule change is substantively identical to Complex Order Reports available through the Exchange's affiliates (Miami International Securities Exchange, LLC ("MIAX") and MIAX Emerald, LLC ("MIAX Emerald")) as it relates to MIAX and MIAX Emerald markets. See MIAX Rule 531(b) and MIAX Emerald Rule 531(b).

⁸ The proposed rule change is substantively identical to Resting Simple Order Reports available through the Exchange's affiliates, MIAX and MIAX Emerald, as it relates to MIAX and MIAX Emerald markets. See MIAX Rule 531(c) and MIAX Emerald Rule 531(c).

⁹ In sum, a "complex order" is "any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the 'legs' or 'components' of the complex order), for the same account, in a conforming or non-conforming ratio. . . ." See Exchange Rule 518(a).

¹⁰ The term "complex strategy" means a particular combination of components and their ratios to one another. New complex strategies can be created as the result of the receipt of a complex order or by the Exchange for a complex strategy that is not currently in the System. The Exchange may limit the number of new complex strategies that may be in the System at a particular time and will communicate this limitation to Members via Regulatory Circular. See Exchange Rule 518(a). The "Strategy Book" is the Exchange's electronic book of complex orders. See Exchange Rule 100. The Strategy Book is organized by complex strategy in that individual orders for a defined complex strategy are organized together in a book that is separate from the orders for a different complex strategy.

¹¹ The term "SBBO" means the Exchange's best bid and offer on the Simple Order Book. See Exchange Rule 100. The Complex SBBO for a particular complex strategy is calculated using the Implied Complex Sapphire Best Bid or Offer ("icSBBO") combined with the best price currently available for that particular complex strategy on the Strategy Book to establish the Exchange's best net

appropriate resources to generate a similar report regarding interactions with the Exchange. Like the Simple Order Report, none of the components of the proposed Complex Order Report include real-time market data.

Members generally would use a liquidity accessing order if there is a high probability that it will execute against an order resting on the Exchange's Simple Order Book. Like the Simple Order Report, the proposed Complex Order Report would identify by how much time an order that may have been marketable missed an execution. In the case of the proposed Complex Order Report, the incoming order would be a complex order submitted to trade against a resting order for a complex strategy. The proposed Complex Order Report will provide greater visibility into the missed trading execution, which will allow Members to optimize their models and trading patterns to yield better execution results when trading complex orders.

Like the Simple Order Report, the proposed Complex Order Report will be a Member-specific report and will help Members to better understand by how much time a particular order, in this case a complex order, missed executing against a specific resting order, thus allowing that Member to determine whether it wants to invest in the necessary resources and technology to mitigate missed executions against certain resting orders on the Exchange's Strategy Book. For example, Member A submits a complex order that is posted to the Strategy Book and then, within 400 microseconds of the entry of Member A's complex order, Member B enters a marketable complex order to execute against Member A's resting complex order. Immediately thereafter, Member C, also within 400 microseconds of the entry of Member A's complex order, sends a marketable complex order to execute against Member A's resting complex order. Because Member B's complex order is received by the Exchange before the complex order for Member C, Member B's complex order executes against Member A's resting complex order. If Member C were to subscribe to the proposed Complex Order Report, it would be provided the data points necessary for that firm to calculate by how much time it missed executing against Member A's resting complex order.

Like the Simple Order Report, the Exchange proposes to provide the proposed Complex Order Report on a T+1 basis. As further described below, the proposed Complex Order Report

will be specifically tailored to the Member that is subscribed to the Complex Order Report and any data included in the Complex Order Report that relates to a Member other than the Member receiving the Complex Order Report will be anonymized.

The Exchange's affiliates, MIAX and MIAX Emerald, adopted their comparable Complex Order Reports in response to demand from their members for data concerning the timeliness of their incoming complex orders and executions against resting orders on those markets.¹⁴ Members of MIAX and MIAX Emerald have found the Simple Order Reports and Complex Order Reports helpful and the Exchange believes that its Members will request similar information from the Exchange regarding their simple orders and complex orders. For MIAX and MIAX Emerald, this came in the form of requests by members to those exchanges' trading operations personnel for information concerning the timeliness of their incoming simple orders and complex orders and efficacy of their attempts to execute against resting liquidity on their books. The purpose of the proposed Complex Order Report is to provide a subscribing Member ("Recipient Member") the necessary data in a standardized format on a T+1 and equal basis.

Similar to current Exchange Rule 531(a) regarding the Simple Order Report, amended Exchange Rule 531(b) would provide that the proposed Complex Order Report is a daily report that provides a Recipient Member with its liquidity response time details for executions of an order resting on the Strategy Book, where that Recipient Member submitted a complex order that attempted to execute against such resting complex order within a certain timeframe.

Complex Order Report Content

The content of the proposed Complex Order Report would be identical to the Simple Order Report, but for two minor differences discussed below. Proposed paragraph (b)(1) of Exchange Rule 531 would describe the content of the proposed Complex Order Report and delineate which information would be provided regarding the resting order,¹⁵

¹⁴ See MIAX Rule 531(b) and MIAX Emerald Rule 531(b). The Exchange notes that its other affiliate, MIAX PEARL, LLC ("MIAX Pearl") only provides for the similar Simple Order Report and Resting Simple Order Report as complex orders are not available for trading on the options trading facility of MIAX Pearl.

¹⁵ Like the Simple Order Report, only displayed orders will be included in the proposed Complex Order Report. The Exchange notes that it does not currently offer any non-displayed order types.

the response that successfully executed against the resting order, and the response submitted by the Recipient Member that missed executing against the resting order. It is important to note that the content of the proposed Complex Order Report will be specific to the Recipient Member and the proposed Complex Order Report will not include any information related to any Member other than the Recipient Member. The Exchange will restrict all other market participants, including the Recipient Member, from receiving another market participant's data.

Resting Order Information. The content of the proposed Complex Order Report set forth under amended Exchange Rule 531(b)(1)(i) is identical to the content of the Simple Order Report under Exchange Rule 531(a)(1)(i). However, as noted above, the content of the proposed Complex Order Report would be limited to incoming complex orders that seek to remove liquidity from the Exchange's Strategy Book.

Amended Exchange Rule 531(b)(1)(i) would provide that the following information would be included in the proposed Complex Order Report regarding the resting order: (A) the time the resting order was received by the Exchange;¹⁶ (B) symbol;¹⁷ (C) order reference number, which is a unique reference number assigned to a new complex order at the time of receipt;¹⁸ (D) whether the Recipient Member is an Affiliate¹⁹ of the Member that entered the resting order;²⁰ (E) origin type (*e.g.*,

¹⁶ This information is also included in the Simple Order Report. See Exchange Rule 531(a)(1)(i)(A).

¹⁷ This information is also included in the Simple Order Report. See Exchange Rule 531(a)(1)(i)(B).

¹⁸ This information is also included in the Simple Order Report. See Exchange Rule 531(a)(1)(i)(C).

¹⁹ The term "affiliate" of or person "affiliated with" another person means a person who, directly, or indirectly, controls, is controlled by, or is under common control with, such other person. See Exchange Rule 100.

²⁰ This information is also included in the Simple Order Report. See Exchange Rule 531(a)(1)(i)(D). The Complex Order Report will simply indicate whether the Recipient Member is an Affiliate of the Member that entered the resting order and not include any other information that may indicate the identity of the Member that entered the resting order.

Priority Customer;²¹ Market Maker²²;²³ (F) side (buy or sell);²⁴ and (G) displayed price and size of the resting order.²⁵

Execution Information. Amended Exchange Rule 531(b)(1)(ii) would provide that the following information would be included in the proposed Complex Order Report regarding the execution of the resting order: (A) the Complex SBBO at the time of execution;²⁶ (B) the Complex ABBO at the time of execution;²⁷ (C) the time the first response that executes against the resting order was received by the Exchange and the size of the execution and type of the response;²⁸ (D) the time difference between the time the resting order was received by the Exchange and the time the first response that executes against the resting order was received by the Exchange;²⁹ and (E) whether the

response was entered by the Recipient Member.³⁰ If the resting order executes against multiple contra-side responses, only the Complex SBBO and Complex ABBO at the time of the execution against the first response will be included.

The content of the proposed Complex Order Report set forth under amended Exchange Rule 531(b)(1)(ii) is identical to the content of the Simple Order Report under Exchange Rule 531(a)(1)(ii) with two minor differences. The Simple Order Report includes the SBBO, which is the Exchange's best bid or offer, and the ABBO, which is the best bid or offer of away exchanges. In their place, the proposed Complex Order Report would include the Complex SBBO and Complex ABBO. The Complex SBBO is calculated using the SBBO for each component of a complex strategy to establish the Exchange's best net bid or offer for a complex strategy. As discussed above, the Complex SBBO is calculated using the icSBBO³¹ combined with the best price currently available on the Strategy Book to establish the Exchange's best net bid or offer for a complex strategy.³² The Complex ABBO is calculated using the ABBO for each component of a complex strategy to establish the away markets' best net bid or offer for a complex strategy using OPRA data. The Exchange is providing the Complex SBBO and Complex ABBO because both are relevant and tailored to a Member that is entering a complex order to remove liquidity as part of a complex strategy and, therefore, more germane to the purpose of the Complex Order Report.

Recipient Member's Response Information. The content of the proposed Complex Order Report set forth under amended Exchange Rule 531(b)(1)(iii) is identical to the content of the Simple Order Report under Exchange Rule 531(a)(1)(iii). Amended

the Simple Order Report. *See* Exchange Rule 531(a)(1)(ii)(D).

³⁰ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(ii)(E).

³¹ The Implied Complex Sapphire Best Bid or Offer ("icSBBO") is a calculation that uses the best price from the Simple Order Book for each component of a complex strategy including displayed and non-displayed trading interest. For stock-option orders, the icSBBO for a complex strategy will be calculated using the best price (whether displayed or non-displayed) on the Simple Order Book in the individual option component(s), and the NBBO in the stock component. *See* Exchange Rule 518(a). The term "NBBO" means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from the appropriate Securities Information Processor ("SIP"). *See id.*

³² *See supra* note 11.

Exchange Rule 531(b)(1)(iii) would provide that the following information would be included in the Complex Order Report regarding complex order(s) sent by the Recipient Member: (A) Recipient Member identifier;³³ (B) the time difference between the time the first response that executes against the resting order was received by the Exchange and the time of each complex order sent by the Recipient Member, regardless of whether it executed or not;³⁴ (C) size and type of each complex order submitted by the Recipient Member;³⁵ and (D) response reference number, which is a unique reference number attached to the response by the Recipient Member.³⁶

Timeframe for Data Included in the Complex Order Report

The timeframe for data to be included the proposed Complex Order Report set forth under amended Exchange Rule 531(b)(2) is identical to the timeframe for data included in the Complex Order Reports that are available for MIAX and MIAX Emerald.³⁷ Proposed paragraph (b)(2) of Exchange Rule 531 would provide that the Complex Order Report would include the data set forth under Exchange Rule 531(b)(1) described above for executions and contra-side responses that occurred within 400 microseconds of the time the resting order was received by the Exchange. The Exchange believes 400 microseconds is the appropriate timeframe because it understands most Members that would be interested in subscribing to the proposed Complex Order Report would submit their incoming liquidity removing complex orders within 400 microseconds of the time a contra-side complex order is posted to the Strategy Book.

Scope of Data Included in the Report

The scope of data to be included the proposed Complex Order Report set forth under amended Exchange Rule 531(b)(3) is identical to the scope of data included in the Simple Order Report

³³ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(iii)(A).

³⁴ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(iii)(B). For purposes of calculating this duration of time, the Exchange will use the time the first response that executes against the resting order and the Recipient Member's response(s) is received by the Exchange's network, both of which would be before the order and response(s) would be received by the System. This time difference would be provided in nanoseconds.

³⁵ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(iii)(C).

³⁶ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(iii)(D).

³⁷ *See* MIAX Rule 531(b)(2) and MIAX Emerald Rule 531(b)(2).

²¹ The term "Priority Customer" means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 to Exchange Rule 100. *See* Exchange Rule 100.

²² The term "Market Maker" or "MM" means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange's Rules. *See* Exchange Rule 100.

²³ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(i)(E).

²⁴ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(i)(F).

²⁵ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(i)(G). The Exchange notes that the displayed price and size are also disseminated via the Exchange's proprietary data feeds.

²⁶ Similar information is included in the Simple Order Report. Exchange Rule 531(b)(1)(ii)(A) would similarly provide that if the resting order executes against multiple contra-side responses, only the Complex SBBO at the time of the execution against the first response will be included.

²⁷ Similar information is included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(ii)(B). Exchange Rule 531(b)(1)(ii)(B) would similarly provide that if the resting order executes against multiple contra-side responses, only the Complex ABBO at the time of the execution against the first response will be included.

²⁸ This information is also included in the Simple Order Report. *See* Exchange Rule 531(a)(1)(ii)(C). The time the Exchange received the response order would be in nanoseconds and would be the time the response was received by the Exchange's network, which is before the time the response would be received by the System. The type of responses that would be identified in the proposed Complex Order Report are Standard Quotes. The term "quote" or "quotation" means a bid or offer entered by a Market Maker as a firm order that updates the Market Maker's previous bid or offer, if any. When the term order is used in the Exchange's Rules and a bid or offer is entered by the Market Maker in the option series to which such Market Maker is registered, such order shall, as applicable, constitute a quote or quotation for purposes of the Exchange's Rules. *See* Exchange Rule 100.

²⁹ The time difference would be provided in nanoseconds. This information is also included in

under Exchange Rule 531(a)(3). Proposed paragraph (b)(3) of Exchange Rule 531 would provide that the Complex Order Report will only include trading data related to the Recipient Member and, subject to the proposed paragraph (4) of Exchange Rule 531(b) described below, will not include any other Member's trading data other than that listed in paragraphs (1)(i) and (ii) of Exchange Rule 531(b), described above. Like the Simple Order Report, the proposed Complex Order Report will not include information related to any Member other than the Recipient Member.³⁸

Historical Data

Proposed paragraph (b)(4) of Exchange Rule 531 would specify that the Complex Order Report will contain historical data from the prior trading day and will be available after the end of the trading day, generally on a T+1 basis. This is identical to the timeframe for when the Simple Order Report is made available.³⁹

Resting Simple Order Report

The Exchange proposes to amend Exchange Rule 531 to provide for the new Resting Simple Order Report.⁴⁰ The proposed Resting Simple Order Report will be an optional product⁴¹ available to Members. But for the modified timeframe and one difference described below, the proposed Resting Simple Order Report would include the same data as the Simple Order Report currently described under Exchange Rule 531(a), except that the Resting Simple Order Report will focus on executions and contra-side responses that occurred after 200 microseconds of the time the resting order was received by the Exchange and within 200 microseconds of receipt of any Member's first attempt to execute against the resting order after the initial 200 microsecond time period has expired as described further below.

The Exchange believes the additional data points from the matching engine outlined below for the proposed Resting Simple Order Report may also help Members gain a better understanding about their interactions with the Exchange. The Exchange believes the proposed Resting Simple Order Report will provide Members with an

opportunity to learn more about better opportunities to access liquidity and receive better execution rates. The proposed Resting Simple Order Report will increase transparency and democratize information so that all firms that subscribe to the proposed Resting Simple Order Report have access to the same information on an equal basis, even for firms that do not have the appropriate resources to generate a similar report regarding interactions with the Exchange. None of the components of the proposed Resting Simple Order Report include real-time market data.

Members generally would use a liquidity accessing order if there is a high probability that it will execute against an order resting on the Simple Order Book. The proposed Resting Simple Order Report would identify by how much time an order that may have been marketable missed an execution but would focus on a later timeframe than the Simple Order Report and Complex Order Report. The proposed Resting Simple Order Report will provide greater visibility into the missed trading execution, which will allow Members to optimize their models and trading patterns to yield better execution results.

The proposed Resting Simple Order Report will be a Member-specific report and will help Members to better understand by how much time a particular order missed executing against a specific resting order, thus allowing that Member to determine whether it wants to invest in the necessary resources and technology to mitigate missed executions against certain resting orders on the Simple Order Book. The Exchange proposes to provide the Resting Simple Order Report on a T+1 basis. As further described below, the proposed Resting Simple Order Report will be specific and tailored to the Member that is subscribed to the Resting Simple Order Report and any data included in the Resting Simple Order Report that relates to a Member other than the Member receiving the Resting Simple Order Report will be anonymized.

The Exchange's affiliates, MIAX, MIAX Pearl, and MIAX Emerald, adopted their comparable Resting Simple Order Reports in response to demand from their members for data concerning the timeliness of their incoming orders and executions against certain resting orders that have been resting on the Simple Order Books of MIAX, MIAX Pearl, and MIAX Emerald, for at least 200 microseconds and within 200 microseconds of receipt of the first attempt to execute against the resting

order after the initial 200 microsecond time period has expired.⁴² Members of MIAX, MIAX Pearl, and MIAX Emerald have found the Resting Simple Order Reports helpful and the Exchange believes that its Members will request similar information from the Exchange regarding their resting simple orders. For MIAX, MIAX Pearl, and MIAX Emerald, this came in the form of requests by members to those exchanges' trading operations personnel for information concerning the timeliness of their incoming simple orders and efficacy of their attempts to execute against resting liquidity on their books. The purpose of the proposed Resting Simple Order Report is to provide Members the necessary data in a standardized format on a T+1 basis to those that subscribe to the Resting Simple Order Report on an equal basis.

Proposed Exchange Rule 531(c) would provide that the Resting Simple Order Report is a daily report that provides a Recipient Member with its liquidity response time details for executions of an order resting on the Simple Order Book, where that Recipient Member attempted to execute against such resting order within an extended timeframe that meets certain criteria described below.

Resting Simple Order Report Content

The content of the proposed Resting Simple Order Report is basically identical to that of the existing Simple Order Report described under Exchange Rule 531(a) with two differences. The first difference is the timeframe of the proposed Resting Simple Order Report mentioned above and described in more detail below. The second difference is that, unlike the existing Simple Order Report, the proposed Resting Simple Order Report would not include the time difference between the time the resting order was received by the Exchange and the time the first response that executes against the resting order was received by the Exchange. Each of these differences are described below. All other aspects of the proposed Resting Simple Order Report are identical to the existing Simple Order Report described under Exchange Rule 531(a).

Like current paragraph (a)(1) of Exchange Rule 531 for the existing Simple Order Report, proposed paragraph (c)(1) of Exchange Rule 531 would describe the content of the proposed Resting Simple Order Report and delineate which information would be provided regarding the resting

³⁸ See Exchange Rule 531(a)(3).

³⁹ See Exchange Rule 531(a)(4).

⁴⁰ The proposed rule change to adopt the Resting Simple Order Report is substantively identical to reports offered by the Exchange's affiliates, MIAX, MIAX Pearl and MIAX Emerald. See MIAX Rule 531(c), MIAX Pearl Rule 531(c), and MIAX Emerald Rule 531(c).

⁴¹ See *supra* note 13.

⁴² See *supra* note 40.

order;⁴³ the response that successfully executed against the resting order, and the response submitted by the Recipient Member that missed executing against the resting order. It is important to note that the content of the Resting Simple Order Report will be specific to the Recipient Member and the Resting Simple Order Report will not include any information related to any Member other than the Recipient Member, other than certain information about the resting order described below. The Exchange will restrict all other market participants, including the Recipient Member, from receiving another market participant's data.

Resting Order Information. Like current paragraph (a)(1)(i) of Exchange Rule 531 for the existing Simple Order Report, proposed Exchange Rule 531(c)(1)(i) would provide that the following information would be included in the Resting Simple Order Report regarding the resting order: (A) the time the resting order was received by the Exchange;⁴⁴ (B) symbol; (C) order reference number, which is a unique reference number assigned to a new order at the time of receipt; (D) whether the Recipient Member is an Affiliate of the Member that entered the resting order;⁴⁵ (E) origin type (e.g., Priority Customer, Market Maker); (F) side (buy or sell); and (G) displayed price and size of the resting order.⁴⁶

Execution Information. Like current paragraph (a)(1)(ii) of Exchange Rule 531 for the existing Simple Order Report, proposed Exchange Rule 531(c)(1)(ii) would provide that the following information would be included in the Resting Simple Order Report regarding the execution of the resting order: (A) the SBBO at the time of execution;⁴⁷ (B) the ABBO at the time

of execution;⁴⁸ (C) the time first response that executes against the resting order was received by the Exchange and the size of the execution and type of the response;⁴⁹ and (D) whether the response was entered by the Recipient Member. If the resting order executes against multiple contra-side responses, only the SBBO and ABBO at the time of the execution against the first response will be included.

Exchange Rule 531(a)(1)(ii)(D) provides that the existing Simple Order Report also includes the time difference between the time the resting order was received by the Exchange and the time the first response that executes against the resting order was received by the Exchange. The proposed Resting Simple Order Report would not include the same information because that timeframe could be for an extended period of time since the proposed Resting Simple Order Report focuses on orders that have been resting on the Simple Order Book for longer than 200 microseconds and, therefore, the Exchange believes is less likely to be valuable to the Recipient Member.

Recipient Member's Response Information. Like current paragraph (a)(1)(iii) of Exchange Rule 531 for the existing Simple Order Report, proposed Rule 531(c)(1)(iii) would provide that the following information would be included in the Resting Simple Order Report regarding response(s) sent by the Recipient Member: (A) Recipient Member identifier; (B) the time difference between the time the first response that executes against the resting order was received by the Exchange and the time of each response sent by the Recipient Member, regardless of whether it executed or not;⁵⁰ (C) size and type of each response submitted by Recipient Member; and (D) response reference number, which is a unique reference number attached to the response by the Recipient Member.

⁴³ Only displayed orders will be included in the Resting Simple Order Report. The Exchange notes that it does not currently offer any non-displayed orders types on its options trading platform.

⁴⁴ The time the Exchange received the resting order would be in nanoseconds and is the time the resting order was received by the Exchange's network.

⁴⁵ The Resting Simple Order Report will simply indicate whether the Recipient Member is an Affiliate of the Member that entered the resting order and not include any other information that may indicate the identity of the Member that entered the resting order.

⁴⁶ The Exchange notes that the displayed price and size are also disseminated via the Exchange's proprietary data feeds and OPRA. The Exchange also notes that the displayed price of the resting order may be different than the ultimate execution price. This may occur when a resting order is displayed and ranked at different prices upon entry to avoid a locked or crossed market.

⁴⁷ Exchange Rule 531(c)(1)(ii)(A) would further provide that if the resting order executes against multiple contra-side responses, only the SBBO at the time of the execution against the first response will be included.

⁴⁸ Exchange Rule 531(c)(1)(ii)(B) would further provide that if the resting order executes against multiple contra-side responses, only the ABBO at the time of the execution against the first response will be included.

⁴⁹ The time the Exchange received the response order would be in nanoseconds and would be the time the response was received by the Exchange's network, which is before the time the response would be received by the System.

⁵⁰ For purposes of calculating this duration of time, the Exchange will use the time the first response that executes against the resting order and the Recipient Member's response(s) is received by the Exchange's network, both of which would be before the order and response(s) would be received by the System. This time difference would be provided in nanoseconds.

Timeframe for Data Included in Report

The timeframe covered by the proposed Resting Simple Order Report is the primary difference between it and the existing Simple Order Report. The existing Simple Order Report provides data for executions and contra-side responses that occurred within 200 microseconds of the time the resting order was received by the Exchange. Meanwhile, the proposed Resting Simple Order Report would include the same data as the Simple Order Report but would focus on executions and contra-side responses that occurred after 200 microseconds of the time the resting order was received by the Exchange, and within 200 microseconds of receipt of any Member's first attempt to execute against the resting order after the initial 200 microsecond time period has expired. More specifically, the resting order must rest on the Simple Order Book for at least 200 microseconds and once that initial 200 microsecond period has passed, a Member must then submit an order to attempt to execute against that resting order. This event starts a second 200 microsecond period within which the proposed Resting Simple Order Report would include data on executions and contra-side responses submitted by the Recipient Member to execute against that resting order.

For example, Member A submits an order that is posted to the Simple Order Book. 200 microseconds passes and Member A's order remains posted to the Simple Order Book. Then Member B enters a marketable order to execute against Member A's resting order, starting the second 200 microsecond window. Within this next 200 microsecond window, Member C sends a marketable order to execute against Member A's resting order. Because Member B's order is received by the Exchange before Member C's order, Member B's order executes against Member A's resting order. The proposed Resting Simple Order Report would provide Member C the data points necessary for that firm to calculate by how much time it missed executing against Member A's resting order.

The above timeframe would be codified under proposed paragraph (c)(2) of Exchange Rule 531 which would provide that the proposed Resting Simple Order Report would include the data set forth under Exchange Rule 531(c)(1) described above for executions and contra-side responses that occurred (i) after 200 microseconds of the time the resting order was received by the Exchange and (ii) within 200 microseconds of receipt

of the first attempt to execute against the resting order after the initial 200 microsecond time period under (c)(2)(i) of this paragraph has expired.

Scope of Data Included in the Resting Simple Order Report

Like current paragraph (a)(3) of Exchange Rule 531 for the existing Simple Order Report, proposed paragraph (c)(3) of Exchange Rule 531 would provide that the proposed Resting Simple Order Report will only include trading data related to the Recipient Member and, subject to the proposed paragraph (4) of Exchange Rule 531(c) described below, will not include any other Member's trading data other than that listed in paragraphs (1)(i) and (ii) of proposed Exchange Rule 531(c), described above.

Historical Data

Like current paragraph (a)(4) of Exchange Rule 531 for the existing Simple Order Report, proposed paragraph (c)(4) of Exchange Rule 531 would specify that the proposed Resting Simple Order Report will contain historical data from the prior trading day and will be available after the end of the trading day, generally on a T+1 basis.

2. Statutory Basis

The Exchange believes the proposed rule changes are consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of section 6(b) of the Act.⁵¹ Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)⁵² requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. This proposal is in keeping with those principles in that it promotes increased transparency through the dissemination of the optional Complex Order Report and Resting Simple Order Report to those interested in subscribing to receive the data. Additionally, the Exchange believes the proposed rule change is consistent with the section

6(b)(5)⁵³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

But for three differences, the description of the proposed Complex Order Report under Exchange Rule 531(b) is identical to that of the Simple Order Report under Exchange Rule 531(a). The first difference concerns the content of the proposed Complex Order Report, which would be limited to incoming complex orders that seek to remove liquidity from the Exchange's Strategy Book. The Simple Order Report includes information about incoming orders seeking to remove liquidity from the Simple Order Book. This difference is immaterial because both reports include basically the same information and seek to serve the same purpose, to provide the Recipient Member with the same type of data necessary for them to evaluate their own trading behavior and order interactions on the Exchange; however, the Simple Order Report contains data relevant to the Simple Order Book while the proposed Complex Order Report contains data relevant to the Strategy Book.

The other two differences are that the Simple Order Report includes the SBBO, which is the Exchange's best bid or offer, and the ABBO, which is the best bid or offer of away exchanges. In their place, the proposed Complex Order Report would include the Complex SBBO and Complex ABBO. As discussed above, the Complex SBBO is calculated using the icSBBO combined with the best price currently available on the Strategy Book to establish the Exchange's best net bid or offer for a complex strategy.⁵⁴ The Complex ABBO is calculated using the ABBO for each component of a complex strategy to establish the away markets' best net bid or offer for a complex strategy using OPRA data. The Exchange is providing the Complex SBBO and Complex ABBO because both are relevant and tailored to a Member that is entering a complex order to remove liquidity as part of a complex strategy and, therefore, more germane to the purpose of the Complex Order Report. The Exchange believes these differences are appropriate because providing the Complex SBBO in place of the SBBO and the Complex ABBO in place of the ABBO are more germane to the purpose of the proposed Complex Order Report.

The timeframe covered by the proposed Resting Simple Order Report is the primary difference between it and the existing Simple Order Report.

However, this difference only pertains to the timeframe covered by each report, with each report containing the exact same data fields with one exception described here. The existing Simple Order Report provides data for executions and contra-side responses that occurred within 200 microseconds of the time the resting order was received by the Exchange. Meanwhile, the proposed Resting Simple Order Report would basically include the same data as the Simple Order Report but would focus on executions and contra-side responses that occurred after 200 microseconds of the time the resting order was received by the Exchange and one additional difference. The one difference is that unlike the existing Simple Order Report, the proposed Resting Simple Order Report would not include the time difference between the time the resting order and first response that executes against the resting order are received by the Exchange. Each report focuses on 200 microsecond windows with the existing Simple Order Report's window starting at the time of receipt of the resting order and the proposed Resting Simple Order Report's window starting with the first attempt to execute against the resting order after the order was resting on the Simple Order Book for at least 200 microseconds.

Like the Simple Order Report, the Exchange believes the proposed Complex Order Report and Resting Simple Order Report will serve to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general protect investors and the public interest by providing Members access to information regarding their trading activity that they may utilize to evaluate their own trading behavior and order interactions. Also, like the Simple Order Report, the proposed Complex Order Report is designed for Members that are interested in gaining insight into latency in connection with complex orders that failed to execute against an order resting on the Exchange's Strategy Book by providing those Members data to analyze by how much time their complex order may have missed an execution against a contra-side order resting on the Strategy Book. Like the existing Simple Order Report, the proposed Resting Simple Order Report is designed for Members that are interested in gaining insight into latency in connection with orders that failed to execute against an order resting on the Exchange's Simple Order Book by

⁵¹ 15 U.S.C. 78f(b).

⁵² 15 U.S.C. 78f(b)(5).

⁵³ *Id.*

⁵⁴ See *supra* note 11.

providing those Members data to analyze by how much time their order may have missed an execution against a contra-side order resting on the Simple Order Book. The Exchange believes that providing this optional latency data to interested Members is consistent with facilitating transactions in securities, removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest because it provides greater visibility into the latency of Members' incoming orders that they may use to optimize their models and trading patterns in an effort to yield better execution results by calculating by how much time their order may have missed an execution. This would, in turn, benefit other market participants who may experience better executions on the Exchange because those that use the proposed Complex Order Report and/or Resting Simple Order Report may recalibrate their trading models and then increase their trading on the Exchange and volume of liquidity removing orders. This could lead to an increase in incoming liquidity removing orders resulting in higher execution rates for Members who primarily place resting orders on either the Strategy Book or Simple Order Book, or both. The proposed Complex Order Report and Resting Simple Order Report may benefit other market participants who would receive greater fill rates, thereby facilitating transactions in securities and perfecting the mechanism of the national market system.

As discussed above, the Exchange's affiliates, MIAX, MIAX Pearl and MIAX Emerald, received ad hoc requests from their members for information regarding the timeliness of their attempts to execute against resting options liquidity on Strategy Books and Simple Order Books of those markets. The proposal promotes just and equitable principles of trade because it would provide latency information in a systematized way and standardized format to any Member that chooses to subscribe to the proposed Complex Order Report or Resting Simple Order Report. As a result, the proposal would also remove impediments to and perfect the mechanism of a free and open market and a national market system by making latency information for liquidity-seeking orders available in a more equalized manner.

The proposal further promotes just and equitable principles of trade by increasing transparency, particularly for Recipient Members of either or both the Complex Order Report and Resting

Simple Order Report that may not have the expertise to generate the same information on their own. The proposed Complex Order Report may better enable Recipient Members to increase the fill rates for their liquidity-seeking Complex Orders and the Resting Simple Order Report may better enable Recipient Members to increase the fill rates for their liquidity-seeking orders. At the same time, as is also discussed above, the Complex Order Report and Resting Simple Order Report promote just and equitable principles of trade and protect investors and the public interest because they are designed to prevent a Recipient Member of either report from learning other Members' sensitive trading information. The Complex Order Report and Resting Simple Order Report would not be real-time market data products, as they would provide only historical trading data for the previous trading day, generally on a T+1 basis. In addition, the data in the Complex Order Report regarding incoming orders that failed to execute would be specific to the Recipient Member's complex orders, and other information in the proposed Complex Order Report regarding resting orders and executions would be anonymized if it relates to a Member other than the Recipient Member. The same is true for the Resting Simple Order Report.

The Complex Order Report and Resting Simple Order Report generally would contain three buckets of information each. The first two buckets include information about the resting order and the execution of the resting order. The Exchange anticipates that this information will be available from the Exchange's proprietary data feeds or derivable from OPRA. For example, for the Complex Order Report, the Exchange plans to offer the Complex Top of Market ("cToM") data feed which will provide real-time quote and last sale information for all displayed orders on the Strategy Book.⁵⁵ For the Resting Simple Order Report, OPRA provides bids, offers, and consolidated last sale and quotation information for options trading on all national securities exchanges, including the Exchange. In addition, the Exchange plans to offer the Top of Market ("ToM") data feed which will provide real-time quote and last

sale information for all displayed orders on the Simple Order Book.⁵⁶

The first bucket of information contained in the proposed Complex Order Report and Resting Simple Order Report for the resting order includes the time the resting order was received by the Exchange, the symbol, unique reference number assigned at the time of receipt, side (buy or sell), and the displayed price and size of the resting order. The symbol, origin type, side (buy or sell), and displayed price and size are also available via the Exchange's proprietary data feeds depending on which report a Member subscribes to. The first bucket of information for both proposed reports would also indicate whether the Recipient Member is an Affiliate of the Member that entered the resting order. This data field for both proposed reports would not indicate the identity of the Member that entered the resting order and would simply allow the Recipient Member to better understand the scenarios in which it may execute against the orders of its Affiliates.⁵⁷

For the proposed Complex Order Report, the second bucket of information pertains to the execution of the resting order and includes the Complex SBBO and Complex ABBO at the time of execution and for the proposed Resting Simple Order Report, pertains to the execution of the resting order and includes the SBBO and ABBO at the time of execution. These data points for both proposed reports are also derivable from information disseminated via OPRA or available via the Exchange's proprietary data feeds, depending on the type of report. The second bucket of information for both reports would also indicate whether the response was entered by the Recipient Member. For both reports, this data point would be simply provided as a convenience and, if not entered by the Recipient Member, this data point would be left blank so as not to include any identifying information about other Member activity. For the Complex Order Report, the second bucket of information would also include the size, time and type of first response⁵⁸ that executes against the resting order; as well as the time difference between the time the resting order and first response

⁵⁶ See MIAX Sapphire Options Exchange User Manual, Version 1.0.0, Section 5.06 (dated December 11, 2023), available at https://www.miaxglobal.com/sites/default/files/job-files/MIAX_Sapphire_User_Manual_v1.0.0_2024_06_18.pdf.

⁵⁷ The Exchange surveils to monitor for aberrant behavior related to internalized trades and identify potential wash sales.

⁵⁸ See *supra* note 25.

⁵⁵ See MIAX Sapphire Options Exchange User Manual, Version 1.0.0, Section 5.07 (dated December 11, 2023), available at https://www.miaxglobal.com/sites/default/files/job-files/MIAX_Sapphire_User_Manual_v1.0.0_2024_06_18.pdf.

that executes against the resting order are received by the Exchange. These data points would assist the Recipient Member in analyzing by how much time their order may have missed an execution against a contra-side order resting on the Strategy Book. For the Resting Simple Order Report, the second bucket of information also includes the size, as well as the time and type of first response that executes against the resting order. These data points would assist the Recipient Member in analyzing by how much time their order may have missed an execution against a contra-side order resting on the Simple Order Book. Unlike the existing Simple Order Report and proposed Complex Order Report, the proposed Resting Simple Order Report would not include the time difference between the time the resting order and first response that executes against the resting order are received by the Exchange. The proposed Resting Simple Order Report would not include this data point because the Exchange understands Recipient Members may not find it useful due to the fact that the proposed Resting Simple Order Report focuses on orders that have been resting on the Simple Order Book for longer than 200 microseconds. Therefore, the Exchange does not propose to include this data point as a means to streamline the proposed Resting Simple Order Report and remove unnecessary data.

For both proposed reports, the third bucket of information would be about the Recipient Member's response(s) and the time their response(s) is received by the Exchange. This would include the time difference between the time the first response that executes against the resting order was received by the Exchange and the time of each response sent by the Recipient Member, regardless of whether it executed or not. As above, for both proposed reports, this data point would assist the Recipient Member in analyzing by how much time their order may have missed an execution against a contra-side order resting on the Strategy Book. This bucket would also include the size and type of each response submitted by the Recipient Member, the Recipient Member identifier, and a response reference number, which is selected by the Recipient Member. Each of these data points are unique to the Recipient Member and should already be known by the Recipient Member even if not included in the Complex Order Report or Resting Simple Order Report, as the case may be.

The Exchange proposes to provide the Complex Order Report and Resting Simple Order Report on a voluntary

basis and no Member will be required to subscribe to either report. The Exchange notes that there is no rule or regulation that requires the Exchange to produce, or that a Member elect to receive, either proposed report. It would be entirely a business decision of each Member to subscribe to either proposed report. The Exchange proposes to offer the Complex Order Report and Resting Simple Order Report as a convenience to Members to provide them with additional information regarding trading activity on the Exchange on a delayed basis after the close of regular trading hours. A Member that chooses to subscribe to either proposed report may discontinue receiving either at any time if that Member determines that the information contained in the Complex Order Report or Resting Simple Order Report is no longer useful.

In summary, the proposed Complex Order Report and Resting Simple Order Report will help to protect a free and open market by providing additional data (offered on an optional basis) to the marketplace and by providing investors with greater choices.⁵⁹ Additionally, the proposal would not permit unfair discrimination because the proposed Complex Order Report and Resting Simple Order Report will be available to all Exchange Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

Inter-Market Competition

The proposed Complex Order Report and Resting Simple Order Report will allow the Exchange to provide new options for Members to receive historical market data. The proposed Complex Order Report and Resting Simple Order Report will also further enhance inter-market competition between exchanges by allowing the Exchange to expand its product offerings to include additional reports to provide latency information requested by Members. The latency information that would be provided in the proposed Complex Order Report and Resting Simple Order Report would enhance competition between exchanges because it would allow Recipient Members to recalibrate their models and trading strategies to improve their overall

trading experience on the Exchange. This may improve the Exchange's overall trading environment resulting in increased liquidity and order flow on the Exchange. In response, other exchanges may similarly seek ways to provide latency related data in an effort to improve their own market quality. Further, at least one other competing exchange offers substantively identical reports as the Exchange's Simple Order Report and proposed Complex Order Report.⁶⁰

Intra-Market Competition

The proposed rule change to offer the optional Complex Order Report and Resting Simple Order Report is in response to Member interest and requests for such information at the Exchange's affiliates, MIAA and MIAA Emerald. The Exchange does not believe the proposed Complex Order Report or Resting Simple Order Report will have an inappropriate burden on intra-market competition between Recipient Members and other Members who choose not to receive either report. As discussed above, the first two buckets of information included in the Complex Order Report and Resting Simple Order Report (with one minor exception described above) contain information about the resting order and the execution of the resting order, both of which are generally available to Members that choose not to receive the Complex Order Report or Resting Simple Order Report from other sources, such as by deriving these data points from OPRA or obtaining them from the Exchange's proprietary data feeds. The third bucket of information pertains to the Recipient Member's response and the time their response is received by the Exchange, information which latency sensitive Members that do not subscribe to the proposed Complex Order Report or Resting Simple Order Report could obtain on their own based on their knowledge of when they sent their response to the Exchange and via timestamp information provided by the acknowledgment message received from the Exchange. However, latency sensitive Members that do not subscribe to the proposed Complex Order Report or Resting Simple Order Report would not be able to obtain the time difference between the time the first response that executes against the resting order was received by the Exchange and the time of each response sent by the Recipient Member. Such latency sensitive Members may not view this information as beneficial based on their own trading models and systems. Other Members

⁵⁹ See Sec. Indus. Fin. Mkts. Ass'n (SIFMA), Initial Decision Release No. 1015, 2016 SEC LEXIS 2278 (ALJ June 1, 2016) (finding the existence of vigorous competition with respect to non-core market data).

⁶⁰ See BOX Exchange LLC Rules 7350(b) and (c).

that do not subscribe to the proposed Complex Order Report or Resting Simple Order Report may not view either proposed report as useful due to their own trading behaviors and business models. Such Members may not be latency sensitive and may be interested primarily in providing resting liquidity on the Exchange's Simple Order Book or Strategy Book, or they may simply be connected to the Exchange for best execution purposes or to comply with the trade-through requirements under Chapter XIV of the Exchange's Rules.⁶¹ Additionally, some Members may already be able to derive a substantial amount of the same data that is provided by some of the components based on their own executions and algorithms.

In sum, if the proposed Complex Order Report or Resting Simple Order Report is unattractive to Members, Members will opt not to receive either report. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to section 19(b)(3)(A)(iii) of the Act⁶² and Rule 19b-4(f)(6)⁶³ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)⁶⁴ normally does not

become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),⁶⁵ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the 30-day operative delay would enable the Exchange to make the Complex Order Report and the Resting Simple Order Report available to Exchange Members on August 12, 2024, the date of the proposed launch of the Exchange, and thus enable the Exchange to make information for liquidity-seeking orders available to Exchange Members in a more equalized and timelier manner. The Exchange states that other options exchanges currently offer substantially similar reports.⁶⁶ For these reasons, and because the proposal does not raise any new or novel issues, the Commission finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.⁶⁷

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)⁶⁸ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-SAPPHIRE-2024-05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-SAPPHIRE-2024-05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-SAPPHIRE-2024-05 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17504 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

⁶¹ Chapter XIV of the Exchange Rules incorporates by reference Rule 1401, Order Protection, of the Exchange's affiliate, MIAAX.

⁶² 15 U.S.C. 78s(b)(3)(A)(iii).

⁶³ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

⁶⁴ 17 CFR 240.19b-4(f)(6).

⁶⁵ 17 CFR 240.19b-4(f)(6)(iii).

⁶⁶ See *supra* notes 7, 8 and 60.

⁶⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁶⁸ 15 U.S.C. 78s(b)(2)(B).

⁶⁹ 17 CFR 200.30-3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35291; File No. 812-15427]

Brookfield Asset Management Private Institutional Capital Adviser (Canada), L.P. and Brookfield Infrastructure Income Fund, Inc.

August 2, 2024.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (the “Act”) granting an exemption from section 23(a)(1) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies and business development companies (as defined under section 2(a)(48) of the Act) to pay investment advisory fees (as described in the application) in shares of their common stock.

APPLICANTS: Brookfield Asset Management Private Institutional Capital Adviser (Canada), L.P. and Brookfield Infrastructure Income Fund, Inc.

FILING DATES: The application was filed on January 20, 2023, and amended on June 23, 2023, October 19, 2023, and May 7, 2024.

HEARING OR NOTIFICATION OF HEARING:

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at *Secretaries-Office@sec.gov* and serving the applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on August 27, 2024, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary at *Secretaries-Office@sec.gov*.

ADDRESSES: The Commission: *Secretaries-Office@sec.gov*. Applicants:

Brian F. Hurley, Esq., Brookfield Infrastructure Income Fund, Inc., Brookfield Place, 225 Liberty Street, New York, NY 10281-1023; with copies to Michael R. Rosella, Esq. and Thomas D. Peeney, Esq., Paul Hastings LLP, 200 Park Avenue, New York, NY 10166.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, or Terri Jordan, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For applicants’ representations, legal analysis, and conditions, please refer to applicants’ third amended and restated application, dated May 7, 2024, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for an applicant using the Company name search field, on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html>. You may also call the SEC’s Public Reference Room at (202) 551-8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17481 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100640; File No. SR-ISE-2024-33]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fee for Remote Hands Service

August 2, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 19, 2024, Nasdaq ISE, LLC (“ISE” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s fee for Remote Hands Services, as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 19, 2024.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/ise/rules>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend a service fee relating to connectivity and co-location services. Specifically, the Exchange proposes to decrease its fee for Remote Hands Services, at General 8, section 1, to \$151.50 per hour.

General 8, section 1 includes the Exchange’s fees that relate to co-location services, including “Remote Hands Services.” The term “Remote Hands Services” refers to the use of Exchange engineers to perform on-site technical support tasks in its Data Center on behalf of its co-located customers, including the following: (1) power cycling of equipment; (2) patching and plugging in cabling and circuits; (3) observing, describing or reporting on display indicators; (4) configuration of hardware components instructed by the customer; (5) diagnosis and repairs as instructed by the customer; (6) swapping hardware components with customer-supplied spares or upgrades; (7) troubleshooting heat related issues as instructed by the Customer; and (8) returning defective equipment to the manufacturer or customer.

Earlier this year, the Exchange increased its \$150 per hour fee for Remote Hands Services, along with other connectivity and co-location services, by 5.5%, to partially account for the cumulative effects of inflation on the value to the Exchange of the revenues it earns through such fees.³ Now, the Exchange proposes to lower the Remote Hands Services fee from its current level, \$158 per hour, to \$151.50 per hour, with the net effect of providing for an overall smaller 1% increase over the original \$150 hourly rate.

The purpose of the proposed change in the Exchange's Remote Hands Services fee is the same as that which the Exchange expressed when it increased the fee by 5.5% earlier this year. That is, the change would enable the Exchange to maintain and improve its market technology and services. Prior to SR-ISE-2024-23, the Exchange had not increased its Remote Hands fee since 2017.⁴ However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.⁵ Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index (“PPI”) for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.⁶ An even more specific gauge of inflation—average hourly earnings (“AHE”) growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees from 2017 to 2024.⁷ Notwithstanding such significant inflation, the Exchange had not increased its Remote Hands Service fees during this time, thereby eroding the value of the revenue it collects through this fee.⁸

³ The Exchange initially filed this proposed pricing change on March 1, 2024 (SR-ISE-2024-09). On April 29, 2024, the Exchange withdrew that filing and submitted SR-ISE-2024-16. On June 27, 2024, the Exchange withdrew and replaced that filing with SR-ISE-2024-23.

⁴ In 2017, the Exchange synchronized its options for connecting to the Exchange with that of its sister exchanges and adopted uniform colocation services, including the Remote Hands Service. See Securities Exchange Act Release No. 34-81903 (October 19, 2017), 82 FR 49450 (October 25, 2017) (SR-ISE-2017-91).

⁵ See <https://www.officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

⁶ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

⁷ See <https://www.bls.gov/web/empsit/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/ceseeb8a.htm> (Last updated July 5, 2024).

⁸ Unregulated competitors providing connectivity and co-location services often have annual price

The proposed fee represents a decrease in the existing \$158 per hour rate, and a net overall 1% increase from the original \$150 per month fee. The 1% fee increase, resulting in a proposed amended rate of \$151.50 per hour, is far below the rates of inflation, as measured by either the CPI, the PPI, or the AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.⁹

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed net price increase over the prior \$150 per hour

increases written into their agreements with customers to account for inflation and rising costs.

⁹ See, e.g., Securities Exchange Act Release No. 34-100342 (June 14, 2024), 89 FR 52132 (June 21, 2024) (SR-CboeBYX-2024-021).

rate. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,¹⁰ in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,¹¹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fee does not properly reflect the value of the service, as fees for the service in question has been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, prior to SR-ISE-2024-23, the Exchange had not increased its Remote Hands Service fee since it introduced the fee in 2017. This means that this fee has fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.¹² Moreover, a more specific and pertinent gauge of inflation—the Producer Price Index (“PPI”) for data processing, hosting and related services, active services pages, and other IT infrastructure provisioning services—increased 16.1% from 2017 to 2024.¹³ An even more specific gauge of inflation—average hourly earnings (“AHE”) growth for Computing Infrastructure—increased 44% for non-managers and 38% for all employees

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4) and (5).

¹² See <https://www.officialdata.org/us/inflation/2017?amount=1> (Last updated February 27, 2024).

¹³ See <https://data.bls.gov/timeseries/PCU5182105182105> (Last updated June 24, 2024).

from 2017 to 2024.¹⁴ Notwithstanding such significant inflation, the Exchange had not increased its connectivity fees until 2024, thereby eroding the value of the revenue it collects through such fee.

The proposed fee represents a decrease from the existing \$158 per hour fee and a 1% overall net increase from the original \$150 per hour fee, which is far below the rates of inflation, as measured by either the CPI, the PPI, or AHE since 2017. Although the Exchange believes it would be reasonable to increase the fee by an amount equal to the full rates of inflation, however measured, to reestablish the initial value of the revenues it earns through its fees, the Exchange does not propose to do this. In fact, the Exchange now proposes to recalibrate even its initial 5.5% fee increase, because the Exchange is sensitive to the sticker shock that customers may experience when the Exchange raises rates. Instead, the Exchange proposes only a modest 1% increase over the prior \$150 per month rate, an amount that the Exchange believes to be reasonable on its face as it is significantly less than various measures of inflation discussed above, and even less than the original 5.5% increase.

The Exchange believes that it is reasonable to increase its fee to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increase. It is reasonable and consistent with the Act for the Commission to

allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.¹⁵ This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for Remote Hands Services, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. "If competitive forces are operative, the

self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior."¹⁶ Accordingly, "the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory."¹⁷ Disincentivizing market participants from purchasing Remote Hands Services for Exchange connectivity would only serve to discourage participation on the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only co-location and connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee change is not unfairly discriminatory because the fee is assessed uniformly across all market participants that voluntarily purchase Remote Hands Services, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the

¹⁴ See <https://www.bls.gov/web/empsit/ceseeb3a.htm> (Last updated July 5, 2024); <https://www.bls.gov/web/empsit/ceseeb8a.htm> (Last updated July 5, 2024).

¹⁵ See Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at <https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary>.

¹⁶ See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR-NYSEArca-2006-21).

¹⁷ *Id.*

competition among consumers) because the Exchange's Remote Hands Services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-ISE-2024-33 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to file number SR-ISE-2024-33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions;

you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-ISE-2024-33 and should be submitted on or before August 29, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17502 Filed 8-7-24; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Small Business Investment Company License Issuance

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Small Business Investment Company (SBIC) Licenses.

Pursuant to the authority granted to the United States Small Business Administration under section 301(c) of the Small Business Investment Act of 1958, as amended, to grant Small Business Investment Company licenses under the Small Business Investment Company Program, this notice satisfies the requirement effective August 17, 2023 under 13 CFR 107.501(a) to publish in the **Federal Register** the names of SBICs with date of licensure and Total Intended Leverage Commitments. The following SBICs received SBIC licenses from July 1, 2024, through July 31, 2024:

SBIC fund name	Date of licensure	Leverage tiers ¹
BIP III SBIC, L.P	7/08/2024	Non-leveraged.
Northstar Mezzanine Partners SBIC II, L.P	7/11/2024	2.0x.
Hercules SBIC V, L.P	7/11/2024	2.0x.
Cultivation Capital Seed Fund III, L.P	7/11/2024	Non-leveraged.
High Street Capital VI SBIC, L.P	7/15/2024	2.0x.
Northcreek Mezzanine Fund IV, L.P	7/15/2024	2.0x.

¹ Maximum amount of Leverage expressed as a multiple of Leverageable Capital pursuant to 13 CFR 107.1150. For all SBIC Licensees that submitted a Management Assessment Questionnaire after August 17, 2023, the Notice of SBIC Licenses will include the Total Intended Leverage Commitment at the time of Licensure.

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁹ 17 CFR 200.30-3(a)(12).

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration.

[FR Doc. 2024–17608 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20486 and #20487; KENTUCKY Disaster Number KY–20005]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of KENTUCKY

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–4804–DR), dated 07/23/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, Landslides, and Mudslides.

Incident Period: 05/21/2024 through 05/27/2024.

DATES: Issued on 08/02/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/23/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Kentucky, dated 07/23/2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Harlan, Perry.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–17619 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20437 and #20438; IDAHO Disaster Number ID–20005]

Administrative Disaster Declaration of a Rural Area for the State of Idaho

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative disaster declaration of a rural area for the State of Idaho dated 08/02/2024.

Incident: Severe Storm, Flooding, Landslides, and Mudslides.

Incident Period: 04/14/2024 through 04/15/2024.

DATES: Issued on 08/02/2024.

Physical Loan Application Deadline Date: 10/01/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 05/02/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration of a rural area, applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Idaho

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250

	Percent
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 204376 and for economic injury is 204380.

The State which received an EIDL Declaration is Idaho.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,
Administrator.

[FR Doc. 2024–17575 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20496 and #20497; IOWA Disaster Number IA–20009]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Iowa (FEMA–4796–DR), dated 07/24/2024.

Incident: Severe Storms, Flooding, Straight-line Winds, and Tornadoes.

Incident Period: 06/16/2024 through 07/23/2024.

DATES: Issued on 08/02/2024.

Physical Loan Application Deadline Date: 09/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/24/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of IOWA, dated 07/24/2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Harrison, Lyon, Monona, Osceola, Pocahontas, Winneshiek, Wright.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–17617 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20415 and #20416; IOWA Disaster Number IA–20005]

Presidential Declaration Amendment of a Major Disaster for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 6.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Iowa (FEMA–4796–DR), dated 06/24/2024.

Incident: Severe Storms, Flooding, Straight-line Winds, and Tornadoes.

Incident Period: 06/16/2024 through 07/23/2024.

DATES: Issued on 08/02/2024.

Physical Loan Application Deadline Date: 08/23/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 03/24/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Iowa, dated 06/24/2024, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Monona.

Contiguous Counties (Economic Injury Loans Only):

Nebraska: Burt

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–17620 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20445 and #20446; TEXAS Disaster Number TX–20016]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4798–DR), dated 07/12/2024.

Incident: Hurricane Beryl.

Incident Period: 07/05/2024 through 07/09/2024.

DATES: Issued on 08/02/2024.

Physical Loan Application Deadline Date: 09/10/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 04/14/2025.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 07/12/2024, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans):

Austin, Bowie, Shelby, Trinity, Waller.

Contiguous Counties (Economic Injury Loans Only):

Texas: Cass, Fayette, Morris, Panola, Red River, Washington

Louisiana: De Soto, Sabine

Arkansas: Little River, Miller

Oklahoma: McCurtain

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–17622 Filed 8–7–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice:12483]

Certification Under Section 7045(a)(2)(A) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2023

By virtue of the authority vested in me by section 7045(a)(2)(A) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2023 (div. K, Pub. L. 117–328) (FY 2023 SFOAA) and Department of State Delegation of Authority 513, I hereby certify that the central government of Guatemala is:

i. combating corruption and impunity, including investigating and prosecuting government officials, military personnel, and police officers credibly alleged to be corrupt;

ii. implementing reforms, policies, and programs to strengthen the rule of law, including increasing the transparency of public institutions, strengthening the independence of judicial and electoral institutions, and improving the transparency of political campaign and political party financing;

iii. protecting the rights of human rights defenders, trade unionists, journalists, civil society groups, opposition political parties, and the independence of the media;

iv. providing effective and accountable law enforcement and security for its citizens, curtailing the role of the military in public security, and upholding due process of law;

v. implementing programs to reduce violence against women and girls;

vi. implementing policies to reduce poverty and promote economic growth and opportunity, including the implementation of reforms to strengthen educational systems, vocational training programs, and programs for at-risk youth;

vii. improving border security and combating human smuggling and trafficking and countering the activities of criminal gangs, drug traffickers, and transnational criminal organizations;

viii. informing its citizens of the dangers of the journey to the southwest border of the United States; and

ix. implementing policies that improve the environment for foreign investment, including executing tax reform in a transparent manner, ensuring effective legal mechanisms for reimbursements of tax refunds owed to United States businesses, and resolving disputes involving the confiscation of real property of United States entities.

This certification shall be published in the **Federal Register** and, along with the accompanying Memorandum of

Justification, shall be reported to Congress.

Dated: July 17, 2024.

Richard R. Verma,
Deputy Secretary for Management and Resources.

[FR Doc. 2024–17517 Filed 8–7–24; 8:45 am]

BILLING CODE 4710–29–P

DEPARTMENT OF STATE

[Public Notice: 12477]

United States Passports Invalid for Travel To, In, or Through the Democratic People's Republic of Korea (DPRK)

AGENCY: Department of State.

ACTION: Notice of extension of passport travel restriction.

SUMMARY: On September 1, 2017, all U.S. passports were declared invalid for travel to, in, or through the Democratic People's Republic of Korea (DPRK), unless specially validated for such travel. The restriction was extended for one year in 2018, 2019, 2020, 2021, 2022, and 2023 and, if not renewed, the restriction is set to expire on August 31, 2024. This notice extends the restriction until August 31, 2025, unless extended or revoked by the Secretary of State.

DATES: The extension of the travel restriction is in effect on September 1, 2024.

FOR FURTHER INFORMATION CONTACT: Jennifer Tinianow, Bureau of Consular Affairs, Passport Services, Office of Adjudication, 202–765–6517.

SUPPLEMENTARY INFORMATION: On September 1, 2017, pursuant to the authority of 22 U.S.C. 211a and Executive Order 11295 (31 FR 10603), and in accordance with 22 CFR 51.63(a)(3), all U.S. passports were declared invalid for travel to, in, or through the DPRK unless specially validated for such travel. The restriction was renewed on September 1 in each year from 2018 through 2023. If not renewed again, the restriction is set to expire on August 31, 2024.

The Department of State has determined there continues to be serious risk to U.S. citizens and nationals of arrest and long-term detention constituting imminent danger to their physical safety, as defined in 22 CFR 51.63(a)(3). Accordingly, all U.S. passports shall remain invalid for travel to, in, or through the DPRK unless specially validated for such travel under the authority of the Secretary of State. This extension to the restriction of travel to the DPRK shall be effective on September 1, 2024, and shall expire

August 31, 2025, unless extended or revoked by the Secretary of State.

Dated: June 14, 2024.

Antony J. Blinken,
Secretary of State.

[FR Doc. 2024–17519 Filed 8–7–24; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Delegation of Authority No. 560]

Delegation of Authority Public Posting of Reports

By virtue of the authority vested in the Secretary of State by the laws of the United States, including 22 U.S.C. 2651a and section 7016(b)(2)(A) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2024 (div. F, Pub. L. 118–47), I hereby delegate to the Under Secretary for Political Affairs and the Under Secretary for Management, to the extent authorized by law, the authority to determine that the public posting of a report to the Congress would compromise national security, including the conduct of diplomacy, or the report contains proprietary or other privileged information.

The reference in this delegation of authority to a statute shall be deemed to be a reference to such statute as amended from time to time and shall be deemed to apply to any provision of law that is the same or substantially the same as such statute. This delegation of authority does not repeal or modify any other delegation of authority currently in effect.

The Secretary, Deputy Secretary, or Deputy Secretary for Management and Resources may exercise any authority or function delegated herein.

This memorandum shall be published in the **Federal Register**.

Dated: July 24, 2024.

Antony J. Blinken,
Secretary of State.

[FR Doc. 2024–17520 Filed 8–7–24; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2006–25040]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received on April 12, 2024,

Capital Metropolitan Transportation Authority (CMTY) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 222 (Use of Locomotive Horns at Public Highway–Rail Grade Crossings), part 229 (Railroad Locomotive Safety Standards), part 231 (Railroad Safety Appliance Standards), part 234 (Grade Crossing Safety), and part 238 (Passenger Equipment Safety Standards). The relevant Docket Number is FRA–2006–25040.

Specifically, CMTY requested to extend its existing relief for its commuter rail system that connects downtown Austin, Texas, with Austin's northern suburbs along 32 miles with 9 stations. CMTY seeks to continue operating a fleet of 6 Stadler GTW diesel multiple unit (DMU) rail vehicles that have operated on the line since 2010. CMTY requests extended relief from the following regulations:

- § 222.21(b), (d), *When must a locomotive horn be used?*
- §§ 229.29(c)(3) and (e), *Air brake system calibration, maintenance, and testing*; and 238.309(b), *Periodic brake equipment maintenance*
- §§ 229.31, *Main reservoir tests*; 229.49(b), *Main reservoir system*; and 229.51(a)(3) and (4), *Aluminum main reservoirs*
- §§ 229.47(b), *Emergency brake valve*; and 238.305(c)(5), *Interior calendar day mechanical inspection of passenger cars*
- § 229.71, *Clearance above top of rail*
- § 229.135(b)(4)(xviii) and (xix), *Event recorders*
- § 231.14(a)–(d), (f), and (g), *Passenger-train cars without end platforms*; § 238.229, *Safety appliances—general*
- § 238.103, *Fire safety*
- § 238.121(c)(2), *Emergency communication*
- § 238.223(a), *Locomotive fuel tanks*; and part 238, appendix D, *Requirements for External Fuel Tanks on Tier I Locomotives*

In support of its request, CMTY explained that their vehicles demonstrate “an equivalent level of safety and compliance,” given the Alternative Vehicle Technology final rule amendments in 49 CFR part 238. CMTY also noted that in this renewal request, they are seeking relief from fewer specific regulatory provisions than previously granted for this fleet of vehicles.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at www.regulations.gov. Follow the online instructions for submitting comments.

Communications received by October 7, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of the U.S. Department of Transportation's (DOT) dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2024-17564 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2024-0068]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received May 24, 2024, a private owner, Tierney Foster Abel (Mr. Abel), petitioned the Federal Railroad Administration (FRA) to extend a

waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR parts 223 (Safety Glazing Standards—Locomotives, Passenger Cars and Cabooses) and 231 (Railroad Safety Appliance Standards). FRA assigned the petition Docket Number FRA-2024-0068.¹

Specifically, Mr. Abel requests relief for steam locomotive HLLR 331 from the safety glazing standards in part 223, as well as § 231.15(b) and (d), *Steam locomotives used in road service—pilot sill-steps, side handholds*, which give requirements for certain safety appliances. The locomotive is operated on 4,500 feet of standard-gage track and only used during special events on the Stone Gables Estate property for a total of about 40 days of service. The petition states that HLLR 331 is used “to educate the public concerning early American railroad history” and will not be used for freight or passenger service. However, it “will occasionally pull some cars appropriate for its historic and educational mission.”

The relief is requested because installation of FRA safety glazing will “substantially change the historic configuration and appearance of the cab” and thereby “ruin the historical appearance.” Additionally, Mr. Abel states that HLLR 331 will not be used for coupling but instead, the locomotive and tender will be “connected by a draw bar that is . . . secured in place so it cannot be removed or otherwise come apart.” Therefore, the “step requirements are unnecessary” and the handholds would “substantially detract from the historic appearance” as the locomotive cab and tender are substantially different heights.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be

¹ Relief for this locomotive, with marking Leviathan 63, was previously granted in Docket Number FRA-2011-0011.

submitted at www.regulations.gov. Follow the online instructions for submitting comments.

Communications received by October 7, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of the U.S. Department of Transportation's (DOT) dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety
Chief Safety Officer.*

[FR Doc. 2024-17567 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2016-0086]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received June 3, 2024, BNSF Railway Company (BNSF) petitioned the Federal Railroad Administration (FRA) to extend the existing test waiver of compliance in Docket Number FRA-2016-0086. The existing relief in this docket provides BNSF, CSX Transportation (CSX), and Kansas City Southern Railway (now known as CPKC) conditional relief from certain provisions of the Federal railroad safety regulations contained at 49 CFR parts 232 (Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-Of-Train Devices), and 229 (Railroad Locomotive Safety Standards). Specifically, the existing relief allows the railroads to test extending the air flow method (AFM) test intervals from

92 days to 184 days on locomotives equipped with the New York Air Brake (NYAB) CCB-II and Fastbrake air brake systems.

In support of its request, BNSF states that “throughout the life of th[e] waiver, the data collected and reported to the FRA has conclusively established that the AFM indicator can successfully and safely maintain calibration setting for a period of at least 184 days,” citing that in a period measured from June to December 2023, “98% of BNSF’s AFM indicators have tested as in-calibration at the 184-day mark.” BNSF also notes that the relief “has crucially enabled alignment between the AFM indicator-calibration interval and the interval for federally mandated periodic locomotive inspections,” as well as additional safety benefits described in the request.

In this petition, BNSF notes that it also seeks to transition this waiver to a permanent waiver in the future, but at this time, is requesting a five-year extension.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at www.regulations.gov. Follow the online instructions for submitting comments.

Communications received by October 7, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of the U.S. Department of Transportation’s (DOT) dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in

the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,
*Associate Administrator for Railroad Safety
Chief Safety Officer.*

[FR Doc. 2024–17565 Filed 8–7–24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2018–0084]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received June 3, 2024, Texas State Railroad/Texas & Eastern Railroad (Petitioner) petitioned the Federal Railroad Administration (FRA) to extend the existing waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 240 (Qualification and Certification of Locomotive Engineers). The relevant Docket Number is FRA–2018–0084.

Specifically, Petitioner requests continued relief from § 240.201, *Implementation*, which requires that only certified persons operate locomotives and trains. The relief would allow noncertified persons to operate a historic locomotive as part of a visitor experience or “Hand on the Throttle” program. In support of its petition, Petitioner notes that the relief would only apply to persons participating in the program, and that participants would be 18 years of age or older and under the direct supervision of a certified and qualified locomotive engineer. Further, all movements would take place during daylight hours and at restricted speed with no opposing train movements, and no public grade crossings will be occupied. Additionally, derail protection will be in place at each end of the track limits.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since

the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at www.regulations.gov. Follow the online instructions for submitting comments.

Communications received by October 7, 2024 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of the U.S. Department of Transportation’s (DOT) dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,
*Associate Administrator for Railroad Safety
Chief Safety Officer.*

[FR Doc. 2024–17566 Filed 8–7–24; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Advisory Council; Public Meeting

AGENCY: Maritime Administration, DOT.
ACTION: Notice of public meeting.

SUMMARY: The U.S. Department of Transportation, Maritime Administration (MARAD) announces a meeting of the U.S. Merchant Marine Academy (USMMA) Advisory Council (Council). During the meeting, the USMMA leadership will provide an update on programs and priorities, including governance, sexual assault and sexual harassment, academics, culture and diversity, and facilities and infrastructure.

DATES: August 29, 2024, from 1:00 p.m. to 3:00 p.m. EST. Written statements to be considered during the meeting must be received via email to

USMMAAdvisoryCouncil@dot.gov no later than August 22, 2024. Requests for accommodations for a disability must be received via email by August 23, 2024.

ADDRESSES: The meeting will be held through a virtual forum. Virtual meeting access information will be available on the USMMA Advisory Council web page and social media channels no later than August 23, 2024. General information about the Council is available at www.maritime.dot.gov/outreach/united-states-merchant-marine-academy-advisory-council.

FOR FURTHER INFORMATION CONTACT: The Council's Designated Federal Officer and Point of Contact, Mary Grice, 202-366-4264 or via email to USMMAAdvisoryCouncil@dot.gov.

SUPPLEMENTARY INFORMATION:

Background

The Council is established pursuant to 46 U.S.C. 51323. The Council operates in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. ch. 10.

The objective and scope of the Council is to provide independent advice and recommendations to the Secretary of Transportation (Secretary) on matters relating to USMMA including in the areas of curriculum development and training programs; diversity, equity, and inclusion; sexual assault prevention and response; infrastructure maintenance and redevelopment; midshipmen health and welfare; governance and administrative policies; and other matters.

Agenda

The meeting agenda will cover, but is not limited to, the following proposed topics:

1. Welcome and opening remarks
2. Public comments
3. Advisory Council's Report
4. Administrative items

Public Participation

This meeting is open to the public and will be held through a virtual forum. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Any member of the public is permitted to file a written statement

with the Council. Written statements should be sent to the Designated Federal Officer listed in the **FOR FURTHER INFORMATION CONTACT** section no later than August 22, 2024.

Only written statements will be considered by the Council; no member of the public will be allowed to present questions or speak during the meeting unless requested to do so by a member of the Council.

(Authority: 46 U.S.C. 51323; 5 U.S.C. 552b; 5 U.S.C. ch. 10; 41 CFR parts 102-3.140 through 102-3.165)

By Order of the Maritime Administrator.
T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2024-17581 Filed 8-7-24; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2024-0103]

Request for Comments on the Renewal of a Previously Approved Information Collection: Approval of Underwriters for Marine Hull Insurance; Correction

AGENCY: Maritime Administration, DOT.

ACTION: Notice, correction.

SUMMARY: On August 2, 2024, the Maritime Administration (MARAD) published a document in the **Federal Register** inviting public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995 (PRA). However, the publication contained an incorrect docket number. This notice reflects the corrected docket number "MARAD-2024-0103" and restates the notice requesting comment. Accordingly, MARAD invites public comments on our intention to request OMB approval to renew an information collection in accordance with the PRA. The proposed collection OMB 2133-0517 (Approval of Underwriters for Marine Hull Insurance) will be used to provide approval of foreign underwriters based on an assessment of their financial condition, the regulatory regime under which they operate, and a statement attesting to a lack of discrimination in their country against U.S. hull insurers. The regulations also require that American underwriters be given an opportunity to compete for every placement, thereby necessitating in some cases certification that such opportunity was offered. We are required to publish this notice in the

Federal Register to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before October 7, 2024.

ADDRESSES: You may submit comments identified by Docket No. MARAD-2024-0103 through one of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Cameryn L. Miller, 202-366-0907, Office of Marine Insurance, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, Email: cameryn.miller@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Approval of Underwriters for Marine Hull Insurance.

OMB Control Number: 2133-0517.

Type of Request: Extension Without Change of a Currently Approved Collection.

Abstract: This collection of information involves the approval of marine hull underwriters to insure MARAD program vessels. Applicants will be required to submit financial data upon which MARAD approval would be based. This information is needed in order that MARAD officials can evaluate the underwriters and determine their suitability for providing marine hull insurance on MARAD vessels.

Respondents: Marine Insurance Underwriters and Brokers.

Affected Public: Businesses or other for profit.

Estimated Number of Respondents: 66.

Estimated Number of Responses: 66.

Estimated Hours per Response: .5–1 hour.

Annual Estimated Total Annual Burden Hours: 49.

Frequency of Response: Once Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–17499 Filed 8–7–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2024–0117; Notice No. 2024–11]

Hazardous Materials: Notice of Public Meeting on the Transportation of Hazardous Materials by Unmanned Aircraft Systems

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Office of Hazardous Materials Safety, and the Federal Aviation Administration (FAA), Security and Hazardous Materials Safety, Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: This notice announces that PHMSA and FAA will host a public meeting to solicit input on implementing provisions in the FAA Reauthorization Act of 2024. This section relates to the transportation of hazardous materials by unmanned aircraft systems (UAS).

DATES: This meeting will take place on August 22, 2024, from 1 p.m. to 4 p.m., Eastern Time.

ADDRESSES: The public meeting will be a web conference. Specific information for this meeting will be posted on the PHMSA website under “Upcoming Events” at <https://www.phmsa.dot.gov/standards-rulemaking/hazmat/standards-materials-standards-and-rulemaking-overview>. This information will include the public meeting date, time, conference dial-in number, and details for registration. You must register to attend the meeting, please register here: [https://events.gcc.teams.microsoft.com/event/64a51604-bd84-4423-aae9-](https://events.gcc.teams.microsoft.com/event/64a51604-bd84-4423-aae9-27e3955cd18c@c4cd245b-44f0-4395-a1aa-3848d258f78b)

[27e3955cd18c@c4cd245b-44f0-4395-a1aa-3848d258f78b](https://events.gcc.teams.microsoft.com/event/64a51604-bd84-4423-aae9-27e3955cd18c@c4cd245b-44f0-4395-a1aa-3848d258f78b).

FOR FURTHER INFORMATION CONTACT:

Steven Andrews, 202–366–8553, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or

Lori Ambers, 405–954–0088, Office of Hazardous Materials Safety, Federal Aviation Administration, U.S. Department of Transportation, 800 Independence Avenue SW, Washington, DC 20591–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On May 16, 2024, President Biden signed the Federal Aviation Administration (FAA) Reauthorization Act of 2024¹ into law. Section 933 of the FAA Reauthorization Act of 2024, titled “Special Authority for Transport of Hazardous Materials by Commercial Package Delivery Unmanned Aircraft Systems” directs the Secretary of Transportation to use a risk-based approach to establish the operational requirements, standards, or special permits necessary to approve or authorize an air carrier to transport hazardous materials by UAS providing common carriage under 14 Code of Federal Regulations (CFR) part 135, or under successor authorities, as applicable, based on the weight, amount, and type of hazardous material being transported and the characteristics of the operations subject to such requirements, standards, or special purposes (see § 933, subsection (a)). Section 933, subsection (e)(1) requires the Secretary to hold a public meeting within 180 days of the enactment of the FAA Reauthorization Act of 2024 to obtain input on the changes necessary to implement § 933.

This joint public meeting, hosted by PHMSA and the FAA, addresses the statutory requirement in § 933, subsection (e)(1) of the FAA Reauthorization Act. PHMSA and the FAA encourage participation in this public meeting from stakeholders and the public to help advance the development of policy for UAS delivery of packages containing hazardous materials.

II. Agenda

At this meeting, PHMSA and the FAA will provide a brief background discussion on § 933 of the FAA Reauthorization Act of 2024. Following

¹ <https://www.congress.gov/bill/118th-congress/house-bill/3935/text>.

this introduction, PHMSA and the FAA will solicit input from the public on actions necessary to implement § 933.

III. Public Participation

The meeting will be open to the public; however, any member of the public who wishes to attend must RSVP to obtain login instructions and access using the following: <https://events.gcc.teams.microsoft.com/event/64a51604-bd84-4423-aae9-27e3955cd18c@c4cd245b-44f0-4395-a1aa-3848d258f78b>. If you plan to present or provide input at this meeting, please file a written copy of your remarks and provide a copy of any visual aids to Mr. Steven Andrews (steven.andrews@dot.gov) and Ms. Lori Ambers (laura.l.ambers@faa.gov) by August 19, 2024.

PHMSA is committed to providing equal access for all citizens and ensuring that information is available in appropriate alternative formats to meet the requirements of persons who have a disability. If you require an alternative version of files provided or alternative accommodations, please contact PHMSA-Accessibility@dot.gov by August 15, 2024.

Signed in Washington, DC, on July 31, 2024.

William S. Schoonover,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2024–17291 Filed 8–7–24; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of Transactions of Exempt Persons Regulations, and FinCEN Form 110, Designation of Exempt Person Report

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, FinCEN invites comments on the proposed renewal, without change, of existing information collection requirements found in Bank Secrecy Act regulations that require a bank to file a FinCEN Form 110, Designation of Exempt Person, to designate eligible customers as exempt persons, such that a bank is not required to file a report

with respect to any transaction in currency over \$10,000 with such customers. In addition to filing this report, the regulations require the bank to take steps to ensure that a person meets the requirements for an exemption, document the basis for the bank's initial conclusion that a person is exempt, annually review the eligibility of certain exempt persons, document compliance with the requirements of FinCEN Form 110, Designation of Exempt Person, and maintain a monitoring system that is reasonably designed to detect, for each account of a non-listed business or payroll customer, transactions in currency requiring a bank to file a suspicious transaction report. This request for comments is made pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments are welcome and must be received on or before October 7, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Refer to Docket Number FINEEN-2024-0015 and Office of Management and Budget (OMB) control number 1506-0012.

- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINEEN-2024-0015 and OMB control number 1506-0012.

Please submit comments by one method only. Comments will be reviewed consistent with the Paperwork Reduction Act of 1995 (PRA) and applicable OMB regulations and guidance. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: FinCEN's Regulatory Support Section at 1-800-767-2825 or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

The legislative framework generally referred to as the Bank Secrecy Act (BSA) consists of the Currency and Foreign Transactions Reporting Act of 1970, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act)¹ and other legislation, including the Anti-Money

Laundering Act of 2020 (AML Act).² The BSA is codified at 12 U.S.C. 1829b and 1951-1960 and 31 U.S.C. 5311-5314 and 5316-5336, and notes thereto, with implementing regulations at 31 CFR chapter X.

The BSA authorizes the Secretary of the Treasury (Secretary) to, *inter alia*, require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, or regulatory matters, risk assessments or proceedings, or in the conduct of intelligence or counter-intelligence activities to protect against terrorism, and to implement anti-money laundering/countering the financing of terrorism (AML/CFT) programs and compliance procedures.³ The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.⁴

Under 31 U.S.C. 5313, the Secretary is authorized to require financial institutions to report currency transactions exceeding \$10,000. Regulations implementing 31 U.S.C. 5313 are found at 31 CFR 1010.310 through 1010.314, 31 CFR 1021.311, and 31 CFR 1021.313. The Money Laundering Suppression Act of 1994 amended the BSA to create certain mandatory exemptions applicable to banks from the requirement for financial institutions to file currency transaction reports (CTRs), and to give the Secretary authority to create additional such exemptions.⁵ Regulations implementing this exemption authority, including by requiring the collection of information on FinCEN Form 110, Designation of Exempt Person ("DOEP Report"), are found at 31 CFR 1020.315.

Under 31 CFR 1020.315(a), a bank is not required to file a CTR with respect to any transaction in currency between exempt persons and the bank, or between an exempt person and other banks that are affiliated with the bank.⁶

31 CFR 1020.315(b) sets out that an exempt person is: (1) a bank, to the extent of such bank's domestic operations; (2) a department or agency

of the United States, of any State, or of any political subdivision of any State; (3) any entity established under the laws of the United States, any State, or any political subdivision of any State, or under an interstate compact, that exercises governmental authority on behalf of the United States, any such State, or any such political subdivision; (4) any entity, other than a bank, whose common stock or analogous equity interests are listed on the New York Stock Exchange, the American Exchange, or the NASDAQ Stock Market (a "listed entity"), provided that, if the listed entity is a financial institution other than a bank, it is an exempt person only to the extent of its domestic operations; (5) any subsidiary, other than a bank, of a listed entity mentioned in the previous item (4) that is organized under the laws of the United States or of any State, provided that the listed entity owns at least 51 percent of the equity interest of the subsidiary, and subject to the qualification that if the subsidiary is a financial institution other than a bank, it is an exempt person only to the extent of its domestic operations; (6) any other commercial enterprise, with certain exceptions, that maintains a transaction account at the bank for at least two months, frequently engages in transactions with the bank in currency in excess of \$10,000, and is incorporated or organized under the laws of, or is registered as and eligible to do business within, the United States or a State (a "non-listed business"), but only to the extent of the non-listed business customer's domestic operations and only with respect to transactions conducted through the non-listed business customer's exemptible accounts; or (7) any other person, with certain exceptions, that maintains a transaction account at the bank for at least two months, operates a firm that frequently withdraws more than \$10,000 in order to pay its U.S. employees in currency, and is incorporated or organized under the laws of, or is registered as and eligible to do business within, the United States or a State (a "payroll customer"), but solely with respect to withdrawals for payroll purposes from existing exemptible accounts.⁷

31 CFR 1020.315(c)(1) requires a bank to designate an exempt person by filing

² The AML Act was enacted as Division F, sections 6001-6511, of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116-283, 134 Stat. 3388 (NDAA).

³ See 31 U.S.C. 5311; see also 12 U.S.C. 1829b(a).

⁴ Treasury Order 180-01 (Jan. 14, 2020).

⁵ Public Law 103-325, Title IV, Section 402 (Sep. 23, 1994), 108 Stat. 2243. These authorities are codified at 31 U.S.C. 5313(d) (mandatory exemptions) and (e) (discretionary exemptions).

⁶ 31 CFR 1010.315(a). The exemption does not apply when the exempt person is acting as agent for another person who is the beneficial owner of the funds that are the subject of the transaction. 31 CFR 1010.315(f).

⁷ In certain circumstances, a limited exemption from the two-month transaction account holding requirement may apply to non-listed business and payroll customers pursuant to the special rule at 31 CFR 1010.315(c)(2)(ii).

¹ USA PATRIOT Act, Public Law 107-56.

the DOEP Report⁸ within 30 calendar days after the day of the first reportable transaction in currency with the person that the bank seeks to exempt from reporting. A bank holding company or one of its bank subsidiaries may make such a designation on behalf of any or all of the bank holding company's bank subsidiaries by listing those bank subsidiaries in the DOEP Report that it files.⁹ However, a bank is not required to file a DOEP Report for transfer of currency to or from: (1) any of the 12 Federal Reserve Banks; (2) a bank, to the extent of such bank's domestic operations; (3) a department or agency of the United States, of any State, or of any political subdivision of any State; or (4) any entity established under the laws of the United States, any State, or any political subdivision of any State, or under an interstate compact between two or more States, that exercises governmental authority on behalf of the United States or any such State or political subdivision.¹⁰

31 CFR 1020.315(d) requires a bank to review at least once annually the continued eligibility of an exempt person that is a (1) listed entity, (2) subsidiary of a listed entity, (3) non-listed business customer, or (4) payroll customer. As part of the annual review, a bank must also review the application to each existing account of a non-listed business or payroll customer of the monitoring system that 31 CFR 1020.315(h)(2) requires the bank to maintain (related to suspicious activity monitoring).

Under 31 CFR 1020.315(e), a bank must take steps to assure itself that an exempt person meets the definition of that term (see 31 CFR 1020.315(b), summarized above), document the basis for its conclusion, and document its compliance with the terms of the exemption, including the operating rules in 31 CFR 1020.315(e)(2)–(9). A bank must also take steps to document compliance with its suspicious activity monitoring obligations under 31 CFR 1020.315(h)(2). The steps that the bank takes under 31 CFR 1020.315(e) must be those that a reasonable and prudent bank would take and document to protect itself from fraud or loss based on misidentification of a person's status and, in the case of the suspicious activity monitoring obligations, to identify suspicious transactions.

31 CFR 1020.315(h)(1) states that the CTR exemption rules do not relieve a bank of its obligation to report any suspicious transactions pursuant to 31 CFR 1020.320, including any suspicious transactions or attempted transactions in currency associated with the accounts of an exempt person, or relieve a bank of any other reporting or recordkeeping obligation imposed under the authority of the BSA.

Under 31 CFR 1020.315(h)(2), a bank must establish and maintain a monitoring system that is reasonably designed to detect, for each account of a non-listed business or payroll customer, transactions in currency that would require a bank to file a suspicious activity report.

II. Paperwork Reduction Act of 1995 (PRA)¹¹

Title: Transactions of exempt person (31 CFR 1020.315), and FinCEN Form 110—DOEP Report.

OMB Control Number: 1506–0012.

Report Number: FinCEN Form 110—DOEP Report.

Abstract: FinCEN is issuing this notice to renew the OMB control number for the transactions of exempt person regulations and the DOEP Report.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review: Renewal without change of a currently approved information collection.

Frequency: As required.

Estimated Number of Respondents: 10,062 banks.¹²

Estimated Number of Responses: 15,105 DOEP Reports.¹³

Estimated Recordkeeping Burden:

In Part 1 of this notice, FinCEN describes the distribution of the estimated number of financial institutions, by type, affected by the regulatory requirements. In Part 2, FinCEN proposes for review and comment a renewal of the calculation of the annual PRA burden that includes a scope and methodology similar to that used in the 2021 notice to renew the OMB control number associated with this information collection requirement.¹⁴

Part 1. Distribution of the Financial Institutions Covered by This Notice

The distribution of financial institutions, by type, covered by this notice is reflected in table 1 below.

TABLE 1—DISTRIBUTION OF FINANCIAL INSTITUTIONS COVERED BY THIS NOTICE, BY TYPE OF FINANCIAL INSTITUTION

Type of financial institution	Number of financial institutions
Banks with a Federal functional regulator (FFR) ^a	9,462
Banks lacking an FFR ^b	600
Total	10,062

^a This estimate of the total number of banks with a federal functional regulator, including credit unions, is based on end of year 2023 data as provided by the FFR: the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of the Comptroller of the Currency, and the National Credit Union Administration.

^b This estimate of active entries as of year-end 2023 incorporates data from both public and non-public sources, including: Call Reports; various State banking/financial institution regulators' websites and directories; the Federal Reserve Board of Governors' Master Account and Services database (<https://federalreserve.gov/paymentsystems/master-account-and-services-database-existing-access.htm>); and data from the OCIF (Oficina del Comisionado de Instituciones Financieras); and was derived in consultation with staff from the Internal Revenue Service's Small Business/Self-Employed Division.

In connection with a variety of initiatives FinCEN is undertaking to implement the AML Act, FinCEN intends to conduct, in the future, additional assessments of the PRA burden associated with BSA requirements.

Part 2. Annual PRA Burden and Cost

FinCEN continues to estimate the annual hourly burden of the designation of exempt persons as one hour per report. This estimate covers the burden of: (1) reporting, which is estimated to require an average of 45 minutes to fill out and file the report; and (2) recordkeeping and maintenance, which is estimated to require an average of 15 minutes per report. FinCEN believes that the information required to be included on the DOEP Report is basic information that banks need to maintain to conduct business. The BSA E-filing

⁸ This is referred to in the regulations as “FinCEN Form 110.” FinCEN has referred to its forms as “reports” since moving to electronic filing.

⁹ 31 CFR 1020.315(c)(1) and (e)(6).

¹⁰ 31 CFR 1020.315(c)(2)(i)(A) and (B).

¹¹ Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

¹² Table 1 below describes the distribution of the types of financial institutions covered by this notice.

¹³ Based on 2023 filings, FinCEN received 15,105 DOEP Reports.

¹⁴ See FinCEN, *Agency Information Collections Activities; Proposed Renewal; Comment Request: Renewal Without Change of Transactions of Exempt Persons Regulations, and FinCEN Report 110, Designation of Exempt Persons Reports*, 86 FR 6964 (Jan. 25, 2021).

system prompts banks to save the report after submission.

FinCEN's estimate of the annual PRA burden, which is based on reporting activity in the previous calendar year,

therefore, is 15,105 hours, as detailed in table 2 below:

TABLE 2—ESTIMATED TOTAL ANNUAL BURDEN HOURS ASSOCIATED WITH COMPLETION AND MAINTENANCE OF THE DOEP REPORTS

Type of financial institution	Number of DOEP reports filed in 2023	Time per report in minutes		Total burden hours per step		Total burden hours
		Reporting	Recordkeeping	Reporting	Record-keeping	
Banks	15,105	45 minutes	15 minutes	11,329	3,776	15,105 ^a

^a FinCEN estimates that the burden to complete and file the DOEP Report for banks was one hour (45 minutes for completion of the report and 15 minutes for recordkeeping). 15,105 DOEP Reports multiplied by 45 minutes and converted to hours equals 11,329 hours. 15,105 DOEP Reports multiplied by 15 minutes and converted to hours equals 3,776 hours. The summation of 11,329 hours and 3,776 hours is 15,105 hours.

FinCEN is utilizing the same fully loaded composite hourly wage rate of \$106.30 utilized in the 2024 notices of proposed rulemaking (NPRMs) entitled Customer Identification Programs for Registered Investment Advisers and

Exempt Reporting Companies and Anti-Money Laundering and Countering the Financing of Terrorism Programs, as well as in recent 60-Day Notices to renew OMB control numbers

corresponding to specific BSA regulations.¹⁵

The total estimated cost of the annual PRA burden is \$2,421,331.50, as reflected in table 3 below:

TABLE 3—ESTIMATED TOTAL COST OF ANNUAL PRA BURDEN

Steps	Burden hours per step	Wage rate	Total cost
Report completion	11,329	\$106.30	\$1,816,038.70
Maintenance/recordkeeping	3,776	106.30	605,292.80
Total cost			2,421,331.50

Estimated Number of Respondents: 10,062 banks, as set out in table 1.

Estimated Total Annual Responses: 15,105 DOEP Reports.¹⁶

Estimated Total Annual Reporting and Recordkeeping Burden: The estimated total annual reporting and recordkeeping burden is approximately 15,105 hours, which is comprised of the total annual reporting and total annual recordkeeping burdens described below.

Estimated Total Annual Reporting Burden: The estimated total annual reporting burden is approximately 11,329 hours, as set out in table 2.

Estimated Total Annual Recordkeeping Burden: The estimated total annual recordkeeping burden is approximately 3,776 hours, as set out in table 2.

Estimated Total Annual Reporting and Recordkeeping Cost: The estimated total annual PRA cost is approximately \$2,421,331.50, as set out in table 3.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Records required to be retained under the BSA must be retained for five years.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information.

Andrea M. Gacki,
Director, Financial Crimes Enforcement Network.

[FR Doc. 2024–17605 Filed 8–7–24; 8:45 am]

BILLING CODE 4810–02–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: August 13, 2024, 2:00 p.m. to 5:00 p.m., Eastern time.

PLACE: This meeting will take place at the Hotel Indigo Traverse City 263 W Grandview Parkway, Traverse City, MI 49684. The meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 962 8943 3049, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is <https://>

¹⁵ See, e.g., FinCEN and SEC, *NPRM Customer Identification Programs for Registered Investment Advisers and Exempt Reporting Advisers*, 89 FR 44571 (May 21, 2024); FinCEN, *NPRM Anti-Money Laundering and Countering the Financing of Terrorism Programs NPRM*, 89 FR 55428 (Jul. 3,

2024); FinCEN, *Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Customer Identification Program Regulatory Requirements for Certain Financial Institutions*, 89 FR 51940 (Jun. 20, 2024); and FinCEN, *Agency Information Collection*

Activities; Proposed Renewal; Comment Request; Renewal Without Change of Due Diligence Programs for Correspondent Accounts for Foreign Financial Institutions and for Private Banking Accounts, 89 FR 49273, (Jun. 11, 2024).

¹⁶ See *supra* note 15.

kellen.zoom.us/meeting/register/tJlvf-CsrTgqHt3AXCQvu_OwnmzBsi8qZzi8H.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Enforcement Subcommittee (the “Subcommittee”) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

- Subcommittee action only to be taken in designated areas on agenda

IV. Review and Approval of Subcommittee Minutes From the April 5, 2024, Meeting—UCR Enforcement Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the April 5, 2024, Subcommittee meeting in Savannah, GA will be reviewed. The Subcommittee will consider action to approve.

V. Review of Enforcement Rates—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will review a variety of tools and activities undertaken in 2024 to conduct enforcement activities in the states.

VI. Discussion on Nonparticipating State Enforcement—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will lead a discussion on enforcement limitations in nonparticipating states.

VII. Discussion of Roadside Enforcement for Carriers Who are Under-Registered—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair, and Representatives From Seikosoftware

The Subcommittee Chair will lead a discussion on the possibility of roadside enforcement for carriers who have been identified as under-registered.

VIII. Discussion and Review of the Current UCR Agreement Pertaining to Enforcement—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will lead a discussion on possible future language suggestions as it relates to the UCR agreement.

IX. Inspector Award for Annual UCR Enforcement—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Chair will lead a discussion on the possibility of establishing an annual Inspector award for excellence in UCR Enforcement.

X. 2025 UCR Awareness Initiatives—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Chair will lead a discussion of and determine dates for the 2025 UCR Awareness Initiatives.

XI. Enforcement Training PPT Development—UCR Enforcement Subcommittee Chair, UCR Enforcement Subcommittee Vice-Chair

The Subcommittee Chair will provide an update on the progress of the creation of the enforcement training PowerPoint as an additional resource for Law Enforcement.

XII. Other Business—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

XIII. Adjournment—UCR Enforcement Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, August 5, 2024 at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION:

Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, eleaman@board.ucr.gov.

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024–17776 Filed 8–6–24; 4:15 pm]

BILLING CODE 4910-YL-P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: August 13, 2024, 10:00 a.m. to 1:00 p.m., Eastern Time.

PLACE: This meeting will take place at the Hotel Indigo Traverse City 263 W Grandview Parkway, Traverse City, MI 49684. This meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 985 7826 0423, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is <https://kellen.zoom.us/meeting/register/tJwocOGqDsuGNfj89k1JERZ2RtllmmXvIO>.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Dispute Resolution Subcommittee (the “Subcommittee”) will conduct a meeting to continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Dispute Resolution Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and

distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Dispute Resolution Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

- Subcommittee action only to be taken in designated areas on agenda

IV. Review and Approval of Subcommittee Minutes From the January 25, 2024 Meeting—UCR Dispute Resolution Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the January 25, 2024 Subcommittee meeting will be reviewed. The Subcommittee will consider action to approve.

V. Discussion of the Dispute Resolution Procedure—UCR Dispute Resolution Subcommittee Chair and UCR Plan Legal Counsel

The UCR Dispute Resolution Subcommittee Chair and UCR Plan Legal Counsel will lead a discussion and review of the current Dispute Resolution Procedure. The document sets forth the current UCR procedure for processing and handling eligible disputes. The document was last amended in January 2024.

VI. Other Business—UCR Dispute Resolution Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

VII. Adjournment—UCR Dispute Resolution Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, August 5, 2024, at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION:

Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305-3783, eleaman@board.ucr.gov.

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024-17758 Filed 8-6-24; 4:15 pm]

BILLING CODE 4910-YL-P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 153

August 8, 2024

Part II

Department of Agriculture

Farm Service Agency

7 CFR Parts 761, 762, et al.

Enhancing Program Access and Delivery for Farm Loans; Final Rule

DEPARTMENT OF AGRICULTURE**Farm Service Agency****7 CFR Parts 761, 762, 764, 765, 766, 768, 769, and 770****RIN 0560–AI61****[Docket No. FSA–2023–003]****Enhancing Program Access and Delivery for Farm Loans****AGENCY:** Farm Service Agency, USDA.**ACTION:** Final rule; with request for comment.

SUMMARY: The Farm Service Agency (FSA) is amending the Farm Loan Programs (FLP) regulations to implement the Distressed Borrower Set-Aside (DBSA) Program and other changes. DBSA will provide a new loan servicing program for financially distressed borrowers that will allow for the deferral of one annual loan installment at a reduced interest rate. DBSA will provide a simpler option to resolve financial distress than existing loan servicing programs. In addition to helping borrowers by adding DBSA as a new loan servicing program, FSA is amending the FLP regulations to revise loan making and servicing to improve program access and delivery. This rule is part of FSA's ongoing efforts for farm loans to remove barriers to capital access and increase opportunities for borrowers to be successful.

DATES:*Effective date:* September 25, 2024.

Comment date: We will consider comments on the information collection requirements under the Paperwork Reduction Act that we receive by: October 7, 2024. We will also consider comments on the rule and may conduct additional rulemaking in the future based on the comments.

ADDRESSES: We invite you to submit comments on the information collection requirements. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to: www.regulations.gov and search for docket ID FSA–2023–0003. Follow the instructions for submitting comments.

Comments will be available for viewing online at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Houston Bruck; telephone: (202) 650–7874; email: houston.bruck@usda.gov. Individuals who require alternative means of communication for program should contact USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service

(both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:**Background**

FSA makes and services a variety of direct and guaranteed loans to farmers who are unable to obtain commercial credit sufficient to meet their needs at reasonable rates and terms. FSA also provides direct loan borrowers with credit counseling and supervision, to increase the borrowers' chance for success. FSA loan applicants are often:

- beginning farmers (BF) and socially disadvantaged (SDA) farmers who do not meet the underwriting requirements of commercial lenders because of insufficient net worth; or
- established farmers who have suffered financial setbacks due to natural disasters or economic downturns.

FSA loan applicants are also often farmers whose short- and long-term operational and personal goals are not well met by commercial lending products. FSA loans are tailored to a farmer's needs and may be used to buy farmland and to finance agricultural production.

The Consolidated Farm and Rural Development Act (CONACT, Pub. L. 87–128, as amended; 7 U.S.C. 1921–2009cc–18) provides the authority for most FLP loans, including farm ownership, operating, and emergency loans.

After FSA provides a loan to a farmer, FSA continues to work with the borrower to monitor the progress of their operation, provide guidance on budgetary issues, and ensure loan repayment. If FSA loan borrowers become financially distressed and are unable to make loan installments as scheduled, or if the borrowers' plans change requiring reconsideration of original terms, FSA staff work with borrowers to explore options to improve profitability. A common solution to resolving financial distress is providing the distressed loan with more flexible rates or terms to improve profitability. These loan servicing options are commonly referred to as the Primary Loan Servicing Program (PLS) and the Disaster Set-Aside Program (DSA).

Section 22006, Farm Loan Immediate Relief for Borrowers with At-Risk Agricultural Operations, of the Inflation Reduction Act of 2022 (IRA, Pub. L. 117–169) authorized \$3.1B in funds for FSA to create and provide certain additional assistance opportunities for distressed farm loan borrowers of FLP loans authorized under the CONACT. To date, FSA has provided historic assistance under IRA Section 22006 to

assist distressed borrowers, including 6 different rounds of payments addressing both long-term and immediate sources of distress. To complement PLS, DSA, and previous IRA assistance, FSA is implementing a new loan modification option, the DBSA Program. DBSA is similar to DSA and will provide a new loan servicing option for financially distressed borrowers that will allow for the deferral of one annual loan installment per loan at a reduced interest rate under certain conditions. DBSA has three important distinctions compared to DSA:

- the deferred payment will accrue at a reduced interest rate,
- the loan must have been outstanding as of September 25, 2024, and
- the borrower does not have to suffer a loss from a declared disaster to qualify for DBSA.

This rule implements DBSA and makes other changes as the next step in FSA's ongoing effort to remove barriers to capital access and increase opportunities for borrowers to be successful. The COVID–19 pandemic highlighted the need for FSA to undertake a culture shift in its approach to farm loans to expand virtual opportunities and implement loan processes to improve turnaround times on financial assistance. For example, for loans overall, recent investments in online education and application platforms are making the loan process simpler to navigate virtually, and new underwriting techniques based on financial benchmarking of FSA's portfolio are expediting the loan process.

FSA is also clarifying and amending information throughout the FLP regulations to make it easier for borrowers to understand program requirements. These changes were developed with significant input from employee associations and the gathering of important insights from lending industry partners and agricultural advocacy groups. Advice and recommendations from agricultural advocacy groups on potential program improvements were carefully considered as FSA developed some of the more substantial changes, including improvements to the direct loan security requirements, cash flow budgeting process, and flexible repayment terms offered on direct loans.

While most of the amendments are not substantially altering existing policy, or are anticipated to impact a relatively small number of farmers, some changes are substantial, impacting nearly all direct loan customers, including changes that amend

requirements for farm assessments, budget development, and loan security. These substantial changes will encourage borrower profitability by expanding opportunities for borrowers to leverage asset equity, and by establishing opportunities to budget for a reasonable amount of cash flow margin to increase working capital reserves and savings, including savings for retirement and education, including the use of flexible repayment terms to achieve essential short- and long-term operational growth goals. These program enhancements reflect FSA's commitment to furthering strong partnerships with commercial lenders, as the borrower growth opportunities from the changes in this rule will result in more financially stable borrowers that are better prepared to transition to commercial banking. The enhancements will also be reflected in the subsidy rates for the respective FLP loan types, per Federal Credit Reform Act (FCRA, 2 U.S.C. 661) and OMB Circular A-11 section 185.

The CONACT requires that all FLP applicants and loans meet certain requirements related to eligibility, security, and feasibility. The changes in this rule ensure FLP regulations continue to align with the CONACT and better reflect the needs of farmers, industry trends, historical data, and modernization of underwriting standards. Although many of the amendments in this rule are technical corrections or clarifications, there are several changes to FLP policy that better reflect customer needs and modernized standards in the greater agricultural lending industry.

This rule marks the most recent example of FSA's dedication to increase equity, improve customer service, and provide opportunities for customers to maximize their financial success.

Throughout this rule, any reference to "farm" or "farmer" also includes "ranch" or "rancher," respectively.

DBSA Program Implementation

This rule is implementing the DBSA Program to assist distressed borrowers whose operations are at financial risk and face the possibility of bankruptcy, liquidation, or foreclosure. Using available funds under section 22006 of IRA, DBSA is a payment deferral program for financially distressed or delinquent borrowers with outstanding direct loans administered under subtitle A (Farm Ownership Loan (FO) Program, Conservation Loan (CL) Program, and Soil and Water Loan (SW) Program), subtitle B (Operating Loan (OL) Program), or subtitle C (Emergency Loan (EM) Program) of the CONACT.

While the DBSA Program will operate similarly to the existing DSA Program, there are important eligibility distinctions. Specifically, deferral under DBSA is only available for eligible direct loans outstanding as of September 25, 2024, and a borrower does not need to have been affected by a declared disaster to qualify. Importantly, and similar to both DSA and PLS eligibility requirements, borrowers requesting DBSA assistance must demonstrate that a set-aside of their current direct loan payment(s) would resolve their financial distress and result in a feasible operating plan.

Payments deferred under DBSA will be repaid at the time of loan maturity and will carry a reduced interest rate of 0.125 percent. This is the lowest interest rate the CONACT authorizes to be applied to loans. The CONACT authorizes the Secretary certain discretion in determining interest rates for the FO, SW, CL, OL, and EM Programs. For FO, CL, SW and OL Programs, the rate must not be in excess of the average yield for Treasury notes with similar maturities to the FO or OL Programs, plus an amount not to exceed 1 percent. The EM Program interest rates determined by the Secretary must be below 8 percent. This reduced interest rate on DBSA:

- is being used to mitigate the adverse impacts of additional interest accrual on the deferred payment for borrowers, and
- increases the likelihood for the long-term success and improves long-term repayment ability of the operation.

DBSA was created in part in response to input from borrowers, FSA staff, and other stakeholders noting that DSA works well to help resolve financial distress without requiring PLS, and that a similar set-aside program would also help many borrowers in financial distress who have not been affected by a natural disaster.

Before this rule, FSA could only offer a deferral on direct loans through PLS or DSA. PLS is different from DBSA because PLS requires a series of loan servicing options to be considered and typically results in the loan being restructured; PLS can also be time consuming for the borrower.

DBSA is expected to be selected by many customers as a viable alternative to DSA and PLS. If a customer does not qualify for a DBSA, for example, if their financial distress cannot be resolved by deferring the current installment to the end of the loan, they may need the more complex loan servicing solutions and formal loan restructuring that is available through PLS.

As a result of the subsidy rate analysis, FSA determined that since the

loan modifications costs of DBSA are funded by section 22006 of IRA, that only those loans that are outstanding as of September 25, 2024, which is the effective date of this rule, will be eligible. The rationale for that is to comply with the statutory authority as FSA paid for the loan modification costs up front based on the current loan portfolio. Borrowers may request DBSA on those loans at any time over the loan period, but may only have 1 DBSA outstanding per loan.

DBSA will provide existing FSA direct loan borrowers who are financially distressed or delinquent with an option to request a one-time deferral of a delinquent or upcoming annual installment instead of using PLS or DSA to address loan repayment issues. A delinquent borrower is defined in 7 CFR 761.2(b) as "a borrower who has failed to make all scheduled payments by the due date," and a financially distressed borrower is defined as "a borrower unable to develop a feasible plan for the current or next production cycle." The amount of the deferral will be limited to the lesser of the amount of the annual installment or the unpaid balance remaining on the installment at the time the DBSA is approved. The deferred amount will have a reduced interest rate of 0.125 percent. The amount deferred, plus interest, will be due at the end of the loan term.

To request DBSA, borrowers must submit a request for DBSA in writing to FSA. The borrower will be required to submit actual production, income, and expense records for the current production cycle, and an operating plan for the upcoming production cycle, unless FSA already has that information on file for the borrower. This information will be analyzed by FSA to validate that a profitable cash flow budget for the current production cycle cannot be developed without deferring the next loan installment due on their outstanding FLP loans. FSA will notify the borrower in writing within 30 days if their request for DBSA is approved or denied, and the borrower must provide required DBSA closing documents within 45 days of approval notification.

DBSA will be implemented in a new subpart J of part 766, with conforming changes in parts 761, 765, and 766.

FLP Regulatory Improvements

In addition to helping borrowers by adding DBSA as a new loan servicing program, throughout the FLP regulations FSA is making discretionary changes to clarify and amend existing delivery processes and program requirements to increase access to FLP,

including making several technical corrections. The various regulatory amendments are listed below, categorized by type as either a clarification, technical correction, non-substantial change, or substantial change.¹ Changes are discussed based on what changes are the most broadly applicable. For example, changes in the definition of “Family Farm” are discussed first along with changes in related terms, followed by the remaining definitions in alphabetical order.

The rule is making clarifications, which are in response to input from borrowers, staff, and other stakeholders. FSA has determined that clarifying the information in the regulation will make it easier for borrowers to understand program requirements. These clarifying amendments do not constitute a change in policy. The specific changes are discussed later in this document. Specifically, this rule clarifies:

- the definitions in 7 CFR 761.2 of Agricultural Commodity, Family Farm, Feasible Plan, Good Faith, Non-Eligible Enterprise, Participated in the Business Operations of a Farm, Related by Blood or Marriage, Relative, and Youth Loan;
- the financial analysis and document submission requirements for existing borrowers in 7 CFR 761.105 and 765.101;
- copies of real estate and equipment leases are required as part of a complete direct loan making or servicing application upon request in 7 CFR 764.51 and 766.102;
- the requirements in 7 CFR 764.51 and 764.101 to determine reasonableness of available credit elsewhere;
- direct loan eligibility credit history requirements in 7 CFR 764.101 apply to all entity members;
- guaranteed loan eligibility credit history requirements in 7 CFR 762.120 when there is previous debt forgiveness;
- the general direct loan managerial eligibility requirement in 7 CFR 764.101 and aligns it with the direct FO requirement;
- the EM requirements in 7 CFR 764.353 to ensure duplicate benefits are not provided;
- the special interest rate for beginning and veteran farmers obtaining a direct Microloan (ML)–OL in 7 CFR 764.254 and for the Indian Tribal Land

Acquisition Program (ITLAP) 7 CFR 770.6;

- the application, eligibility, and loan security requirements for transfer and assumption requests in 7 CFR 765.402, 765.403 and 765.404; and
- equitable relief provisions in 7 CFR 768.1.

In addition to the clarifying amendments, FSA is making technical corrections to existing regulatory requirements that do not constitute a change in policy. Specifically, this rule corrects minor grammatical or typographical errors throughout 7 CFR 761 to 769, including correcting both “writedown” and “write down” to “write-down.”

The majority of amendments in the rule are changes in policy, most of which are non-substantial changes to existing regulatory requirements. Those amendments that are policy changes, but considered non-substantial in nature, include:

- in 7 CFR 761.2, revising the “family farm” definition to include commercial foraging operations for the purposes of operating loan assistance where commodities are foraged on Indian land, and adding definitions for “commercially foraged”, “Indian land” and “Indian Tribe;”
- requiring all guaranteed lenders to receive FSA approval of a transfer and assumption to ensure applicants satisfy eligibility requirements in 7 CFR 762.142;
- authorizing subordinations of loan security for a guaranteed lender to refinance its own debt in 7 CFR 762.142;
- removing borrower production training requirements throughout 7 CFR part 764 that are often waived, but maintaining the important borrower financial training requirements;
- authorizing direct OL security to be a junior lien on real estate in 7 CFR 764.251 when the purpose of the loan is to finance minor real estate repairs or improvements, and establishing lease terms for those circumstances;
- increasing the direct youth operating loan limit in 7 CFR 764.303 from \$5,000 to \$10,000;
- the experience eligibility requirements for direct FOs in 7 CFR 764.152;
- changing the EM formula for production loss used for determining the EM amount in 7 CFR 764.352;
- in 7 CFR 765.102, allowing direct loans that are only in non-monetary default for failure of the borrower to comply with graduation requirements to be converted to non-program loans instead of FSA proceeding with foreclosure action;

- providing specific response timeframes and FSA notification requirements for direct loan subordination requests in 7 CFR 765.205;
- changing the requirements in 7 CFR 765.252 for the lease of FSA security to provide borrowers additional flexibility;
- in 7 CFR 765.352 authorizing a portion of the proceeds from the sale of loan security to be retained by the borrower to pay capital gains taxes;
- establishing a State Executive Director’s authority to extend PLS application deadlines in extraordinary circumstances in 7 CFR 766.101;
- expanding reasons that a delinquency may be due to circumstances beyond the control of a borrower for the purposes of PLS in 7 CFR 766.104 to include catastrophic medical expenses for the care of family member of a borrower or entity member;
- establishing timeframes in 7 CFR 766.115 for a borrower to obtain an independent appraisal if they dispute an FSA appraisal;
- making minor adjustments and edits to the form for the Notice of Availability of Loan Servicing to Borrowers Who Are 90 Days Past Due in 7 CFR 766, Subpart C, Appendix A (form FSA–2510) and the related form for Iowa in Appendix B, to reflect the changes implemented in this rule and make minor technical corrections (the changes are not intended to change the information being collected); and
- making changes in 7 CFR 769 to the Heirs’ Property Relending Program (HPRP), including expanding the application period.

The most substantial changes to the Farm Loan Programs regulations are those that apply to all borrowers and are intended to promote profitable farming operations. These changes will be incorporated into the subsidy rate for the relevant loan programs per FCRA. Specifically, this rule:

- establishes requirements for the development of farm operating plans and farm assessments in 7 CFR 761.103, 761.104, and 762.124, to ensure consideration of a reasonable amount of cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education;
- provides all eligible applicants the option to receive flexible repayment terms, including maximum direct loan repayment terms and an option for interest-only payments during the first year for certain types of direct loans in 7 CFR 764.154, 764.254, and 764.354;
- modifies direct FO, OL, and EM additional loan security requirements in 7 CFR 764.103, 764.106, 766.56, and

¹ To assist in navigating the various changes in this rule, FSA categorized the amendments as either clarifications, technical corrections, non-substantial changes, or substantial changes. A substantial change is an amendment to FLP policy that is anticipated to impact the majority of applicants or borrowers, while a non-substantial change is a change that is anticipated to impact a relatively small number of customers.

766.112, specifically by reducing the additional security requirement for all loan making and servicing requests, removing the additional security requirement for all MLs and FOs with a down payment, removing the requirement that non-real estate assets be used as additional security for FOs, removing the requirement that a personal residence be provided as additional security, and removing the requirement for a lien on all assets to be provided to receive PLS assistance, DSA assistance, or for guaranteed loans being restructured with a balloon payment in 7 CFR 762.145;

- adds 7 CFR 766.120, which provides an alternative to PLS, allowing for a simplified extension of repayment terms when a balloon payment comes due; and
- expands opportunities in 7 CFR 765.305 and 765.351 for the release of a limited amount of direct loan security without compensation in certain circumstances.

Discussion of Substantial Changes

The following discussion provides additional detail on the amendments identified as substantial changes. Below that, non-substantial changes, clarifications, and technical corrections are discussed, in that order.

Farm Operating Plan Development and Farm Assessments

Developing a reasonable farm operating plan is essential for a farming operation to be successful. An important component of developing a farm operating plan includes considering the amount of reserves and cash flow margin necessary to support operational stability and growth. This will benefit farmers by providing the opportunity to create farm operating plans with budgets that include a reasonable amount of cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education. This rule amends 7 CFR 761.103 and 761.104(f) to provide opportunity for FSA's farm assessments and borrowers' farm operating plans to allow for savings to support long-term operational financial stability and growth, including savings to ensure personal financial stability. Amendments to 7 CFR 761.103 also build consideration of borrowers' short- and long-term goals for their operation into annual farm assessments, as required by the CONACT, including progress towards graduation to commercial credit or eventual self-financing. This encourages farmers to consider customized FSA loan repayment terms that may better meet

the goals of their proposed farming plan, including equal, unequal, interest-only, and balloon payments, as part of developing that plan. This rule amends 7 CFR 762.124 to clarify that flexible repayment terms may also be necessary to support guaranteed loan customers.

Farm operating plans that are unable to adequately fund working capital reserves and savings often indicate financial distress, which can lead to the need for additional loans or for FSA to provide loan servicing options. Flexible repayment terms help to ensure that adequate working capital reserves and savings are available for investments as opportunities arise. Through the promotion of flexible repayment terms, FSA is providing the best terms available to a borrower up front that maximize the opportunity to achieve adequate reserves and savings, as opposed to waiting for the operation to become distressed under the weight of excessive debt service obligations before a loan can be restructured with reduced payment requirements. Rather than the traditional approach of equity growth through accelerated debt repayment, flexible repayment terms support borrower equity growth by allowing borrowers the freedom to accumulate working capital reserves to make strategic investments in a timely manner, resulting in substantially more equity growth than would otherwise be realized through accelerated debt repayment.

Direct Loan Repayment Terms

The maximum repayment term for direct loans is 40 years for an FO and 7 years for an OL. Determining the appropriate repayment term within those limits has historically required FSA to apply its discretion based on an individualized analysis of the applicant's ability to repay and the useful life of the security, which can result in inconsistency in the terms offered to applicants. This rule will standardize all repayment schedules offered to applicants to provide a greater opportunity to build operational stability and be successful. Updates to 7 CFR 764.154(b)(1), 764.254(b)(2), 764.354(b)(4) and (5) require all FOs, OLs, and EMs for purposes other than family living and farm operating expenses, to be scheduled over a term equal to the lesser of the useful life of security or the maximum term authorized by law, unless the applicant otherwise requests a shorter term in writing. This rule does not affect the repayment term provided on Down Payment Loans, which is established by the CONACT to be 20 years or less. FSA will continue to offer Down Payment

Loans to customers with a repayment term of 20 years unless the applicant desires a shorter term to be considered.

Additionally, this rule amends the standard repayment term for the ML-FO Program. FSA developed ML to better serve the unique financial operating needs of new, niche, and small family farm operations. MLs offer more relaxed application requirements and serve as an attractive loan option, particularly for smaller and non-traditional farm operations that often face limited financing options.

While there is no difference between the maximum repayment term for an OL or an ML-OL (7 years), the ML-FO has been limited by regulation to a 25-year maximum repayment term, substantially less than the 40-year term of an FO. Since the ML-FO is targeted to small, start-up, and niche farming operations, the more restricted repayment term may put additional financial constraint on applicants who may already have limited financial resources. This rule amends 7 CFR 764.154(b) to allow for a maximum repayment term of 40 years for an ML-FO. Should a ML-FO applicant determine it to be in their best interest to receive a loan term less than 40 years, for example, to benefit from paying less total interest over the life of their loan, the applicant may request a shorter term in writing. Additionally, borrowers may reduce their interest cost over the life of a loan by making additional payments if they are able and desire to do so as FSA loans carry no pre-payment penalty.

In addition, FSA emphasizes the use of flexible repayment terms to ensure adequate working capital reserves and savings can be accumulated by the borrower. As mentioned above, to ensure all borrowers have an opportunity to grow adequate working capital reserves and savings, all applicants will be offered an opportunity for a repayment plan on new term loan requests that includes an interest-only installment during the first year of the loan. An interest-only installment the first year of a loan can result in a substantial boost to reserves and savings, enabling the borrower to make strategic investments to grow their operation without having to take on additional debt. For borrowers who elect the first-year interest-only installment plan, principal reduction will typically begin after the sale of crops or livestock produced during the second year of the loan. This rule makes these changes in 7 CFR 764.154(b)(2) and (3), 764.254(b)(3) and (4), and 764.354(b)(6) and (7).

Prior to this rule, FSA structured most loans using equally amortized

installments to repay a loan, which can put undue stress on already strained operating budgets. As a result, a borrower was more likely to become distressed and request PLS, a time-consuming process for both borrowers and FSA, which typically resulted in outcomes similar to those available through flexible repayment terms. Under flexible repayment terms for loans other than Down Payment FOs where the CONACT requires equally amortized payments, scheduled loan installments can be structured to reflect the expected cash flows used to analyze repayment, providing borrowers with greater financial flexibility over the life of the loan and enabling cash flow budgets to include projections for reasonable working capital reserves and savings. Flexible repayment terms for these loans can include interest-only installments, partial principal payments, and balloon installments. This rule clarifies that flexible repayment terms may include interest-only installments for up to 3 years, which can be used if FSA determines it necessary to reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education. While principal reduction on loans is important to begin to support borrower growth and ensure FSA loans remain fully secured, interest-only payments beyond 3 years remain an option only when FSA determines that interest-only payments are necessary to establish a new enterprise, develop a farm, or recover from a disaster or economic reversal.

Providing the option of flexible repayment terms at the time of loan approval enables all borrowers to receive the benefits of a deferral of principal without having to first become financially distressed or defaulting on their loan in order to access the loan servicing options of PLS, DBSA, or DSA. Providing more flexible repayment terms allows borrowers to make timely and strategic investments to grow their operations. As specified above, flexible repayment terms have the potential to reduce program delinquency and will provide borrowers with more options to meet the short- and long-term goals of the farm business, and to generate reasonable working capital reserves and savings, including savings for retirement and education.

For loans with balloon installments scheduled, borrowers have been required to go through the process of applying for PLS to extend the repayment schedule of their loan. This process is not customer-friendly and makes little sense for a borrower who

has repaid as agreed throughout the initial loan term. Accordingly, this rule adds 7 CFR 766.120 to enable a borrower to receive a simple extension of repayment terms for up to an additional 8 years from the date the balloon payment comes due. This will provide the borrower with repayment terms similar to what they would receive through PLS, but without needing to go through the PLS process. Under PLS, an operating loan can be rescheduled for a term up to 15 years. Accordingly, this option aligns with that PLS provision by permitting an extension of up to 8 years for repayment of the ballooning loan where the original maturity date was no more than 7 years from the date of loan closing.

To ensure this option is adequate to meet the borrower's needs, it is available only to borrowers who have a history of successful repayment of their loans, including making full installments for the last 3 years on the ballooning loan. For other borrowers, PLS will continue to be available. Additionally, this option is not available on loans where repayment terms have already been altered by PLS, or that have an outstanding DSA or DBSA, as the terms of those updated repayment agreements cannot be accommodated with a basic extension of the original loan terms.

Loan Security

This rule amends additional direct loan security and collateral servicing requirements to better enable borrowers to leverage assets and make strategic investments in their operations. This rule does not amend guaranteed loan security requirements. Additional loan security is collateral in excess of what is needed to fully secure the loan.

Specifically:

- Additional direct loan security requirements in 7 CFR 764.103(c) requires a 125 percent loan security margin when available for direct loans, which is a change from the current requirement of 150 percent. The amendment also requires that real estate assets only be provided as additional security for direct FOs. Consistent with the current regulation and policy, if the borrower does not have the additional security available to pledge, FSA may still be able to make the direct loan if the loan is fully secured; additional security will only be taken "when available."

- This rule also amends 7 CFR 764.103(c) to expand the circumstances in which no additional security is required, to now include all Microloans and FOs for which a cash down payment has been provided (similar to

the existing Down Payment Loan Program, which does not require additional security).

- This rule removes direct loan making requirements for a personal residence to be used as additional security for direct loans in 7 CFR 764.106(d) under certain conditions.

- The reduced additional security requirement of 125 percent security margin, where available, is also being applied to PLS in 7 CFR 766.112(a); however, a lien on the personal residence will still be required during PLS if necessary to achieve a 125 percent security margin.

- This rule also amends the DSA additional security requirement by removing 7 CFR 766.56 so that additional security will not be required to be pledged if a customer requires DSA Program assistance, consistent with the new DBSA Program.

- This rule removes a requirement in 7 CFR 762.145(b)(7) that required guaranteed lenders to take a lien on all assets when restructuring a loan with a balloon installment.

- This rule provides processes for an expedited release of certain direct loan security in 7 CFR 765.305(c) and 765.351(f) after a period of successful loan repayment, further promoting borrower growth and saving significant staff time monitoring loan security that is not essential to loan repayment.

These fiscally responsible data-driven changes ensure that FSA is not overcollateralized and allows borrowers to leverage the equity in their assets to grow their operations. Since 1994, the regulation has required direct loans to be secured by not only the assets purchased or improved with loan funds, but also an additional amount of security equal to 50 percent of the direct loan amount, if available. FSA determined that this requirement created a significant cost in both time and resources to perfect a lien on additional property, which has been determined to not be necessary for FSA to be fully secured, and also constrained borrowers from using equity to acquire capital needed for expansion for other business purposes.

A lien on assets purchased or improved with direct loan funds will still be required to provide adequate security for FSA farm loans. However, FSA recognizes that excessive additional security requirements that are unnecessary to significantly mitigate losses to the Government can ultimately restrict a borrower's ability to grow their operation by accessing asset equity. While this rule removes certain additional security provisions where FSA has determined taxpayer resources

remain adequately protected (see following analysis), all loans will continue to be sufficiently collateralized. The existing additional security requirements also result in an ineffective use of FSA resources, as staff are required to monitor and service the often-unnecessary additional security liens. These changes are estimated to reduce administrative time by over 8,000 hours annually as staff will realize a reduced number of on-site inspections to evaluate collateral and less time updating security documents, including renewals of expiring liens.

Revising the direct loan security margin in 7 CFR 764.103(c) to 125 percent, reduces the amount of additional security required for a direct loan by half, from 50 percent of the loan amount down to 25 percent. FSA has determined that security at least equal to 125 percent of the loan amount, where available, will provide adequate assurance of repayment. In fact, since fiscal year (FY) 2000, the average security margin for loans that experienced a loss was 120 percent at the time the loan was made, which is below the revised threshold. Accordingly, this revised amount of additional security aligns not only with historic portfolio performance data, but also with the loan security expectations by other government lending regulators. Furthermore, in the infrequent situation where FSA does liquidate security (approximately 4.1 percent of all accounts since FY 2000), the average administrative cost to FSA is less than 10 percent of the security value. This is substantially below the 25 percent additional security amount required in this rule, which provides an amount sufficient to cover estimated FSA administrative costs in the majority of liquidation circumstances. The requirement for additional security can be particularly important to protect the government from program losses for higher-risk direct OLs where primary security is often crops, livestock, or equipment with security values that are more volatile than real estate. However, for direct loans where real estate serves as adequate security, such as FOs, the additional security provision can result in FSA initially requiring more security than is necessary to protect the government's interests.

Prior to this rule, FSA perfected additional security lien interests on short-term non-real estate security items such as crops, livestock, and equipment, even if the loan was secured by more robust forms of collateral—such as real estate—as in the case of an FO. Requiring a lien on short-term assets for long-term debt significantly hinders a

borrower's ability to leverage those assets to obtain reasonable rates and terms through commercial lenders for operating purposes, thereby delaying graduation to commercial credit or making progress towards self-financing, which are primary FLP objectives.

For FSA direct loans, additional non-real estate security assets are rarely relied upon for repayment of debt primarily secured by real estate, even in cases of foreclosure. The FSA data show losses on direct real estate loans are reduced when the loan-to-value at the time of liquidation is below 95 percent, as demonstrated in the Down Payment Loan Program. In the Down Payment Loan Program, applicants are required to provide a 5 percent cash down payment, and additional security is not required to be pledged. The FSA Down Payment Loan Program has an average historical loss rate from 2000 through 2023 of less than 0.14 percent, which is significantly lower than the average FO Program loss rate of 0.96 percent. This further demonstrates that additional security is generally unnecessary for successful repayment of real estate debts when even a small amount of equity exists in the real property security.

Accordingly, this rule changes the additional security required for direct FOs to only be other real property. As discussed, when a loan is secured by real estate it is rare that FSA would rely on non-real estate assets to avoid a loss. This change to 7 CFR 764.103(c) will improve FSA internal processes by removing the need for FSA staff to maintain security interests that are unnecessary to adequately safeguard taxpayer resources, saving the time and cost of security inspections, and allowing borrowers to leverage asset equity to improve their operation.

This rule extends the list of existing exemptions from additional security requirements in 7 CFR 764.103(c) to include any direct FO where the applicant supplies a 5 percent cash down payment of the purchase price. This exemption has historically been available only for the Down Payment Loan Program, where the CONACT limits the security required. As discussed, the Down Payment Loan Program was a significant success, with the lowest delinquency and loss rate of any current FLP loan. Where a similar down payment is provided by an applicant of a regular FO, FSA expects similar low delinquency and loss rates. This expanded exemption will provide increased incentive for applicants to provide a cash down payment that improves the FSA security position without additional security needing to be pledged by the applicant.

This rule further extends the list of existing exemptions from additional security requirements in 7 CFR 764.103(c) to include any ML. This exemption will improve access to MLs, which are predominantly made to small and beginning farmers. Prior to this rule, only term MLs (such as direct loans for equipment or real estate purchases) were exempt from additional security requirements. This rule extends the exemption to any ML, including those for annual operating expenses. The average ML delinquency rates for 2017 through 2021 (13 percent for operating ML-OL and 3.6 percent for ML-FO) are approximately half that of their regular OL or FO counterparts. The annual ML-OL delinquency rate is also approximately 5 percent lower than the regular annual OL delinquency rate. Overall, the ML Program has a solid history of stronger repayment performance compared to most other farm loan programs. ML historical performance supports that program integrity can be maintained while extending the additional security exemption to all MLs.

This rule specifies in 7 CFR 764.106(d) that the personal residence will not be required for direct loans provided that the loan is fully secured by assets that have a value equal to the loan amount and the residence is on no more than 10 acres or the minimum amount able to be parceled into a separate legal lot. Reducing the frequency of personal residences to serve as additional security improves a borrower's ability to provide for basic housing needs in the event of financial distress. FSA has rarely relied on equity in a borrower's home pledged as additional security to ensure repayment, even in situations of distress. However, a lien on the personal residence will be required should the borrower ultimately require PLS.

Additionally, the rule applies the revised direct loan making security levels to the servicing of the loan by requiring additional security of up to 25 percent of the loan amount to be taken as a requirement of PLS, which is a reduction from the existing requirement for a lien on all assets. These changes in 7 CFR 766.112(a) will result in improved program delivery by reducing the administrative burden of maintaining and tracking unnecessary additional security as noted above, while furthering program objectives by improving the prospects of borrower graduation as borrowers are able to leverage asset equity to accelerate financial growth. Historical portfolio performance data reflect that the average security margin on accounts that

experience a loss is 120 percent, which is below the 125 percent threshold provided by this change. In addition, less than a third of any of the approximately 4.1 percent of farm loans with losses had a security margin of greater than 125 percent. Therefore, there is only a limited pool of loans in the portfolio (less than 1.5 percent) that are estimated to be potentially vulnerable to increased losses when requiring less security at the time of loan making.

This rule removes 7 CFR 766.56, which previously required that borrowers provide a lien on all assets in order to receive DSA. All loans are originally made with adequate security to fully secure the FSA debt, so the requirement for a lien on all assets typically results in the FSA debt being more than adequately secured, which may prohibit the borrower from leveraging equity in assets, or preventing the sale of assets, if necessary to fully recover from a disaster.

A similar requirement in 7 CFR 762.145(b)(7) is also being removed that previously required a lien to be taken on all assets by a guaranteed lender when restructuring a loan with a balloon installment.

Release of Security Interest and Partial Release of Real Estate Security

The regulations in 7 CFR 765.305 specify the conditions that must be met for FSA to release its security interest. The regulations in 7 CFR 765.351 specify that the borrower must obtain prior consent from FSA for any transactions affecting the real estate security, including when a borrower sells, exchanges, or requests a partial release of security. FSA has historically authorized the release of a limited amount of security without compensation in limited circumstances.

This rule is amending 7 CFR 765.305(c) and 765.351(f) to allow a borrower to receive a lien release of certain security items if they have a demonstrated history of making all payments as scheduled with FSA for the previous 36 months and the loan will be adequately secured after the release. Unencumbering security in excess of 125 percent of the outstanding loan balance allows the borrower to sell the property and improve the borrower's cash position, make the asset available to pledge as collateral for other loans or purposes, or allow the borrower to leverage equity attributed to the rise in the appraised value of the asset for other investments. In order to provide greater flexibility to borrowers, FSA is removing the requirement that the

borrower retain the security and use it as collateral for other credit; however, the transaction must still enhance the program objectives of the FLP loan under 7 CFR 765.301(f) and 765.351(a)(1). A borrower who has made timely payments over the most recent 36 months demonstrates a likely ability to meet scheduled loan payments going forward. Data from FY 2000 to 2023 reflect that accounts with a recorded loss were in financial distress within the first 3 years of loan closing 76 percent of the time. Accordingly, while this policy change may result in an increase in losses, all FSA loans will remain fully secured even after a partial release, and historical data reflect that the vast majority of the time a customer who successfully repays for 3 consecutive years does not incur a loss to the government. The release of security in excess of 125 percent of the outstanding FSA loan balance, will support a borrower's ability to grow their operation by accessing asset equity and will also save significant staff time maintaining liens on assets that are not needed to adequately safeguard taxpayer resources.

Discussion of Non-Substantial Changes

The following discussion provides additional detail on the amendments identified as non-substantial changes.

Definition of Family Farm, Commercially Foraged, Indian Land, and Indian Tribe

This rule revises the definition of "Family farm" in 7 CFR 761.2(b) to include commercial foraging operations as an eligible family farm for the purposes of operating loans where commodities are commercially foraged on Indian land. This rule adds corresponding definitions for "commercially foraged", "Indian land" and "Indian Tribe." While the commercial foraging space has limited participation nationwide, the industry has unique cultural relevance in certain regions. For example, commercial foraging is an important aspect of several Native American Tribal cultures, with a rich history stretching back for generations. Foraging is often done on Indian land managed by an Indian American Tribe. Opening FLP assistance to these operators is a significant step in supporting USDA's commitment and trust responsibility to federally recognized Tribes. While assistance is not limited only to Native American producers, applicants that commercially forage must comply with all local rules and regulations pertaining to foraging on Indian land. The new definitions of "Indian land" and

"Indian Tribe" are only used for the commercial foraging provisions established in this rule, and are based on existing definitions of "Indian land" and "Indian Tribe" used in Federal programs to cover commercial foraging on lands owned by an Indian Tribe, restricted fee land owned by an Indian Tribe, and land held in trust for an Indian Tribe. The definition of "Indian land" excludes land held in trust for or owned by individuals.

Guaranteed Servicing Related to Collateral

FSA may subordinate its security interest on a direct loan for many purposes, including when a new guaranteed loan is being considered to refinance the debt of another lender. When the lender requesting the guarantee is limited only to refinancing the debt of another lender, and not its own non-guaranteed debt, the lender faces the risk of the borrower going to a different lender to refinance the non-guaranteed debt of the current guaranteed lender. The new lender could then apply for an FSA guarantee and a subordination of the direct loan, while the existing lender will lose its borrower. This amendment to 7 CFR 762.142(c) allows a subordination of direct loan debt when a lender requests a guarantee on a loan to refinance any debt, including its own.

Similarly, FSA may allow a lender to subordinate its interest in basic security which secures a guaranteed loan in cases in which the subordination is required to allow another lender to refinance an existing prior lien. When the lender requesting the refinance is limited only to refinancing the existing debt of another lender, and not its own debt, the lender faces the risk of the borrower going to a different lender to refinance the debt. The existing lender will lose its borrower, while the new lender will be granted the subordination on the guaranteed loan debt. This rule allows a subordination of guaranteed loan debt when a lender requests to refinance any debt, including its own.

Guaranteed Loan Transfer and Assumption Requirements

Standard Eligible Lender and Certified Lender Program lenders are required to obtain FSA concurrence to process a transfer and assumption of a guaranteed loan. This rule amends 7 CFR 762.142(d) to require Preferred Lender Program lenders to also obtain FSA concurrence to ensure transferee eligibility and ensure that FSA records accurately reflect the transferee as operator and debtor.

Borrower Production Training

Section 359 of the CONACT requires the educational training needs of each direct loan applicant to be evaluated, with training options provided when needed. Under this authority, FSA evaluates the need of each direct loan applicant to complete borrower training. The borrower then contracts with an approved third-party vendor to provide the training deemed necessary by FSA. This is an important component of FSA's process for granting direct FLP assistance and is consistent with FSA's focus on progression lending.

While borrower financial training has ample training vendors available, and has been essential to the success of many producers, borrower production training options are limited, and efforts to improve borrower production knowledge via mandated training courses are generally ineffective. While most financial training concepts are applicable across all farm types and regions, applicable production training material is specific to agricultural regions and enterprises. There is a substantial lack of vendors providing production training because most organizations that request FSA approval to be an authorized training vendor lack the effective resources to provide production training specific to the varied regions and enterprises. Due to a lack of viable industry-specific production training vendors, FSA provides nearly all direct loan customers a waiver of production training requirements, with less than 5 percent of direct loan customers required to complete borrower production training.

While borrower production training lacks authorized vendors and is generally ineffective at improving borrower production knowledge, private mentorships and relationships built by the borrower themselves are typically the most beneficial production training a producer receives. Therefore, this rule removes all references to borrower production training in 7 CFR 764. However, borrower financial training requirements remain unchanged.

FSA Lien Position on Real Estate Repaired or Improved With Direct OL Funds

FSA uses direct OL funds to finance minor real estate repairs or improvements, provided the loan can be repaid within 7 years. Construction or improvements amortized over periods longer than 7 years generally align better with direct FO purposes and are not financed with direct OL funds.

While smaller repairs or improvements can be financed by either an OL or FO, an applicant may find it beneficial to apply for an OL in certain instances, such as when FO funds are limited, or when an applicant has reached FO term limits. However, security requirements vary slightly for an FO and OL.

For any OL, security must be a first lien on assets purchased or improved with direct loan funds, while an FO may be secured by real estate in a junior lien position. FSA is amending the OL security requirements in 7 CFR 764.255 for loans where the purpose is to make minor repairs or improvements to allow a lien in junior lien position to serve as adequate security.

In 7 CFR 764.251(a)(11), FSA is requiring that for improvements on leased property, the lease must allow the borrower full use of the improvement over the life of the security or have a provision compensating the borrower for any remaining economic life in the event the lease is terminated.

Increase Loan Limit of the Youth Loan Program

This rule is amending 7 CFR 764.303(b) to allow FSA to double the direct Youth Loan (YL) limit on the total principal balance owed by an applicant on all YLs at any one time from \$5,000 to \$10,000. FSA makes direct loans to applicants 10 through 20 years old to finance income-producing projects of modest size in connection with their participation in 4–H, Future Farmers of America (FFA), Tribal youth groups, or similar agricultural youth organizations. The project being financed with an FSA YL provides an opportunity for the young person to acquire experience and education in agriculture-related skills.

YL application activity has steadily fallen in recent years, with YL applications totaling 3,795 in FY 2017, 3,201 in FY 2018, 2,788 in FY 2019, 2,451 in FY 2020, 1,568 in FY 2021, and 1,370 in FY 2022.

An important factor affecting decreased application activity for YL is the relatively small maximum outstanding loan limit of \$5,000 per individual. The \$5,000 limit has been unchanged since 1988, without adjustment for the significant inflation since that time. The rate of inflation of agricultural inputs is considered to be approximately equal to the Consumer Price Index (CPI). CPI figures indicate that the buying power of \$5,000 in 1988 equals more than \$10,000 today. The \$5,000 loan limit is often not adequate to provide the young person enough to finance their intended projects. During

FY 2017 through 2022, the average amount requested per YL applicant was \$4,578, which supports the need for this increase above the previous \$5,000 limitation.

Direct FO Eligibility—Farm Experience

As specified in the CONACT, one of the eligibility requirements for direct FOs is that an applicant must have participated in the business operations of a farm or ranch, or possess other adequate experience as determined by the Secretary. In the rule published March 9, 2022, (87 FR 13117–13127) that implemented provisions of the 2018 Farm Bill, FSA provided eight specific areas of experience that may be allowed as substitutes for 2 of the 3 years of actual experience. In some combinations, the experiences may meet the requirement for all 3 years.

FSA amends 7 CFR 764.152(d) to require that in the case of an entity, at least one member who will be the operator of the farm must meet these experience requirements. Prior to this rule, the majority of entity members needed to meet the experience requirement, which can limit participation for certain entities whose membership includes individuals with minimal actual farming experience. This amendment expands credit opportunities for applicants.

Emergency Loan Loss Calculations

The EM Program is triggered when a qualifying disaster or emergency is designated by the Secretary of Agriculture or declared by the President. These direct loans help producers recover from disaster-related physical and production losses.

The maximum amount FSA is able to lend for a production loss EM is determined according to 7 CFR 764.353(c); it is determined in part by reducing the calculated production loss by any compensation or insurance payments related to the disaster. This reduction is required so that the applicant will not receive duplicate payments from both an EM and Federal Crop Insurance indemnity payment, or other government payment, as stated in 7 CFR 764.352(k).

In recent years, the USDA Risk Management Agency's Revenue Protection policies have become more popular, and many Federal crop insurance policies sold today provide some form of revenue protection. Revenue Protection policies insure producers against certain yield losses, as well as against revenue losses caused by a reduction in the harvest price compared to a projected price.

Indemnity payments triggered by a Revenue Protection policy do not differentiate between the amount of the payment generated from production or price loss. Since FSA is unable to provide duplicate Federal benefits due to crop losses under 7 CFR 764.352(k) and 42 U.S.C. 5155, this rule amends 7 CFR 764.353(c)(4) to clarify that any compensation or insurance indemnities related to the loss will be subtracted in the calculations to arrive at FSA's maximum EM production loss loan amount.

Prior to this rule, producers who suffered a production loss but were made whole by a Revenue Protection insurance policy could still qualify for an EM since only specific disaster-related insurance payments were reduced. Now, any insurance indemnity payments are deducted from the formula to determine the EM amount, thereby better protecting against duplicate payments.

This rule amends the production loss threshold necessary to qualify for the EM Program in 7 CFR 764.352(h) to allow EM eligibility if a producer sustains a disaster yield that is below the normal production yield of the crop. By default, the CONACT provides eligibility for EMs based on production losses if an applicant has sustained at least a 30 percent production loss. However, the CONACT provides the Secretary discretion to set a lesser percent of production loss as the threshold for eligibility. The production loss threshold has historically been set at the maximum 30 percent threshold, which can prohibit producers from accessing EM assistance necessary to adequately recover from a disaster. FSA is removing the 30 percent threshold such that to qualify for EM assistance the disaster yield must have simply been below the normal production yield of the crop. This change will expand EM opportunities for customers who have a demonstrated loss and are in a financially vulnerable position. Establishing a specific threshold restricts the opportunities for recovery aid, and thus it is reasonable to expand potential program benefits to any eligible producer who has suffered a demonstrated production loss as a result of the declared disaster. FSA notes that the 7 CFR 764.353(b)(3) limitation remains in place that ensures loan amounts do not exceed 100 percent of the total actual production loss sustained by the applicant.

Borrower Graduation Requirements

An existing direct loan borrower must refinance their direct loans with a commercial lender at reasonable rates

and terms when they have the financial ability to do so. Failure to graduate to commercial credit is considered non-monetary default and the account is referred for acceleration and foreclosure action. While these cases are not frequent, with only 68 instances since FY 2010, final action on these accelerated, non-monetary default loans to full foreclosure and loan settlement is often delayed for years. In these cases, during that delay, the farm loan borrower continues to receive the excess benefit which they are no longer qualified for. For example, the borrower continues to receive a reduced interest rate by not refinancing, even though the financial review reflects that refinancing is an option. As an alternative to non-monetary foreclosure on accounts that would otherwise be in good standing, this rule amends 7 CFR 765.102 to provide for accounts to be converted to non-program status if the borrower fails to comply with graduation requirements or to submit requested financial documents necessary to evaluate a borrower's ability to graduate. Conversion of such loans to non-program status with higher interest rates and restrictive loan terms ensures appropriate use of taxpayer resources, with subsidized program loan benefits being provided only to borrowers in compliance with program requirements. This rule is applicable to all future accounts as it requires a borrower to acknowledge this alternative as a condition of the FSA direct loan. For existing customers to take advantage of this provision, they must acknowledge and accept the conditions separately.

Subordination of Liens

FSA has a clearly defined process for direct loan making and special servicing applications to provide an applicant written notice if additional information is required to make an application complete. A complete subordination application request also includes multiple documents, and borrowers need to be afforded the same opportunity to be notified of any outstanding information necessary to have a subordination request processed. This rule amends 7 CFR 765.205(b) to specify that FSA will process incomplete subordination requests in the same manner as is required for incomplete direct loan making requests.

Lease of Security

The lease of non-real estate security can often be in the best interest of FSA. For example, an apiary with beehives that serve as security may desire to lease beehives to other farms for pollination purposes, thereby generating income to

ensure success of the operator with minimal deterioration to the security. This rule amends 7 CFR 765.252(c) to allow the lease of non-real estate security in certain situations that are in the best interest of FSA.

Additionally, the regulation in 7 CFR 765.252(a) requires borrowers to obtain approval to lease the surface of real estate security. In August 2021, this provision was amended to limit leases for nonfarm enterprises. This rule amends the wording in 7 CFR 765.252(a)(4) to correctly reference "significant acreage of the security." Consent is only required for surface leases on the portions of a farm operation that serve as FSA security.

Use of Proceeds From Sale of Security

When borrowers sell basic security, they are often subject to capital gains taxes. FSA does not allow proceeds from the sale of basic security to be used for family living or farm operating expenses, which leaves borrowers with limited options to pay capital gains taxes. While historic exception requests for this purpose have been limited, with less than three requests typically made each year, this can be a significant hardship for borrowers with limited financial means to cover the taxes. This rule adds 7 CFR 765.352(a)(4) to allow a borrower to use a portion of proceeds from the sale of basic security to pay capital gains taxes in limited circumstances. Specifically, retention of a portion of proceeds necessary to pay capital gains taxes will only be authorized if the FSA debt remains fully secured and the borrower is not otherwise able to adequately cover the tax liability through reasonable means or obtain non-FSA credit to cover the amount of the taxes.

Borrower Loan Servicing Deadline Extension

The 2018 Farm Bill amended section 331D of the CONACT to permit State Executive Directors to extend the 60-day PLS application deadline in extraordinary circumstances. This flexibility is added to the regulation in 7 CFR 766.101(e).

Borrower Eligibility Requirements for PLS

The rule amends 7 CFR 766.104(a)(1)(vi) to add catastrophic medical expenses for a family member in the household of a borrower or entity member, in the case of an entity borrower, as circumstances beyond the control of the borrower leading to delinquency or financial distress for the purposes of PLS eligibility.

Deadline for Disputing an Appraisal

Borrowers requesting PLS who do not agree with the FSA appraisal are provided the opportunity to appeal the valuation by submitting their own independent appraisal. This rule amends 7 CFR 766.115(a) to establish a deadline of 90 days for the borrower to obtain and submit an independent appraisal to FSA. FSA has extensive experience in coordinating, contracting, and obtaining a completed agricultural real estate appraisal, with the process traditionally taking anywhere from 30 to 60 days. Accordingly, 90 days is a reasonable amount of time for a borrower to obtain a new valuation and this amount of time ensures that all servicing appeal requests are processed timely.

Notification for PLS

FSA will provide, by certified mail, the PLS notice to borrowers who are at least 90 days past due; this notice is included in the regulation as required by the CONACT, section 331D (7 U.S.C. 1981d). The FSA-2510 "Notice of Availability of Loan Servicing to Borrowers who are 90 days past due" is included as Appendix A and B to Subpart C of 7 CFR part 766.

FSA is amending FSA-2510 to incorporate the following changes:

1. Add copies of real estate leases (if applicable to the farm operation) as items necessary for a complete application;
2. Remove references to "good faith;"
3. Add "catastrophic medical expenses for the care of a family member of a borrower or entity member, in the case of an entity borrower" as a circumstance causing delinquency or financial distress beyond the borrower's control for qualification for PLS;
4. Replace the reference to obsolete form SCS-CPA-026 with NRCS-CPA-026e;
5. Remove reference to several forms for a complete loan servicing application as the forms have been consolidated into a single form FSA-2001;
6. Add verification of nonfarm income as a requirement for a complete loan servicing application, which has always been a requirement but was erroneously not included in this form previously;
7. Add a required statement to advise borrowers of the potential tax liability after FSA cancels debt, which may be realized after a write-down, current market value buyout, or debt settlement; and
8. Remove the words "writedown" and "write down" throughout the document and add "write-down" in their places.

Heirs' Property Relending Program Technical Corrections

The initial regulation for HPRP was published on August 9, 2021 (86 FR 43381-43397), implementing HPRP, which was authorized in the 2018 Farm Bill. In processing the initial HPRP applications, FSA found several areas in need of correction to address the intermediary's HPRP cash accounts, remove barriers to program usage, and encourage intermediary lender participation. FSA is making these changes in 7 CFR part 769, including removing the previous deadline for an intermediary lender to request a loan and to provide for the use of a deposit agreement to securitize HPRP cash accounts in 7 CFR 769.162(a)(1). Additionally, FSA is amending 7 CFR 769.164(d)(9)(ii) to clarify that funds advanced to an intermediary lender that are unused for 6 months must be returned to FSA unless FSA provides a written exception.

Discussion of Clarifications

The following discussion provides additional detail on the amendments identified as clarifications.

Definition of Agricultural Commodity

This rule amends the "Agricultural commodity" definition in 7 CFR 761.2(b) to clarify that ornamental plants are an eligible commodity. The definition of "Agricultural commodity" has included, and continues to include, "nursery crops." When ornamental plants are produced commercially in a typical nursery setting, FSA considers ornamental plants an eligible commodity. Ornamental plants are now specifically named as a separate eligible commodity to clarify that ornamental plants are an eligible commodity. To be considered an ornamental plant, the plant must still be produced commercially in a nursery setting that may include both covered and open-air growing facilities.

Definition of Family Farm and Non-Eligible Enterprise

This rule revises the definition of "Family farm" in 7 CFR 761.2(b) to clarify that for FLP purposes, a farm must not be a non-eligible enterprise, which includes those farms that do not produce agricultural commodities for uses associated with human consumption, fiber, or draft² use. Some operations may be agricultural in nature, but the intended use of the commodity is not for human

consumption, fiber, or draft use. Those operations are not eligible for FLP assistance as they are considered a "non-eligible enterprise" as defined in 7 CFR 761.2(b). For example, a rancher who raises primarily rodeo livestock for sport purposes is not eligible for FLP assistance as it is considered a non-eligible enterprise. This rule revises the definitions of family farm and non-eligible enterprise to clarify that the agricultural commodities must be produced for the use of food, fiber, or draft.

Definition of Feasible Plan

This rule amends the definition of "Feasible plan" in 7 CFR 761.2(b) to clarify that when unequal or interest-only installments are scheduled during the initial year(s) of the farm operating plan, a cash flow budget or farm operating plan must be prepared that reflect a typical cycle. This change is consistent with the requirement for other situations in which the planned cash flow budget or farm operating plan is atypical, for example, due to cash or inventory on hand, new enterprises, carryover debt, atypical planned purchases, or important operating changes.

Definition of Good Faith

This rule amends the definition of "Good faith" in 7 CFR 761.2(b) to clarify that instances of fraud, waste, or conversion, if substantiated by a legal opinion from the Office of General Counsel (OGC), are an additional independent basis when determining if an applicant or borrower has acted in good faith. To demonstrate good faith an applicant or borrower must adhere to all written agreements with FSA, including any loan agreements, security instruments, farm operating plans, and agreements for use of proceeds. Many actions that qualify as fraud, waste, or conversion also constitute a clear violation of FSA's loan agreement, security instruments, farm operation plans, and agreements for use of proceeds, in which case substantiation by a legal opinion from OGC will not be needed.

Definition of Participated in the Business Operations of a Farm

This rule amends the definition of "Participated in the business operations of a farm" in 7 CFR 761.2(b) to clarify that owning a farm does not necessarily mean an individual has participated in the business operations of a farm. For example, an absentee landowner who has not been involved in operating, producing, laboring, or making decisions related to operating a farm

² Draft use means domesticated animals used for working purposes, most typically in drawing heavy loads and heavy labor.

may not possess the necessary experience to ensure a reasonable prospect of loan repayment. A landowner without experience related to managerial or operational responsibilities of a farm or specific farm training does not satisfy the definition. This definition applies only to the direct loan eligibility, which requires certain managerial experience and direct farm ownership experience from applicants in order to ensure a reasonable prospect of success in the proposed farming operations and, therefore, a reasonable prospect of loan repayment.

Definitions of Related by Blood or Marriage and Relative

The CONACT requires that loans be provided to operators of family farms, and allows for applications from entities, provided that the majority interest is held by members that will operate the farm or are related by blood or marriage, as defined by the Secretary. Family farms often consist of familial relationships beyond traditional immediate family members, for example, parent and child, and increasingly include cousins, half-siblings, and in-laws. To clarify that farm loan assistance is available to family farms comprised of a variety of familial relations, this rule amends the definitions of “Related by Blood or Marriage” and “Relative” in 7 CFR 761.2(b) to include additional familial relationships. These expanded definitions will allow FSA to expand program access and support generational transfers and succession planning.

Definition of Youth Loan

The 2014 Farm Bill removed requirements that an individual must reside in a rural location to be eligible for a “Youth loan.” While FSA has administratively adopted this change since 2014, FSA will formally recognize the updated definition in 7 CFR 761.2(b) with this clarification. Furthermore, FSA removes the term “Rural youth,” as it is no longer a requirement after the 2014 Farm Bill change.

Clarify Analysis Requirements

In the FSA final rule published on August 9, 2021, FSA amended analysis requirements in 7 CFR 761.105(a). The process for completing the analysis in 7 CFR 761.105(b) was not amended consistent with those changes at that time so FSA is clarifying in this rule how the analysis will be completed. A typical analysis includes a review of the prior production cycle’s actual income, expense, and production performance,

as well as a farm operating plan for the new operating cycle. These financial documents should be prepared by the borrower, with FSA assistance when necessary. Under the regulation, a financial analysis is required if a new direct loan or subordination request is made, or if the account is, or was recently, financially distressed or delinquent. However, an analysis may also be required if FSA believes it is necessary to assist with developing an operation or to address concerns regarding borrower compliance with agreements. FSA also removes references to “year-end” analysis in 7 CFR 761.105 to avoid confusion regarding the potential timing of a required analysis.

The regulation in 7 CFR 765.101(c) requires a borrower to submit all information that FSA requests in conjunction with the routine review of the borrower’s financial condition. A review of Federal income tax returns is an important component to ensure that FSA can complete an accurate analysis. This rule clarifies that, in alignment with current practice, borrowers should expect and be prepared to comply with a request for Federal income tax returns as part of the review of the borrower’s financial condition.

Credit Elsewhere Determinations

With the exception of conservation loans, direct farm loan eligibility criteria require applicants to be unable to obtain sufficient credit elsewhere to finance their actual needs at reasonable rates and terms. FSA does not specifically require written denial letters from area lenders for an applicant to qualify for assistance, except in unique circumstances, such as to comply with statutory requirements for EMs.

Some applicants are able to obtain credit from other sources, but the rates and terms offered by those creditors may be at excessive interest rates with unreasonable fees, terms, or collateral requirements that are inconsistent with regional agricultural lending standards and do not meet the needs of the applicant. To aid in determining whether or not available credit elsewhere is reasonable, this rule clarifies 7 CFR 764.51(b)(6) and 764.101(e)(1) to require FSA approval officials to analyze the rates and terms of available credit to ensure they support the generation of a reasonable amount of cash flow margin to increase working capital reserves and savings necessary for operational stability and growth, including reasonable savings for retirement and education. This rule clarifies that for the rates and terms of external credit to be reasonable it must

provide a reasonable opportunity for long-term growth. FSA approval officials will determine a reasonable amount of cash flow margin to increase working capital reserves and savings by referencing available resources, including regional lending standards and farm financial and classification ratios.

Direct Loan Making and Servicing Application Requirements

A complete analysis of a farming operation often requires a review of existing and proposed real estate and equipment leases. Additionally, FSA has regularly required submission of documents such as contracts or purchase options, especially when the contract or option is related to property for which the loan is requested. This rule adds 7 CFR 766.102(a)(8) and revises 7 CFR 764.51(b)(10) to clarify that an applicant must provide leases, contracts, options, or other agreements to FSA, upon request, as part of a complete direct loan making or servicing application. Additionally, this rule revises 7 CFR 764.51(b)(10) to clarify that the requested documents are those that are associated with the borrower’s “operation.”

This rule also amends 7 CFR 766.102(a) to correct a reference to an obsolete regulation, and to remove the requirement for borrowers to sign an acknowledgement form to request direct loan servicing, as the acknowledgement has been consolidated into the FSA–2001 application for direct loan servicing, which is required for all such requests.

Direct Loan Eligibility—Entity Credit History

An applicant’s credit history is considered in nearly every lender’s analysis of risk associated with the extension of credit. FSA also considers credit history when determining an applicant’s eligibility for direct loans. To qualify for a direct loan from FSA an applicant must demonstrate acceptable credit history. However, unlike many commercial lenders, FSA does not base an ultimate eligibility decision on the applicant’s credit score. FSA does not find an applicant’s credit history to be unacceptable if the applicant has no record of past credit, or if an applicant has a history of failure to repay past debts due to circumstances outside of the applicant’s control.

Since family farms do not always obtain debt that demonstrates relevant credit history in the name of the applicant entity, FSA must assess the credit history of the underlying entity members in order to adequately assess

credit worthiness requirements. FSA is amending 7 CFR 764.101(d) to clarify the current and historic requirement that in the case of an entity, all individual entity members must satisfy credit history requirements. The clarification will more closely align the credit history eligibility standard with other eligibility criteria that more clearly specify the individual entity member requirements.

Guaranteed Loan Eligibility—Credit History

All guaranteed loan applicants must meet basic eligibility criteria. Two of the existing criteria require that an applicant must not have caused FSA a previous loss (except in limited circumstances), and the applicant must meet creditworthiness requirements by demonstrating a successful history of repaying debts as they come due. Applicants sometimes repay previous losses to the government, but creditworthiness requirements still must be assessed to ensure the applicant represents a good prospect of loan repayment. This rule amends 7 CFR 762.120 to clarify even if a previous loss is repaid, the applicant must still satisfy creditworthiness requirements in order to receive new guaranteed loan assistance.

Direct Loan Eligibility—Managerial Ability

Farmers experience significantly different challenges compared to other business operators. To assist direct loan applicants to be successful and to manage FSA's credit risk, eligible direct loan applicants must demonstrate that they possess sufficient managerial ability to ensure reasonable prospects of loan repayment. Applicants may demonstrate the required managerial ability in a variety of ways, including through education, on-the-job training, and actual farming experience (7 CFR 764.101(i)).

Entity applicants are required to demonstrate managerial experience. Entity structures cannot possess experience, but rather it is the individual entity members who possess the managerial ability necessary to satisfy the requirements. FSA is clarifying the CONACT requirement that for an entity applicant to satisfy the managerial ability eligibility requirement, the individuals holding a majority interest in the entity must possess the required experience.

FSA is clarifying that a history of an entity applicant simply owning a farm does not necessarily satisfy managerial ability requirements. As discussed above, amendments to the definition of

“Participated in the Business Operations of a Farm” clarify that simply owning a farm does not necessarily mean an individual has participated in the business operations. Consistent with this definition change and the reasons discussed above, the word “owner” has been removed from 7 CFR 764.101(i)(3).

FSA is also clarifying the lookback period for FSA to consider prior farming experience for an applicant to meet the eligibility requirement based on farming experience prior to the date of the direct loan application in 7 CFR 764.101(i)(3). There has been confusion among applicants due to the use of two different lookback periods for similar experience requirements in the regulations. For certain specific direct FO experience requirements, the lookback period is 10 years, yet the lookback period for farming experience to meet the general managerial ability requirement has been 5 years. FSA is amending the lookback period for farming experience to meet the general managerial ability requirement from 5 years to 10 years to align more closely with the farm experience eligibility requirement specific to direct FO applicants, as provided in 7 CFR 764.152(d). FSA recognizes that increasingly available online education resources and mentorship opportunities can ensure applicants have a reasonable prospect for success, even if their actual farming managerial experience was gained more than 5, but less than 10, years ago. Accordingly, FSA is confident that expanding the general managerial ability experience lookback period to align with the FO lookback period will expand opportunity for applicant access to credit.

Microloan (ML)–OL and Indian Tribal Land Acquisition Program (ITLAP) Interest Rate Clarification

The CONACT provides a special interest rate for ML–OL in Section 316(a)(2). ITLAP is authorized outside of the CONACT, but loans made under ITLAP are subject to the interest rate provisions under the CONACT applicable to the low-income farm ownership loan program at Section 307(a)(3)(B) that provides a reduced interest rate for limited resource applicants. In both cases, the interest rate formula is inherently ambiguous, making it difficult to determine the appropriate interest rate for these direct loans. FSA is amending 7 CFR 764.254(a)(4) and 770.6(b) to clarify that the interest rate for ML–OLs and ITLAP is equal to the existing OL rate and FO rate, respectively, but not to exceed 5 percent. This change will resolve the

existing confusion about the requirements and benefit applicants by providing a rate ceiling that is consistent with the reasonable historic interpretation of the CONACT interest rate formula. The CONACT does not provide for a special interest rate for ML–FOs. FSA will continue to determine the ML–FO rate using the same methodology as a regular FO.

Transfer and Assumption Application Requirements

This rule adds 7 CFR 765.402(f) and (g), 765.403(f) and (g), and 765.404(g) to clarify that transfer and assumption requests require a complete application from transferees to ensure borrower eligibility and the feasibility of the operation, and to clarify that all direct loan security must be transferred to the new borrower as a condition of approval.

Equitable Relief Technical Corrections

The equitable relief provisions published in 7 CFR 768.1 on March 9, 2022 (87 FR 13117–13127) require minor technical correction to clarify in 7 CFR 768.1(a) that equitable relief may be considered for the borrower or borrower's loan due to noncompliance with either legal or regulatory requirements.

Notice and Comment, Effective Date, and Exemptions

The Administrative Procedure Act (APA, 5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts. This rule involves a program for loans and thus falls within the exemption for rules related to loans. FSA is requesting comments on this rule to determine if additional improvements need to be made in the future to the regulations.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996.

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act) requires a delay in the effective date for 60 days from the date of publication to allow for Congressional review of rules that meet the criteria specified in 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs has determined that this rule does not meet the criteria in 5 U.S.C. 804(2).

Therefore, this rule is effective September 25, 2024.

Executive Orders 12866, 13563, and 14904

Executive Order 12866 (as amended by Executive Order 14904), “Regulatory Planning and Review,” and Executive Order 13563, “Improving Regulation and Regulatory Review,” direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) designated this rule as significant under Executive Order 12866, “Regulatory Planning and Review,” and therefore, OMB has reviewed this rule. The costs and benefits of this rule are summarized below. The full cost benefit analysis is available on [regulations.gov](https://www.regulations.gov).

Cost Benefit Analysis Summary

The cost benefit analysis covers implementation of an improved approach to loan servicing for FSA farm loan programs that is designed to remove barriers to capital access and increase flexibilities for borrowers. This new approach includes a newly created DBSA Program that can be used by both distressed and delinquent borrowers. In addition, numerous modifications to existing programs are being made that offer borrowers greater flexibility and improve their amount of working capital—regardless of whether they are distressed or delinquent.

All changes to the loan programs that are anticipated to impact the net present value of the cost of providing loans, loan guarantees, or modification therefore, will be incorporated into subsidy cost for each relevant risk category and cohort year of loans or loan guarantees.³ While the effective date for this final rule is September 25, 2024, USDA’s ability to modify outstanding loans and loan guarantees, and enter into obligation for new loans and loan guarantees with the revised provisions specified in this final rule are subject to

2 U.S.C. 661(D) and 661b(a), and OMB Circular A–11 section 185.3(s).

The changes in this final rule are consistent with numerous aspects of FSA’s ongoing efforts to remove barriers to capital access and increase opportunities for FLP borrowers to be successful. The subsidy rate and cost impact of the changes in this final rule vary across the types of changes, including some increases and decreases. Specifically, introducing more flexible repayment terms is expected to increase income receipts and reduce program subsidy costs for several direct loan programs. Several changes, such as reduced security requirements and flexible repayment terms are also expected to increase subsidy costs as a result of increased losses or decreased recoveries. FSA anticipates administrative savings from reduced workload in processing primary loan servicing and monitoring security instruments and an overall reduction in burden.

Prior to this rule, only PLS and the DSA Program were available to help distressed borrowers on an ongoing basis. PLS involves restructuring the loan, usually by deferring some or all of the borrower’s upcoming installment payments to the end of the loan term. Alternatively, if the borrower is operating in a county that is declared a major disaster, they can apply for loan servicing through the DSA Program. If the borrower selects PLS, they must provide a significant amount of financial information and develop a projection of income and expenses for the next year.

With this rule, DBSA offers both distressed and delinquent direct borrowers—along with FSA field staff—a more streamlined opportunity to help navigate financial difficulties. DBSA allows financially distressed or delinquent direct loan borrowers—with FOs, OLs, CLs, SWs, or EMs—to request a one-time deferral of a delinquent or upcoming annual installment. The amount of the deferral is limited to the lesser of the amount of the annual installment or the unpaid balance remaining on the installment at the time the DBSA is approved. The amount deferred has a reduced interest rate of 0.125 percent, the lowest interest rate authorized by the CONACT.

DBSA only applies to outstanding loans as of September 25, 2024, the date the rule becomes effective, and as a result, the cost of implementing the regulation (loan modification cost) reflects:

(1) the reduction in the present value of interest receipts (due to the 0.125 percent noted above), and

(2) the reduction in the present value of principal installments over the life of DBSA.

Consequently, FSA will pay the for the modification cost of DBSA upfront using funds from section 22006 of the Inflation Reduction Act.

In addition to DBSA, the rule contains interrelated provisions that provide borrowers with expanded opportunities to allocate working capital toward long-term financial goals. For example, the rule provides all direct loan applicants the option to receive flexible repayment terms for most loan requests (including interest-only payments during the first year, partial principal payments, and longer loan maturity terms). These flexibilities free up some of the borrowers’ funds that would otherwise have been used to make larger loan payments. Funds can be used to ensure that their farm operating plan budgets have additional funding to increase working capital reserves and savings, including reasonable savings for retirement and education. These changes are expected to increase interest payments to USDA, which would reduce program subsidy costs, but the changes are also expected to result in an increase in defaults and would increase subsidy costs. Implementation of the changes in this rule are subject to FSA reflecting subsidy costs in accordance with 2 U.S.C. 661(D) and 661b(a), and OMB Circular A–11 section 185.3(s).

Further, the rule lowers the security margin required of the borrower from 150 to 125 percent at the time of loan origination, while still requiring all loans to be fully secured. If the applicant does not have sufficient assets to achieve this security margin, FSA still provides the loan as long as there is adequate security to ensure a 100 percent security margin. However, if additional security is available, FSA currently requires a lien on additional security assets in order to achieve a 150 percent security margin. A requirement this high, however, can hinder the ability of customers to leverage assets into additional growth opportunities. In addition, FSA will no longer take the primary residence as additional security and will not require non-real estate assets to be pledged as additional security for real estate loans. The rule also expands the opportunity for a borrower to request a partial release of certain security if they have a demonstrated history of positive repayment with FSA for the previous 36 months (including scheduled principal reductions) and the loan will still be adequately secured after the release. FSA currently allows for the release of unnecessary security in limited

³ The definition of subsidy cost and other relevant guidance to Federal agencies regarding the calculation of subsidy rates, modification costs estimates, and other aspects of FCRA implementation are specified in OMB Circular A–11 section 185.

circumstances, but this provision will facilitate the process for all borrowers who have several years of successful loan repayment. While these security changes can have significant benefit to borrowers, they are expected to result in a reduction in recoveries, which would increase subsidy costs. Implementation of the changes in this rule are subject to FSA reflecting subsidy costs in accordance with 2 U.S.C. 661(D) and 661b(a), and OMB Circular A–11 section 185.3(s).

In addition to the more significant items above, the rule is making changes to other direct and guaranteed loan provisions. For example, the rule clarifies that catastrophic medical expenses for the care of a family member of the borrower or entity member could be a justification for financial distress and makes them eligible for PLS; the maximum value of youth loans is increased from \$5,000 to \$10,000 to account for inflation; and other minor changes. The cost impact from these smaller changes is expected to be de minimus.

Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulation for compliance with NEPA (7 CFR part 799). The DBSA Program is being implemented as a servicing tool to help financially distressed borrowers. In addition to adding DBSA, FSA is making discretionary changes throughout the FLP regulations to clarify and amend existing delivery processes, program requirements, and technical corrections or clarifications.

The provisions of this rule regarding DBSA is covered by the Categorical Exclusions, found in 7 CFR part 799.31(b)(1)(iii) for debt set-asides when no Extraordinary Circumstances (§ 799.33) exist. The discretionary changes to the regulations are covered by the Categorical Exclusions, found in 7 CFR 799.31(b)(3)(i) for issuing minor technical corrections to regulations, handbooks, and internal guidance, as well as amendments to regulations when no Extraordinary Circumstances (§ 799.33) exist.

Through this review, FSA has determined that neither the implementation of the DBSA Program and the participation in the DBSA Program, nor the discretionary changes to the regulations, constitutes major Federal actions that would significantly

affect the quality of the human environment, individually or cumulatively. Therefore, FSA will not prepare an environmental assessment or environmental impact statement for this rule; this rule serves as documentation of the programmatic environmental compliance decision for this Federal action.

Executive Order 12372

Executive Order 12372, “Intergovernmental Review of Federal Programs,” requires consultation with State and local officials that would be directly affected by proposed Federal financial assistance. The objectives of the Executive Order are to foster an intergovernmental partnership and a strengthened Federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal Financial assistance and direct Federal development. For reasons specified in the final rule related notice regarding 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), the programs and activities within this rule are excluded from the scope of Executive Order 12372.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988, “Civil Justice Reform.” This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial actions may be brought regarding the provisions of this rule the administrative appeal provisions of 7 CFR part 11 and 780 are to be exhausted.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, “Federalism.” The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the Federal government and the States, or the distribution of power and responsibilities among the various levels of government, except as required by law. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

This rule has been reviewed for compliance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires federal agencies to consult and coordinate with Tribes on a

government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

FSA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have significant Tribal implications that require ongoing adherence to Executive Order 13175 at this time. Tribal governments are not eligible for FSA direct and guaranteed loans, so the reach of this rule and impact with Tribes is somewhat limited. Tribes are eligible for FSA’s Highly Fractionated Indian Land Loan Program (HFIL) and ITLAP. USDA and FSA have conducted a series of Tribal consultations to obtain input from Tribes and Native producers on our FSA loan programs.

Specifically, we received considerable feedback in 2021, 2022, and 2023 on how USDA can better incorporate traditional foods into FPAC programs as a whole. In fact, one of the top four tribal barriers in 2021 USDA Tribal Consultations was the need to improve and expand support for traditional foods and food ways into FSA and FPAC programs.

In response, in 2022, Administrator Zach Ducheneaux formalized an advisory group of the leadership team to address recommendations by Tribal leadership in USDA Tribal Consultations, reduce barriers to program participation and implement priorities for Indian Country. In the 2022 and 2023 USDA Tribal Consultations, USDA requested more specific input from Tribal leaders on traditional food ways and crops, including wild rice, that Tribal Nations seek to be added into USDA programs.

As a result, this rule includes wild rice and other Tribal foraging practices in Indian Country where it was previously excluded. This is one of the actions FSA has made to be more inclusive to Tribal agricultural producers in indigenous ways in broadly applicable loan programs by improving the interpretation of the authorizing law in the regulation. If a Tribe requests further consultation, FSA will coordinate with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications are not expressly mandated by law.

The Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures of \$100 million or more in any 1 year for State, local, or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA for State, local, or Tribal governments, or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Federal Assistance Programs

The title and number of the Federal assistance programs, as found in the Assistance Listing⁴ to which this rule applies are:

- 10.099 Conservation Loans;
- 10.404 Emergency Loans;
- 10.406 Farm Operating Loans; and
- 10.407 Farm Ownership Loans.

Paperwork Reduction Act

For the various regulatory changes being made by this rule, FSA will continue to use some forms that already are currently approved under the OMB control number of 0560–0233, 0560–0237 and 0560–0238.

This rule does not change the following approved information collection under OMB control numbers:

- 0560–0155, Guaranteed Farm Loan Programs, OMB Expiration Date of November 2026;
- 0560–0233, Farm Loan Programs—Direct Loan Servicing, OMB Expiration Date of October 2024;
- 0560–0237, Farm Loan Programs—Direct Loan Making, OMB Expiration Date of January 2026;
- 0560–0238, Farm Loan Programs—General Program Administration, OMB Expiration Date of October 2026; and
- 0560–0317, Online Loan Application, OMB Expiration Date of November 2026.

For the information collection changes related to the existing approvals under 0560–0155, Guaranteed Farm Loan Programs, and 0560–0317, Online Loan Application, there are no new

forms, no changes in the per response time for the information collection activities, and not changes in the number of respondents.

For the information collection changes related to the existing approval under 0560–0233, operationally, there is a potential increase of approximately 2,000 in the number of respondents, related to an increase in the requests for DBSA and DSA. The approved burden estimates for 0560–0233 includes 8,692 DSA applications annually. Actual requests over the last 5 years have averaged 786 applications, so the anticipated increase in requests is well within the existing approved burden estimate.

For the information collection changes related to the existing approval under 0560–0236, operationally, there is a potential increase in requests for security releases and leasing of property. The approved burden estimates for 0560–0236 includes 455 requests for lease security annually. Actual lease security requests have averaged less than 100, so the anticipated increase in requests is well within the existing approved burden estimate. As explained below, the form used for requesting security releases is expected to increase in the number of respondents beyond what is currently approved for the form under 0560–0236.

For the information collection changes related to the existing approval under 0560–0237, operationally, FSA expects an increase in the actual number of respondents due to increasing the youth loan limit. This might increase the youth loan demand by a few hundred applications. The approved burden estimates for 0560–0237 includes 4,410 applications annually. The 5-year average has only been 2,056 applications, so the anticipated increase in youth loans is well within the existing approved burden estimate.

This rule does increase the expected number of respondents who will request a release of security using form FSA–2061—Application for partial release or consent. That form is approved under OMB 0560–0236, Farm Loan Programs: Direct Loan Servicing, Regular. FSA requested an emergency approval from OMB to cover the increase of the borrowers in using a release of security (Form FSA–2061—Application for partial release or consent). The rest of this section provides the information related to the requests for comments for these changes.

Information Collection Request; Request for Comments

FSA is requesting comments from all interested individuals and organizations on a new information collection associated with the release of security (the form FSA–2061) for the Direct Loan Servicing—Regular information collection activity. This rule expands opportunities to release liens on additional collateral for borrowers with a demonstrated history of successful direct loan repayment. After 3 years of successful loan repayment and principal reduction, a borrower can request FSA to release liens on additional security items provided the loan will continue to be fully secured. The borrower formally requests to be considered for a release of security using form FSA–2061—Application of Partial Release or Consent. FLP anticipates an increase in the use of the FSA–2061 as more borrowers will be able to qualify for a lien release than before.

OMB Control Number: 0560–New.

Type of Request: New Collection.

Abstract: This information collection is required to support Direct Loan Servicing—Regular information collection activity to cover the increase of the borrowers to qualify for a lien release.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per response multiplied by the estimated total annual responses.

Public reporting burden for this information collection is estimated to average 0.50 hours per response.

Type of Respondents: Producers or farmers.

Estimated Annual Number of Respondents: 4,747.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 4,747.

Estimated Average Time per Response: 0.50 hours.

Estimated Total Annual Burden on Respondents: 2,374.

FSA is requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected; and

⁴ See <https://sam.gov/content/assistance-listings>.

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720-2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

List of Subjects

7 CFR Part 761

Accounting, Loan programs—agriculture, Rural areas.

7 CFR Parts 764 Through 766 and 768 Through 770

Agriculture, Credit, Loan programs—agriculture.

For the reasons discussed above, FSA amends 7 CFR chapter VII as follows:

PART 761—FARM LOAN PROGRAMS; GENERAL PROGRAM ADMINISTRATION

■ 1. The authority citation for part 761 continues to read as follows:

Authority: 5 U.S.C. 301 and 7 U.S.C. 1989.

Subpart A—General Provisions

■ 2. Amend § 761.2 as follows:

■ a. In the undesignated introductory paragraph, remove the words “767 and”;

■ b. In paragraph (a) add the abbreviation for DBSA in alphabetical order; and

■ c. In paragraph (b):

■ i. In the definition of “Administrative appraisal review”, redesignate paragraphs (1) and (2) as paragraphs (i) and (ii);

■ ii. In the definition of “Agricultural commodity”, remove the words “forage, nursery” and add “forage, ornamental plants, nursery” in their place;

■ iii. Revise the definition of “Beginning farmer”;

■ iv. Add a definition of “Commercially foraged” in alphabetical order;

■ v. Revise the definition of “Debt forgiveness”;

■ vi. Remove the definition of “Debt writedown”;

■ vii. Add the definitions of “Debt write-down” and “Distressed Borrower Set-Aside” in alphabetical order;

■ viii. Revise the definition of “Equitable relief”;

■ ix. Revise the definition of “Essential family living and farm operating expenses”;

■ x. In the definition of “Established farmer”, redesignate paragraphs (1) through (6) as paragraphs (i) through (vi);

■ xi. Revise the definition of “Family farm”;

■ xii. In the definition of “Farm Ownership loan”, remove the word “Downpayment” and add “Down Payment” in its place;

■ xiii. Revise the definition of “Feasible plan”;

■ xiv. In the definition of “Financially viable operation”, redesignate

paragraphs (1) through (4) as paragraphs (i) through (iv);

■ xv. Revise the definition of “Good faith”;

■ xvi. Add definitions of “Indian land” and “Indian Tribe” in alphabetical order;

■ xvii. In the definition of “Limited resource interest rate”, redesignate paragraphs (1) and (2) as paragraphs (i) and (ii);

■ xviii. Revise the definitions of “Non-eligible enterprise”, “Non-essential assets”, “Normal production yield”, “Participated in the business operations of a farm”, “Primary loan servicing programs”, “Related by blood or marriage”, and “Relative”;

■ xix. Remove the definition of “Rural youth”;

■ xx. In the definition of “Restructuring”, remove the word “writedown” and add “write-down” in its place;

■ xxi. In the definition of “Shared Appreciation Agreement”, remove the word “writedown” and add “write-down” both places it occurs; and

■ xxii. In the definition of “Youth loan”, remove the word “rural”.

The additions and revisions read as follows.

§ 761.2 Abbreviations and definitions.

* * * * *

(a) * * *

DBSA Distressed Borrower Set-Aside.

* * * * *

(b) * * *

Beginning farmer is an individual or entity who:

(i) Meets the loan eligibility requirements for a direct or guaranteed CL, FO, or OL, as applicable;

(ii) Has not operated a farm for more than 10 years. This requirement applies to all members of an entity;

(iii) Will materially and substantially participate in the operation of the farm:

(A) In the case of a loan made to an individual, individually or with the family members, material and substantial participation requires that the individual provide substantial day-to-day labor and management of the farm, consistent with the practices in the county or State where the farm is located; or

(B) In the case of a loan made to an entity, all members must materially and substantially participate in the operation of the farm. Material and substantial participation requires that the member provide some amount of the management, or labor and management necessary for day-to-day activities, such that if the individual did not provide these inputs, operation of the farm would be seriously impaired;

(iv) Agrees to participate in any loan assessment and borrower training required by Agency regulations;

(v) Except for an OL applicant, does not own real farm property or who, directly or through interests in family farm entities owns real farm property, the aggregate acreage of which does not exceed 30 percent of the average farm acreage of the farms in the county where the property is located. If the farm is located in more than one county, the average farm acreage of the county where the applicant's residence is located will be used in the calculation. If the applicant's residence is not located on the farm or if the applicant is an entity, the average farm acreage of the county where the major portion of the farm is located will be used. The average county farm acreage will be determined from the most recent Census of Agriculture;

(vi) Demonstrates that the available resources of the applicant and spouse (if any) are not sufficient to enable the applicant to enter or continue farming on a viable scale; and

(vii) In the case of an entity:

(A) All the members are related by blood or marriage; and

(B) All the members are beginning farmers.

Commercially foraged means the harvesting of naturally occurring plants, or plantlike material, including fungi, that develop with limited management of the resource.

Debt forgiveness means the reduction or termination of a debt under the Act in a manner that results in a loss to the Agency:

(i) Debt forgiveness includes:

(A) Writing down or writing off a debt pursuant to 7 U.S.C. 2001;

(B) Cancellation of remaining amounts owed after compromising, adjusting, reducing, or charging off a debt or claim pursuant to 7 U.S.C. 1981;

(C) Paying a loss pursuant to 7 U.S.C. 2005 on a FLP loan guaranteed by the Agency;

(D) Discharging a debt as a result of bankruptcy; or

(E) Releases of liability which result in a loss to the Agency.

(ii) Debt forgiveness does not include:

(A) Debt reduction through a conservation contract;

(B) Any write-down provided as part of the resolution of a discrimination complaint against the Agency;

(C) Prior debt forgiveness that has been repaid in its entirety;

(D) Consolidation, rescheduling, reamortization, or deferral of a loan; and

(E) Forgiveness of a YL debt due to circumstances beyond the borrower's control.

Debt write-down means the reduction of the borrower's debt to that amount the Agency determines to be collectible based on an analysis of the security value and the borrower's ability to pay.

Distressed borrower set-aside means the deferral of payment of an annual loan installment to the Agency to the end of the loan term in accordance with part 766, subpart J, of this chapter.

Equitable relief means relief provided in accordance with part 7 CFR 768.1.

Essential family living and farm operating expenses means those expenses that:

(i) Are those that are basic, crucial, or indispensable;

(ii) Are determined by the Agency based on the following considerations:

(A) The specific borrower's operation;

(B) What is typical for that type of operation in the area; and

(C) What is an efficient method of production considering the borrower's resources; and

(iii) Include, but are not limited to, essential: Household operating expenses; food, including lunches; clothing and personal care; health and medical expenses, including medical insurance; house repair and sanitation; school and religious expenses; transportation; hired labor; machinery repair; farm building and fence repair; interest on loans and credit or purchase agreement; rent on equipment, land, and buildings; feed for animals; seed, fertilizer, pesticides, herbicides, spray materials and other necessary farm supplies; livestock expenses, including medical supplies, artificial insemination, and veterinarian bills; machinery hire; fuel and oil; taxes; water charges; personal, property and crop insurance; auto and truck expenses; and utility payments.

Family farm means a business operation that:

(i) Produces agricultural commodities, including agricultural commodities commercially foraged on Indian land for the purposes of OLs, for sale in sufficient quantities so that it is recognized as a farm rather than a rural residence or non-eligible enterprise;

(ii) Has both physical labor and management provided as follows:

(A) The majority of day-to-day, operational decisions, and all strategic management decisions are made by:

(1) The borrower, with input and assistance allowed from persons who are either related by blood or marriage to an individual borrower; or

(2) The members responsible for operating the farm, in the case of an entity; and

(B) A substantial amount of labor to operate the farm is provided by:

(1) The borrower, with input and assistance allowed from persons who are either related by blood or marriage to an individual borrower; or

(2) The members responsible for operating the farm, in the case of an entity;

(iii) May use full-time hired labor in amounts only to supplement family labor; and

(iv) May use reasonable amounts of temporary labor for seasonal peak workload periods or intermittently for labor intensive activities.

* * * * *

Feasible plan means when an applicant or borrower's cash flow budget or farm operating plan indicates that there is sufficient cash inflow to pay all cash outflow. If a loan approval or servicing action exceeds one production cycle and the planned cash flow budget or farm operating plan is atypical due to an interest-only or otherwise unequal installment, cash or inventory on hand, new enterprises, carryover debt, atypical planned purchases, important operating changes, or other reasons, a cash flow budget or farm operating plan must be prepared that reflects a typical cycle. If the request is for only one cycle, a feasible plan for only that production cycle is required for approval.

* * * * *

Good faith means when an applicant or borrower provides current, complete, and truthful information when applying for assistance and in all past dealings with the Agency and adheres to all written agreements with the Agency including loan agreements, security instruments, farm operating plans, and agreements for use of proceeds. If the borrower's inability to adhere to all agreements is due to circumstances beyond the borrower's control, the Agency will consider the borrower to have acted in good faith. In addition, the Agency may also consider fraud, waste, or conversion actions when determining if an applicant or borrower has acted in good faith. Such determinations of fraud, waste, or conversion that are substantiated by a legal opinion from OGC constitute an independent basis for determinations of not having acted in good faith.

* * * * *

Indian land, for the purposes of the definition of "family farm" in this section, means land, or an interest therein, that is:

(i) Owned by an Indian Tribe;

(ii) Owned by an Indian Tribe and is subject to restrictions against alienation or encumbrance by the United States; or
(iii) Held in trust by the United States for an Indian Tribe.

* * * * *

Indian Tribe means any Indian Tribe, band, nation, pueblo, or other organized group or community, including any Alaska Native village or regional corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601–1629h), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

* * * * *

Non-eligible enterprise means a business that meets the criteria in any one of the following categories:

(i) Produces exotic animals, birds, or aquatic organisms or their products that may be agricultural in nature, but are not primarily associated with agricultural production, for example, there is no established or stable market for them, or production is speculative in nature;

(ii) Produces animals, birds, or aquatic organisms ordinarily used for pets, companionship, sport, or pleasure and not primarily associated with human consumption, fiber, or draft use;

(iii) Primarily markets goods or provides services which might be agriculturally related, but are not produced by the farming operation; or

(iv) Processes or markets farm products when the majority of the commodities processed or marketed are not produced by the farming operation.

Non-essential assets mean assets in which the borrower has an ownership interest, that:

(i) Do not contribute to:

(A) Income to pay essential family living expenses, or

(B) The farming operation; and

(ii) Are not exempt from judgment creditors or in a bankruptcy action.

* * * * *

Normal production yield means, as used in 7 CFR part 764 for EMs:

(i) The per acre actual production history of the crops produced by the farming operation used to determine Federal crop insurance payments or payment under the Noninsured Crop Disaster Assistance Program for the production year during which the disaster occurred;

(ii) The applicant's own production records, or the records of production on which FSA Farm Program payments are made contained in the applicant's Farm Program file, if available, for the previous 3 years, when the actual

production history in paragraph (i) of this definition is not available;

(iii) The county average production yield, when the production records outlined in paragraphs (i) and (ii) of this definition are not available.

Participated in the business operations of a farm means that an individual has:

(i) Been the manager or operator of a farming operation for the year's complete production cycle as evidenced by tax returns, FSA farm records or similar documentation;

(ii) Been employed as a farm manager or farm management consultant for the year's complete production cycle; or

(iii) Participated in the operation of a farm by virtue of being raised on a farm or having worked on a farm (which can include a farm-related apprenticeship, internship, or similar educational program with applied work experience) with significant responsibility for the day-to-day decisions for the year's complete production cycle, which may include selection of seed varieties, weed control programs, input suppliers, livestock feeding programs, or decisions to replace or repair equipment.

Primary loan servicing programs means:

(i) Loan consolidation and rescheduling, or reamortization;

(ii) Interest rate reduction, including use of the limited resource rate program;

(iii) Deferral;

(iv) Write-down of the principal or accumulated interest; or

(v) Any combination of paragraphs (i) through (iv) of this definition.

Related by blood or marriage is being connected to one another as husband, wife, parent, child, brother, sister, uncle, aunt, grandparent, son, daughter, sibling, stepparent, stepson, stepdaughter, stepbrother, stepsister, half-brother, half-sister, son-in-law, daughter-in-law, father-in-law, mother-in-law, nephew, niece, cousin, grandson, granddaughter, or the spouses of any of those individuals. "Related by blood or marriage" is used for consistency with a requirement in the CONACT. It has the same meaning as the word "relative" for the Farm Loan Programs regulations in this Chapter.

Relative means the spouse and anyone having one of the following relationships to an applicant or borrower: parent, son, daughter, sibling, stepparent, stepson, stepdaughter, stepbrother, stepsister, half-brother, half-sister, son-in-law, daughter-in-law, father-in-law, mother-in-law, uncle, aunt, nephew, niece, cousin, grandparent, grandson, granddaughter, or the spouses of any of those individuals. Relative has the same

meaning as the term "related by blood or marriage" for the Farm Loan Programs regulations in this Chapter.

* * * * *

Subpart C—Progression Lending

§ 761.102 [Amended]

■ 3. In § 761.102, amend paragraph (b)(1) by removing the word "year-end analyses,".

■ 4. Amend § 761.103 as follows:

■ a. In paragraph (a)(3), remove the word "progressive" and add "progression" in its place, and remove the words "in the shortest time practicable" and add "at reasonable rates and terms" in their place; and
■ b. Revise paragraphs (b)(3) and (c)(3) and (4).

The revisions read as follows:

§ 761.103 Farm assessment.

* * * * *

(b) * * *

(3) The short- and long-term goals of the operation, including goals to reasonably increase working capital reserves and savings, including reasonable savings for retirement and education, to support operational stability and growth, and goals for progression towards graduation to commercial credit or eventual self-financing;

* * * * *

(c) * * *

(3) The short- and long-term goals of the operation, including goals to reasonably increase working capital reserves and savings, including reasonable savings for retirement and education, to support operational stability and growth, and goals for progression towards graduation to commercial credit or eventual self-financing;

(4) The short- and long-term financial viability of the farming operation, including a marketing plan, and available production history, as applicable;

* * * * *

■ 5. Amend § 761.104 as follows.

■ a. Redesignate paragraphs (f) and (g) as paragraphs (g) and (h), respectively;

■ b. Add new paragraph (f); and

■ c. In newly redesignated paragraph (g), remove "paragraph (g)" and add in its place "paragraph (h)" in its place.

The addition reads as follow.

§ 761.104 Developing the farm operating plan.

* * * * *

(f) Development of farm operating plans and determination of appropriate repayment terms must include

consideration of a reasonable amount of cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education, to support operational stability and growth.

* * * * *

■ 6. Amend § 761.105 as follows:

■ a. Revise the section heading;

■ b. In paragraph (a), remove the words “a year-end” and add “an” in its place; and

■ c. Revise paragraph (b).

The revisions read as follows:

§ 761.105 Analysis.

* * * * *

(b) The analysis must include a review of the previous production cycle’s actual income, expense, and production performance, as well as a farm operating plan for the new operating cycle.

PART 762—GUARANTEED FARM LOANS

■ 7. The authority citation for part 762 continues to read as follows:

Authority: 5 U.S.C. 301 and 7 U.S.C. 1989.

■ 8. In § 762.120, add paragraph (a)(3) to read as follows:

§ 762.120 Applicant eligibility.

(a) * * *

(3) If the debt forgiveness is resolved by repayment of the Agency’s loss, the Agency may still consider the debt forgiveness in determining the applicant’s creditworthiness.

* * * * *

■ 9. In § 762.124 revise paragraph (e)(1) to read as follows:

§ 762.124 Interest rates, terms, charges, and fees.

* * * * *

(e) * * *

(1) Extended repayment schedules may include equal, unequal, or balloon installments if needed by a borrower on any guaranteed loan to establish a new enterprise, develop a farm, recover from a disaster or an economical reversal, or reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education.

* * * * *

■ 10. Amend § 762.142 as follows:

■ a. In paragraph (c)(1)(iii), remove the words “the debt of another lender” and add “debt” in their place;

■ b. In paragraph (c)(3)(ii), remove the words “to allow another lender”;

■ c. In paragraph (d)(1), remove the words “For standard eligible and CLP lenders, the” and add “The” in their place;

■ d. Revise paragraph (d)(2);

■ e. Remove paragraph (d)(3);

■ f. Redesignate paragraphs (d)(4) through (10) as paragraphs (d)(3) through (9), respectively; and

■ g. Revise newly redesignated paragraph (d)(5).

The revisions read as follows.

§ 762.142 Servicing related to collateral.

* * * * *

(d) * * *

(2) The transferee must apply for a loan in accordance with § 762.110, and provide any other information requested by the Agency to evaluate the transfer and assumption request. A current appraisal is required unless the lien position of the guaranteed loan will not change.

* * * * *

(5) The transferee must meet the eligibility requirements and loan limitations for the loan being transferred, including all requirements relating to loan rates and terms, loan security, feasibility, and environmental and other laws applicable to an applicant under this part, except for a current appraisal when permitted in paragraph (d)(2) of this section.

* * * * *

■ 11. Amend § 762.145 as follows:

■ a. In paragraph (a)(3)(i), remove the words “write down” and add “write-down” in their place;

■ b. In paragraph (a)(3)(ii), remove the word “writedown” and add “write-down” in its place;

■ c. In paragraph (a)(3)(iii), remove the words “write down” and add “write-down” in its place;

■ d. Revise paragraph (b)(4);

■ e. In paragraph (b)(7), remove the words “take a lien on all assets and”;

■ f. In paragraph (e), remove the word “writedown” wherever it appears and add “write-down” in its place;

■ g. In paragraph (e)(1), remove the words “write down” and add “write-down” in its place;

■ h. In paragraph (e)(2), remove the word “writedown” and add “write-down” in its place;

■ i. In paragraph (e)(7), remove the word “writedown” and add “write-down” in its place both times it appears;

■ j. In paragraph (e)(8), remove the word “writedown” and add “write-down” in its place;

■ k. In paragraph (e)(9), remove the word “writedown” wherever it appears and add “write-down” in its place;

■ l. In paragraph (e)(10), remove the word “writedown” and add “write-down” in its place both times it appears;

■ m. In paragraph (e)(12)(ii), remove the word “writedown” and add “write-down” in its place;

■ n. In paragraph (e)(12)(iii)

introductory text, remove the word “writedown” and add “write-down” in its place and

■ o. In paragraph (e)(12)(iii)(C), remove the word “writedown” and add “write-down” in its place.

The revisions read as follows:

§ 762.145 Restructured guaranteed loans.

* * * * *

(b) * * *

(4) Loans can be restructured using a balloon payment, equal installments, or unequal installments. Under no circumstances may crops or livestock, other than breeding livestock, be the only security for a loan to be rescheduled using a balloon payment. If a balloon payment is used, the projected value of the security must indicate that the loan will be fully secured when the balloon payment becomes due. The projected value will be derived from a current appraisal adjusted for depreciation of depreciable property, such as buildings and other improvements, that occurs until the balloon payment is due. For other security, a current appraisal is required. The lender is required to project the security value at the time the balloon payment is due based on the remaining life of the security, or the depreciation schedule on the borrower’s Federal income tax return. Loans restructured with a balloon payment that are secured by real estate will have a minimum term of 5 years, and other loans will have a minimum term of 3 years before the scheduled balloon payment. If statutory limits on terms of loans prevent the minimum terms, balloon payments may not be used. If the loan is rescheduled with unequal installments, a feasible plan, as defined in § 762.2(b), must be projected for when installments are scheduled to increase.

* * * * *

§ 762.147 [Amended]

■ 12. In § 762.147, amend paragraphs (b)(2)(i) and (iv) by removing the word “writedown” and adding “write-down” in their places.

§ 762.150 [Amended]

■ 13. In § 762.150, amend paragraph (j) by removing the word “writedown” wherever it appears and adding “write-down” in its place.

PART 764—DIRECT LOAN MAKING

■ 14. The authority citation for part 764 continues to read as follows:

Authority: 5 U.S.C. 301 and 7 U.S.C. 1989.

Subpart B—Loan Application Process

- 15. In § 764.51, revise paragraphs (b)(6) and (10) to read as follows:

§ 764.51 Loan application.

* * * * *

(b) * * *

(6) Except for CL, documentation that the applicant and each member of an entity applicant cannot obtain sufficient credit elsewhere on reasonable rates and terms, including a loan guaranteed by the Agency. The authorized Agency official will evaluate and document whether or not rates and terms of available credit in the applicant's region will result in a reasonable amount of cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education, to support operational stability and growth;

* * * * *

(10) A legal description of the farm property owned or to be acquired and, upon Agency request, any leases, contracts, options, and other agreements related to the operation;

* * * * *

Subpart C—Requirements for All Direct Program Loans

- 16. Amend § 764.101 as follows:

- a. Revise paragraphs (d), (e)(1), and (i);
- b. In paragraph (l), remove the word “ownership” and add “ownership” in its place.

The revisions read as follows:

§ 764.101 General eligibility requirements.

* * * * *

(d) *Credit history.* The applicant, and all entity members in the case of an entity, must have acceptable credit history demonstrated by debt repayment.

(1) As part of the credit history, the Agency will determine whether the applicant, and all entity members in the case of an entity, will carry out the terms and conditions of the loan and deal with the Agency in good faith. In making this determination, the Agency may examine whether the applicant, and all entity members in the case of an entity, has properly fulfilled its obligations to other parties, including other agencies of the Federal Government.

(2) When the applicant, or an entity member in the case of an entity, caused the Agency a loss by receiving debt forgiveness, the applicant may be ineligible for assistance in accordance with eligibility requirements for the specific loan type. If the debt forgiveness is cured by repayment of the

Agency's loss, the Agency may still consider the debt forgiveness in determining the applicant's credit worthiness.

(3) A history of failures to repay past debts as they came due will demonstrate unacceptable credit history when the ability to repay was within the control of the applicant, or entity member in the case of an entity. The circumstances in paragraphs (d)(3)(i) through (iv) of this section, for example, do not automatically indicate an unacceptable credit history:

(i) Foreclosures, judgments, delinquent payments which occurred more than 36 months before the application, if no recent similar situations have occurred, or Agency delinquencies that have been resolved through loan servicing programs available under 7 CFR part 766;

(ii) Isolated incidents of delinquent payments which do not represent a general pattern of unsatisfactory or slow payment;

(iii) “No history” of credit transactions; and

(iv) Recent foreclosure, judgment, bankruptcy, or delinquent payment of the applicant, or an entity member in the case of an entity, when it can be satisfactorily demonstrated that the adverse action or delinquency was caused by circumstances that were of a temporary nature and beyond the individual's control; or the result of a refusal to make full payment because of defective goods or services or other justifiable dispute relating to the purchase or contract for goods or services.

* * * * *

(e) * * *

(1) Loan amounts, rates, and terms available in the marketplace. The authorized Agency official will evaluate and document whether rates and terms of available credit will result in a reasonable amount of cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education, to support operational stability and growth; and

* * * * *

(i) *Managerial ability.* The applicant, and in the case of an entity, the individuals holding a majority interest in the entity, must have sufficient managerial ability to assure reasonable prospects of loan repayment, as determined by the Agency. Managerial ability must be demonstrated by:

(1) *Education.* For example, the applicant or entity member obtained a 4-year college degree in agricultural business, horticulture, animal science, agronomy, or other agricultural-related field;

(2) *On-the-job training.* For example, the applicant or entity member is currently working on a farm as part of an apprenticeship program;

(3) *Farming experience.* For example, the applicant or entity member has been a manager or operator of a farm business for at least one entire production cycle or for MLs, made for OL purposes, the applicant may have obtained and successfully repaid one FSA Youth-OL. Farm experience of the applicant, without regard to any lapse of time between the farm experience and the new application, will be taken into consideration in determining loan eligibility. If farm experience occurred more than 10 years prior to the date of the new application, the applicant must demonstrate sufficient on-the-job training or education within the last 10 years to demonstrate managerial ability; or

(4) *Alternatives for MLs made for OL purposes.* Applicants for MLs made for OL purposes, also may demonstrate managerial ability by one of the following:

(i) Certification of a past participation with an agriculture-related organization, such as, but not limited to, 4-H Club, FFA, beginning farmer and rancher development programs, or Community Based Organizations, that demonstrates experience in a related agricultural enterprise; or

(ii) A written description of a self-directed apprenticeship combined with either prior sufficient experience working on a farm or significant small business management experience. As a condition of receiving the loan, the self-directed apprenticeship requires that the applicant seek, receive, and apply guidance from a qualified person during the first cycle of production and marketing typical for the applicant's specific operation. The individual providing the guidance must be knowledgeable in production, management, and marketing practices that are pertinent to the applicant's operation, and agree to form a developmental partnership with the applicant to share knowledge, skills, information, and perspective of agriculture to foster the applicant's development of technical skills and management ability.

* * * * *

- 17. In § 764.103, revise paragraph (c) to read as follows:

§ 764.103 General security requirements.

* * * * *

(c) An additional amount of security will be required, if available, to reach a 125 percent security margin. Total loan

security in excess of what is needed to achieve a security margin of 125 percent will only be taken when it is not practicable to separate the security, or if necessary to satisfy the requirements of § 764.254(b)(2)(i). Loans that do not require additional security are down payment loans, MLs, youth loans, and FOs for the purchase of a farm where the applicant provides a cash down payment equal to 5 percent or greater of the purchase price. Non-real estate assets will not be taken as additional security for any loan where real estate serves as adequate security.

■ 18. Amend § 764.106 as follows:

- a. Revise paragraph (d); and
- b. In paragraph (e), remove the words “accounts, personal” and add “accounts, education savings accounts, personal” in their place.

The revision reads as follows:

§ 764.106 General real estate security requirements.

* * * * *

(d) Unless the applicant provides a written request for an exemption, when the property includes the primary personal residence and appurtenances of the applicant or any entity member(s) and:

(1) They are located on a separate parcel of up to the greater of 10 acres or the minimum size that meets all State and local requirements for a division into a separate legal lot; and

(2) The security requirements of § 764.103(b) can be satisfied without the use of the primary personal residence and appurtenances;

* * * * *

Subpart D—Farm Ownership Loan Program

§ 764.152 [Amended]

■ 19. Amend § 764.152 as follows:

- a. In paragraph (d) introductory text, remove the words “one or more members constituting a majority interest” and add “at least one member who will be the operator of the family farm” in their place; and
- b. In paragraph (d)(2), remove the word “applicant” and add “applicant, or in the case of an entity at least one member who will be the operator of the family farm,” in its place.

■ 20. In § 764.154, revise paragraph (b) to read as follows:

§ 764.154 Rates and terms.

* * * * *

(b) *Terms.* The repayment terms are:

(1) The standard repayment term of an FO will be equal to the useful life of the security or 40 years, whichever is less. Repayment terms less than the standard

term must be requested by the applicant in writing. In no event will the term be more than 40 years from the date of the note. Repayment schedules may include equal installments, or unequal installments if needed to establish a new enterprise, develop a farm, recover from a disaster or economic reversal, or reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education. Notwithstanding any other provision of this section, repayment schedules must be designed to ensure the loan is fully secured for the life of the loan.

(2) The first installment of an FO will be an interest-only installment scheduled 12 months from the date of loan closing. An alternative repayment agreement that schedules the first installment sooner than 12 months from the date of closing, or in an amount greater than interest-only, may be provided upon written request from the applicant, or if the Agency determines it necessary to ensure the loan is fully secured for the life of the loan.

(3) The minimum scheduled installments for the first 3 years of an FO must be the interest accrued on the principal balance. Interest-only installments may be permitted for additional years, if determined necessary by the Agency, to establish a new enterprise where production income is delayed, to develop a farm, or to recover from a disaster or economic reversal.

Subpart G—Operating Loan Program

■ 21. In § 764.251, revise paragraph (a)(11) to read as follows:

§ 764.251 Operating loan uses.

(a) * * *

(11) Costs for minor real estate repairs or improvements, provided the loan is made primarily for agricultural purposes and can be repaid within 7 years. In the case of leased property, the applicant must have a lease to ensure use of the improvement over its useful life or to ensure that the applicant receives compensation for any remaining economic life upon termination of the lease.

■ 22. Amend § 764.254 as follows:

- a. Revise paragraphs (a)(4), (b)(1) introductory text, (i), and (2); and
- b. Add paragraphs (b)(3) and (4).

The revisions and addition read as follows:

§ 764.254 Rates and terms.

(a) * * *

(4) The Agency’s Direct ML—OL interest rate on an ML to a beginning

farmer or veteran farmer is available in each Agency office. The interest rate will be the lower of the regular direct OL interest rate in effect at the time of loan approval or loan closing, or 5 percent.

(b) * * *

(1) The Agency schedules repayment of OL loans made for annual farm operating and family living expenses when planned income is projected to be available.

(i) The term of the loan may not exceed 24 months from the date of the note, except as provided in paragraph (b)(1)(ii) of this section.

* * * * *

(2) The standard repayment term of all other OLs must be equal to the useful life of the security or 7 years, whichever is less. Repayment terms less than the standard term must be requested by the applicant in writing. In no event will the term of the loan exceed 7 years from the date of the note. Repayment schedules may include equal installments, or unequal or balloon installments if needed to establish a new enterprise, develop a farm, recover from a disaster or economic reversal, or reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education. Notwithstanding any other provision of this section, repayment schedules must be designed to ensure the loan is fully secured for the life of the loan. Loans with balloon installments:

(i) Must be secured by an amount projected at the time of loan closing to be at least equal to the direct loan balance outstanding at the time the balloon installment comes due, which may exceed the additional security requirements of § 764.103(c) of this chapter. Total loan security in excess of the requirements of this provision (paragraph (b)(2)(i) of this section) will only be taken when it is not practicable to separate the security. Crops, livestock other than breeding stock, or livestock products produced are not adequate collateral for such loans.

(ii) Are only authorized when the applicant can project the ability to refinance or restructure the remaining debt at the time the balloon payment comes due based on the expected financial condition of the operation, the depreciated value of the collateral, and the principal balance on the loan.

(iii) Are not authorized when loan funds are used for real estate repairs or improvements.

(3) The first installment of an OL, for purposes other than annual farm operating and family living expenses,

will be an interest-only installment scheduled 12 months from the date of loan closing. An alternative repayment agreement that schedules the first installment sooner than 12 months from the date of closing, or in an amount greater than interest-only, may be provided upon written request from the applicant, or if the Agency determines it necessary to ensure the loan is fully secured for the life of the loan.

(4) The minimum scheduled installments for the first 3 years of an OL, for purposes other than annual farm operating and family living expenses, must be the interest accrued on the principal balance. Interest-only installments may be permitted for additional years, if determined necessary by the Agency, to establish a new enterprise where production income is delayed, to develop a farm, or to recover from a disaster or economic reversal.

■ 23. Amend § 764.255 as follows:

■ a. Revise paragraph (b) introductory text;

■ b. In paragraph (c)(1), remove “amount, and up to 150 percent, when available” and add “amount” in its place.

■ c. Revise paragraph (c)(2); and

■ d. Add paragraph (d).

The revisions and addition read as follows:

§ 764.255 Security requirements.

* * * * *

(b) Except for MLs or OLs made for the purpose of minor real estate repairs or improvements, by a:

* * * * *

(c) * * *

(2) For loans made for purposes other than annual operating purposes or for the purpose of minor real estate repairs or improvements, loans must be secured by a first lien on farm property or products purchased with loan funds and having a security value of at least 100 percent of the loan amount.

* * * * *

(d) For OLs made for the purpose of minor real estate repairs or improvements, the Agency must obtain a lien on the real estate repaired or improved in accordance with the requirements of § 764.104, while also ensuring the provisions of § 764.103(b) requiring adequate security are satisfied.

Subpart H—Youth Loan Program

§ 764.303 [Amended]

■ 24. In § 764.303, amend paragraph (b) by removing “\$5,000” and adding “\$10,000” in its place.

Subpart I—Emergency Loan Program

§ 764.352 [Amended]

■ 25. Amend § 764.352 as follows:

■ a. In paragraph (f) remove the words “write down” and add “write-down” their place; and

■ b. In paragraph (h) remove the words “at least 30 percent”.

§ 764.353 [Amended]

■ 26. In § 764.353, amend paragraph (c)(4) by removing the words “other disaster” and removing the word “production”.

■ 27. Amend § 764.354 as follows:

■ a. Revise paragraphs (b)(1), (3), (4), and (5); and

■ b. Add paragraphs (b)(6) and (7).

The revisions and addition read as follows.

§ 764.354 Rates and terms.

* * * * *

(b) * * *

(1) The Agency schedules repayment of EMs based on the useful life of the security and the type of loss.

* * * * *

(3) EMs for annual farm operating and family living expenses, except expenses associated with establishing a perennial crop that are subject to paragraph (b)(4), must be repaid within 12 months. The Agency may extend this term to not more than 24 months to accommodate the production cycle of the agricultural commodities.

(4) The standard repayment term of an EM for production losses or physical losses to chattel security (including assets with an expected life between 1 and 7 years) will be equal to the useful life of the security or 7 years, whichever is less. Repayment terms less than the standard term must be requested by the applicant in writing. The Agency may extend the repayment term up to a total length not to exceed 20 years, if adequate security is available, and repayment schedules may include equal installments, or unequal installments, if needed to establish a new enterprise, develop a farm, recover from a disaster or economic reversal, or reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education, and security is adequate to support the term of the loan. Notwithstanding any other provision of this section, repayment schedules must be designed to ensure the loan is fully secured for the life of the loan.

(5) The standard repayment term of an EM for physical losses to real estate will be equal to the useful life of the security

or 40 years, whichever is less.

Repayment terms less than the standard term must be requested by the applicant in writing. In no event will the term be more than 40 years from the date of the note, and repayment schedules may include equal installments, or unequal installments, if needed to establish a new enterprise, develop a farm, recover from a disaster or economic reversal, or reasonably increase cash flow margin to increase working capital reserves and savings, including reasonable savings for retirement and education, and security is adequate to support the term of the loan. Notwithstanding any other provision of this section, repayment schedules must be designed to ensure the loan is fully secured for the life of the loan.

(6) The first installment of an EM, for purposes other than annual farm operating and family living expenses, will be an interest-only installment scheduled 12 months from the date of loan closing. An alternative repayment agreement that schedules the first installment sooner than 12 months from the date of closing, or in an amount greater than interest-only, may be provided upon written request from the applicant, or if the Agency determines it necessary to ensure the loan is fully secured for the life of the loan.

(7) The minimum scheduled installments for the first 3 years of an EM, for purposes other than annual farm operating and family living expenses, must be the interest accrued on the principal balance. Interest-only installments may be permitted for additional years, if determined necessary by Agency, to establish a new enterprise where production income is delayed, to develop a farm, or to recover from a disaster or economic reversal.

Subpart J—Loan Decision and Closing

§ 764.402 [Amended]

■ 28. In § 764.402, amend paragraph (d)(3)(vii) by removing the words “related as a family member” and adding “a relative” in their place.

Subpart K—Borrower Training and Training Vendor Requirements

§ 764.451 [Amended]

■ 29. In § 764.451, amend the undesignated introductory paragraph by removing the words “production and financial management” and adding it with “borrower” in its place.

§ 764.452 [Amended]

■ 30. Amend § 764.452 as follows:

■ a. In paragraph (a), remove the words “production and”;

- b. In paragraph (a)(2), remove the words “production or”
- c. Remove paragraphs (b) and (d);
- d. Redesignate paragraph (c) as paragraph (b); and
- e. Redesignate paragraphs (e) through (g) as paragraphs (c) through (e).

§ 764.453 [Amended]

- 31. Amend § 764.453 as follows:
- a. In paragraph (b), remove the words “production, financial management, or both,” and add “financial management” in their place.
- b. In paragraph (c), remove the words “production and”.

§ 764.455 [Amended]

- 32. Amend § 764.455 by removing the words “production and”.

§ 764.457 [Amended]

- 33. Amend § 764.457 as follows:
- a. Remove paragraph (b)(6);
- b. In paragraph (b)(4), add the word “and” at the end;
- c. In paragraph (b)(5), remove the word “; and” and add a period in its place;
- d. Remove paragraph (c)(3); and
- e. In paragraph (c)(1), remove the word “planning,” and adding “planning; or” in its place.

PART 765—DIRECT LOAN SERVICING—REGULAR

- 34. The authority citation for part 765 continues to read as follows:

Authority: 5 U.S.C. 301 and 7 U.S.C. 1989.

Subpart C—Borrower Graduation

- 35. In § 765.101, revise paragraph (c) to read as follows:

§ 765.101 Borrower graduation requirements.

* * * * *

(c) The borrower must submit all information that the Agency requests in conjunction with the review of the borrower’s financial condition, including Federal income tax returns.

* * * * *

- 36. Revise § 765.102 to read as follows:

§ 765.102 Borrower non-compliance with graduation requirements.

(a) Borrower failure to fulfill all graduation requirements, including failure to submit information as specified in § 765.101(c) of this chapter, within the time-period specified by the Agency constitutes default on the loan. Except as provided in paragraph (b) of this section, the Agency will accelerate the borrower’s loan without offering

servicing options provided in 7 CFR part 766 if any outstanding direct loan was closed prior to September 25, 2024.

(b) If all outstanding direct loans were closed after September 25, 2024, or when the borrower makes a written request in response to the Agency’s notification of intent to accelerate within provided timeframes, the Agency will convert the debt to a non-program loan under the following conditions:

- (1) It is in the interest of the Agency;
- (2) The debt will be subject to the interest rate for non-program loans in effect at the time of default;
- (3) The debt will be serviced as a non-program loan; and
- (4) The term of the non-program loan will be:

(i) For FOs, the Agency will schedule repayment in equal installments over the lesser of the remaining number of years on the loan, the useful life of security, or 25 years.

(ii) For OLs, the Agency will schedule repayment in equal installments over the lesser of the remaining number of years on the loan, the useful life of security or 5 years.

Subpart E—Protecting the Agency’s Security Interest

- 37. Amend § 765.205 as follows:

■ a. Redesignate paragraphs (b) through (d) as paragraphs (c) through (e), respectively; and

■ b. Add a new paragraph (b).

The addition reads as follows.

§ 765.205 Subordination of liens.

* * * * *

(b) *Incomplete applications.* Incomplete applications will be processed in accordance with 7 CFR 764.52.

* * * * *

Subpart F—Required Use and Operation of Agency Security

- 38. Amend § 765.252 as follows:

■ a. In paragraph (a)(3), remove the word “and”;

■ b. In paragraph (a)(4), remove the words “the operation” and add “the Agency’s security” in their place, and remove the period at the end of the paragraph.

■ c. In paragraph (a)(5), remove the word “Government” and add “Agency” in its place; and

■ d. Revise paragraph (c).

The revision reads as follows.

§ 765.252 Lease of security.

* * * * *

(c) *Lease of chattel security.* The borrower must request prior approval to lease chattel security. The Agency will

approve requests provided the following conditions are met:

(1) The term of lease does not exceed 12 months and does not automatically renew;

(2) The lease does not contain an option to purchase;

(3) The lease does not hinder the future operation or success of the farm, or, if the borrower has ceased to operate the farm, the requirements specified in § 765.253 are met;

(4) The lease must be in the best interest of the Agency as determined by the authorized Agency official;

(5) Leased security must be accessible and readily identifiable at all times. Leased livestock must be branded, tagged, or be otherwise specifically identifiable; and

(6) The lease and any contracts or agreements in connection with the lease must be reviewed and approved by the Agency.

§ 765.303 [Amended]

- 39. Amend § 765.303 as follows:

■ a. In paragraph (c)(2) remove the word “needs” and add “farming needs” in its place; and

■ b. In paragraph (c)(3) remove the word “needs” and add “farming needs” in its place.

- 40. In § 765.305, revise paragraph (c) to read as follows:

§ 765.305 Release of security interest.

* * * * *

(c) The Agency will release its lien on chattel security without compensation, after written request from the borrower, provided all the following criteria are satisfied:

(1) The borrower is current on all loan accounts with FSA and has not received PLS, DBSA, or DSA on any loan within the last 36 months;

(2) The borrower has paid in full scheduled direct term loan installments that include principal reduction in each of the last 3 calendar years;

(3) After the release, the security margin on each Agency direct loan will be 125 percent (or more, if it is not practicable to separate the property, if necessary to ensure the loan is fully secured for the life of the loan, or if the borrower requests only a portion of Agency security to be released). The value of the retained and released security will normally be based on appraisals obtained as specified in § 761.7 of this chapter; however, well-documented recent sales of similar properties can be used if the Agency determines a supportable decision can be made without current appraisals;

(4) Any asset requested for release must serve only as security for term

loan(s) that have been outstanding for at least the prior 36 months and cannot serve as adequate security for another existing Agency direct loan; and

(5) Except for CL, the borrower is unable to fully graduate as specified in § 765.101.

Subpart H—Partial Release of Real Estate Security

■ 41. Amend § 765.351 as follows:

■ a. In paragraph (a)(3), remove the words “received by the borrower” and add “paid” in their place; and

■ b. Revise paragraph (f).

The revision reads as follows.

§ 765.351 Requirements to obtain Agency consent.

* * * * *

(f) *Release without compensation.*

Real estate security may be released by FSA without compensation upon written request from the borrower when the requirements of paragraph (a) of this section, except paragraph (a)(3) of this section, are met, and all the following criteria are satisfied:

(1) The borrower is current on all loan accounts with FSA and has not received PLS, DBSA, or DSA on any loan within the last 36 months;

(2) The borrower has paid in full direct term loan installments that include principal reduction in each of the last 3 calendar years;

(3) The property released will not interfere with access to or operation of the remaining farm;

(4) Essential buildings and facilities will not be released if they reduce the utility or marketability of the remaining property;

(5) Any issues arising due to legal descriptions, surveys, environmental concerns, utilities are the borrower's responsibility, and no costs or fees will be paid by FSA;

(6) After the release, the security margin on each Agency direct loan will be 125 percent (or more, if it is not practicable to separate the property, if necessary to ensure the loan is fully secured for the life of the loan, or if the borrower requests only a portion of Agency security to be released). The value of the retained and released security will normally be based on appraisals obtained as specified in § 761.7 of this chapter; however, well-documented recent sales of similar properties can be used if the Agency determines a supportable decision can be made without current appraisals;

(7) Any asset requested for release must serve only as security for term loan(s) that have been outstanding for at least the prior 36 months and cannot

serve as adequate security for another existing Agency direct loan; and

(8) Except for CL, the borrower is unable to fully graduate as specified in § 765.101.

■ 42. In § 765.352, add paragraph (a)(4) to read as follows:

§ 765.352 Use of proceeds.

* * * * *

(4) To pay capital gains taxes on real estate transactions when the following conditions are met:

(i) The borrower is unable to obtain commercial credit at reasonable rates and terms to pay the capital gains taxes;

(ii) The Agency approves the amount to be retained to pay capital gains taxes;

(iii) The remaining Agency debt is fully secured;

(iv) All other lienholders will:

(A) Be fully satisfied from the sale, or

(B) Consent to the use of proceeds to be used to pay capital gains taxes;

(v) At the borrower's expense, funds will be held in escrow, or deposited in a supervised bank account in accordance with subpart B of part 761 of this chapter; and

(vi) Funds that are not used within 18 months towards the capital gains taxes will be remitted to the Agency.

Subpart I—Transfer of Security and Assumption of Debt

■ 43. Amend § 765.402 as follows:

■ a. Revise paragraphs (b), (d), and

(e)(1); and

■ b. Add paragraphs (f) and (g).

The revisions and additions read as follows.

§ 765.402 Transfer of security and loan assumption on same rates and terms.

* * * * *

(b) A relative of the borrower or an entity comprised solely of relatives of the borrower assumes the debt along with the original borrower;

* * * * *

(d) A new entity consisting of the same members as the borrower entity buys the borrower entity and continues to operate the farm in accordance with loan requirements; or

(e) * * *

(1) An individual borrower, the transferee must be a relative of the original borrower or an entity in which the entity members are comprised solely of relatives of the original borrower.

* * * * *

(f) *Application requirements.*

Transferees must submit a complete application in accordance with § 764.51 of this chapter.

(g) *Security.* All security must be transferred to the transferee with

possession taken in accordance with the requirements of part 764 of this chapter for the type of loan being assumed.

■ 44. In § 765.403, add paragraphs (f) and (g) to read as follows:

§ 765.403 Transfer of security to and assumption of debt by eligible applicants.

* * * * *

(f) *Application requirements.*

Transferees must submit a complete application in accordance with 7 CFR 764.51.

(g) *Security.* All security must be transferred to the transferee with possession taken in accordance with the requirements of part 764 of this chapter for the type of loan being assumed.

■ 45. In § 765.404 revise paragraph (d) and add paragraph (g) to read as follows.

§ 765.404 Transfer of security to and assumption of debt by ineligible applicants.

* * * * *

(d) *Down payment.* Non-program transferees must make a down payment to the Agency of not less than 10 percent of the lesser of the market value or unpaid debt.

* * * * *

(g) *Security.* All security must be transferred to the transferee with possession taken in accordance with the requirements of part 764 of this chapter for the type of loan being assumed.

PART 766—DIRECT LOAN SERVICING—SPECIAL

■ 46. The authority citation for part 766 continues to read as follows:

Authority: 5 U.S.C. 301, 7 U.S.C. 1989, and 7 U.S.C. 1981d(c).

Subpart A—Overview

■ 47. In § 766.1, revise paragraph (b)(1)(i) to read as follows.

§ 766.1 Introduction.

* * * * *

(b) * * *

(1) * * *

(i) May not receive DSA under subpart B of this part or DBSA under subpart J of this part;

* * * * *

Subpart B—Disaster Set-Aside

§ 766.52 [Amended]

■ 48. Amend § 766.52 as follows:

■ a. In paragraph (b)(3) remove the number “90” and add “150” in its place.

■ b. In paragraph (b)(6) remove the words “a DSA” and add “a DBSA or DSA” in its place.

■ 49. Revise § 766.54(b)(2) to read as follows:

§ 766.54 Borrower application requirements.

* * * * *

(b) * * *

(2) The borrower must provide any additional information requested by the Agency.

§ 766.56 [Removed]

■ 50. Remove § 766.56.

Subpart C—Loan Servicing Programs

■ 51. Amend § 766.101 by adding paragraph (e) to read as follows:

§ 766.101 Initial Agency notification to borrower of loan servicing programs.

* * * * *

(e) *SED extension authority.* In extraordinary circumstances, after the application period described in paragraphs (d)(2) and (3) of this section has expired, the SED may extend the application deadline when requested by the borrower in writing.

■ 52. Amend § 766.102(a) as follows:

■ a. Remove paragraph (a)(1);

■ b. Redesignate paragraphs (a)(2) through (8) as paragraphs (a)(1) through (7), respectively;

■ c. In newly redesignated paragraph (a)(4) remove the words “subpart G of 7 CFR part 1940” and add “part 799 of this chapter” in their place;

■ d. In newly redesignated paragraph (a)(6), remove the words “statements; and” and add “statements;” in their place;

■ e. In newly redesignated paragraph (a)(7), remove the period at the end and add “; and” in its place; and

■ f. Add new paragraph (a)(8).

The addition reads as follows:

§ 766.102 Borrower application requirements.

(a) * * *

(8) Upon Agency request, any leases, contracts, options, and other agreements related to the operation.

■ 53. In § 766.104, amend paragraph (a)(1) as follows:

■ a. In paragraph (a)(1)(iv), remove the word “or” at the end;

■ b. In paragraph (a)(1)(v), remove the period at the end; and replace with “; or”; and

■ c. Add paragraph (a)(1)(vi).

The addition reads as follows.

§ 766.104 Borrower eligibility requirements.

(a) * * *

(1) * * *

(vi) Catastrophic medical expenses for the care of a family member of the borrower or entity member, in the case of an entity borrower.

* * * * *

§ 766.105 [Amended]

■ 54. Amend § 766.105 as follows:

■ a. In paragraph (a)(4), remove the word “Writedown” and add “Write-down” in its place; and

■ b. In paragraph (c)(1)(i), remove the word “writedown” and add “write-down” in its place.

§ 766.107 [Amended]

■ 55. Amend § 766.107 as follows:

■ a. In paragraph (a)(9), add “or J” after “subpart B”, and remove the words “deferral or DSA” and add “deferral, DBSA, or DSA” in their place; and

■ b. In paragraph (b)(6), remove the words “subpart B of” and add “subpart B or J of” in their place, and remove the words “deferral or DSA” and add “deferral, DBSA, or DSA” in their place.

■ 56. Amend § 766.111 as follows:

■ a. Revise the section heading;

■ b. In paragraph (a), introductory text, remove the word “writedown” and add “write-down” in its place;

■ c. In paragraph (b), introductory text, remove the word “writedown” and add “write-down” in its place;

■ d. Revise paragraph (b)(1);

■ e. In paragraph (b)(3), remove the word “writedown” and add “write-down” in its place.

The revisions read as follows:

§ 766.111 Write-down.

* * * * *

(b) * * *

(1) Rescheduling, consolidation, reamortization, deferral or some combination of these options on all of the borrower's loans would not result in a feasible plan with a 110 percent debt service margin. If a feasible plan is achieved with a debt service margin of 101 percent or more, the Agency will permit a borrower to accept a non-write-down servicing offer and waive the right to a write-down offer when the write-down offer will require additional time and appraisals to fully develop. If after obtaining an appraisal a feasible plan is achieved with and without a write-down and the borrower meets all the eligibility requirements, both options will be offered, and the borrower may choose one option.

* * * * *

■ 57. Revise § 766.112 to read as follows:

§ 766.112 Additional security for restructured loans.

(a) If the borrower is delinquent prior to restructuring, an additional amount of security will be required, if available, to reach a 125 percent security margin when the Agency is servicing a loan, except as provided in paragraph (b) of

this section. Total loan security in excess of what is needed to achieve a security margin of 125 percent will only be taken when it is not practicable to separate the security.

(b) The Agency will take the best lien obtainable on assets of the borrower and co-borrowers to meet the 125 percent security margin requirement, except that the following assets will not be considered available to meet this requirement:

(1) When taking a lien on an asset will prevent the borrower from obtaining credit from other sources;

(2) When an asset could have significant environmental problems or costs as described in part 799 of this chapter;

(3) When the Agency cannot obtain a valid lien;

(4) When an asset is subsistence livestock, cash, special collateral accounts the borrower uses for the farming operation, retirement accounts, education savings accounts, personal vehicles necessary for family living, household contents, or small equipment such as hand tools and lawn mowers; or

(5) When a contractor holds title to a livestock or crop enterprise, or the borrower manages the enterprise under a share lease or share agreement.

■ 58. In § 766.115, revise paragraphs (a)(1), (2) introductory text, (3) introductory text, and (3)(ii) to read as follows.

§ 766.115 Challenging the Agency appraisal.

(a) * * *

(1) Obtain a USPAP compliant technical appraisal review prepared by a State Certified General Appraiser of the Agency's appraisal and provide it to the Agency within 90 days of the request for reconsideration or appeal and prior to reconsideration or the appeal hearing;

(2) Obtain an independent appraisal within 90 days of the request for reconsideration or appeal request and completed in accordance with § 761.7 as part of the request or reconsideration or appeals process. The borrower must:

* * * * *

(3) Use the second appraisal completed under paragraph (a)(2) of this section to negotiate the Agency's appraisal.

* * * * *

(ii) If the difference between the two appraisals is greater than five percent, the borrower may request a third appraisal within 30 days from the date the second appraisal is provided to the Agency. The Agency and the borrower will share the cost of the third appraisal

equally. The average of the two appraisals closest in value will serve as the final value.

* * * * *

■ 59. Add § 766.120 to read as follows:

§ 766.120 Extending maturity date and installment schedule for direct loans with a balloon payment.

(a) At a borrower's written request, the maturity date and installment schedule of a direct term loan with a balloon payment may be extended for up to an additional 8 years from the original maturity date using an addendum to the promissory note when the:

(1) Loan was originally amortized for no more than 15 years with a balloon payment scheduled in the final year of the loan;

(2) Loan has not received PLS, DBSA, or DSA;

(3) Borrower has made all scheduled loan installments in the last 36 months;

(4) Balloon payment is due in less than 12 months;

(5) Borrower does not have an outstanding DBSA or DSA on any loan;

(6) Borrower has not received PLS on any loan in the last 36 months;

(7) Borrower has only had equal installments scheduled on any direct term loan in the last 36 months;

(8) Borrower's direct loans are fully secured with each loan having a security value of at least 100 percent of the remaining balance of the loan;

(9) Borrower is unable to partially or fully graduate;

(10) Borrower has acted in good faith;

(11) Borrower is not otherwise financially distressed or delinquent;

(12) Borrower must pay a portion of the interest due on the loan; and

(13) Addendum is signed by the borrower before the original maturity date.

(b) In no event may the loan exceed applicable term limits described in this part.

Subpart E—Servicing Shared Appreciation Agreements and Net Recovery Buyout Agreements

§ 766.201 [Amended]

■ 60. In § 766.201, amend paragraphs (a)(2) and (b) introductory text by removing the word “writedown” and add “write-down” in its places.

§ 766.203 [Amended]

■ 61. In § 766.203, amend paragraphs (a)(1), (2), and (c) by removing the word “writedown” and adding “write-down” in its places.

Subpart H—Loan Liquidation

§ 766.351 [Amended]

■ 62. In § 766.351, amend paragraph (a)(3) by removing the words “family member” and adding “relative” in their place.

§ 766.356 [Amended]

■ 63. In § 766.356, amend paragraph (b)(1)(iii)(B) by removing the word “writedown” and adding “write-down” in its place.

■ 64. Add subpart J, consisting of §§ 766.451 to 766.458, to read as follows:

Subpart J—DBSA

Sec.

766.451 General.

766.452 Eligibility.

766.453 DBSA amount limitations.

766.454 Borrower application requirements.

766.455 Borrower acceptance of DBSA.

766.456 Payments toward DBSA installments.

766.457 Canceling a DBSA agreement.

766.458 Reversal of DBSA.

§ 766.451 General.

(a) DBSA is available to borrowers with at least one outstanding program loan authorized in subtitle A, B, or C of the CONACT (the loan must be an OL, FO, CL, SW, or EM), and who are a delinquent borrower or financially distressed borrower.

(b) DBSA is not intended to circumvent other servicing available under this part.

§ 766.452 Eligibility.

(a) *Borrower eligibility.* The borrower must meet all the following requirements to be eligible for DBSA:

(1) The borrower must currently be operating the farm. Farmers who have rented out their land base for cash are not considered to be operating the farm.

(2) The borrower must have acted in good faith, and the borrower's inability to make the current or upcoming scheduled loan payments must be for reasons not within the borrower's control.

(3) The borrower cannot have more than one DBSA on each loan.

(4) The borrower does not have sufficient income available to pay all family living and farm operating expenses, other creditors, and debts to the Agency. This determination will be based on:

(i) The borrower's actual production, income and expense records; and

(ii) Any other records required by the Agency;

(5) For the next production cycle, the borrower must develop a feasible plan

showing that the borrower will at least be able to pay all operating expenses and taxes due during the year, essential family living expenses, and meet scheduled payments on all debts, including Agency debts. The borrower must provide documentation required to support the farm operating plan.

(6) The borrower must not be in non-monetary default.

(7) The borrower must not be ineligible due to disqualification resulting from Federal crop insurance violation according to 7 CFR part 718.

(8) The borrower must not become 165 days past due before the appropriate Agency DBSA documents are executed.

(b) *Loan eligibility.* The loan must meet all the following requirements to be eligible for DBSA:

(1) To be considered for DBSA the loan must have been either an OL, FO, CL, SW or EM outstanding prior to September 25, 2024.

(2) All of the borrower's program and non-program loans must be current after the Agency completes DBSA for the scheduled payment installment.

(3) All FLP loans must either be current or less than 150 days past due at the time the complete application for DBSA is received by the Agency.

(4) The Agency has not accelerated the borrower's account.

(5) For any loan that will receive DBSA, the remaining term of the loan must equal or exceed 2 years from the due date of the DBSA agreement.

(6) The loan must not have an existing DBSA or DSA in place.

(7) The loan must not have been consolidated with any other loan that would not be eligible for DBSA on its own merits.

§ 766.453 DBSA amount limitations.

(a) The DBSA amount is limited to the lesser of:

(1) The amount of the delinquent installment or upcoming scheduled installment; or

(2) The amount the borrower is unable to pay the Agency. Borrowers are required to pay any portion of an installment they are able to pay.

(b) The amount set aside will be the unpaid balance remaining on the installment at the time DBSA is complete. The amount will include the unpaid interest and any principal that would be credited to the account as if the installment were paid on the due date, taking into consideration any payments applied to principal and interest since the due date.

(c) Recoverable cost items may not be set aside.

§ 766.454 Borrower application requirements.

(a) *Requests for DBSA.* To request DBSA:

(1) A borrower must submit a request for DBSA to the Agency in writing.

(2) All borrowers liable for the loan must sign the DBSA request.

(b) *Required financial information.* When requesting DBSA:

(1) The borrower must submit actual production, income, and expense records for the current and upcoming production cycle unless the Agency already has that information for the borrower.

(2) The borrower must provide any additional information requested by the Agency.

§ 766.455 Borrower acceptance of DBSA.

Subject to the 165-calendar day limitation in § 766.452(a)(8), the borrower must execute the appropriate Agency documents within 45 days after the borrower receives notification of Agency approval of DBSA, which will

be within 30 days of having submitted a complete application.

§ 766.456 Payments toward DBSA installments.

(a) *Interest accrual.* Interest will accrue on any principal portion of the DBSA installment at the rate of one eighth of a percent.

(b) *Due date.* The DBSA amount, including interest accrued on the principal portion of the set-aside, is due on or before the final due date of the loan.

(c) *Applying payments.* The Agency will apply borrower payments toward DBSA installments first to interest and then to principal.

§ 766.457 Canceling a DBSA agreement.

(a) The Agency will cancel a DBSA agreement if the Agency takes any PLS action on the loan.

(b) The Agency will cancel a DBSA agreement if the borrower pays the:

(1) Current market value buyout in accordance with § 766.113; or

(2) The set-aside installment.

§ 766.458 Reversal of DBSA.

If the Agency determines that the borrower received an unauthorized DBSA, the Agency will reverse the DBSA agreement after all appeals are concluded.

■ 65. Revise appendix A to subpart C to read as follows:

Appendix A to Subpart C of Part 766—FSA-2510, Notice of Availability of Loan Servicing to Borrowers Who Are 90 Days Past Due

This appendix A contains the notification (form letter) that the Farm Service Agency will send to borrowers who are at least 90 days past due on their loan payments. It provides information about the loan servicing that is available to the borrower. As stated below on the notification, the borrower is to respond within 60 days from receiving the notification (see § 766.101(b)(2) and (d)(2) for the requirements). The notification is provided here as required by 7 U.S.C. 1981d.

BILLING CODE 3410-E2-P

FSA-2510
(03-26-24)U.S. DEPARTMENT OF AGRICULTURE
Farm Service Agency

Position 4

**NOTICE OF AVAILABILITY OF LOAN SERVICING
TO BORROWERS WHO ARE 90 DAYS PAST DUE**

Date

Borrower's Name
Borrower Name/Address
Borrower Address
City, State, Zip Code

MAILING INSTRUCTIONS

The Farm Service Agency (FSA) is committed to supporting the success of America's farmers and ranchers. In reviewing your Farm Loan Programs (FLP) loan account, we have determined that you are seriously delinquent on your FLP loan payment. This notice informs you of options that may be available to you. FSA's loan servicing options including, primary loan servicing, conservation contract, current market value buyout, homestead protection, and debt settlement may help you repay your loan or retain your farm property and settle your FLP debt.

How to apply

To apply, you must complete, and provide all items required in section (f), as applicable, within 60 days of the date you receive this notice.

Help in responding to this notice

The servicing options available to you may become complicated. You may need assistance in understanding the options available to you and their impact on your operation. An attorney can help assist you in understanding your options or there may be organizations that offer free or low-cost advice to farmers in your state. Contact your State Department of Agriculture or the U.S. Department of Agriculture (USDA) Extension Service for services in your state. You may contact your local service center with any questions.

Note: Agency employees cannot recommend a particular attorney or organization.

Who will decide if you qualify?

After you submit a complete application, FSA will determine if you meet all eligibility requirements and can develop a farm operating plan that shows that you can pay all debts and expenses.

What happens if you do not bring the account current or apply within 60 days?

FSA will accelerate your loans if you do not bring your account current or timely apply for loan servicing. This means FSA will take legal action to collect all the money you owe to FSA under FLP. After acceleration of your loan accounts, FSA will start foreclosure proceedings. FSA will be required to repossess or take legal action to sell your real estate, personal property, crops, livestock, equipment, or any other assets in which FSA has a security interest. FSA will also be required to obtain and file judgments against you and your property or refer your account to the Department of the Treasury for collection.

Included with this notice you will find information on:Servicing Options

- (a) Primary loan servicing;
- (b) Conservation contract;
- (c) Current market value buyout;
- (d) Homestead protection;
- (e) Debt settlement;

Application Details

- (f) Application forms, documentation, and information needed to apply;
- (g) How to get copies of Agency handbooks and forms;

Appeal Options

- (h) Reconsideration, mediation, and appeal to The National Appeals Division (NAD);
- (i) Challenging FSA appraisal; and
- (j) Acceleration and foreclosure.

(a) Primary Loan ServicingEligibility

You must meet the following eligibility requirements to obtain primary loan servicing:

- (1) You must resolve all non-monetary defaults prior to closing the servicing action.
- (2) If you are also financially distressed or delinquent, it must be due to at least one of the following circumstances beyond your control:
 - (i) Illness, injury, or death of a borrower or other individual who operates the farm;
 - (ii) Natural disaster, adverse weather, disease, or insect damage which caused severe loss of agricultural production;
 - (iii) Widespread economic conditions such as low commodity prices;
 - (iv) Damage or destruction of property essential to the farming operation;
 - (v) Loss of, or reduction in, your or your spouse's essential non-farm income; or
 - (vi) Catastrophic medical expenses for the care of a family member of a borrower or entity member, in the case of an entity borrower.
- (3) You do not have non-essential assets for which the net recovery value is sufficient to pay the delinquent portion of the loan. FSA cannot write-down or write off debt that you could pay with the value of your equity in these assets.
- (4) You must have acted in accordance with your loan agreements in all past dealings with FSA.

Time limits

If FSA determines that you can develop a feasible plan and are eligible for primary loan servicing, you will have 45 days from the date you receive FSA's offer to accept loan servicing.

Lien requirements

If you are offered loan servicing and accept the offer, you must agree to give FSA a lien on 125% of your other assets, if available, and you must provide this lien at closing.

Youth Loans

If you have a Youth Loan, it is not eligible for debt write-down, current market value buyout, or limited resource interest rates, but can be rescheduled or deferred. This has no effect on any other loans you may have with FSA.

Loan consolidation, rescheduling, and reamortization

In loan consolidation, the unpaid balance of two or more operating loans can be combined into one larger operating loan.

In loan rescheduling, the repayment schedule may be changed to cure the delinquency and give you new terms to repay loans made for equipment, livestock, or annual operating purposes.

In loan reamortization, the repayment schedule may be changed to cure the delinquency and give you a new schedule of repayment on loans made for real estate purposes.

When loans are consolidated, rescheduled or reamortized, the interest rate will be the lesser of:

- The interest rate for that type of loan on the date a complete servicing application was received;
- The interest rate for that type of loan on the date of restructure; or
- The lowest original loan note rate on any of the original notes being restructured.

In addition, FSA will consider the maximum loan terms.

Limited resource interest rate

Limited resource interest rates are available for certain types of loans. If you have existing loans which are not at the limited resource rate, and a limited resource rate is available, FSA will consider reducing the rate of the loans. The limited resource interest rate can be as low as five percent.

For information about current interest rates, or to understand if you qualify for limited resource rates, contact your local FSA Service Center.

Loan deferral

Partial or full payments of principal and interest may be temporarily delayed for up to 5 years. You will only be considered for loan deferral if the loan servicing programs discussed above will not allow you to pay all essential family living and farm operating expenses, maintain your property, and pay your debts.

You must be able to show through a farm operating plan that you are unable to pay all essential family living and farm operating expenses, maintain your property, and pay your debts. The farm operating plan must also show that you will be able to pay your full installment at the end of the deferral period.

The interest that accrues during the deferral period must be paid in yearly payments for the rest of the loan term after the deferral period ends.

Debt write-down

Debt write-down can reduce the principal and interest on your loan. FSA offers a write-down only when the loan servicing programs discussed above and the conservation contract program, if requested, will not result in a feasible plan. To receive debt write-down, the value of your restructured loan must be equal to or greater than the recovery value to FSA from foreclosure and repossession of your security property.

The recovery value is the market value of:

- (1) The collateral pledged as security for FLP loans minus expenses (such as the sale costs, attorneys' fees, management costs, taxes, and payment of prior liens) on the collateral that FSA would have to pay if it foreclosed, or repossessed, and sold the collateral;
- (2) Any collateral that is not in your possession and has not been released for sale by FSA in writing; and
- (3) Any other non-essential assets you may own.

A qualified appraiser determines the value of the collateral and any other assets you own. You may receive a write-down only if you have not previously received any form of debt forgiveness on any other FLP direct loan. The maximum amount of debt that can be written down on all direct loans is \$300,000.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

Shared Appreciation Agreement

If you own real estate and receive a debt write-down, you must sign a Shared Appreciation Agreement. The term of the agreement is 5 years. Under the terms of the agreement you must repay all or a part of the amount written down at the maturity of your Shared Appreciation Agreement if your real estate collateral increased in value.

Payment of shared appreciation will be required prior to the maturity of your Shared Appreciation Agreement if you:

- (1) Sell or convey the real estate;
- (2) Stop farming;
- (3) Pay off your entire FLP debt; or
- (4) Have your FLP accounts accelerated by FSA.

If any of these events occur within the first 4 years of the Shared Appreciation you will be required to pay 75 percent of the increase in value of the real estate. If any of these events occur after the fourth anniversary of the agreement, or if the Shared Appreciation Agreement matures without having previously been fully triggered, you will have to pay only 50 percent of the increase in value. You will not have to pay more than the amount of the debt written down.

(b) Conservation Contract

You may request a conservation contract to protect highly erodible land, wetlands, or wildlife habitats located on your real estate property that serves as security for your FLP debt. In exchange for such contract, FSA would reduce your FLP debt. The amount of land left after the contract must be sufficient to continue your farming operation.

(c) Current Market Value Buyout

If the analysis of your debt shows that you cannot achieve a feasible plan even if the present value of your FLP debt is reduced to the value of the security, FSA may offer you buyout of your FLP debt. You would pay the market value of all FLP security and non-essential assets, minus any prior liens. The market value is determined by a current appraisal completed by a qualified appraiser. In exchange, your loans would be satisfied.

Limits

To receive a current market value buyout offer:

- (1) You must not have previously received any form of debt forgiveness from FSA on any other direct FLP loan;
- (2) The maximum debt to be written off with buyout does not exceed \$300,000; and
- (3) You must not have non-essential assets with a net recovery value sufficient to pay your account current.

Eligibility

To qualify, you must prove that:

- (1) You cannot repay your delinquent FLP debt due to circumstances beyond your control; and
- (2) You have acted in all past dealings with FSA in accordance with your loan agreements.

Time limits

To buyout your FLP debt at the current market value, you must pay FSA within 90 days of the date you receive the offer.

Method of payment

To buyout your FLP debt at the current market value, you must pay electronically or by cashier's check, certified check or U.S. Treasury check. The checks should be made payable to FSA and provided to your local FSA servicing office for processing. FSA will not make or guarantee a loan for this purpose.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

(d) Homestead Protection

Under the homestead protection program, you may repurchase your primary residence, certain outbuildings, and up to 10 acres of land. If you cannot pay electronically or by cashier's check, certified check or U.S. Treasury check or Agency financing is not available, you may lease your primary residence. The lease will include an option for you to purchase the property you lease.

This program may apply when primary loan servicing, the conservation contract program, or current market value buyout is not available or not accepted.

You must agree to give FSA title to your land at the time FSA signs the Homestead Protection Agreement with you. FSA will compute the costs of taking title including the cost of paying other creditors with outstanding liens on the property. FSA will take title only if it can obtain a positive recovery.

Eligibility requirements

- (1) Your gross annual income from the farming operation must have been similar to other comparable operations in your area in at least 2 of the last 6 years.
- (2) Sixty percent (60%) of your gross annual income in at least 2 of the last 6 years must have come from the farming operation.
- (3) You must have lived in your homestead property for 6 years immediately before your application. If you had to leave for less than 12 months during the 6-year period and you had no control over the circumstances, you may still qualify.
- (4) You must be the owner of the property immediately prior to FSA obtaining the title.

Property restrictions and easements

FSA may place restrictions or easements on your property which restrict your use if the property is located in a special area or has special characteristics. These restrictions and easements will be placed in leases and in deeds on properties containing wetlands, floodplains, endangered species, wild and scenic rivers, historic and cultural properties, coastal barriers, and highly erodible lands.

Leasing the homestead property

- (1) You must pay rent to FSA to lease the property determined eligible for homestead protection. The rent FSA charges will be similar to comparable property in your area.
- (2) You must maintain the property in good condition during the term of the lease.
- (3) You may lease the property for up to 5 years but no less than 3 years.
- (4) You cannot sublease the property.
- (5) If you do not make the rental payments to FSA, FSA will cancel the lease and take legal action.
- (6) Lease payments are not applied toward the final purchase price of the property.

Purchasing the homestead protection property

You can repurchase your homestead property at market value at any time during the lease. The market value of the property will be decided by a qualified appraiser and will reflect the value of the land after any placement of a restriction or easement such as a wetland conservation easement.

(e) Debt Settlement

You can apply for debt settlement at any time; however, these programs are usually only used after it has been determined that primary loan servicing programs and the conservation contract program cannot help you. Under the debt settlement programs, the FLP debt you owe FSA may be settled for less than the amount you owe. These programs are subject to the discretion of FSA and are not a matter of entitlement or right. If you do not have any Agency security, you may apply for debt settlement only. If you do not apply, or do not receive approval of a debt settlement request, your FLP loan accounts will be forwarded to the Department of the Treasury for collection.

Settlement alternatives

Settlement alternatives include:

- (1) Compromise: A lump-sum payment of less than the total FLP debt owed;
- (2) Adjustment: Two or more payments of less than the total amount owed to FSA. Payments can be spread out over a maximum of 5 years if FSA determines you will be able to make the payments as they become due; and
- (3) Cancellation: Satisfaction of Agency debt without payment.

Processing and requirements

If you sell loan collateral, you must apply the proceeds from the sale to your FLP loans before you can be considered for debt settlement. In the case of compromise or adjustment you may keep your collateral, if you pay FSA the market value of your collateral along with any additional amount FSA determines you are able to pay.

Debt amounts which are collectible through administrative offset, through judgment, by the Department of the Treasury, or by other means will not be settled through debt settlement procedures. You must certify that you do not have assets or income in addition to what you stated in your application. If you qualify, your application must also be approved by the State Executive Director or the Administrator, depending on the amount of the debt to be settled.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

Application Details

(f) Forms, documentation, and information needed to apply

A complete application for primary loan servicing must include items (1) through (4). Additional information is required as noted if you want to be considered for the conservation contract program or debt settlement programs. If you need help to complete the required forms, you may request an FSA official to assist you. The forms for requirements (1), and (4) are included with this package.

- (1) FSA-2001, "Application for Direct Loan Assistance." This form is required with application submission.
- (2) AD-1026, "Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) Certification." You will be required to complete this form if the one you have on file does not reflect all the land you own and lease.
- (3) NRCS-CPA-026e, "Highly Erodible Land and Wetland Conservation Determination." This form must be obtained from and completed by the Natural Resources Conservation Service office, if not already on file with FSA.
- (4) FSA-2732, "Debt Settlement Application." Complete this form only if you wish to apply for debt settlement. You must also comply with any FSA request for additional information needed to process a debt settlement request.
- (5) If you are applying for a conservation contract, a map or aerial photo is required of your farm identifying the portion of the land and approximate number of acres to be considered.
- (6) Copies of real estate leases are required (if applicable to the farm operation).
- (7) Verification of non-farm income is required.

Divorced spouses

If you are an FLP borrower who has left the farming operation due to divorce, you may request release of liability. To be released of liability after a divorce, you must present FSA with the following within 60 days of receiving this notice:

- (1) A divorce decree or property settlement document which states the remaining party will be responsible for all repayment to FSA;
- (2) Evidence that you have conveyed your ownership interest in FLP security to the remaining party; and
- (3) Evidence that you do not have any repayment ability for the FLP loan through cash, income, or other non-essential assets.

FSA will make a determination on your request and will inform you of the decision within 60 days of receiving your request.

If you are not released of liability, you will need to include all of your relevant financial information if applying for primary loan servicing, homestead protection, or debt settlement programs.

(g) How to get copies of FSA handbooks and forms

Copies of the forms for requirements in Forms, Documentation and Information section, numbers (1), (2) and (5) have been included in this package. You may obtain copies of FSA handbooks, which include the pertinent regulations, describing available programs or additional copies of forms from your local FSA Service office.

(h) Reconsideration, mediation, and appeal to NAD

Reconsideration, mediation, and appeal rights pursuant to 7 CFR parts 780 and 11, respectively, will be provided to you if FSA makes an adverse decision on your request for loan servicing or prior to acceleration of your account.

Reconsideration – according to FSA’s appeal procedures in 7 CFR part 780.

Mediation – according to FSA’s appeal procedures in 7 CFR part 780.

Appeal to NAD – according to the NAD appeal procedures in 7 CFR part 11.

(i) Challenging FSA appraisal

If you timely submit a complete application for primary loan servicing, but disagree with the appraisal used by the FSA for processing your request, you may 1) obtain a Uniform Standards of Professional Appraisal Practice compliant technical appraisal review by a State Certified General Appraiser of the FSA appraisal and submit it to FSA prior to reconsideration or an appeal hearing, 2) obtain an independent appraisal, and 3) possibly negotiate the appraised value based on the specifics of the two appraisals.

If this applies to you, FSA will provide additional information in the notification letter advising you of the Agency’s decision concerning your loan servicing application.

(j) Acceleration and foreclosure

If you do not appeal an adverse determination, if you appeal, but are denied relief on appeal, or if you do not otherwise resolve your delinquency, FSA will accelerate your loan accounts and will be required to demand payment of the entire debt. You may prevent Agency foreclosure on the loan collateral if, with prior Agency approval, you:

- (1) Sell all loan collateral for not less than its market value and apply all proceeds to your creditors in order of lien priority.
- (2) Transfer the collateral to someone else and have that person assume all or part of your FLP debt, or
- (3) Transfer the collateral to FSA.

If any of these options result in payment of less than the amount you owe, you may apply for debt settlement, even if you applied before and were denied. However, applications for debt settlement filed after the 60-day time period provided in this notice will not delay acceleration, administrative offset, and foreclosure.

If FSA determines that you cannot qualify for debt settlement, you can:

- (1) Pay your FLP loan accounts current;
- (2) Pay your FLP loan accounts in full;
- (3) Request reconsideration, mediation or appeal.

If your real estate security contains your primary residence and becomes inventory property of FSA, homestead protection rights will be provided.

The servicing programs described by this Notice are subject to applicable Agency regulations published at 7 CFR Part 766.

For more information or if you have any questions, please contact [this office or the specific office name] at [County Office Address] or telephone [Phone Number].

1A. Authorized Agency Official Name	1B. Signature	1C. Title

Federal Equal Credit Opportunity Act Statement: *The Federal Equal Credit Opportunity Act prohibits creditors from discriminating against credit applicants on the basis of race, color, religion, national origin, sex, marital status, age (provided the applicant has the capacity to enter a binding contract); because all or part of the applicant's income derives from any public assistance program; or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act. The Federal agency that administers compliance with this law is the Federal Trade Commission, Equal Credit Opportunity, Washington, D.C. 20580.*

Paperwork Reduction Act (PRA) Statement: *This information collection is exempted from the Paperwork Reduction Act as specified in 5 CFR 1320.4(a)(2) because the form is used when FSA conducts administrative action against individuals or debtors.*

Non-Discrimination Statement: *In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.*

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at http://www.ascr.usda.gov/complaint_filing_cust.html and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture Office of the Assistant Secretary for Civil Rights 1400 Independence Avenue, SW Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

■ 66. Revise appendix B to subpart C to read as follows:

**Appendix B to Subpart C of Part 766—
FSA–2510–IA, Notice of Availability of
Loan Servicing to Borrowers Who Are
90 Days Past Due (for Use In Iowa
Only)**

This appendix contains the notification (form letter) that the Farm Service Agency will send to borrowers with loans in Iowa who are at least 90 days past due on their

loan payments. It provides information about the loan servicing that is available to the borrower. As stated below on the notification, the borrower is to respond within 60 days from receiving the notification (see § 766.101(b)(2) and (d)(2) for the requirements). The notification is provided here as required by 7 U.S.C. 1981d.

BILLING CODE 3410–E2–P

FSA-2510 IA
(03-26-24)

U.S. DEPARTMENT OF AGRICULTURE
Farm Service Agency

Position 4

**NOTICE OF AVAILABILITY OF LOAN SERVICING
TO BORROWERS WHO ARE 90 DAYS PAST DUE**

Date

Borrower's Name
Borrower Name/Address
Borrower Address
City, State, Zip Code

MAILING INSTRUCTIONS

The Farm Service Agency (FSA) is committed to supporting the success of America's farmers and ranchers. In reviewing your Farm Loan Programs (FLP) loan account, we have determined that you are seriously delinquent on your FLP loan payment. This notice informs you of options that may be available to you. FSA's loan servicing options including, primary loan servicing, conservation contract, current market value buyout, homestead protection, and debt settlement may help you repay your loan or retain your farm property and settle your FLP debt.

How to apply

To apply, you must complete, and provide all items required in section (f), as applicable, within 60 days of the date you receive this notice.

Help in responding to this notice

The servicing options available to you may become complicated. You may need assistance in understanding the options available to you and their impact on your operation. An attorney can help assist you in understanding your options or there may be organizations that offer free or low-cost advice to farmers in your state. Contact your State Department of Agriculture or the U.S. Department of Agriculture (USDA) Extension Service for services in your state. You may contact your local service center with any questions.

Note: Agency employees cannot recommend a particular attorney or organization.

Who will decide if you qualify?

After you submit a complete application, FSA will determine if you meet all eligibility requirements and can develop a farm operating plan that shows that you can pay all debts and expenses.

What happens if you do not bring the account current or apply within 60 days?

FSA will accelerate your loans if you do not bring your account current or timely apply for loan servicing. This means FSA will take legal action to collect all the money you owe to FSA under FLP. After acceleration of your loan accounts, FSA will start foreclosure proceedings. FSA will be required to repossess or take legal action to sell your real estate, personal property, crops, livestock, equipment, or any other assets in which FSA has a security interest. FSA will also be required to obtain and file judgments against you and your property or refer your account to the Department of the Treasury for collection.

Included with this notice you will find information on:

Servicing Options

- (a) Primary loan servicing;
- (b) Conservation contract;
- (c) Current market value buyout;
- (d) Homestead protection;
- (e) Debt settlement;

Application Details

- (f) Application forms, documentation, and information needed to apply;
- (g) How to get copies of Agency handbooks and forms;

Appeal Options

- (h) Reconsideration, mediation, and appeal to The National Appeals Division (NAD);
- (i) Challenging FSA appraisal; and
- (j) Acceleration and foreclosure.

(a) Primary Loan ServicingEligibility

You must meet the following eligibility requirements to obtain primary loan servicing:

- (1) You must resolve all non-monetary defaults prior to closing the servicing action.
- (2) If you are also financially distressed or delinquent, it must be due to at least one of the following circumstances beyond your control:
 - (i) Illness, injury, or death of a borrower or other individual who operates the farm;
 - (ii) Natural disaster, adverse weather, disease, or insect damage which caused severe loss of agricultural production;
 - (iii) Widespread economic conditions such as low commodity prices;
 - (iv) Damage or destruction of property essential to the farming operation;
 - (v) Loss of, or reduction in, your or your spouse's essential non-farm income; or
 - (vi) Catastrophic medical expenses for the care of a family member of a borrower or entity member, in the case of an entity borrower.
- (3) You do not have non-essential assets for which the net recovery value is sufficient to pay the delinquent portion of the loan. FSA cannot write-down or write off debt that you could pay with the value of your equity in these assets.
- (4) You must have acted in accordance with your loan agreements in all past dealings with FSA.

Time limits

If FSA determines that you can develop a feasible plan and are eligible for primary loan servicing, you will have 45 days from the date you receive FSA's offer to accept loan servicing.

Lien requirements

If you are offered loan servicing and accept the offer, you must agree to give FSA a lien on 125% of your other assets, if available, and you must provide this lien at closing.

Youth Loans

If you have a Youth Loan, it is not eligible for debt write-down, current market value buyout, or limited resource interest rates, but can be rescheduled or deferred. This has no effect on any other loans you may have with FSA.

Loan consolidation, rescheduling, and reamortization

In loan consolidation, the unpaid balance of two or more operating loans can be combined into one larger operating loan.

In loan rescheduling, the repayment schedule may be changed to cure the delinquency and give you new terms to repay loans made for equipment, livestock, or annual operating purposes.

In loan reamortization, the repayment schedule may be changed to cure the delinquency and give you a new schedule of repayment on loans made for real estate purposes.

When loans are consolidated, rescheduled or reamortized, the interest rate will be the lesser of:

- The interest rate for that type of loan on the date a complete servicing application was received;
- The interest rate for that type of loan on the date of restructure; or
- The lowest original loan note rate on any of the original notes being restructured.

In addition, FSA will consider the maximum loan terms.

Limited resource interest rate

Limited resource interest rates are available for certain types of loans. If you have existing loans which are not at the limited resource rate, and a limited resource rate is available, FSA will consider reducing the rate of the loans. The limited resource interest rate can be as low as five percent.

For information about current interest rates, or to understand if you qualify for limited resource rates, contact your local FSA Service Center.

Loan deferral

Partial or full payments of principal and interest may be temporarily delayed for up to 5 years. You will only be considered for loan deferral if the loan servicing programs discussed above will not allow you to pay all essential family living and farm operating expenses, maintain your property, and pay your debts.

You must be able to show through a farm operating plan that you are unable to pay all essential family living and farm operating expenses, maintain your property, and pay your debts. The farm operating plan must also show that you will be able to pay your full installment at the end of the deferral period.

The interest that accrues during the deferral period must be paid in yearly payments for the rest of the loan term after the deferral period ends.

Debt write-down

Debt write-down can reduce the principal and interest on your loan. FSA offers a write-down only when the loan servicing programs discussed above and the conservation contract program, if requested, will not result in a feasible plan. To receive debt write-down, the value of your restructured loan must be equal to or greater than the recovery value to FSA from foreclosure and repossession of your security property.

The recovery value is the market value of:

- (1) The collateral pledged as security for FLP loans minus expenses (such as the sale costs, attorneys' fees, management costs, taxes, and payment of prior liens) on the collateral that FSA would have to pay if it foreclosed, or repossessed, and sold the collateral;
- (2) Any collateral that is not in your possession and has not been released for sale by FSA in writing; and
- (3) Any other non-essential assets you may own.

A qualified appraiser determines the value of the collateral and any other assets you own. You may receive a write-down only if you have not previously received any form of debt forgiveness on any other FLP direct loan. The maximum amount of debt that can be written down on all direct loans is \$300,000.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

Shared Appreciation Agreement

If you own real estate and receive a debt write-down, you must sign a Shared Appreciation Agreement. The term of the agreement is 5 years. Under the terms of the agreement you must repay all or a part of the amount written down at the maturity of your Shared Appreciation Agreement if your real estate collateral increased in value.

Payment of shared appreciation will be required prior to the maturity of your Shared Appreciation Agreement if you:

- (1) Sell or convey the real estate;
- (2) Stop farming;
- (3) Pay off your entire FLP debt; or
- (4) Have your FLP accounts accelerated by FSA.

If any of these events occur within the first 4 years of the Shared Appreciation you will be required to pay 75 percent of the increase in value of the real estate. If any of these events occur after the fourth anniversary of the agreement, or if the Shared Appreciation Agreement matures without having previously been fully triggered, you will have to pay only 50 percent of the increase in value. You will not have to pay more than the amount of the debt written down.

(b) Conservation Contract

You may request a conservation contract to protect highly erodible land, wetlands, or wildlife habitats located on your real estate property that serves as security for your FLP debt. In exchange for such contract, FSA would reduce your FLP debt. The amount of land left after the contract must be sufficient to continue your farming operation.

(c) Current Market Value Buyout

If the analysis of your debt shows that you cannot achieve a feasible plan even if the present value of your FLP debt is reduced to the value of the security, FSA may offer you buyout of your FLP debt. You would pay the market value of all FLP security and non-essential assets, minus any prior liens. The market value is determined by a current appraisal completed by a qualified appraiser. In exchange, your loans would be satisfied.

Limits

To receive a current market value buyout offer:

- (1) You must not have previously received any form of debt forgiveness from FSA on any other direct FLP loan;
- (2) The maximum debt to be written off with buyout does not exceed \$300,000; and
- (3) You must not have non-essential assets with a net recovery value sufficient to pay your account current.

Eligibility

To qualify, you must prove that:

- (1) You cannot repay your delinquent FLP debt due to circumstances beyond your control; and
- (2) You have acted in all past dealings with FSA in accordance with your loan agreements.

Time limits

To buyout your FLP debt at the current market value, you must pay FSA within 90 days of the date you receive the offer.

Method of payment

To buyout your FLP debt at the current market value, you must pay electronically or by cashier's check, certified check or U.S. Treasury check. The checks should be made payable to FSA and provided to your local FSA servicing office for processing. FSA will not make or guarantee a loan for this purpose.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

(d) Homestead Protection

Under the homestead protection program, you may repurchase your primary residence, certain outbuildings, and up to 40 acres of land. If you cannot pay electronically or by cashier's check, certified check or U.S. Treasury check or Agency financing is not available, you may lease your primary residence. The lease will include an option for you to purchase the property you lease.

This program may apply when primary loan servicing, the conservation contract program, or current market value buyout is not available or not accepted.

You must agree to give FSA title to your land at the time FSA signs the Homestead Protection Agreement with you. FSA will compute the costs of taking title including the cost of paying other creditors with outstanding liens on the property. FSA will take title only if it can obtain a positive recovery.

Eligibility requirements

- (1) Your gross annual income from the farming operation must have been similar to other comparable operations in your area in at least 2 of the last 6 years.
- (2) Sixty percent (60%) of your gross annual income in at least 2 of the last 6 years must have come from the farming operation.
- (3) You must have lived in your homestead property for 6 years immediately before your application. If you had to leave for less than 12 months during the 6-year period and you had no control over the circumstances, you may still qualify.
- (4) You must be the owner of the property immediately prior to FSA obtaining the title.

Property restrictions and easements

FSA may place restrictions or easements on your property which restrict your use if the property is located in a special area or has special characteristics. These restrictions and easements will be placed in leases and in deeds on properties containing wetlands, floodplains, endangered species, wild and scenic rivers, historic and cultural properties, coastal barriers, and highly erodible lands.

Leasing the homestead property

- (1) You must pay rent to FSA to lease the property determined eligible for homestead protection. The rent FSA charges will be similar to comparable property in your area.
- (2) You must maintain the property in good condition during the term of the lease.
- (3) You may lease the property for up to 5 years but no less than 3 years.
- (4) You cannot sublease the property.
- (5) If you do not make the rental payments to FSA, FSA will cancel the lease and take legal action.
- (6) Lease payments are not applied toward the final purchase price of the property.

Purchasing the homestead protection property

You can repurchase your homestead property at market value at any time during the lease. The market value of the property will be decided by a qualified appraiser and will reflect the value of the land after any placement of a restriction or easement such as a wetland conservation easement.

(e) Debt Settlement

You can apply for debt settlement at any time; however, these programs are usually only used after it has been determined that primary loan servicing programs and the conservation contract program cannot help you. Under the debt settlement programs, the FLP debt you owe FSA may be settled for less than the amount you owe. These programs are subject to the discretion of FSA and are not a matter of entitlement or right. If you do not have any Agency security, you may apply for debt settlement only. If you do not apply, or do not receive approval of a debt settlement request, your FLP loan accounts will be forwarded to the Department of the Treasury for collection.

Settlement alternatives

Settlement alternatives include:

- (1) Compromise: A lump-sum payment of less than the total FLP debt owed;
- (2) Adjustment: Two or more payments of less than the total amount owed to FSA. Payments can be spread out over a maximum of 5 years if FSA determines you will be able to make the payments as they become due; and
- (3) Cancellation: Satisfaction of Agency debt without payment.

Processing and requirements

If you sell loan collateral, you must apply the proceeds from the sale to your FLP loans before you can be considered for debt settlement. In the case of compromise or adjustment you may keep your collateral, if you pay FSA the market value of your collateral along with any additional amount FSA determines you are able to pay.

Debt amounts which are collectible through administrative offset, through judgment, by the Department of the Treasury, or by other means will not be settled through debt settlement procedures. You must certify that you do not have assets or income in addition to what you stated in your application. If you qualify, your application must also be approved by the State Executive Director or the Administrator, depending on the amount of the debt to be settled.

Any debt the borrower owes that FSA has written off, written down, or charged off will be reported to the Internal Revenue Service in accordance with reporting requirements at 26 U.S.C. 6050P and the related implementing regulations.

Application Details

(f) Forms, documentation, and information needed to apply

A complete application for primary loan servicing must include items (1) through (4). Additional information is required as noted if you want to be considered for the conservation contract program or debt settlement programs. If you need help to complete the required forms, you may request an FSA official to assist you. The forms for requirements (1), and (4) are included with this package.

- (1) FSA-2001, "Application for Direct Loan Assistance." This form is required with application submission.
- (2) AD-1026, "Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) Certification." You will be required to complete this form if the one you have on file does not reflect all the land you own and lease.
- (3) NRCS-CPA-026e, "Highly Erodible Land and Wetland Conservation Determination." This form must be obtained from and completed by the Natural Resources Conservation Service office, if not already on file with FSA.
- (4) FSA-2732, "Debt Settlement Application." Complete this form only if you wish to apply for debt settlement. You must also comply with any FSA request for additional information needed to process a debt settlement request.
- (5) If you are applying for a conservation contract, a map or aerial photo is required of your farm identifying the portion of the land and approximate number of acres to be considered.
- (6) Copies of real estate leases are required (if applicable to the farm operation).
- (7) Verification of non-farm income is required.

Divorced spouses

If you are an FLP borrower who has left the farming operation due to divorce, you may request release of liability. To be released of liability after a divorce, you must present FSA with the following within 60 days of receiving this notice:

- (1) A divorce decree or property settlement document which states the remaining party will be responsible for all repayment to FSA;
- (2) Evidence that you have conveyed your ownership interest in FLP security to the remaining party; and
- (3) Evidence that you do not have any repayment ability for the FLP loan through cash, income, or other non-essential assets.

FSA will make a determination on your request and will inform you of the decision within 60 days of receiving your request.

If you are not released of liability, you will need to include all of your relevant financial information if applying for primary loan servicing, homestead protection, or debt settlement programs.

(g) How to get copies of FSA handbooks and forms

Copies of the forms for requirements in Forms, Documentation and Information section, numbers (1), (2) and (5) have been included in this package. You may obtain copies of FSA handbooks, which include the pertinent regulations, describing available programs or additional copies of forms from your local FSA Service office.

(h) Reconsideration, mediation, and appeal to NAD

Reconsideration, mediation, and appeal rights pursuant to 7 CFR parts 780 and 11, respectively, will be provided to you if FSA makes an adverse decision on your request for loan servicing or prior to acceleration of your account.

Reconsideration— according to FSA’s appeal procedures in 7 CFR part 780.

Mediation— according to FSA’s appeal procedures in 7 CFR part 780.

Appeal to NAD— according to the NAD appeal procedures in 7 CFR part 11.

(i) Challenging FSA appraisal

If you timely submit a complete application for primary loan servicing, but disagree with the appraisal used by the FSA for processing your request, you may 1) obtain a Uniform Standards of Professional Appraisal Practice compliant technical appraisal review by a State Certified General Appraiser of the FSA appraisal and submit it to FSA prior to reconsideration or an appeal hearing, 2) obtain an independent appraisal, and 3) possibly negotiate the appraised value based on the specifics of the two appraisals.

If this applies to you, FSA will provide additional information in the notification letter advising you of the Agency’s decision concerning your loan servicing application.

(j) Acceleration and foreclosure

If you do not appeal an adverse determination, if you appeal, but are denied relief on appeal, or if you do not otherwise resolve your delinquency, FSA will accelerate your loan accounts and will be required to demand payment of the entire debt. You may prevent Agency foreclosure on the loan collateral if, with prior Agency approval, you:

- (1) Sell all loan collateral for not less than its market value and apply all proceeds to your creditors in order of lien priority.
- (2) Transfer the collateral to someone else and have that person assume all or part of your FLP debt, or
- (3) Transfer the collateral to FSA.

If any of these options result in payment of less than the amount you owe, you may apply for debt settlement, even if you applied before and were denied. However, applications for debt settlement filed after the 60-day time period provided in this notice will not delay acceleration, administrative offset, and foreclosure.

If FSA determines that you cannot qualify for debt settlement, you can:

- (1) Pay your FLP loan accounts current;
- (2) Pay your FLP loan accounts in full;
- (3) Request reconsideration, mediation or appeal.

If your real estate security contains your primary residence and becomes inventory property of FSA, homestead protection rights will be provided.

The servicing programs described by this Notice are subject to applicable Agency regulations published at 7 CFR Part 766.

For more information or if you have any questions, please contact [this office or the specific office name] at [County Office Address] or telephone [Phone Number].

1A. Authorized Agency Official Name	1B. Signature	1C. Title

Federal Equal Credit Opportunity Act Statement: *The Federal Equal Credit Opportunity Act prohibits creditors from discriminating against credit applicants on the basis of race, color, religion, national origin, sex, marital status, age (provided the applicant has the capacity to enter a binding contract); because all or part of the applicant's income derives from any public assistance program; or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act. The Federal agency that administers compliance with this law is the Federal Trade Commission, Equal Credit Opportunity, Washington, D.C. 20580.*

Paperwork Reduction Act (PRA) Statement: *This information collection is exempted from the Paperwork Reduction Act as specified in 5 CFR 1320.4(a)(2) because the form is used when FSA conducts administrative action against individuals or debtors.*

Non-Discrimination Statement: *In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.*

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at http://www.ascr.usda.gov/complaint_filing_cust.html and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture Office of the Assistant Secretary for Civil Rights 1400 Independence Avenue, SW Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

BILLING CODE 3410-E2-C

PA768—EQUITABLE RELIEF

■ 67. The authority citation for part 768 continues to read as follows:

Authority: 5 U.S.C. 301 and 7 U.S.C. 1989.

§ 768.1 [Amended]

■ 68. Amend § 768.1 as follows:

- a. In paragraph (a) introductory text remove the words “Agency loan requirements in this chapter” and add “direct FO, OL, or EM requirements” in its places;
- b. In paragraph (a)(1) and (a)(1)(ii), remove the words “in this chapter”.
- c. In paragraph (a)(3)(ii), remove the words “for the loan”.

PART 769—FARM LOAN PROGRAMS RELENDING PROGRAMS

■ 69. The authority citation for part 769 continues to read as follows:

Authority: 5 U.S.C. 301, 7 U.S.C. 1989 and 25 U.S.C. 488.

Subpart B—Heirs’ Property Relending Program

■ 70. Amend § 769.157 as follows:

- a. In paragraph (b) introductory text, remove the words “instrument, and” and add “instruments, if available,”; and
- b. Revise paragraph (b)(15).
The revision reads as follow.

§ 769.157 Intermediary’s relending plan.

* * * * *

- (b) * * *
(15) A description of the requirements for maintaining adequate hazard insurance, workmen’s compensation insurance on ultimate recipients, and flood insurance.

■ 71. Revise § 769.159 to read as follows:

§ 769.159 Processing loan applications.

(a) *Intermediary loan application review.* The Agency will review submitted applications from intermediaries for compliance with the provisions of this subpart.

(b) *Loan approval.* Loan approval is subject to the availability of funds. The loan will be considered approved for the intermediary on the date the Agency signs the obligation of funds confirmation.

(c) *Preferences for loan funding.* When necessary to address funding constraints, the Agency will fund eligible applications from intermediaries in the order specified in paragraphs (c)(1) through (4) of this section:

- (1) First, to those with not less than 10 years of experience serving socially disadvantaged farmers and ranchers that are located in states that have adopted a statute consisting of an enactment or adoption of the Uniform Partition of Heirs Property Act, as approved and recommended for enactment in all States by the National Conference of Commissioners on Uniform State Laws in 2010, that relend to owners of heirs property (as defined by the Uniform Partition of Heirs Property Act);
- (2) Second, to those that have applications from ultimate recipients

already in process, or that have a history of successfully relending previous HPRP funds;

(3) Multiple applications in the same priority tier, will be processed based by date of application received; and

(4) Any remaining applications, after priority tiers 1 and 2 have been funded as specified in paragraphs (c)(1) and (2) of this section, will be funded in order of the date the application was received.

(d) *Current information required.* Information supplied by the intermediary in the loan application must be updated by the intermediary if the information is more than 90 days old at the time of loan closing.

■ 72. In § 769.162, revise paragraph (a)(1) to read as follows:

§ 769.162 Security.

(a) * * *

(1) Primary security for HPRP loan will consist of a pledge by the intermediary of all assets now or hereafter placed in the HPRP revolving loan fund, including cash and investments, notes receivable from ultimate recipients, and the intermediary's security interest in collateral pledged by ultimate recipients. A first lien in the intermediary's HPRP revolving loan fund account(s) will be accomplished by a deposit agreement. The deposit agreement with the depository bank will perfect the Agency's security interest in the intermediary's depository accounts. The deposit agreement must be approved by the Agency. The deposit agreement will not require the Agency's

signature for withdrawals. The intermediary must use a depository bank that agrees to waive its offset and recoupment rights against the depository account and subordinate any liens it may have against the HPRP depository account in favor of the Agency;

* * * * *

■ 73. Amend § 769.164 as follows:

■ a. Revise the section heading;

■ b. In paragraph (d)(8) remove the word "and" at the end of the paragraph;

■ c. In paragraph (d)(9) introductory text, remove the period at the end and add a colon in its place;

■ d. In paragraph (d)(9)(i) remove the period at the end and add a semicolon and the word "and" in its place; and

■ e. Revise paragraphs (d)(9)(ii) and (10).

The revisions read as follows:

§ 769.164 Post-award requirements.

* * * * *

(d) * * *

(9) * * *

(ii) Any funds that have not been used within 6 months to make loans to an ultimate recipient must be returned to the Agency unless the Agency provides a written exception based on evidence satisfactory to the Agency that funds will be used within an additional 6 months;

(10) All reserves and other cash in the HPRP revolving loan fund must be deposited in accounts in banks or other financial institutions. Such accounts must be fully covered by Federal deposit insurance or the HPRP revolving

loan fund must be protected by alternative measures approved by the Agency. The account must be interest-bearing, if feasible, and any interest earned on the account remains a part of the HPRP revolving loan fund; and

* * * * *

PART 770—INDIAN TRIBAL LANDS ACQUISITION LOANS

■ 74. The authority citation for part 770 is revised to read as follows:

Authority: 5 U.S.C. 301 and 25 U.S.C. 5136.

■ 75. In § 770.6, revise paragraph (b) to read as follows:

§ 770.6 Rates and terms.

* * * * *

(b) *Interest rate.* The interest rate charged by the Agency will be the lower of the interest rate in effect at the time of the loan approval or loan closing, which is the current rate available in any FSA office. The rate will be equal to the interest rate for direct farm ownership loans not to exceed 5 percent. Except as provided in § 770.10(b) of this chapter, the interest rate will be fixed for the life of the loan.

§ 770.10 [Amended]

■ 76. Amend § 770.10(e)(4)(i) to remove the word "writedown" and add "write-down" in its place.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2024-16828 Filed 8-7-24; 8:45 am]

BILLING CODE 3410-E2-P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 153

August 8, 2024

Part III

Environmental Protection Agency

40 CFR Part 751

1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA); Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 751****[EPA-HQ-OPPT-2020-0471; FRL-8156-01-OCSPP]****RIN 2070-AK73****1-Bromopropane (1-BP); Regulation Under the Toxic Substances Control Act (TSCA)****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to address the unreasonable risk of injury to human health presented by 1-bromopropane (1-BP) (CASRN 106-94-5), also known as n-propyl bromide, under its conditions of use as documented in EPA's August 2020 Risk Evaluation for 1-BP and the December 2022 Revised Risk Determination for 1-BP prepared under the Toxic Substances Control Act (TSCA). 1-BP is a widely used solvent in a variety of occupational and consumer applications, including vapor degreasing, aerosol degreasing, adhesives and sealants, and in insulation. EPA determined that 1-BP presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to 1-BP, including neurotoxicity, developmental toxicity from acute and chronic inhalation exposures and dermal exposures, and cancer from chronic inhalation exposures. TSCA requires that EPA address by rule any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation and apply requirements to the extent necessary so the chemical no longer presents unreasonable risk. To address the identified unreasonable risk, EPA is proposing requirements to, among other things, prevent consumer access to the chemical, restrict the industrial and commercial use of the chemical while also allowing for a reasonable transition period where an industrial and commercial use of the chemical is being prohibited, and protect workers from the unreasonable risk of 1-BP while on the job.

DATES: Comments must be received on or before September 23, 2024. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before September 9, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0471, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information: Bethany Masten, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number (202) 564-8803; email address: 1BP_TSCA@epa.gov.

For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Does this action apply to me?***1. General Applicability**

You may be potentially affected by the proposed action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of 1-BP or products containing 1-BP. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities include:

- Crude Petroleum Extraction (NAICS code 211120).
- All Other Specialty Trade Contractors (NAICS code 238990).
- Broadwoven Fabric Mills (NAICS code 313210).
- Nonwoven Fabric Mills (NAICS code 313230).
- Textile and Fabric Finishing Mills (NAICS code 313310).
- Fabric Coating Mills (NAICS code 313320).
- Prefabricated Wood Building Manufacturing (NAICS code 321992).
- Paper Bag and Coated and Treated Paper Manufacturing (NAICS code 322220).
- Commercial Screen Printing (NAICS code 323113).

- Petroleum Refineries (NAICS code 324110).
- All Other Petroleum and Coal Products Manufacturing (NAICS code 324199).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199).
- Paint and Coating Manufacturing (NAICS code 325510).
- Adhesive Manufacturing (NAICS code 325520).
- Soap and Other Detergent Manufacturing (NAICS code 325611).
- Polish and Other Sanitation Good Manufacturing (NAICS code 325612).
- Photographic Film, Paper, Plate, and Chemical Manufacturing (NAICS code 325992).
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998).
- Polystyrene Foam Product Manufacturing (NAICS code 326140).
- Urethane and Other Foam Product (except Polystyrene) Product Manufacturing (NAICS code 326150).
- Tire Manufacturing (except Retreading) (NAICS code 326211).
- Tire Retreading (NAICS code 326221).
- Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220).
- All Other Rubber Product Manufacturing (NAICS code 326299).
- Other Concrete Product Manufacturing (NAICS code 327390).
- Gypsum Product Manufacturing (NAICS code 327420).
- Cement Manufacturing (NAICS code 327310).
- Iron and Steel Mills and Ferroalloy Manufacturing (NAICS code 331110).
- Iron and Steel Pipe and Tube Manufacturing from Purchased Steel (NAICS code 331210).
- Rolled Steel Shape Manufacturing (NAICS code 332221).
- Steel Wire Drawing (NAICS code 331222).
- Nonferrous Metal (except Aluminum) Smelting and Refining (NAICS code 331410).
- Copper Rolling, Drawing, Extruding, and Alloying (NAICS code 331420).
- Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding (NAICS code 331491).
- Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum) (NAICS code 331492).
- Nonferrous Metal Die-Casting Foundries (NAICS code 331523).
- Iron and Steel Forging (NAICS code 332111).

- Nonferrous Forging (NAICS code 332112).
- Custom Roll Forming (NAICS code 332114).
- Powder Metallurgy Part Manufacturing (NAICS code 332117).
- Metal Crown, Closure, and Other Metal Stamping (except Automotive) (NAICS code 332119).
- Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing (NAICS code 332215).
- Saw Blade and Handtool Manufacturing (NAICS code 332216).
- Other Fabricated Wire Product Manufacturing (NAICS code 332618).
- Metal Window and Door Manufacturing (NAICS code 332321).
- Machine Shops (NAICS code 332710).
- Precision Turned Product Manufacturing (NAICS code 332721).
- Bolt, Nut, Screw, Rivet, and Washer Manufacturing (NAICS code 332722).
- Industrial Valve Manufacturing (NAICS code 332911).
- Metal Heat Treating (NAICS code 332811).
- Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers (NAICS code 332812).
- Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS code 332813).
- Industrial Valve Manufacturing (NAICS code 332911).
- Fluid Power Valve and Hose Fitting Manufacturing (NAICS code 332912).
- Plumbing Fixture Fitting and Trim Manufacturing (NAICS code 332913).
- Other Metal Valve and Pipe Fitting Manufacturing (NAICS code 332919).
- Ball and Roller Bearing Manufacturing (NAICS code 332991).
- Small Arms Ammunition Manufacturing (NAICS code 332992).
- Ammunition (except Small Arms) Manufacturing (NAICS code 332993).
- Small Arms, Ordnance, and Ordnance Accessories Manufacturing (NAICS code 332994).
- Fabricated Pipe and Pipe Fitting Manufacturing (NAICS code 332996).
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999).
- Other Industrial Machinery Manufacturing (NAICS code 333249).
- Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing (NAICS code 333415).
- Special Die and Tool, Die Set, Jig, and Fixture Manufacturing (NAICS code 333514).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing (NAICS code 333612).
- Air and Gas Compressor Manufacturing (NAICS code 333912).
- Measuring, Dispensing, and Other Pumping Equipment Manufacturing (NAICS code 333914).
- Elevator and Moving Stairway Manufacturing (NAICS code 333921).
- Conveyor and Conveying Equipment Manufacturing (NAICS code 333922).
- Overhead Traveling Crane, Hoist, and Monorail System Manufacturing (NAICS code 333923).
- Industrial Process Furnace and Oven Manufacturing (NAICS code 333924).
- Power-Driven Handtool Manufacturing (NAICS code 333991).
- Welding and Soldering Equipment Manufacturing (NAICS code 333992).
- Packaging Machinery Manufacturing (NAICS code 333993).
- Industrial Process Furnace and Oven Manufacturing (NAICS code 333994).
- Fluid Power Cylinder and Actuator Manufacturing (NAICS code 333995).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- All Other Miscellaneous General Purpose Machinery Manufacturing (NAICS code 333998).
- Audio and Video Equipment Manufacturing (NAICS code 334310).
- Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing (NAICS code 334416).
- Electronic Connector Manufacturing (NAICS code 334417).
- Printed Circuit Assembly (Electronic Assembly) Manufacturing (NAICS code 334418).
- Other Electronic Component Manufacturing (NAICS code 334419).
- Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing (NAICS code 334511).
- Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use (NAICS code 334512).
- Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables (NAICS code 334513).
- Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals (NAICS code 334515).
- Residential Electric Lighting Fixture Manufacturing (NAICS code 335131).
- Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing (NAICS code 335132).
- Electric Lamp Bulb and Other Lighting Equipment Manufacturing (NAICS code 335139).
- Power, Distribution, and Specialty Transformer Manufacturing (NAICS code 335311).
- Motor and Generator Manufacturing (NAICS code 335312).
- Switchgear and Switchboard Apparatus Manufacturing (NAICS code 335313).
- Relay and Industrial Control Manufacturing (NAICS code 335314).
- Fiber Optic Cable Manufacturing (NAICS code 335921).
- Current-Carrying Wiring Device Manufacturing (NAICS code 335931).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Automobile and Light Duty Motor Vehicle Manufacturing (NAICS code 336110).
- Heavy Duty Truck Manufacturing (NAICS code 336120).
- Motor Vehicle Body Manufacturing (NAICS code 336211).
- Truck Trailer Manufacturing (NAICS code 336212).
- Motor Home Manufacturing (NAICS code 336213).
- Travel Trailer and Camper Manufacturing (NAICS code 336214).
- Motor Vehicle Gasoline Engine and Engine Parts Manufacturing (NAICS code 336310).
- Motor Vehicle Electrical and Electronic Equipment Manufacturing (NAICS code 336320).
- Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing (NAICS code 336330).
- Motor Vehicle Brake System Manufacturing (NAICS code 336340).
- Motor Vehicle Transmission and Power Train Parts Manufacturing (NAICS code 336350).
- Motor Vehicle Seating and Interior Trim Manufacturing (NAICS code 336360).
- Motor Vehicle Metal Manufacturing (NAICS code 336370).
- Other Motor Vehicle Parts Manufacturing (NAICS code 336390).
- Aircraft Manufacturing (NAICS code 336411).
- Aircraft Engine and Engine Parts Manufacturing (NAICS code 336412).
- Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS code 336413).
- Guided Missile and Space Vehicle Manufacturing (NAICS code 336414).
- Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing (NAICS code 336415).
- Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing (NAICS code 336419).
- Railroad Rolling Stock Manufacturing (NAICS code 336510).
- Ship Building and Repairing (NAICS code 336611).

- Wood Kitchen Cabinet and Countertop Manufacturing (NAICS code 337110).
- Upholstered Household Furniture Manufacturing (NAICS code 337121).
- Nonupholstered Wood Household Furniture Manufacturing (NAICS code 337122).
- Institutional Furniture Manufacturing (NAICS code 337127).
- Wood Office Furniture Manufacturing (NAICS code 337211).
- Surgical Appliance and Supplies Manufacturing (NAICS code 339113).
- Dental Equipment and Supplies Manufacturing (NAICS code 339114).
- Jewelry and Silverware Manufacturing (NAICS code 339910).
- Sporting and Athletic Goods Manufacturing (NAICS code 339920).
- Gasket, Packing, and Sealing Device Manufacturing (NAICS code 339991).
- Fastener, Button, Needle, and Pin Manufacturing (NAICS code 339993).
- All Other Miscellaneous Manufacturing (NAICS code 339999).
- Metal Service Centers and Other Metal Merchant Wholesalers (NAICS code 423510).
- Industrial Machinery and Equipment Merchant Wholesalers (NAICS code 423830).
- Drugs and Druggists' Sundries Merchant Wholesalers (NAICS code 424210).
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).
- New Car Dealers (NAICS code 441110).
- Used Car Dealers (NAICS code 441120).
- Home Centers (NAICS code 444110).
- Paint and Wallpaper Stores (NAICS code 444120).
- Electronics and Appliance Retailers (NAICS code 449210).
- Sporting Goods Stores (NAICS code 459110).
- Scheduled Passenger Air Transportation (NAICS code 481111).
- Other Support Activities for Air Transportation (NAICS code 488190).
- Other Warehousing and Storage (NAICS code 493190).
- Miscellaneous Intermediation (NAICS code 523910).
- Portfolio Management and Investment Advice (NAICS code 523940).
- Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology) (NAICS code 541715).
- Research and Development in the Social Sciences and Humanities (NAICS code 541720).
- Janitorial Services (NAICS code 561720).

- Carpet and Upholstery Cleaning Services (NAICS code 561740).
- Hazardous Waste Treatment and Disposal (NAICS code 562211).
- Junior Colleges (NAICS code 611210).
- Colleges, Universities, and Professional Schools (NAICS code 611230).
- General Automotive Repair (NAICS code 811111).
- Specialized Automotive Repair (NAICS code 811114).
- Automotive Body, Paint, and Interior Repair and Maintenance (NAICS code 811121).
- Automotive Glass Replacement Shops (NAICS code 811122).
- Automotive Oil Change and Lubrication Shops (NAICS code 811191).
- All Other Automotive Repair and Maintenance (NAICS code 811198).
- Other Electronic and Precision Equipment Repair and Maintenance (NAICS code 811210).
- Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance (NAICS code 811310).
- Home and Garden Equipment Repair and Maintenance (NAICS code 811411).
- Other Personal and Household Goods Repair and Maintenance (NAICS code 811490).
- Coin-Operated Laundries and Drycleaners (NAICS code 812310).
- Drycleaning and Laundry Services (except Coin-Operated) (NAICS code 812320).

2. Applicability to Importers and Exporters

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are subject to TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

C. What action is the Agency taking?

Pursuant to TSCA section 6(b), EPA determined that 1-BP presents an unreasonable risk of injury to health, without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) and susceptible life stages identified as relevant to the 2020 Risk Evaluation for 1-BP by EPA, under the conditions of use (Refs. 1, 2). The term "conditions of use" is defined at TSCA section 3(4) (15 U.S.C. 2602(4)) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. A detailed description of the conditions of use that EPA identified, evaluated and determined to contribute to EPA's determination that 1-BP presents an unreasonable risk is included in Unit III.B.1. EPA notes that all conditions of use of 1-BP (excluding the commercial and consumer use of 1-BP in insulation) are subject to this proposal. Accordingly, to address the unreasonable risk, EPA is proposing, under TSCA section 6(a), to:

(i) Prohibit the manufacture (including import), processing, and distribution in commerce of 1-BP for all consumer uses (excluding insulation for building and construction materials), outlined in Unit IV.A.1.;

(ii) Prohibit the manufacture (including import), processing and distribution in commerce of 1-BP for four industrial and commercial uses, outlined in Unit IV.A.1.;

(iii) Require strict workplace controls, including a 1-BP Workplace Chemical Protection Program (WCPP), which would include requirements to meet an inhalation exposure concentration limit,

for seven occupational conditions of use of 1-BP, outlined in Unit IV.A.2.;

(iv) Require the use of prescriptive controls for six occupational conditions of use of 1-BP, outlined in Unit IV.A.3.;

(v) Require purchasers to provide sellers with a self-certification, which would document the purchaser's commitment to comply with the 1-BP WCPP, for six occupational conditions of use of 1-BP, outlined in Unit IV.A.2.;

and

(vi) Establish recordkeeping and downstream notification requirements outlined in Unit IV.A.4.

In addition, in each of the proposed rules under TSCA section 6(a), EPA is proposing to amend the general provisions of 40 CFR 751, subpart A, to define "ECEL," and "exposure group," so that these definitions may be commonly applied to this and other rules under TSCA section 6 that would be codified in 40 CFR part 751. EPA seeks public comment on all aspects of this proposed rule.

D. Why is the Agency taking this action?

Under TSCA section 6(a), "[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule . . . apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk." 1-BP was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in August 2020 (Ref. 1). In addition, EPA issued a revised unreasonable risk determination in December 2022 (Ref. 2), determining that 1-BP, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that 1-BP no longer presents such risk. The unreasonable risk is described in Unit III.B.2. and the conditions of use that contribute to the unreasonable risk for 1-BP are described in Unit III.B.1.

1-BP's hazards are well established. EPA's 2020 Risk Evaluation for 1-BP considered the hazards associated with exposure to 1-BP and determined that 1-BP presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to 1-BP. While some of the risks of adverse effects from 1-BP exposure may be acute and experienced for only a short duration, other health

risks may be chronic and result in long-term impacts that are irreversible (e.g., developmental toxicity, cancer). The most sensitive adverse health effect of 1-BP exposure is developmental toxicity. Other significant adverse health effects include reproductive toxicity, liver toxicity, kidney toxicity, neurotoxicity, other developmental toxicity, and cancer. For this proposed rulemaking, EPA has determined that protecting at the cancer endpoint would also address the risk for other acute or chronic non-cancer endpoints. This proposed rule, once final, would eliminate the unreasonable risk to human health from the TSCA conditions of use of 1-BP, as identified in the 2020 Risk Evaluation for 1-BP and the revised unreasonable risk determination for 1-BP in December 2022. This proposed rule, once final, is part of EPA's efforts to advance the Biden Cancer Moonshot policy, reducing exposure to carcinogens in the environment as part of a national effort to accelerate the rate of progress against cancer, reduce the cancer death rate, and improve the life experience of those living with and surviving cancer and their caregivers.

EPA is not proposing a complete ban on 1-BP. This rule proposes to allow certain uses of 1-BP to continue provided that sufficient worker protections are in place to address the unreasonable risk for certain occupational conditions of use. For the conditions of use for which EPA is proposing strict workplace controls under a WCPP, EPA expects that many workplaces already have stringent controls in place that reduce exposures to 1-BP; for some workplaces, such as those using 1-BP in vapor degreasing, EPA understands that these existing controls may already reduce exposure enough to meet the inhalation exposure concentration limit proposed in this rulemaking (Ref. 1).

Accordingly, EPA is proposing strict workplace controls to address the unreasonable risk and to allow continued use of 1-BP for several conditions of use, including processing for incorporation into formulation, mixture, or reaction products; use in vapor degreasing; use in cold cleaning; use in aerosol spray degreasers/cleaners; use in electronic and electronic products and metal products; use in asphalt extraction and laboratory chemicals; processing as a reactant/intermediate; and use in coatings for temperature indicators, which, in total, comprise an estimated 97% of the current production volume of 1-BP. EPA is proposing to prohibit certain conditions of use of 1-BP, including

manufacture (including import), processing, and distribution in commerce of 1-BP for all consumer use, excluding the use of 1-BP in insulation; use in dry cleaning and spot cleaning, adhesives and sealants, liquid cleaners, automotive care products, anti-adhesive agents, functional fluids, and arts, crafts, and hobby materials, comprising an estimated 3% of the current production volume of 1-BP. Unit IV.A. describes EPA's proposed regulatory action and Unit IV.B. describes the alternative regulatory actions considered as required under TSCA section 6(c)(2)(A). The rationale for the proposed regulatory action and alternative regulatory actions, including what is feasible and appropriate for each condition of use, is described in Unit V., and the TSCA section 6 requirements considered in developing the regulatory actions are described in Unit III.B.3.

E. What are the estimated incremental impacts of this action?

EPA has prepared an Economic Analysis (EA) of the potential incremental impacts associated with this rulemaking that can be found in the rulemaking docket and is briefly summarized here (Ref. 3). The cost of the proposed rule is estimated to be \$14.8 million annualized over 20 years at a 3% discount rate and \$15.5 million annualized over 20 years at a 7% discount rate. These costs take compliance with implementation of a WCPP into consideration, which would include an existing chemical exposure limit (ECEL) of 0.05 ppm (0.25 mg/m³) for inhalation exposures as an 8-hour time-weighted average (TWA), applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products. The estimates discussed in the preamble reflect the central estimates for the number of sites and workers affected rather than the low- or high-end estimates. The sensitivity analysis in Chapter 11 presents the estimated costs, benefits, and net benefits for low, central, and high estimates of affected sites, workers, and occupational non-users (ONUs). The economic impact on users of 1-BP for vapor degreasing is unclear because some users may not be able to continue using their current equipment (open-top vapor degreasers). Based on engagement with industry, including public comments received on the draft risk evaluation and draft revised unreasonable risk determination for 1-BP, EPA expects workplaces engaged in vapor degreasing to have the ability to implement a WCPP that would include an ECEL, PPE requirements, and ancillary requirements. EPA estimates

that complying with the WCPP would cost vapor degreasing users \$13.8 million while prohibition would cost vapor degreasing users \$174.8 million (3% discount rate annualized over 20 years). Vapor degreasing is used in several advanced manufacturing industries, including aerospace, automotive, energy, medical devices, and others (Ref. 3).

The actions proposed in this rulemaking are expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. The monetized benefits of this rulemaking are approximately \$27.2 million annualized over 20 years at a 3% discount rate and \$12.9 million annualized over 20 years at a 7% discount rate. The monetized benefits include potential reductions in risk of colon and lung cancers. Non-monetized benefits include risk reduction of liver toxicity, kidney toxicity, reproductive toxicity, developmental toxicity, and neurotoxicity (peripheral neuropathy) (Ref. 3).

As described in more detail in the Economic Analysis, the Agency analyzed the demographic characteristics of several populations that would be impacted by this rulemaking (Ref. 3). In general, workers in affected industries and regions, as well as residents of nearby communities, are similar to workers and residents nationwide. Data limitations prevent EPA from conducting a more comprehensive environmental justice (EJ) analysis that would identify the incremental impacts of the regulatory options and assess the extent to which they mitigate or exacerbate any disproportionate impacts in communities with EJ concerns.

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with

procedures set forth in 40 CFR part 2 and/or 40 CFR part 703, as applicable.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. Overview of 1-BP

This proposed rule applies to 1-BP (CASRN 106–94–5) and is specifically intended to address the unreasonable risk of injury to health EPA has identified in the 2020 Risk Evaluation for 1-BP and the 2022 revised unreasonable risk determination, as described in Unit III.B.2. 1-BP is a colorless, volatile liquid with a mildly sweet odor that is produced in and imported into the United States. 1-BP is manufactured, processed, distributed, used, and disposed of as part of many industrial, commercial, and consumer conditions of use.

As outlined in further detail in Unit III.B.1., 1-BP is used as a solvent in cleaning and degreasing operations (including vapor degreasing, cold cleaning, and aerosol degreasing), spray adhesives, and dry cleaning. 1-BP is also used as a reactant in the manufacturing of other chemical substances. Consumer uses of 1-BP include aerosol degreasers, spot cleaners, and stain removers. 1-BP is also used in insulation for building and construction materials. According to data submitted for the 2016 submission period under EPA's Chemical Data Reporting (CDR) rule, the total aggregate annual production volume of 1-BP in the U.S. increased from 15.4 million pounds to 25.8 million pounds between 2012 and 2015 (Ref. 4). The total aggregate annual production volume ranged from 1 to 50 million pounds between 2016 and 2019 according to CDR (Ref. 5).

B. Regulatory Actions Pertaining to 1-BP

Because of its adverse health effects, 1-BP is subject to several Federal laws and regulations in the United States and is also subject to regulation by some States and other countries. A summary of EPA regulations pertaining to 1-BP, as well as other Federal, state, and international regulations, is in the docket and in Appendix A of the 2020 Risk Evaluation for 1-BP (Refs. 6, 1). EPA acknowledges that additional 1-BP regulatory steps occurred after 2020, including the addition of 1-BP as a Hazardous Air Pollutant (HAP) to the

Clean Air Act list in January 2022, as discussed in Unit X.C.5.

C. Consideration of Occupational Safety and Health Administration (OSHA) Occupational Health Standards in TSCA Risk Evaluations and TSCA Risk Management Actions

Although EPA must consider and factor in, to the extent practicable, certain non-risk factors as part of TSCA section 6(a) rulemaking (see TSCA section 6(c)(2)), EPA must nonetheless still ensure that the selected regulatory requirements apply “to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk.” 15 U.S.C. 2605(a). This requirement to eliminate unreasonable risk is distinguishable from approaches mandated by some other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) considerations in the setting of standards.

Congress intended for EPA to consider occupational risks from chemicals it evaluates under TSCA, among other potential exposures, as relevant and appropriate. As noted previously, section 6(b) of TSCA requires EPA to evaluate risks to PESS identified as relevant by the Administrator. TSCA section 3(12) defines the term “potentially exposed or susceptible subpopulation” as “a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”

The OSH Act similarly requires OSHA to evaluate risk specific to workers prior to promulgating new or revised standards and requires OSHA standards to substantially reduce significant risk to the extent feasible, even if workers are exposed over a full working lifetime. See 29 U.S.C. 655(b)(5); *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion).

Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, as this section outlines, there

are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements (Ref. 6) when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community.

1. OSHA Requirements

OSHA's mission is to ensure that employees work in safe and healthful conditions. The OSH Act establishes requirements that each employer comply with the General Duty Clause of the Act (29 U.S.C. 654(a)), as well as with occupational safety and health standards issued under the Act.

a. General Duty Clause of the OSH Act

The General Duty Clause of the OSH Act requires employers to keep their workplaces free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, PPE, or other specific protective measures that EPA could potentially consider when developing its risk evaluations or risk management requirements. OSHA, under limited circumstances, has cited the General Duty Clause for regulating exposure to chemicals. To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL), a TWA based on an employee's average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded (Ref. 7). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.

b. OSHA Standards

OSHA standards are issued pursuant to the OSH Act and are found in title 29 of the CFR. There are separate standards for general industry, laboratories,

construction, maritime and agriculture sectors, and general standards applicable to a number of sectors (e.g., OSHA's Respiratory Protection standard). OSHA has numerous standards that apply to employers who operate chemical manufacturing and processing facilities, as well as to downstream employers whose employees may be occupationally exposed to hazardous chemicals.

OSHA sets legally enforceable limits on the airborne concentrations of hazardous chemicals, referred to as PELs, established for employers to protect their workers against the health effects of exposure to hazardous substances (29 CFR part 1910, subpart Z, part 1915, subpart Z, and part 1926, subparts D and Z). Under section 6(a) of the OSH Act, OSHA was permitted an initial 2-year window after the passage of the Act to adopt "any national consensus standard and any established Federal standard." 29 U.S.C. 655(a). OSHA used this authority in 1971 to establish PELs that were adopted from Federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits (OELs) were selected based on the American Conference of Governmental Industrial Hygienists (ACGIH) 1968 list of Threshold Limit Values (TLVs). In addition, about 25 exposure limits recommended by the American Standards Association (now called the American National Standards Institute (ANSI) were adopted as PELs.

Following the 2-year window provided under section 6(a) of the OSH Act for adoption of national consensus and existing Federal standards, OSHA has issued health standards following the requirements in section 6(b) of the Act. OSHA has established approximately 30 PELs under section 6(b)(5) as part of comprehensive substance-specific standards that include additional requirements for protective measures such as use of PPE, establishment of regulated areas, exposure assessment, hygiene facilities, medical surveillance, and training. These ancillary provisions in substance-specific OSHA standards further mitigate residual risk that could be present due to exposure at the PEL.

OSHA has not established a PEL for 1-BP and for those it has, in many instances, scientific evidence has accumulated suggesting that the current limits of many PELs are not sufficiently protective. Unlike EPA's requirements under TSCA to address unreasonable risk, health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent

that it is technologically and economically feasible. OSHA's legal requirement to demonstrate that its section 6(b)(5) standards are technologically and economically feasible at the time they are promulgated often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers.

TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints and working populations than OSHA's risk evaluations typically contemplate, and EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. The following section discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

2. Consideration of OSHA Standards in TSCA Risk Evaluations

When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). (It should be noted that there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place.)

In addition, EPA believes it may be appropriate to also evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA may evaluate risk

under scenarios that consider industry or sector best practices for industrial hygiene that are clearly articulated to the Agency, when doing so serves to inform its risk management efforts. Characterizing risks using scenarios that reflect different levels of mitigation can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified (see Unit II.C.2.b. and Unit II.C.3.).

a. Risk Characterization for Unreasonable Risk Determination

When making unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that all workers are always equipped with and appropriately using sufficient PPE, although it does not question the veracity of public comments received on the 2020 Risk Evaluation for 1-BP regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to PESS (workers and occupational non-users (ONUs)) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. Mitigation scenarios included in the EPA risk evaluation in order to inform its risk management efforts (*e.g.*, scenarios considering use of PPE) likely represent current practice in many facilities where companies effectively address worker and bystander safety requirements. However, the Agency cannot assume that all facilities across all uses of the chemical substances will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA makes its determinations of unreasonable risk based on scenarios that do not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on such scenarios should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that

unreasonable risk may exist: (1) for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by an OSHA State Plan; (2) because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

b. Risk Evaluation To Inform Risk Management Requirements

In addition to the scenarios described previously, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.*, chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency to help inform risk management decisions.

3. Consideration of OSHA Standards in TSCA Risk Management Actions

When undertaking risk management actions, EPA: (1) Develops occupational risk mitigation measures to address any unreasonable risk identified by EPA, striving for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls (Ref. 8), when those measures would address an unreasonable risk; and (2) Ensures that EPA requirements apply to all potentially exposed workers in accordance with TSCA requirements. Consistent with TSCA section 9(d), EPA consults and coordinates TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements.

Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, broadly applicable regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply to them or not be sufficient to address the unreasonable risk.

4. 1-BP and OSHA Requirements

EPA incorporated the considerations described earlier in this unit in the 2020 Risk Evaluation for 1-BP, the December 2022 revised unreasonable risk

determination for 1-BP, and this proposed risk management rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for 1-BP, EPA presented risk estimates based on workers' exposures with and without respiratory protection. EPA determined that even when respirators with APF 50 are used by workers, most of the conditions of use evaluated presented an unreasonable risk. Additional consideration of OSHA standards in the revised unreasonable risk determination is discussed further in the **Federal Register** notice announcing that document (Ref. 9). In Units III.B.3. and V., EPA outlines the importance of considering the hierarchy of controls utilized by the industrial hygiene community (hereafter referred to as "hierarchy of controls") when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for 1-BP. The hierarchy of controls is a prioritization of exposure control strategies from most preferred to least preferred techniques. In order of precedence, they are: elimination of the hazard, substitution with a less hazardous substance, engineering controls, administrative controls such as training or exclusion zones with warning signs, and, finally, use of PPE (Ref. 8). Under the hierarchy of controls, the use of respirators (and all PPE) should only be considered after all other measures have been taken to reduce exposures. As discussed in Units IV.A. and V.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators to address unreasonable risk to workers; instead, EPA is proposing prohibitions for or affecting certain conditions of use, a WCPP for most occupational conditions of use, self-certification for certain occupational conditions of use, and prescriptive controls for certain occupational conditions of use. The WCPP would require consideration of the hierarchy of controls before use of respirators and other PPE. The WCPP is discussed in full in Units IV.A.2. and V.A.1.b.

In accordance with the approach described earlier in Unit II.C.3., EPA intends for this regulation to be as consistent as possible with the existing OSHA standards, with additional requirements as necessary to address the unreasonable risk. One notable difference between the WCPP and the OSHA standards are the exposure limits. The WCPP would include an ECEL of 0.05 ppm as an 8-hour TWA to address unreasonable risks for chronic cancer and non-cancer and acute non-

cancer inhalation endpoints. EPA recognizes that there is no OSHA PEL for 1-BP; however, OSHA and the National Institute for Occupational Safety and Health (NIOSH) issued a Hazard Alert in 2013, which indicates a recommended time-weighted average threshold limit value (TWA-TLV) of 10 ppm by the American Conference of Governmental Industrial Hygienists (Ref. 10). However, in 2011, ACGIH recommended 0.10 ppm as the TWA-TLV value for 1-BP and adopted this value in 2014. (Ref. 10). OSHA also released an Enforcement Policy for Respiratory Hazards Not Covered by OSHA Permissible Exposure Limits that explains OSHA requirements and the applicability of this policy pertaining to 1-BP exposure limits under certain conditions (Ref. 11).

The TSCA ECEL value for 1-BP is a lower value than other existing OELs, discussed in Unit II.C.5., because many of those OELs are outdated, and they may not fully capture either the complete database of studies considered in the 2020 Risk Evaluation for 1-BP or more recent advances in modeling and scientific interpretation of toxicological data applied in the calculation of the 1-BP ECEL. EPA considers the 1-BP ECEL to represent the best available science under TSCA section 26(h) because it was derived from information in the 2020 Risk Evaluation for 1-BP, which was subject to peer review, and which is the result of a systematic review approach that investigated the reasonably available information in order to identify relevant adverse health effects. Additionally, by using the information from the 2020 Risk Evaluation for 1-BP, the ECEL incorporates advanced modeling and peer-reviewed methodologies, and accounts for exposures to potentially exposed or susceptible subpopulations, as required by TSCA.

For 1-BP, the TSCA ECEL is an 8-hour occupational inhalation exposure limit based on cancer inhalation risks and takes into consideration the uncertainties identified in the 2020 Risk Evaluation for 1-BP (Ref. 12). The ECEL represents the concentration at which an adult human, including a member of a PESS, would be unlikely to suffer adverse effects if exposed for a working lifetime. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health from occupational inhalation exposures. In addition to the ECEL, as part of this rulemaking, EPA is proposing an ECEL action level. An ECEL action level, similar to other OEL frameworks, is

typically a value lower than the ECEL value, that would trigger additional monitoring to ensure that workers are not exposed to concentrations above the ECEL.

For 1-BP, the ECEL of 0.05 ppm is based on the cancer endpoints. As demonstrated in the ECEL memo, cancer from chronic inhalation exposures is the basis of the 1-BP ECEL (Ref. 12). As discussed in Units II.D., III.B., and VII.D., the TSCA ECEL represents the best available science at time of publication of the 2020 Risk Evaluation for 1-BP.

5. 1-BP and Other Occupational Exposure Limits

EPA is aware of other OELs for 1-BP, including the California Division of Occupational Safety and Health (Cal/OSHA) PEL and the ACGIH TLV. The 2014 8-hour TWA TLV recommended by the ACGIH is 0.10 ppm. This TLV is based on the potential for neurotoxicity, liver toxicity, and reproductive/developmental toxicity. While a variety of studies covering numerous health effects are discussed in the report, the most relevant study cited (Ref. 13) reported “diminished vibration sensation and lower scores in memory and mood tests” in workers at measured occupational exposures as low as 0.34 ppm. The TLV appears to be semi-quantitative and not directly extrapolated from any individual point of departure. The August 2020 TSCA Risk Evaluation for 1-BP discussed the Ichihara results (Ref. 1, 13), however they were considered ambiguous due to 1-BP co-exposures that may have significantly contributed to the observed neurotoxicity. The TLV report also discusses the NTP 2011 cancer results that were the basis of the TSCA ECEL, however linear low-dose extrapolation was not performed in order to derive a lower TLV.

The 2014 Cal/OSHA PEL is 5 ppm, higher than the ACGIH TLV, and has a skin notation, meaning that a worker’s skin, eyes and mouth should be protected from any contact with 1-BP (Ref. 14). The Cal/OSHA PEL is based on reproductive and developmental toxicity (observed in animal studies) and technological feasibility assessments from industry (Ref. 14).

D. Summary of EPA’s Risk Evaluation Activities on 1-Bromopropane

In December 2016, EPA selected 1-BP as one of the first 10 chemicals for risk evaluation under TSCA section 6 (Ref. 15). EPA published the scope of the 1-BP risk evaluation in June 2017 (82 FR 31592, July 7, 2017), and, after receiving public comments, published the

problem formulation in June 2018 (83 FR 26998, June 11, 2018). In August 2019, EPA published a draft risk evaluation (84 FR 39830, August 12, 2019), and, after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the 2020 Risk Evaluation for 1-BP in August 2020 in accordance with TSCA section 6(b) (85 FR 48687, August 12, 2020). EPA subsequently issued a draft revised TSCA unreasonable risk determination for 1-BP (87 FR 43265, July 20, 2022), and after public notice and receipt of comments, published a revised Unreasonable Risk Determination for 1-BP (87 FR 77603, December 2022). The 2020 Risk Evaluation for 1-BP and supplemental materials are in docket EPA-HQ-OPPT-2019-0235, with the December 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process are in docket EPA-HQ-OPPT-2016-0741, on <https://www.regulations.gov>.

1. 2020 Risk Evaluation

In the 2020 Risk Evaluation for 1-BP, EPA evaluated risks associated with 25 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal. Descriptions of these conditions of use are in Unit III.B.1. The 2020 Risk Evaluation for 1-BP identified significant adverse health effects associated with exposure to 1-BP, including developmental toxicity from acute and chronic inhalation exposures and dermal exposures, and cancer from chronic inhalation exposures to 1-BP. A further discussion of the hazards of 1-BP is included in Unit III.B.2.

2. Revised Unreasonable Risk Determination

EPA has been revisiting specific aspects of its first ten TSCA existing chemical risk evaluations, including the 2020 Risk Evaluation for 1-BP, to ensure that the risk evaluations upon which risk management decisions are made better align with TSCA’s objective of protecting human health and the environment. For 1-BP, EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for 1-BP and issued a final revised unreasonable risk determination on December 2022 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for 1-BP pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (“Protecting Public Health and the Environment and Restoring Science to Tackle the Climate

Crisis”) and other Administration priorities (Refs. 16, 17, and 18). The revisions consisted of making the risk determination based on the whole-chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior “no unreasonable risk” determinations and withdrawing the associated TSCA section 6(i)(1) “no unreasonable risk” order); and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

In determining whether 1-BP presents unreasonable risk under the conditions of use, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health (including cancer and non-cancer risks) and human exposure to the substance under the conditions of use (including duration, magnitude, and frequency of exposure); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any PESS); susceptible life stages; the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.

EPA determined that 1-BP presents an unreasonable risk of injury to health. The contributions to the unreasonable risk determination are risks to workers and ONUs (workers who do not directly handle the chemical but perform work in an area where the chemical is present) due to occupational exposures to 1-BP (*i.e.*, during manufacture, processing, industrial and commercial uses, disposal); and to consumers and bystanders associated with consumer uses of 1-BP due to exposures from consumer use of 1-BP and products containing 1-BP. EPA did not identify risks of injury to the environment that contribute to the unreasonable risk determination for 1-BP. The 1-BP conditions of use that contribute to EPA’s determination that the chemical substance poses unreasonable risk to health are listed in the unreasonable risk determination (Ref. 2) and also in Unit III.B.1., with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the proposed regulatory provisions.

While the 2020 Risk Evaluation for 1-BP estimated different risks for occupational non-users and workers, the benchmark (and thus the ECEL value) is the same for both populations. That is, while workers and occupational non-

users may have different exposure patterns, the level of exposure such that risks are no longer unreasonable is the same for both workers and occupational non-users. Thus, for the purposes of risk management, the distinction between worker and occupational non-user is no longer relevant, and both are encompassed by the proposed definition of a potentially exposed person, as outlined in Unit IV.A.2.a. EPA notes that this proposed definition is intended to apply to occupational workplaces as part of implementation of the WCPP, and recognizes that other individuals or communities may be exposed to 1-BP as consumers, members of fenceline communities, or members of the general population.

3. Fenceline Screening Analysis

The 2020 TSCA Risk Evaluation for 1-BP excluded the assessment of certain exposure pathways that were or could be regulated under another EPA-administered statute (see section 1.4.2 of the August 2020 Risk Evaluation for 1-BP (Refs. 1, 2). This resulted in the ambient air pathway for 1-BP exposure not being fully assessed for human health risk to the general population. The August 2020 Risk Evaluation for 1-BP did assess the water pathway based on fate and monitoring and modeling data, which determined there was no presence of 1-BP (Ref. 1). In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations could lead to a failure to identify and protect fenceline communities (Refs. 9; 15). EPA then conducted a screening analysis to identify whether there may be potential risks to people living near the fenceline of facilities releasing 1-BP.

In order to determine whether there may be potential risk to the general population in proximity to a facility releasing 1-BP, EPA developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, which was presented to the SACC in March 2022, with a report issued by the SACC on May 18, 2022 (Ref. 19). This analysis is discussed in Unit VI.A.

III. Regulatory Approach

A. Background

Under TSCA section 6(a), if the Administrator determines, through a TSCA section 6(b) risk evaluation that the manufacture (including import), processing, distribution in commerce,

use, or disposal of a chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more of the following requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (section 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a particular use (section 6(a)(2)).
- Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use specified (section 6(a)(2)).
- Require clear and adequate minimum warning and instructions with respect to the substance or mixture’s use, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance or mixture (section 6(a)(3)).
- Require manufacturers and processors of the substance or mixture to make and retain certain records or conduct certain monitoring or testing (section 6(a)(4)).
- Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (section 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal of the substance or mixture, or any article containing such substance or mixture, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (section 6(a)(6)).
- Direct manufacturers or processors of the substance or mixture to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance or mixture (section 6(a)(7)).

As described in Unit III.B.3., EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk found to be present in the 2020 Risk Evaluation for 1-BP and the final revised unreasonable risk determination, so that 1-BP no longer presents such

unreasonable risk. EPA's proposed regulatory action and two alternative regulatory actions are described in Unit IV. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions and is providing notice that based on consideration of comments and any new information submitted to EPA during the comment period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action. The public should understand that public comments could result in changes to elements of the proposed and alternative regulatory actions when this rulemaking is finalized. For example, elements such as timelines for phase out could be lengthened or shortened, ECEs could be modified, or the WCPP could have conditions added or eliminated, or uses proposed to be prohibited could be allowed with a WCPP or uses proposed to be allowed with a WCPP could be prohibited.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use if EPA finds that: (1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; (2) Compliance with the requirement, as applied with respect to the specific condition of use would significantly disrupt the national economy, national security, or critical infrastructure; or (3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. At this time, EPA is not proposing to grant TSCA section 6(g) exemptions in this proposed rulemaking.

TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating TSCA section 6(a) rules, to consider and include a statement addressing certain factors, including the costs and benefits and the cost effectiveness of the regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. A description of all TSCA section 6 requirements considered in developing this proposed regulatory action is in Unit III.B.3., and Unit V.B. includes more information regarding EPA's consideration of exemptions and alternatives. TSCA section 6(c)(2)(C) requires that in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an

appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as substitutes when the proposed prohibition or restriction takes effect. Unit IV.B. includes more information regarding EPA's consideration of alternatives, and Unit VI. provides more information on EPA's considerations more broadly under TSCA section 6(c)(2).

EPA carried out required consultations as described in this unit and also considered impacts on children's environmental health as part of its approach to developing this TSCA section 6 regulatory action.

1. Consultations

EPA conducted consultations and outreach in developing this proposed regulatory action. The Agency held a federalism consultation from October 22, 2020, until January 23, 2021, as part of this rulemaking process and pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999). This included a background presentation on September 9, 2020, and a consultation meeting on October 22, 2020. During the consultation, EPA met with State and local officials early in the process of developing the proposed action in order to receive meaningful and timely input into its development (Ref. 20). During the consultation, participants and EPA discussed preemption, EPA's authority under TSCA section 6 to regulate identified unreasonable risks, what activities would be potentially regulated in the proposed rule; and the relationship between TSCA and existing statutes—particularly the Clean Air Act (CAA) (Ref. 20).

1-BP is not manufactured (including imported), processed, distributed in commerce, or regulated by Tribal governments. However, EPA consulted with Tribal officials during the development of this proposed action (Ref. 21). The Agency held a Tribal consultation from October 7, 2020, to January 8, 2021, with meetings on November 12 and 17, 2020. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for 1-BP, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from tribes

(Ref. 21). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates of communities that might be subject to disproportionate risk from the exposures to 1-BP, such as low-income populations, and indigenous peoples. EPA's Environmental Justice (EJ) consultation occurred from November 4, 2020, through January 18, 2021. On November 16 and 19, 2020, EPA held public meetings as part of this consultation. These meetings were held pursuant to EPA policy to advance meaningful community engagement as part of the goal of environmental justice. During the consultations, participants and EPA discussed risk management under TSCA section 6(a), types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and the relationship between TSCA and existing statutes, particularly the Clean Air Act. In general, commenters supported strong regulation of 1-BP to protect lower-income communities and workers. Commenters also supported strong outreach to affected communities, encouraged EPA to follow the NIOSH hierarchy of controls in regulating 1-BP, favored prohibitions, and noted the uncertainties associated with use of personal protective equipment (e.g., in some cases, use of PPE did not provide adequate protection given the exposure scenario). (Ref. 22)

As required by section 609(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, EPA convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to this proposed rule's requirements (Ref. 23). EPA met with SERs before and during Panel proceedings, on November 5, 2020, and May 11, 2021. Panel recommendations are in Unit X.C. and in the Initial Regulatory Flexibility Analysis (IRFA) (Ref. 24); the Panel report is in the docket (Ref. 23). EPA requests comment on all elements of the IRFA, and, in particular, the flexibilities that EPA has identified following input from the SERs during the SBAR process. Additional requests for comment based on Panel recommendations are in Unit VIII.

Units X.C., X.E., X.F., and X.J. provide more information regarding the consultations.

2. Other Stakeholder Engagement

In addition to the formal consultations described in Unit X., EPA held a webinar on September 30, 2020, providing an overview of the TSCA risk management process and the risk evaluation findings for 1-BP. EPA also presented on the risk evaluation and risk management under TSCA for 1-BP at a Small Business Administration (SBA) Office of Advocacy Environmental roundtable on September 11, 2020. At both events EPA staff provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for 1-BP (Ref. 25). Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, EPA engaged in discussions with representatives from different industries, non-governmental organizations, technical experts and users of 1-BP. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 26); meeting materials and summaries are also in the docket. The purpose of these discussions was to create awareness and educate stakeholders and regulated entities on the provisions for risk management required under TSCA section 6(a); explain the risk evaluation findings; obtain input from manufacturers, processors, distributors, users, academics, advisory councils, and members of the public health community about uses of 1-BP; identify workplace practices, engineering controls, administrative controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to 1-BP under the conditions of use; understand the importance of 1-BP in the various uses subject to this proposed rule; compile knowledge about critical uses, substitute chemicals or alternative methods; identify various standards and performance specifications; and generate potential risk reduction strategies. EPA has met with, or otherwise communicated with, a variety of companies, trade associations and non-governmental organizations to discuss the topics outlined in this paragraph; a list of external meetings held during the development of this proposed rule is in the docket. (Ref. 26).

3. Children's Environmental Health

EPA's *Policy on Children's Health* (Ref. 27) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from

conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." Infants, children, and pregnant women are life stages that are listed as examples of subpopulations that may be considered relevant "potentially exposed or susceptible subpopulations" in the TSCA section 3(12) definition of that term. In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements under TSCA section 6(a) so that 1-BP no longer presents an unreasonable risk (including unreasonable risk to PESS).

The 2020 Risk Evaluation for 1-BP considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. For occupational use, the risk evaluation considered males (≤ 16 years of age) and females of reproductive age (≤ 16 years of age to less than 54 years of age) for both dermal and inhalation exposures. For consumer use, EPA evaluated dermal and inhalation exposures for children ages 11–15 and 16–20 years of age, and the evaluation of inhalation exposures to bystanders includes infants, toddlers, and older children. Several health effects of 1-BP exposure are relevant to early life stages, including developmental toxicity (*i.e.* increases in post-implantation loss), and other adverse effects including reproductive toxicity and cancer.

B. Regulatory Assessment of 1-BP

1. Description of Conditions of Use

This unit describes the TSCA conditions of use that contribute to EPA's unreasonable risk determination for the chemical substance 1-BP. Condition of use descriptions were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for 1-BP and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes and stakeholder engagements. For additional descriptions of the conditions of use, including process descriptions and worker activities

considered in the risk evaluation, see the Problem Formulation of the 2020 Risk Evaluation for 1-BP, the 2020 Risk Evaluation for 1-BP, and supplemental files (Refs. 28, 1, 29). EPA acknowledges that some of the terms in this unit may be defined under other statutes, however the descriptions here are intended to provide clarity to the regulated entities who will implement the provisions of this rulemaking under TSCA section 6(a).

a. Manufacturing (Including Import)

i. Domestic Manufacture

This condition of use refers to the making or producing of a chemical substance within the United States (including manufacturing for export), or the extraction of a component chemical substance from a previously existing chemical substance or a complex combination of substances.

ii. Import

This condition of use refers to the act of causing a chemical substance or mixture to arrive within the customs territory of the United States.

b. Processing

i. Processing as a Reactant/Intermediate

This condition of use refers to processing 1-BP in chemical reactions for the manufacturing of another chemical substance or product. Through processing as a reactant or intermediate, 1-BP serves as a feedstock in the production of another chemical product via a chemical reaction in which 1-BP is completely consumed. For example, 1-BP is used as a reactant in the production of other organic and inorganic chemicals, pesticides, fertilizers, and other agricultural chemicals.

ii. Processing: Incorporation Into a Formulation, Mixture, or Reaction Products

This condition of use refers to when 1-BP is added to a product (or product mixture) prior to further distribution of the product.

iii. Processing: Incorporation Into Articles

This condition of use refers to when 1-BP becomes an integral component of an article distributed for industrial, commercial, or consumer use. An article refers to a manufactured item which: (1) Is formed to a specific shape or design during manufacture; (2) has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) has either no change of chemical composition during its end

use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles, except that fluids are particles that are not considered articles regardless of shape or design. 40 CFR 704.3

iv. Processing by Repackaging

This condition of use refers to the preparation of a chemical substance or mixture for distribution in commerce in a different form, state, or quantity. This includes transferring of 1-BP from a bulk container into smaller containers.

v. Recycling

This condition of use refers to processing waste streams of 1-BP at a third-party site for the purpose of recovering materials or otherwise preparing the waste for reuse instead of disposal. Waste solvents can be restored via solvent reclamation/recycling. The recovery process may involve an initial vapor recovery or mechanical separation step followed by distillation, purification, and final packaging.

c. Industrial and Commercial Use

i. Industrial and Commercial Use as Solvent for Open-Top Batch and In-Line Conveyorized Vapor Degreasing

This condition of use refers to the industrial and commercial use of 1-BP as a solvent for cleaning and degreasing through the process of heating 1-BP to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using batch open-top and in-line conveyorized vapor degreaser machines.

ii. Industrial and Commercial Use as Solvent for Closed-Loop Batch Vapor Degreasing

This condition of use refers to the industrial and commercial use of 1-BP as a solvent for cleaning and degreasing through the process of heating 1-BP to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using batch closed-loop degreaser machines.

iii. Industrial and Commercial Use as Solvent for Cold Cleaning

This condition of use refers to the industrial and commercial use of 1-BP as a non-boiling solvent in cold cleaning machines, including simple spray sinks and dip tanks, to remove dirt, oils, greases, and other surface contaminants from metal and other parts.

iv. Industrial and Commercial Use as Solvent for Aerosol Spray Degreaser/Cleaner

This condition of use refers to the industrial and commercial use of 1-BP as a solvent in degreasing and cleaning products to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from electronics, metals, and other fabricated materials. This description does not apply to use of 1-BP in products intended for automotive care, anti-adhesive agents for mold cleaning and release products, adhesive accelerants for arts, crafts, and hobby materials, or functional fluids, which are described in "Other industrial and commercial uses" in this unit, or dry cleaning solvents and stain removers, which are described in "Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers" in this unit.

v. Industrial and Commercial Use in Adhesives and Sealants

This condition of use refers to the industrial and commercial use of 1-BP as a solvent in spray adhesives and sealants for foam cushion manufacturing and fabrication (e.g., the furniture industry).

vi. Industrial and Commercial Use in Dry Cleaning Solvents, Spot Cleaners and Stain Removers

This condition of use refers to the industrial and commercial use of 1-BP in products for spot cleaning and as a solvent in degreasing and cleaning applications to remove dirt, grease, stains, spots, and foreign matter from garments at dry cleaning facilities. This includes dry cleaning facilities using third generation (dry-to-dry, non-vented machines with refrigerated condensers), fourth generation (dry-to-dry, non-vented machines with both refrigerated condensers and carbon adsorbers as secondary vapor controls), or fifth generation (dry-to-dry, non-vented machines with secondary vapor controls, a monitor inside the machine drum, and an interlocking system to ensure the concentration is below approximately 300 ppm before the loading door can be opened) 1-BP dry cleaning machines. In addition to use as a solvent in dry cleaning equipment, 1-BP is found in products to spot clean garments to remove stains or spots before and after dry cleaning treatment.

vii. Industrial and Commercial Use in Coin and Scissor Cleaner (Liquid, Spray, or Aerosol Cleaners)

This condition of use refers to the industrial and commercial use of 1-BP in aerosol and non-aerosol product formulations, designed to clean collectible coins and scissors.

viii. Commercial Use in Insulation

This condition of use refers to the commercial use of 1-BP in insulation material in the form of rigid board insulation, which can be used for interior and exterior applications including walls, ceilings, roofs, foundations, basements, and crawl spaces in commercial and residential buildings.

ix. Other Industrial and Commercial Uses

This condition of use refers to the industrial and commercial uses of 1-BP in a variety of other aerosol and non-aerosol uses not already described previously in this unit.

- *Aerosol mold cleaning and release:*

This refers to the industrial and commercial use of 1-BP in aerosol mold cleaning and release products used to coat the molds for injection moldings, compression molding, blow molding, and extrusion applications.

- *Asphalt extraction:* This refers to the industrial and commercial use of 1-BP for asphalt extraction in centrifuge extractors, vacuum extractors, and reflux extractors to separate asphalt from the aggregate and filler material to allow for determination of asphalt content.

- *Automotive care products:* This condition of use also refers to the industrial and commercial use of 1-BP in aerosolized products, particularly engine degreasers and brake cleaners, to remove residual contaminants from fabricated parts.

- *General purpose degreaser:* This refers to the industrial and commercial use of 1-BP in aerosolized and non-aerosolized products used in industrial settings, with usage varying widely by facility to clean and maintain equipment (primarily during plant shutdowns) and also used for heavy duty transportation maintenance (e.g., maintaining buses, trains, trucks, etc.).

- *High voltage cable cleaner:* This refers to the industrial and commercial use of 1-BP in both aerosolized and non-aerosolized cleaning products to clean the semi-conductive cores of high voltage cables when splicing and terminating cables.

- *Refrigerant flush:* This refers to the industrial and commercial use of 1-BP

in products used to clean refrigeration lines in various industries, and flush oxygen lines in hospitals and in the aerospace industry.

- *Temperature indicators:* This refers to the industrial and commercial use of 1-BP in temperature-indicating fluids and coatings, which can be applied to fabrics, rubber, plastics, glass, and/or polished metals.

- *Other uses:* This refers to the industrial and commercial use of 1-BP in a variety of other products such as an adhesive accelerant, a coating component for pipes and fixtures, functional fluids (closed/open systems), cutting oils, and as a laboratory chemical for research and development.

d. Consumer Use

i. Consumer Use as a Solvent in Aerosol Spray Degreasers/Cleaners

This condition of use refers to the consumer use of 1-BP in aerosolized products to dissolve oils, greases, and similar materials from textiles, glassware, metal surfaces, and other articles. This includes the use of 1-BP in aerosolized products for cleaning or degreasing in electronic degreasers.

ii. Consumer Use in Spot Cleaners or Stain Removers

This condition of use refers to the consumer use of 1-BP for cleaning and furniture care in the form of spot cleaners or stain removers to remove dirt, grease, stains, and foreign matter from furniture or furnishings, or to cleanse, sanitize, or improve the appearance of surfaces.

iii. Consumer Use in Liquid Cleaners (e.g., Coin and Scissor Cleaners)

This condition of use refers to the consumer use of 1-BP in liquid cleaning products to dissolve oils, greases, and stains, or to cleanse, sanitize, or improve the appearance of surfaces.

iv. Consumer Use in Liquid Spray/Aerosol Cleaners

This condition of use refers to the consumer use of 1-BP in liquid and aerosolized products for cleaning and furniture care to remove dirt, grease, and stains, or to cleanse, scour, polish, protect, or improve the appearance of surfaces.

v. Consumer Use in Arts, Crafts and Hobby Materials (Adhesive Accelerant)

This condition of use refers to the consumer use of 1-BP in aerosolized products for arts, crafts, and hobby activities to accelerate the time it takes for the adhesive to dry.

vi. Consumer Use in Automotive Care Products (Refrigerant Flush)

This condition of use refers to the consumer use of 1-BP in liquid cleaning products to dissolve and flush out foreign materials from coils of an automobile AC coil.

vii. Consumer Use in Anti-Adhesive Agents (Mold Cleaning and Release Products)

This condition of use refers to the consumer use of 1-BP in products for mold cleaning and release. These products are used as anti-adhesive agents to prevent bonding between other substances by discouraging surface attachments.

e. Disposal

This condition of use refers to the process of disposing generated waste streams of 1-BP that are collected and transported to a third-party site for their final disposition, such as waste incineration or landfilling.

f. Terminology in This Proposed Rule

For purposes of this proposed rulemaking, “occupational conditions of use” refers to the TSCA conditions of use described in Units III.B.1.a., b., c., and e. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for 1-BP for purposes of distinguishing scenarios, the Agency clarified then and clarifies now that EPA interprets the authority Congress gave to the Agency to “regulat[e] any manner or method of commercial use” under TSCA section 6(a)(5) to reach both industrial and commercial uses.

Additionally, in the 2020 Risk Evaluation for the chemical substance 1-BP, EPA identified and assessed all known, intended, and reasonably foreseen industrial, commercial, and consumer uses of 1-BP, and determined in the December 2022 final revised unreasonable risk determination that 1-BP as a whole chemical substance presents unreasonable risks to health and the environment. EPA determined that all industrial, commercial, and consumer uses of 1-BP evaluated in the 2020 Risk Evaluation for 1-BP contribute to the EPA determination that 1-BP presents unreasonable risk of injury to health, except for the use of 1-BP in insulation. As such, for purposes of this risk management rulemaking, “consumer use” refers to all known, intended, and reasonably foreseen consumer uses of 1-BP, except for the use of 1-BP in insulation. Likewise, for the purpose of this risk management rulemaking, “industrial and commercial use” refers to all industrial and

commercial uses, including known, intended, or reasonably foreseen 1-BP industrial and commercial use, except for the use of 1-BP in insulation.

EPA is not proposing to incorporate the descriptions of known, intended or reasonably foreseen uses in Unit III.B.1.a. through e. into the regulatory text as definitions because these uses represent the specific uses evaluated in the 2020 Risk Evaluation for 1-BP. This risk evaluation was used to inform EPA’s determination that 1-BP presents unreasonable risk. EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2020 Risk Evaluation for 1-BP that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for 1-BP and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation if EPA were to promulgate a regulation that contains a list of the industrial and commercial conditions of use evaluated in the 2020 Risk Evaluation for 1-BP.

EPA also requests comment on whether, rather than just excluding the consumer and commercial uses of 1-BP in insulation from the prohibitions and other requirements in this risk management rulemaking, EPA should more broadly exclude the use of articles under TSCA section 6(c)(2)(E), which would also exclude the use of 1-BP in articles that were not specifically evaluated in the 2020 Risk Evaluation for 1-BP, and if so, whether and how to define “article” for the purposes of this rulemaking.

EPA further notes that this proposed rule does not apply to any substance excluded from the definition of “chemical substance” under TSCA 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

2. Description of Unreasonable Risk Under the Conditions of Use

EPA has determined that 1-BP presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks (Ref. 2). As described in the TSCA

section 6(b) 2020 Risk Evaluation for 1-BP, EPA identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to 1-BP, and cancer from chronic inhalation and dermal exposures to 1-BP (Ref. 1). For this proposed rulemaking, EPA has determined that protecting people from 1-BP-related cancer would also protect people from unreasonable risks for other 1-BP-related acute or chronic adverse health effects. EPA identified non-cancer adverse effects from acute inhalation and dermal exposures and non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use (Ref. 1). Additional risks associated with other adverse effects (e.g., developmental toxicity, reproductive toxicity, liver toxicity, kidney toxicity, neurotoxicity) were identified for acute and chronic exposures. EPA also concluded, based on EPA's Guidelines for Carcinogen Risk Assessment (Ref. 30), that 1-BP is considered to be carcinogenic to workers and ONUs by all routes of exposure and calculated cancer risks from chronic inhalation and dermal exposures. Unit VI.A. summarizes the health effects and the magnitude of the exposures (Ref. 1).

To make the unreasonable risk determination for 1-BP, EPA evaluated exposures to workers, ONUs, consumer users, and bystanders to consumer use, using reasonably available monitoring and modeling data for inhalation and dermal exposures (Ref. 2). The August 2020 Risk Evaluation for 1-BP did assess the water pathway based on environmental fate characteristics and monitoring and modeling data. Based on this analysis, EPA determined that 1-BP would be unlikely to be present in surface water (Ref. 1). EPA conducted a screening level analysis to determine whether there may be potential risks from the ambient air pathway to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities and the ongoing revisions of National Emission Standards for Hazardous Air Pollutants (NESHAPs) under the CAA is in Unit VI.A.

For the 2020 Risk Evaluation for 1-BP, EPA considered PESS. EPA identified the following groups as PESS: workers, ONUs, consumers, bystanders, and those with certain pre-existing health conditions, higher body fat content, or particular genetic polymorphisms (Ref. 1). Furthermore, the developing fetus and (by extension) women of childbearing age were identified as susceptible life stages (Ref. 1). All PESS and susceptible life stages are included in the quantitative and

qualitative analyses described in the risk evaluation and were considered in the determination of unreasonable risk for 1-BP. As discussed in Units II.D. and VI.A., the 2020 Risk Evaluation for 1-BP did not fully assess the ambient air exposure pathways to the general population in the published risk evaluation; this may have caused some risks to be unaccounted for in the risk evaluation and in EPA's risk determination. EPA considers people in communities in proximity to facilities using 1-BP who are exposed to 1-BP through the ambient air pathway to constitute a subset of the general population and categorizes them as fenceline communities; they may also be considered PESS. See Unit VI.A. for further discussion on assessing and protecting against risk to fenceline communities.

3. Description of TSCA Section 6 Requirements for Risk Management

EPA examined the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to eliminate the unreasonable risk for 1-BP. This unit summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. outlines how EPA applied these considerations specifically to managing the unreasonable risk from 1-BP.

As required, EPA developed a proposed regulatory action and one or more primary alternative regulatory actions, which are described in Units IV.A. and IV.B., respectively. To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk, inhalation and dermal, and the exposed populations. For occupational conditions of use (see Unit III.B.1.f.), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA does not have direct authority to regulate consumer use. Therefore, EPA considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of 1-BP at different points in the supply chain to eliminate exposures or restrict the availability of 1-BP and 1-BP-containing products for consumer use in order to address the unreasonable risk.

As required by TSCA Section 6(c)(2), EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its

decisions: (1) the effects of 1-BP on health and the environment, (2) the magnitude of exposure to 1-BP of human beings and the environment, (3) the benefits of 1-BP for various uses, and (4) the reasonably ascertainable economic consequences of the rule. In evaluating the reasonably ascertainable economic consequences of the proposed rule, EPA considered (1) the likely effect of the proposed rule on the national economy, small business, technological innovation, the environment, and public health, (2) the costs and benefits of the proposed regulatory action and one or more primary alternative regulatory actions considered, and (3) the cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered. See Unit VI. for further discussion related to TSCA section 6(c)(2)(A) considerations, including the statement of effects of the proposed rule with respect to these considerations.

EPA also considered the regulatory authority under TSCA and other statutes such as the OSH Act, the Consumer Product Safety Act (CPSA), and other EPA-administered statutes to examine (1) whether there are opportunities for all or part of risk management action on 1-BP to be addressed under other statutes, such that a referral may be warranted under TSCA sections 9(a) or 9(b); or (2) whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes to minimize confusion to the regulated entities and the general public.

In addition, EPA followed other TSCA requirements such as considering the availability of alternatives when contemplating prohibition or a substantial restriction (TSCA section 6(c)(2)(C), as outlined in Unit V.B.), and setting proposed compliance dates in accordance with the requirements in TSCA section 6(d)(1) (described in the proposed and alternative regulatory actions in Unit IV.).

To the extent information was reasonably available, when selecting regulatory actions, EPA considered pollution prevention and the hierarchy of controls adopted by OSHA and NIOSH, with the goal of identifying risk management control methods that are permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the regulated entities where appropriate. EPA considered the information presented in the 2020 Risk Evaluation for 1-BP, as well as additional input from stakeholders (as described in Unit III.A.), and anticipated

compliance strategies from regulated entities.

Taken together, these considerations led EPA to the proposed regulatory action and primary alternative regulatory actions described in Unit IV. Additional details related to how the requirements in this unit were incorporated into development of those actions are in Unit V.

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this proposed rule in addressing them independently, EPA generally intends the rule's provisions to be severable from each other. EPA expects to provide additional detail on severability in the final rule once the Agency has considered public comments and finalized the regulatory language.

IV. Proposed and Alternative Regulatory Actions

This unit describes the proposed regulatory action by EPA so that 1-BP will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section 6(c)(2)(A), EPA must consider the costs and benefits and the cost-effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of 1-BP, the proposed regulatory action is described in Unit IV.A. and the two alternative regulatory actions considered are described in Unit IV.B. An overview of the proposed regulatory action and two alternative regulatory actions for each condition of use is in Unit IV.C. The rationale for the proposed and alternative regulatory actions and associated compliance timeframes are discussed in this unit and in more detail in Unit V.A.

A. Proposed Regulatory Action

EPA is proposing under TSCA section 6(a) to: (1) prohibit the manufacture (including import), processing, and distribution in commerce of 1-BP for all consumer uses, excluding the use of 1-BP in insulation, outlined in Unit IV.A.1.b.; (2) prohibit the industrial and commercial use of 1-BP for four occupational uses, and the manufacture (including import), processing, and distribution in commerce of 1-BP for those uses, outlined in Unit IV.A.1.a.; (3) require strict workplace controls, including a 1-BP WCPP, which would include requirements to meet an inhalation exposure concentration limit and use of gloves for seven occupational conditions of use, outlined in Unit IV.A.2.; (4) require self-certification, which would document the purchaser's commitment to comply with the 1-BP

WCPP, for six occupational conditions of use, outlined in Unit IV.A.1.4.; (5) require the use of prescriptive controls for six occupational conditions of use, outlined in Unit IV.A.1.3.; and (6) establish recordkeeping and downstream notification requirements, outlined in Unit IV.A.5. Pursuant to TSCA section 12(a)(2), this proposed rule would apply to 1-BP even if being manufactured, processed, or distributed in commerce solely for export from the United States because EPA has determined that 1-BP presents an unreasonable risk to health within the United States or to the environment of the United States.

EPA notes that some uses identified for prohibitions, the WCPP, or self-certification were identified within larger conditions of use in the 2020 Risk Evaluation for 1-BP. The regulatory action proposed for each use is described in this unit, and the rationale is provided in Unit V.

1. Prohibitions of Manufacturing, Processing, Distribution in Commerce, and Use

a. Prohibition of Certain Industrial and Commercial Uses and Manufacturing, Processing, and Distribution of 1-BP for Those Uses

EPA is proposing to prohibit the manufacturing, processing, distribution in commerce, and use of 1-BP for industrial and commercial uses of 1-BP except for those uses which would continue under the WCPP, self-certification, and/or prescriptive controls. The proposed prohibitions under TSCA would not apply to any use of 1-BP that is excluded from TSCA's definition of "chemical substance" under TSCA section 3(2)(B)(ii)(vi). This proposed prohibition would include a prohibition on the manufacturing (including import), processing, distribution in commerce, and use of 1-BP for the following industrial and commercial uses:

- In adhesives and sealants;
- In dry cleaning solvents, spot cleaners and stain removers;
- In coin and scissor cleaner (liquid, spray, or aerosol cleaners); and
- In other uses in arts, crafts, hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); functional fluids (closed/open-systems)—refrigerant/cutting oils.

As discussed in Units III.B.3. and V.A., based on consideration of alternatives under TSCA section 6(c)(2)(C), uncertainty relative to the

feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad ranges of work environments and activities, and the irreversible health effects associated with 1-BP exposures, EPA has determined that prohibition is the best way to address the unreasonable risks from 1-BP contributed by the conditions of use identified in this unit. As noted in Unit III.B.1.f., this proposal does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi).

EPA is proposing to stagger the compliance dates for the proposed prohibitions described in this unit, such that the requirements would come into effect in 6 months for manufacturers, 9 months for processors, 12 months for distributing to retailers, 15 months for all distributors (including retailers), and 18 months for industrial and commercial users after the publication date of the final rule. When proposing these compliance dates as required under TSCA section 6(d), EPA considered the irreversible health effects and risks associated with 1-BP exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time would be needed for products to clear the channels of trade. For 1-BP, for the conditions of use EPA is proposing to prohibit, the Agency believes either 1-BP may no longer be used, or regulated entities would be able to meet the proposed regulatory compliance timeframes, due to availability of alternatives. EPA recognizes that for other proposed regulations under TSCA section 6, including methylene chloride (88 FR 28284, May 3, 2023 (FRL-8155-02-OCSP)), perchloroethylene (88 FR 39652, June 16, 2023) (FRL-8329-02-OCSP), and carbon tetrachloride (88 FR 49180, July 28, 2023) (FRL-8206-01-OCSP), public comments have provided information in support of longer compliance timeframes. Similarly, for 1-BP, EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the use of substitutes; comments should include documentation such as the specific use of the chemical throughout the supply chain; concrete steps taken to identify, test, and qualify substitutes for those uses (including details on the substitutes tested and the specific certifications that would require updating); and estimates of the time

required to identify, test, and qualify substitutes with supporting documentation. EPA also requests comment on whether there are other considerations that should apply. EPA may finalize shorter or significantly longer compliance timeframes based on consideration of public comments. EPA would also like comment on whether it should consider a *de minimis* level of 1-BP in formulations for certain continuing industrial and commercial uses to account for impurities (e.g., 0.1% or 0.5%) when finalizing these prohibitions, and, if so, what level should be considered *de minimis*.

b. Prohibition of Manufacturing, Processing and Distribution in Commerce of 1-BP for Consumer Use

In the 2020 Risk Evaluation for 1-BP, EPA evaluated consumer uses of 1-BP:

- As a solvent in aerosol spray degreasers/cleaners;
- In spot cleaners and stain removers;
- In liquid coin cleaners (e.g., coin and scissor cleaners);
- In liquid spray/aerosol cleaners;
- In arts, crafts, hobby materials (adhesive accelerant);
- In automotive care products (refrigerant flush);
- In anti-adhesive agents (mold cleaning and release products); and
- In building/construction materials in insulation.

The consumer uses evaluated in the 2020 Risk Evaluation for 1-BP constitute all known, intended, and reasonably foreseen consumer uses of 1-BP. EPA determined that all of these consumer uses, except for the use of 1-BP in insulation, contribute to unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, “consumer use” refers to all consumer uses including known, intended, and reasonably foreseen consumer uses for 1-BP. EPA is proposing to prohibit the manufacturing, processing, and distribution in commerce of 1-BP for consumer use, except for the consumer use of 1-BP in insulation.

As discussed in Units III.B.3. and V.A., based on consideration of the severity of the hazards of 1-BP in conjunction with the limited options available to adequately address the identified unreasonable risk to consumers and bystanders under TSCA section 6(a), EPA is proposing to address the unreasonable risk from consumer use by prohibiting the manufacturing (including import), processing, and distribution in commerce of 1-BP for consumer use, in order to remove 1-BP and products containing 1-BP from the market,

thereby effectively eliminating instances of consumer use that contribute to the unreasonable risk of injury to health.

Additionally, EPA is proposing to prohibit retailers from distributing in commerce 1-BP, including any 1-BP-containing products except insulation products, in order to prevent products intended for industrial and commercial use from being purchased by consumers. A retailer is any person or business entity that distributes or makes available chemical substances or products containing chemical substances to consumers, including through e-commerce internet sales or distribution. If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (as EPA proposes to define that term in 40 CFR 751.5). For a distributor not to be considered a retailer, the distributor must distribute or make available chemical substances solely to commercial or industrial end-users or businesses. Prohibiting manufacturers (including importers), processors, and distributors from distributing 1-BP, or any products except insulation containing 1-BP, to retailers would prevent retailers from making these products available to consumers, which would help address that part of the unreasonable risk associated with consumer use of 1-BP. EPA is requesting comment on commercial distribution channels or systems that would allow for distribution to commercial users while preventing retailers from making these products available to consumers, or feasible distribution channels for commercial users that have been developed in analogous situations, including information on whether there are market barriers to such systems.

EPA is proposing that the prohibitions of manufacturing, processing, and distribution in commerce of 1-BP for consumer use described in this unit would become effective in 6 months for manufacturers, 9 months for processors, 12 months for distributing to retailers, and 15 months for all other distributors (including retailers) after the publication date of the final rule in the **Federal Register**. EPA considered the irreversible health effects and risks associated with 1-BP when proposing compliance dates. EPA has no reasonably available information indicating these proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for

example, for products to clear the channels of trade. EPA may finalize shorter or significantly longer compliance timeframes based on public comment.

2. Workplace Chemical Protection Program (WCPP)

a. Overview

As described in Unit III.B.3., under TSCA section 6(a), EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to health or the environment from a chemical substance is no longer presented. The TSCA section 6(a) requirements provide EPA the authority to limit or restrict a number of activities, alone or in combination, including the manufacture, processing, distribution in commerce, commercial use, and disposal of the chemical substance. Given this authority, EPA may find it appropriate in certain circumstances to propose requirements under a WCPP for certain occupational (i.e., manufacturing, processing, industrial and commercial use, and disposal) conditions of use. A WCPP for 1-BP would encompass the inhalation exposure limit and action level, the associated implementation requirements, and may include other components, such as respiratory protection or dermal protection, as described in this unit to ensure that the chemical substance no longer presents unreasonable risk. Under a WCPP, owners or operators would have some flexibility, within the parameters outlined in this unit, regarding how they prevent exceedances of the identified EPA exposure limit thresholds. In the case of 1-BP, meeting the EPA exposure limits, in tandem with other requirements as listed in this proposed rule, for certain occupational conditions of use would address unreasonable risk to potentially exposed persons from inhalation and dermal exposure.

EPA uses the term “potentially exposed person” in this unit and in the regulatory text to include workers, occupational non-users, employees, independent contractors, employers, and all other persons in the work area where 1-BP is present and who may be exposed to 1-BP under the conditions of use for which a WCPP would apply. One important reason to define a potentially exposed person for the purposes of a WCPP as any person who may be exposed in the workplace is to emphasize the broad scope of exposures which must be categorized when

implementing a WCPP. EPA notes that this definition is intended to apply only in the context of risk management, and specifically in the context of a WCPP (e.g., workers directly using the chemical, workers in the vicinity of the use, students in a laboratory setting). The term is not intended as a replacement for the term Potentially Exposed or Susceptible Subpopulation as defined by TSCA section 3(12). EPA additionally recognizes that other individuals or communities may be exposed to 1-BP as consumers, members of fence-line communities, or members of the general population, which is separate and apart from those potentially exposed for the purposes of the regulatory requirements of the WCPP. In those instances, where regulatory requirements address exposures unrelated to a WCPP EPA would use distinct terminology to refer to those other populations. EPA's intention is to require a comprehensive WCPP that would address the unreasonable risk from 1-BP to potentially exposed persons directly handling the chemical or in the area where the chemical is being used.

Similarly, the 2020 risk evaluation for 1-BP did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of 1-BP. EPA uses the term "owner or operator" to describe the entity responsible for implementing the WCPP for workplaces where an applicable condition of use of 1-BP is occurring. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

An ECEL is a risk-based inhalation exposure threshold. The ECEL would be accompanied by monitoring, training, recordkeeping and other requirements to help ensure that the threshold is not exceeded. With an ECEL, regulated entities have some flexibility, within certain parameters outlined in this unit, for preventing exceedances of the identified exposure threshold. Therefore, EPA generally refers to the ECEL and ancillary requirements as a non-prescriptive approach. In the case of 1-BP, the exposure threshold identified by EPA for certain occupational conditions of use would mitigate unreasonable risks from inhalation exposure contributed by those conditions of use for potentially exposed persons.

This unit includes a summary of the proposed 1-BP WCPP, including a description of the ECEL; proposed implementation requirements and a TSCA ECEL action level; proposed monitoring requirements; a description

of potential exposure controls, which consider the hierarchy of controls; information that may be used to inform PPE selection; and additional requirements proposed for recordkeeping, and worker training, participation, and notification. This unit also describes compliance timeframes for these proposed requirements.

b. Existing Chemical Exposure Limit (ECEL)

i. ECEL and ECEL Action Level

To reduce exposures in the workplace and address the unreasonable risk of injury to health resulting from inhalation exposures to 1-BP identified under the occupational conditions of use in the TSCA 2020 Risk Evaluation for 1-BP, EPA is proposing an ECEL of 0.05 parts per million (ppm) (0.25 mg/m³) for inhalation exposures to 1-BP as an 8-hour TWA. This ECEL is based on the cancer inhalation unit risk (IUR) at a risk level of 1×10^{-4} , which is the most sensitive hazard value across acute, chronic non-cancer, and cancer endpoints, (Refs. 12, 1). As described in the ECEL memo documenting EPA's approach for determining the exposure limit, EPA expects that, at the ECEL value of 0.05 ppm based on the cancer endpoint, a worker or ONU is protected against other endpoints, including developmental effects.

EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL would eliminate the contribution to the unreasonable risk of injury to health for 1-BP resulting from inhalation exposures in an occupational setting. EPA is proposing to establish requirements to meet an ECEL as part of the WCPP for:

- Manufacturing (domestic manufacturing);
- Processing as incorporation into a formulation, mixture, or reaction products;
- Industrial and commercial use as a solvent in open-top and in-line batch vapor degreasing;
- Industrial and commercial use as a solvent in closed-loop vapor degreasing;
- Industrial and commercial use as a solvent for cleaning and degreasing in cold cleaners;
- Industrial and commercial use as a solvent in aerosol spray degreaser/cleaner; and
- Industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals; asphalt extraction; and coatings for temperature indicators.

Each owner or operator of a workplace where these conditions of

use occur would be responsible for compliance with the ECEL and the associated requirements. EPA's description for how the requirements related to an ECEL would address the unreasonable risk resulting from inhalation exposures and the rationale for this regulatory approach are outlined in Units III.B.3. and V.A.

If ambient exposures are kept at or below the 8-hour ECEL of 0.05 ppm, EPA expects that a potentially exposed person in the workplace would be protected against non-cancer effects resulting from occupational exposures, as well as excess risk of cancer (Ref. 12).

EPA is also proposing to establish an ECEL action level of 0.03 ppm as an 8-hour TWA for 1-BP. Air concentrations at or above the action level would trigger more frequent periodic monitoring of exposures to 1-BP, as described in this unit. EPA is proposing to adopt the action level approach in implementing the TSCA ECEL, consistent with the action level approach utilized by OSHA in the implementation of OSHA standards. As explained by OSHA, due to the variable nature of employee exposures, compliance with an action level provides employers with greater assurance that their employees will not be exposed to concentrations above the PELs (Ref. 31). EPA agrees with this reasoning and, like OSHA, expects the inclusion of an ECEL action level will stimulate innovation within industry to reduce exposures to levels below the action level. Therefore, EPA has identified a need for an action level for 1-BP and is proposing a level that is lower than the 8-hour ECEL, which is in alignment with the precedented approach established under most OSHA standards. EPA is soliciting comment regarding an ECEL action level that is lower than the ECEL.

In summary, EPA is proposing that each owner or operator of a workplace subject to the ECEL must ensure that no person is exposed to airborne concentration of 1-BP in excess of 0.05 ppm as an 8-hr TWA, with an action level identified as 0.03 ppm as an 8-hr TWA. For conditions of use for which requirements to meet an ECEL are being proposed, EPA believes that the regulated community has the ability to detect the values for the ECEL and ECEL action level as they are above the threshold of 1-BP monitoring devices, which can detect concentration levels as low as ≤ 0.0005 ppm (Ref. 12). The Agency has also identified personal breathing zone air sampling devices with a minimum limit of quantitation and level of detection at the ECEL level. (Ref. 12) EPA is requesting comment on

issues around the viability of current analytical methods and detection limits for occupational 1-BP sampling and/or monitoring methods, including information on the availability of laboratory capacity needed to meet the proposed standard, and the costs associated with such testing. EPA's methodology and inputs for the ECEL value are directly derived from the peer reviewed analysis in the August 2020 Risk Evaluation, which was also subject to public comment. See Ref 2 for additional information on the ECEL value and cancer risk. As with all aspects of this rulemaking, the public is welcome to comment on the methodology for the ECEL value and ECEL action level.

EPA expects that many workplaces already have stringent controls in place that reduce exposures to 1-BP; for some workplaces, including those engaged in vapor degreasing, cold cleaning, and use of 1-BP in electronics and electronic products, EPA understands that these existing controls may already reduce 1-BP air concentration levels to near or below the ECEL (Ref. 32). As discussed further in Unit V.A.1., for some conditions of use for which EPA is proposing the ECEL, data were submitted during the risk evaluation that indicate inhalation exposures may already be near or below the ECEL for some facilities, indicating that such facilities may already be in compliance with the proposed ECEL. As noted previously in this unit, EPA expects that, if inhalation exposures for affected occupational conditions of use are kept at or below the ECEL, potentially exposed persons reasonably likely to be exposed in the workplace would be protected from the unreasonable risk.

EPA is also proposing to require owners or operators to comply with additional requirements under the WCPP that would be needed to ensure successful implementation of the ECEL.

ii. Monitoring Results

Overview. Monitoring requirements are a key component of implementing EPA's proposed WCPP. Initial monitoring for 1-BP is critical for establishing a baseline of exposure for potentially exposed persons; similarly, periodic exposure monitoring assures continued compliance so that potentially exposed persons in the workplace are not exposed to levels that would result in an unreasonable risk of injury. Periodic exposure monitoring frequency could change if certain conditions are met, which are described in this unit. Additionally, in some cases, a change in workplace conditions with potential to impact exposure levels

would warrant additional monitoring, which is also described. To ensure compliance with monitoring activities, EPA proposes exposure monitoring recordkeeping requirements outlined in this unit.

Initial Exposure Monitoring. Under the proposed regulation, each owner or operator of a workplace where any conditions of use listed earlier in this unit is occurring would be required to perform initial exposure monitoring to determine the extent of exposure of potentially exposed persons to 1-BP. Initial monitoring would notify owner or operators of the magnitude of possible exposures to their potentially exposed persons with respect to their unique work conditions and environments. The results of the initial exposure monitoring would determine the frequency of future periodic monitoring, whether additional exposure controls are necessary (such as engineering controls, administrative controls, and/or respiratory protection), and whether the owner or operator would need to demarcate a regulated area as described in this unit.

EPA is proposing to require each owner or operator to establish an initial baseline monitoring sample to determine the magnitude of exposure for all persons who may be exposed to 1-BP within 33 months for Federal agencies and Federal contractors acting for or on behalf of the Federal Government and within 6 months after the date of publication of the final rule in the **Federal Register** for non-Federal owners and operators, or within 30 days of introduction of 1-BP into the workplace, whichever is later. Where 1-BP is present in the workplace, each owner or operator would be required to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person or taking personal breathing zone air samples that are representative of each potentially exposed person's exposure performing the same or substantially similar operations in each work shift, in each job classification, and in each work area (hereinafter identified as an "exposure group"). Personal breathing zone air samples are representative of the 8-hour TWA of all potentially exposed persons in an exposure group if the samples are of at least one person's full-shift exposure who represents the highest potential 1-BP exposures in that exposure group. Monitoring samples must be taken when and where the operating conditions are best representative of each potentially exposed person's full-shift exposures. EPA expects that owners and operators

would attempt to monitor a baseline for all of the tasks during the same timeframe; however, EPA understands that certain tasks occur less frequently, and EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving 1-BP where exposures may approach the ECEL action level. If the owner or operator chooses a representative sample, such sampling must include persons that are the closest to the source of 1-BP, so that the monitoring results are representative of the most highly exposed persons in the workplace.

EPA also recognizes that some entities may already have exposure monitoring data. If the owner or operator has monitoring data conducted within five years prior to the effective date of the final rule and the monitoring satisfies all other requirements of this section, including the requirement that the data represent the highest 1-BP exposures likely to occur under reasonably foreseeable conditions of use, the owner or operator may rely on such earlier monitoring results for the initial baseline monitoring sample.

Periodic exposure monitoring. EPA is proposing to require each owner or operator to conduct, for those exposure groups that exceed the following airborne concentration levels, the following periodic monitoring:

- If samples taken during the initial exposure monitoring reveal a concentration below the ECEL action level (<0.03 ppm 8-hr TWA), the owner or operator must repeat the periodic exposure monitoring at least once every 5 years.
- If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (>0.05 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 3 months of the most recent exposure monitoring.
- If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level (≥ 0.03 ppm 8-hour TWA) but at or below the ECEL (≤ 0.05 ppb 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 6 months of the most recent exposure monitoring.
- If the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the ECEL action level, the owner or operator must repeat such monitoring within 6 months of the most recent monitoring until two consecutive monitoring measurements, taken at least seven days apart, are below the ECEL action level (<0.03 ppb 8-hour TWA), at which time the owner

or operator must repeat the periodic exposure monitoring at least once every 5 years.

Additionally, in instances where an owner or operator does not manufacture, process, use, or dispose of 1-BP for a condition of use for which the WCPP is proposed over the entirety of time since the last required periodic monitoring event, EPA is proposing that the owner or operator would be

permitted to forgo the next periodic monitoring event. However, documentation of cessation of use of 1-BP would be required and periodic monitoring would be required to resume should the owner or operator restart any of the conditions of use listed in Unit IV.A.2. for which the WCPP is proposed. The timeframe for periodic monitoring after an owner or operator restarts a condition of use would be

based on the most recent monitoring measurements and the timeframe would begin from the date of restart.

The proposed periodic monitoring requirements are also outlined in Table 1. EPA requests comment on the proposed timeframes for periodic monitoring outlined in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on public comment.

TABLE 1—PERIODIC MONITORING REQUIREMENTS

Air concentration condition	Periodic monitoring requirement
If initial exposure monitoring is below the ECEL action level (<0.03 ppm 8-hour TWA).	Periodic exposure monitoring is required at least once every five years.
If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (>0.05 ppm 8-hr TWA).	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level, but at or below the ECEL (≥ 0.03 ppm 8-hr TWA, ≤ 0.05 ppm 8-hr TWA).	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart within a 6 month period, indicate exposure is below the ECEL action level (<0.03 ppm 8-hr TWA).	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which the ECEL would be required but does not manufacture, process, use, or dispose of 1-BP in that condition of use over the entirety of time since the last required monitoring event.	The owner or operator may forgo the next periodic monitoring event. However, documentation of cessation of use of 1-BP is required and periodic monitoring would be required immediately when the owner or operator resumes any condition of use.

Additional exposure monitoring. In addition to the initial and periodic exposure monitoring, EPA is proposing that each owner or operator conduct additional exposure monitoring within 30 days after there has been a change in the production, process, control equipment, personnel or work practices that may reasonably be expected to result in new or additional exposures at or above the ECEL action level, or when the owner or operator has any reason to believe that new or additional exposures at or above the ECEL action level have occurred, for example if an owner or operator receives information from potentially exposed person(s) suggesting that such new or additional exposures may have occurred. In the event of start-up, shutdown, spills, leaks, ruptures or other breakdowns or unexpected releases that may lead to employee exposure, EPA is proposing that each owner or operator must conduct exposure monitoring of potentially exposed persons (using personal breathing zone sampling) within 30 days after the conclusion of the start-up or shutdown and/or the cleanup of the spill or repair of the leak, rupture or other breakdown. An additional exposure monitoring event may result in an increased frequency of periodic monitoring. For example, if the initial monitoring results from a workplace are above the ECEL action level, but below the ECEL, periodic monitoring is required every 6 months. If additional

monitoring is performed because increased exposures are suspected, and the results are above the ECEL, subsequent periodic monitoring would have to be performed every 3 months. The required additional exposure monitoring should not delay implementation of any necessary cleanup or other remedial action to reduce the exposures to persons in the workplace.

EPA is requesting comment on the proposed timeframe of within 30 days to conduct additional exposure monitoring after there has been a change in the production, process, control equipment, personnel or work practices may reasonably be expected to result in new or additional exposures at or above the ECEL action level, or when the owner or operator has any reason to believe that new or additional exposures at or above the ECEL action level have occurred. EPA is also requesting comment on the proposed timeframe of within 30 days to conduct additional exposure monitoring after the cleanup of the spill or repair of the leak, rupture or other breakdown.

Other monitoring requirements. For each monitoring event, EPA is proposing to require owners or operators to ensure that their methods are accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of 1-BP. Also, EPA is proposing to require use of appropriate sampling and analytical methods used to determine 1-

BP exposure such as use of an analytical method already approved by EPA, OSHA or NIOSH, or another analytical method that has been demonstrated to meet the proposed accuracy requirement at an appropriate level of detection for the ECEL and ECEL action level by a laboratory in compliance with the Good Laboratory Practice Standards at 40 CFR part 792, or use of a laboratory accredited by the AIHA or another industry-recognized program, as required by proposed 751.807(b)(2)(i)(C). Additionally, EPA is proposing to require owners and operators to re-monitor within 15 working days after receipt of the results of any exposure monitoring when results indicate non-detect or air monitoring equipment malfunction, unless an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.

EPA is also proposing to require that each owner or operator maintain exposure monitoring records that include the following information for each monitoring event:

(A) Dates, duration, and results of each sample taken.

(B) All measurements that may be necessary to determine the conditions (e.g., work site temperatures, humidity, ventilation rates, monitoring equipment type and calibration dates) that may affect the monitoring results.

(C) Name, workplace address, work shift, job classification, and work area of the person monitored; documentation of all potentially exposed persons whose exposures the monitoring is intended to represent if using a representative sample; and type of respiratory protective device worn by the monitored person, if any.

(D) Use of appropriate sampling and analytical methods, such as analytical methods already approved by EPA, OSHA or NIOSH, or compliance with an analytical method verification procedure.

(E) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792.

(F) Information regarding air monitoring equipment, including: type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

iii. Incorporation of the Hierarchy of Controls

EPA is proposing to require owners or operators to implement the WCPP in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. Pollution prevention, also known as source reduction, is any practice that reduces, eliminates, or prevents pollution at its source (*e.g.*, elimination and substitution). Similarly, the hierarchy of controls includes, in order of preference, elimination, substitution, engineering controls, and administrative controls, prior to relying on PPE as a means of controlling exposures (Ref. 8). EPA is proposing to require owners or operators to reduce inhalation exposures to or below the ECEL in accordance with the hierarchy of controls. EPA expects that, for conditions of use for which EPA is proposing a WCPP, compliance at most workplaces would be part of an existing industrial hygiene program. Workplaces that cannot feasibly eliminate the source of 1-BP emissions or replace 1-BP with a substitute would have to use engineering and/or administrative controls to implement process changes to reduce exposures to the extent feasible, following the hierarchy of controls (Ref. 8). If an owner or operator chooses to replace 1-BP with a substitute, EPA recommends that they carefully review the available hazard and exposure information on the potential substitutes to avoid a substitute chemical that might later be found to present unreasonable risks or be subject to regulation (sometimes referred to as a “regrettable substitute”).

If an effort to identify and implement feasible exposure controls such as elimination, substitution, engineering controls, and administrative controls is not sufficient to reduce exposures to or below the ECEL for all persons in the workplace, EPA proposes to require each owner or operator to use such controls to reduce 1-BP concentrations in the workplace to the lowest levels achievable and, only after levels cannot be further reduced, supplement these controls using respiratory protection before persons are permitted to enter a regulated area, as described in this unit. In such cases, EPA would require that the owner or operator provide those persons exposed or who may be exposed to 1-BP by inhalation above the ECEL with respirators sufficient to ensure that their exposures do not exceed the ECEL, as described in this unit. EPA also proposes to require that each owner or operator document their evaluation of elimination, substitution, engineering and administrative exposure control strategies, and if applicable the reasons why they found these strategies infeasible to control exposures to or below the ECEL, in an exposure control plan as described in this unit. In addition, a regulated entity would be prohibited from rotating work schedules of potentially exposed persons to comply with the ECEL 8-hour TWA. EPA may require more, less, or different documentation regarding exposure control strategies in the final rule based on consideration of public comments.

The Agency understands that certain engineering controls can reduce exposures to people inside the workplace but may lead to increased ventilation of 1-BP outside of the workplace, thereby increasing risks to people in fence-line communities of adverse health effects from exposures to 1-BP in ambient air. Therefore, EPA is proposing to prohibit increased releases of 1-BP to outdoor air associated with the implementation of the WCPP. This proposed requirement is intended to avoid unintended increases in exposures to people from 1-BP emissions to ambient air. The proposed rule would require owners and operators to attest in their WCPP exposure control plan that engineering controls selected do not increase emissions of 1-BP to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of 1-BP to ambient air. EPA requests comment on how this proposed requirement may impact the availability, feasibility, or cost of

engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

iv. Regulated Area

Based on the exposure monitoring, EPA is proposing to require that owners or operators of workplaces subject to a WCPP demarcate any area where airborne concentrations of 1-BP exceed or are reasonably expected to exceed the ECEL. Regulated areas would be demarcated using administrative controls, such as warning signs or highly visible signifiers, in multiple languages as appropriate (*e.g.*, based on languages spoken by potentially exposed persons), placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from any potentially exposed person who lacks proper training, is not wearing required PPE as described in this unit or is otherwise unauthorized to enter. EPA is proposing to require owners and operators to demarcate and establish a regulated area beginning 36 months for Federal agencies and Federal contractors acting for or on behalf of the Federal Government and beginning 9 months for non-Federal owners and operators after the date of publication of the final rule, or within 4 after introduction of 1-BP into the workplace if 1-BP use commences 9 months after the date of publication of the final rule in the **Federal Register**. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA’s General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

v. Notification of Monitoring Results

EPA proposes that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate location accessible to all persons whose exposure is represented by the monitoring, such as public spaces or common areas, outside the regulated area. This notice must include the exposure monitoring results, identification and explanation of the ECEL and ECEL action level in plain language, any corresponding required respiratory protection, if applicable, the quantity, location, manner of 1-BP use and identified releases of 1-BP that could result in exposure to 1-BP at the time of monitoring. The notice must also include a description of actions

taken by the owner or operator to reduce inhalation exposures to or below the ECEL, if applicable, or refer to a document available to the potentially exposed persons which states the actions to be taken to reduce exposures, and must be posted in multiple languages if necessary (e.g., notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest group of workers who cannot readily comprehend or read English).

c. Personal Protective Equipment (PPE) Program

Where elimination, substitution, engineering controls, and administrative controls are not feasible to reduce the air concentration to or below the ECEL for all potentially exposed persons, EPA is proposing to require implementation of a respiratory PPE program in alignment with OSHA's Respiratory Protection Standard at 29 CFR 1910.134. EPA is also proposing to require implementation of a dermal PPE program. Owners and operators would be required to provide PPE, including respiratory protection and dermal protection selected in accordance with the guidelines described in this unit, that is of safe design and construction for the work to be performed. EPA is proposing to require owners and operators to ensure each potentially exposed person who is required by this unit to wear PPE to use and maintain PPE in a sanitary, reliable, and undamaged condition. Owners and operators would be required to select and provide PPE that properly fits each potentially exposed person who is required by this unit to use PPE and communicate PPE selections to each affected person.

As part of the PPE program, EPA is also proposing that owners and operators must comply with OSHA's PPE training requirements at 29 CFR 1910.132(f) or 29 CFR 1910.134(k) for application of a PPE training program, including providing training on proper use of PPE (e.g., when and where PPE is necessary, proper application, wear, and removal of PPE, maintenance, useful life, and disposal of PPE). EPA is proposing that owners and operators would provide PPE training to each potentially exposed person who is required by this unit to wear PPE prior to or at the time of initial assignment to a job involving potential exposure to 1-BP. Owners and operators would also have to re-train each affected person at least once annually or whenever the owner or operator has reason to believe that a previously trained person does

not have the required understanding and skill to properly use PPE, or when changes in the workplace or in the PPE to be used render the previous training obsolete.

This unit includes a description of the PPE Program, including proposed PPE as it relates to respiratory protection, proposed PPE as it relates to dermal protection, and other proposed requirements such as additional training for respirators and recordkeeping to support implementation of a PPE program.

i. Respiratory Protection

Where elimination, substitution, engineering controls, and administrative controls are not feasible to reduce the air concentration to or below the ECEL, EPA proposes to set minimum respiratory PPE requirements based on an entity's most recent measured air concentration and the level of PPE that EPA determined would be needed to reduce exposure to the ECEL. In those circumstances, EPA is proposing to require a respiratory protection PPE program with worksite-specific procedures and elements for required respirator use. The respiratory protection PPE program proposed by EPA would be based on the most recent exposure monitoring concentration measured as an 8-hour TWA and would be administered by a suitably trained program administrator. EPA is also proposing to require each owner or operator select respiratory protection in accordance with the guidelines described in this unit and 29 CFR 1910.134(a) through (l), except (d)(1)(iii) for proper respirator use, maintenance, fit-testing, medical evaluation, and training. EPA is not proposing to cross reference 29 CFR 1910.134(d)(1)(iii) because the proposed WCPP contains requirements for identifying 1-BP respiratory hazards in the workplace, including monitoring requirements.

Required Respiratory Protection. EPA is proposing to require that each owner or operator supply a respirator, selected in accordance with this unit, to each person who enters a regulated area within 3 months after the receipt of any exposure monitoring that indicates exposures exceeding the ECEL, or receipt of any exposure monitoring that indicates non-detect or air monitoring equipment malfunction resulting in an unknown concentration, and thereafter must ensure that all persons within the regulated area are using the provided respirators whenever 1-BP exposures exceed or can reasonably be expected to exceed the ECEL, or receipt that indicate non-detect or air monitoring equipment malfunction resulting in an unknown

concentration. Given the risks associated with 1-BP exposure above the ECEL, prompt compliance with the respiratory protection requirements is important, but EPA expects that most owners or operators will need some time after the exposure monitoring results are received to acquire the correct respirators and establish a respiratory protection program, including training, fit-testing, and medical evaluations. EPA believes that 3 months should be sufficient for this purpose. EPA is also proposing that owners or operators who are required to administer a respiratory protection PPE program must supply a respirator selected in accordance with 29 CFR 1910.134(d)(1) (except (d)(1)(iii)). Additionally, EPA is proposing that the owner or operator must ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. 29 CFR 1910.134(d)(3)(iii), which EPA is proposing to cross-reference, requires either the use of respirators with an end-of-life service indicator certified by NIOSH for the contaminant, in this case 1-BP, or implementation of a change schedule for canisters and cartridges that ensures that they are changed before the end of their service life. EPA is also requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene (29 CFR 1910.1051), or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (29 CFR 1910.1028(g)(3)(D)).

EPA is proposing to establish minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the following proposed requirements may be used. While this unit includes respirator selection requirements for respirators of assigned protection factors (APF) of 1,000 or greater, EPA does not anticipate that respirators beyond APF 50 would be widely or regularly used to address unreasonable risk, particularly when other controls are put in place. EPA is proposing the following requirements for respiratory protection, based on the exposure monitoring concentrations measured as an 8-hour TWA that exceed the ECEL (0.05 ppm):

- *If the measured exposure concentration is at or below 0.05 ppm:* no respiratory protection is required.

- *If the measured exposure concentration is above 0.05 ppm and less than or equal to 0.5 ppm (10 times ECEL):* Any NIOSH Approved® air-purifying half mask respirator equipped with organic vapor cartridges or canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in demand mode equipped with a half mask; or any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a demand mode equipped with a half mask [APF 10].

- *If the measured exposure concentration is above 0.50 ppm and less than or equal to 1.25 ppm (25 times ECEL):* Any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) equipped with a loose-fitting facepiece or hood/helmet equipped with organic vapor cartridges or canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood [APF 25].

- *If the measured exposure concentration is above 1.25 ppm and less than or equal to 2.5 ppm (50 times ECEL):* Any NIOSH Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous flow mode equipped with a half mask; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in a pressure-demand or other positive-pressure mode with a half mask; or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet/hood [APF 50].

- *If the measured exposure concentration is above 2.5 ppm and less than or equal to 50 ppm (1,000 times ECEL):* Any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) equipped with a full facepiece equipped with organic vapor cartridges or canisters; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with full facepiece; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a helmet or hood and has been tested to

demonstrate performance at a level of a protection of APF 1,000 or greater. [APF 1,000].

- *If the measured exposure concentration is greater than 50 ppm (10,000 times ECEL) or the concentration is unknown:* Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or helmet/hood [APF 10,000].

EPA proposes to require that owners and operators document respiratory protection used and PPE program implementation. EPA proposes to require that owners and operators document in the exposure control plan or other documentation of the facility's safety and health program information relevant to the respiratory program, including records on the name, workplace address, work shift, job classification, work area, and type of respirator worn (if any) by each potentially exposed person, maintenance, and fit-testing, as described in 29 CFR 1910.134(f), and training in accordance with 29 CFR 1910.132(f) and 29 CFR 1910.134(k).

ii. Dermal Protection

EPA is proposing to require owners or operators to provide and ensure potential exposed persons use chemically resistant gloves made of supported polyvinyl alcohol or a multiple-layer laminated material, in accordance with the OSHA/NIOSH Hazard Alert (Ref. 14), in combination with specific activity training (e.g., procedure for glove removal and disposal) for tasks where dermal exposure can be expected to occur. EPA is proposing that owners and operators must also consider other glove factors, such as whether gloves are tested using American Society for Testing Material (ASTM) F73 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact, compatibility of multiple chemicals used simultaneously while wearing 1-BP-resistant gloves, glove liners, permeation, degree of dexterity required to perform a task, and temperature, as identified in the Hand Protection section of OSHA's Personal Protection Equipment Guidance (Ref. 33), when selecting appropriate dermal PPE. EPA requests comment on the degree to which additional guidance or requirements related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should incorporate additional dermal protection requirements into the

exposure control plan for dermal exposures.

d. General WCPP Requirements

i. Exposure Control Plan

EPA proposes to require that owners and operators document their exposure control strategy and implementation in an exposure control plan. This may be accomplished by adding EPA-required information to any existing documentation of a facility's safety and health program developed as part of meeting OSHA requirements or other safety and health standards. EPA proposes to require that each owner or operator document in the exposure control plan the following:

(A) Identification and rationale of hierarchy of controls used or not used in the following sequence: elimination of 1-BP, substitution of 1-BP, engineering controls, and administrative controls to reduce 1-BP exposures in the workplace to either at or below the ECEL or to the lowest level achievable;

(B) The exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

(C) If exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;

(D) Actions that must be taken to implement exposure controls selected, including proper installation, regular inspections, maintenance, training or other actions;

(E) Description of any regulated area and how it is demarcated, and identification of authorized persons;

(F) Attestation that exposure controls selected do not increase emissions of 1-BP to ambient air outside of the workplace and whether additional equipment was installed to capture or otherwise prevent increased emissions of 1-BP to ambient air;

(G) Description of activities conducted by the owner or operator to review and update the exposure control plan as necessary, but at least every 5 years, to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls;

EPA is proposing that non-Federal owners or operators implement an exposure control plan within 12 months after date of publication of the final rule in the **Federal Register**. EPA requests comment on any advantages or drawbacks for this timeline.

ii. Workplace Information and Training

EPA is also proposing to require implementation of a training program in alignment with the OSHA Hazard Communication Standard (29 CFR 1910.1200) and the OSHA General Industry Standard for Methylene Chloride (29 CFR 1910.1052). To ensure that potentially exposed persons in the workplace are informed of the hazards associated with 1-BP exposure, EPA is proposing to require that owners or operators of workplaces subject to the WCPP institute a training and information program for potentially exposed persons and assure their participation in the training and information program.

As part of the training and information program, the owner or operator would be required to provide information and comprehensive training in an understandable manner (*i.e.*, plain language), considering factors such as the skills required to perform the work activity and the existing skill level of the staff performing the work, and in multiple languages as appropriate (*e.g.*, based on languages spoken by potentially exposed persons). This information and training would have to be provided to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to 1-BP. Owners and operators would be required to provide information and training, as referenced in the OSHA Hazard Communication Standard, to all potentially exposed persons that includes: (A) The requirements of the 1-BP WCPP and how to access or obtain a copy of the requirements of the WCPP, including but not limited to the exposure control plan, monitoring requirements, and PPE program; (B) the quantity, location, manner of use, release, and storage of 1-BP and the specific operations in the workplace that could result in 1-BP exposure; (C) principles of safe use and handling of 1-BP in the workplace, including specific measures the owner or operator has implemented to reduce inhalation exposure at or below the ECEL or prevent dermal contact with 1-BP, such as work practices and PPE used; (D) the methods and observations that may be used to detect the presence or release of 1-BP in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of 1-BP when being released, etc.); and (E) the acute and chronic health hazards of 1-BP as detailed on relevant SDSs.

In addition to providing training at the time of initial assignment to a job

involving potential exposure to 1-BP, and in alignment with the OSHA General Industry Standard for Beryllium (20 CFR 1910.1024), owners and operators subject to the 1-BP WCPP would be required to re-train each potentially exposed person annually to ensure they understand the principles of safe use and handling of 1-BP in the workplace. Owners and operators would also need to update the training as necessary whenever there are changes in the workplace, such as new tasks or modifications of tasks, in particular, whenever there are changes in the workplace that increase exposure to 1-BP or where potentially exposed persons' exposure to 1-BP can reasonably be expected to exceed the action level. To support compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP would be required to provide to the EPA, upon request, all available materials related to workplace information and training.

iii. Workplace Participation

EPA encourages owners and operators to consult with persons that have potential for exposure on the development and implementation of exposure control plans and PPE (including respirators) programs. EPA is proposing to require owners or operators to provide potentially exposed persons regular access to the exposure control plans, exposure monitoring records, and PPE program implementation and documentation. To ensure compliance in workplace participation, EPA is proposing that the owner or operator document the notice to and ability of any potentially exposed person to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to 1-BP exposure in the workplace. EPA is also proposing that potentially exposed persons be permitted to observe exposure monitoring. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program. EPA is also requesting comment on whether EPA should include provisions allowing potentially exposed persons to designate a representative who would then be permitted to observe exposure monitoring and have regular access to exposure-related information at the request of the potentially exposed person.

iv. Recordkeeping

To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to a WCPP retain compliance records for five years. EPA is proposing to require records to include: (A) The exposure control plan; (B) PPE program implementation and documentation, including as necessary, respiratory protection and dermal protection used and related PPE training; and (C) information and training provided to each person prior to or at the time of initial assignment and any re-training.

In addition, EPA is proposing that owners and operators subject to the WCPP ECEL requirements maintain records to include: (D) the exposure monitoring records; (E) notification of exposure monitoring results; (F) to the extent that the owner or operator relies on prior exposure monitoring data, records that demonstrates that it meets all of the requirements of this section; and (G) the occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes air concentrations to be above the ECEL, and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to 1-BP.

The owners and operators, upon request by EPA, would be required to make all records that are maintained as described in this unit available to EPA. All records required to be maintained by this unit could be kept in the most administratively convenient form (electronic or paper).

v. Compliance Timeframes

EPA is proposing to require each non-Federal owner and operator of a workplace, other than Federal agencies and Federal contractors acting for or on behalf of the Federal Government, subject to an ECEL conduct initial baseline monitoring according to the process outlined in this unit by 6 months after date of publication of the final rule in the **Federal Register** or within 30 days of introduction of 1-BP into the workplace if 1-BP use commences at least 6 months after the date of publication. EPA is proposing to require each non-Federal owner or operator ensure the airborne concentration of 1-BP does not exceed the ECEL for all persons within 9 months after date of publication of the final rule in the **Federal Register**, or beginning 4 months after introduction of 1-BP into the workplace if 1-BP use commences at least 6 months after the date of publication. EPA is also proposing to require non-Federal

owners and operators to establish and maintain a regulated area within 9 months after the date of publication of the final rule in the **Federal Register**, or beginning 4 months after introduction of 1-BP into the workplace if 1-BP use commences at least 9 months after the date of publication. If applicable, each non-Federal owner or operator must provide respiratory protection sufficient to reduce inhalation exposure to or below the ECEL to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring that indicates exposures exceeding the ECEL or, if using monitoring data conducted within 5 years prior to the effective date of the final rule that satisfies all other requirements of this section, within 6 months after the date of publication of the final rule in the **Federal Register**. Non-Federal regulated entities must then proceed accordingly to implement an exposure control plan within 12 months after date of publication of the final rule in the **Federal Register**. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within the timeframes identified in this unit, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit, including establishment of a PPE program and development of an exposure control plan.

With regard to the compliance timeframe for those occupational conditions of use which are subject to dermal requirements under the WCPP, EPA is proposing to require each non-Federal owner or operator of a workplace subject to dermal requirements to provide dermal protection as outlined in this unit by 9 months after publication of the final rule in the **Federal Register**.

However, EPA is concerned about the ability of certain departments and agencies of the Federal Government, as well as Federal contractors acting for or on behalf of the Federal Government, to comply with these timeframes. For example, complying with these timeframes could impact the ability of the Department of Defense to continue to engage in vapor degreasing. While, for example, 29 CFR 1960 sets forth procedures and guidelines for ensuring that Federal workers are protected in comparable ways to their non-Federal counterparts, EPA believes that compliance with this proposed rulemaking would require increased and different preparations on the part of Federal agencies. For example, Federal agencies must follow procurement requirements which will likely result in

increased compliance timelines. In addition, these requirements would require support in the Federal budget, which, for some agencies, is a multi-year process. Therefore, EPA is generally providing three years for agencies of the Federal Government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP. Further, because military construction must follow a lengthy Congressional approval process prior to contracting for and beginning any actual construction work, which takes a minimum of 5 years, EPA is also proposing 5 years after the date of the publication of the final rule for the Department of Defense and Federal contractors acting for or on behalf of the Department of Defense if ongoing or planned construction is necessary to implement the feasible controls required by the WCPP to reduce exposure to or below the ECEL.

When proposing these compliance dates as required under TSCA section 6(d), EPA considered irreversible health effects and risks associated with 1-BP exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be impacted, or that additional time is needed to implement all aspects of the WCPP. However, EPA requests comment on whether additional time is needed or if there are available substitutes for these applications. As discussed in Unit IV.A.1., EPA recognizes that recent proposed rulemakings under TSCA section 6(a) have received public comments requesting longer compliance timeframes. For 1-BP, EPA believes that the proposed compliance timeframes for the WCPP described in this unit may present fewer compliance challenges for non-Federal owners and operators than those described by commenters on other rules; for example, under the WCPP, owners or operators would have some flexibility, within the parameters outlined in this unit, regarding how they prevent exceedances of the ECEL. EPA may finalize shorter or longer compliance timeframes based on consideration of public comments.

3. Prescriptive Controls

a. Overview

In contrast to the proposed non-prescriptive requirements of the ECEL where regulated entities would have flexibility to select controls in accordance with the hierarchy of controls to comply with the parameters outlined in this unit, EPA may also find it appropriate in certain circumstances

to require specific prescriptive controls for certain occupational conditions of use. In the 2020 Risk Evaluation for 1-BP, EPA identified that the use of gloves would reduce dermal exposures from 1-BP adequate to address the unreasonable risk driven by dermal exposures. Therefore, EPA is proposing to require the use of chemically-resistant gloves made of supported polyvinyl alcohol or multiple-layer laminated materials for certain occupational conditions of use, as described in this unit. This unit describes proposed requirements for the gloves, including additional requirements proposed for recordkeeping. This unit also describes compliance timeframes for these proposed requirements.

b. Glove Requirements

For the conditions of use that would not otherwise be prohibited under this proposed regulation or subject to the WCPP, EPA is proposing the owner or operator apply prescriptive controls to reduce dermal exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to 1-BP. Specifically, EPA is proposing that the owner or operator supply and ensure the use of chemically-resistant gloves made of supported polyvinyl alcohol or multiple-layer laminated materials, by all persons likely to be dermally exposed to 1-BP (including industrial and commercial products containing 1-BP). EPA is proposing to establish glove requirements for:

- Manufacturing (import);
- Processing as a reactant;
- Processing as incorporation into articles;
- Processing by repackaging;
- Recycling; and
- Disposal.

EPA is proposing to require owners or operators of a facility engaged in one or more uses of 1-BP as listed in this unit, to supply and ensure proper use of gloves, as described in this unit and in accordance with the 2020 Risk Evaluation for 1-BP and the OSHA/NIOSH Hazard Alert (Ref. 14). In the 2020 Risk Evaluation for 1-BP, EPA identified the use of gloves with a protection factor (PF) of 5 as adequate to address the unreasonable risk presented by dermal exposures to 1-BP. As described in the 2020 Risk Evaluation for 1-BP, a glove with a protection factor of 5 is a glove “with available permeation data indicating that the material of construction offers good protection for the substance.”

To further ensure correct glove usage, owners or operators must provide

training in accordance with 29 CFR 1910.132(f) to all persons required to use gloves prior to or at the time of initial assignment to a job involving exposure to 1-BP. EPA is proposing such training be conducted at least annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use gloves, or when changes in the workplace or in gloves to be used render the previous training obsolete.

To further ensure compliance, EPA proposes to require that owners and operators document the following information, as applicable: (A) The name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle 1-BP or handle equipment or materials on which 1-BP may present; (B) the type of glove being used at the facility, either supported polyvinyl alcohol or multiple-layer laminates; and (C) appropriately sized gloves and training on proper application, wear, and removal of gloves, and proper care/disposal of gloves.

EPA is soliciting comments on the requirements proposed in this unit for glove requirements. In addition, EPA understands that some workplaces rinse and reuse gloves after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing gloves. EPA also requests comment on the degree to which additional guidance related to use of gloves might be appropriate. EPA notes that disposal of gloves would be addressed by hazardous wastes requirements under 40 CFR 261.33.

EPA is proposing to require each non-Federal owner or operator supply chemically-resistant gloves made of supported polyvinyl alcohol or multiple-layer laminate, in accordance with this unit, to each potentially exposed person within 6 months after publication of the final rule.

As described in Unit IV.A.2.d.v, EPA is concerned about the ability of certain departments and agencies of the Federal Government, as well as Federal contractors acting for or on behalf of the Federal Government, to comply with the proposed timeframes for non-Federal owners and operators. For example, procurement requirements and the need for Federal budget support to implement these requirements will likely result in increased compliance timelines. Therefore, EPA is proposing 36 months for agencies of the Federal Government and their contractors, when acting for or on behalf of the Federal government, to provide and ensure the use of gloves that are chemically-resistant to 1-

bromopropane, made of supported polyvinyl alcohol or a multiple-layer laminated materials, by all persons likely to be dermally exposed to 1-bromopropane (including products containing 1-bromopropane).

4. Self-Certification

To ensure the safe and appropriate use of 1-BP, EPA is proposing to require most owners or operators who implement the WCPP to also self-certify as to their implementation of and compliance with the WCPP as a condition of the ability to purchase and use 1-BP in accordance with this regulation. EPA is proposing to establish requirements to self-certify for:

- Processing as incorporation into a formulation, mixture, or reaction product;
- Industrial and commercial use as a solvent in open-top and in-line batch vapor degreasing;
- Industrial and commercial use as a solvent in closed-loop vapor degreasing;
- Industrial and commercial use as a solvent for cleaning and degreasing in cold cleaners;
- Industrial and commercial use as a solvent in aerosol spray degreaser/cleaner; and
- Industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals; asphalt extraction; and coatings for temperature indicators.

EPA is proposing a point-of-sale self-certification requirement in order to purchase and subsequently use 1-BP for those facilities that have the ability to implement and comply with a WCPP. As discussed further in Unit V.A.1.d., this self-certification would further ensure that only facilities able to implement and comply with a WCPP are able to purchase and use 1-BP. Under a self-certification requirement, entities would submit a self-certification to the distributor each time 1-BP is purchased. The self-certification would consist of a statement indicating that the facility is implementing a WCPP that would include an ECEL, PPE requirements, and ancillary requirements, the self-certification would be signed and presented by the facility owner or operator or person authorized to do so.

Self-Certification Statement. Owners or operators who wish to continue or begin purchasing 1-BP for one or more conditions of use as outlined in this unit must self-certify that each facility engaged in one or more such conditions of use is implementing and complying with all aspects of the WCPP, as outlined in Unit IV.A.2. EPA is

proposing the following self-certification statement:

I certify each of the following statements under penalty of law. This document was prepared under my direction and supervision. This facility's implementation of the WCPP for 1-bromopropane was evaluated by qualified personnel with industrial hygiene qualifications or similar experience and that this facility has implemented and complies with the WCPP for 1-bromopropane. Based on my inquiry of the individual or individuals who manage the facility and/or those individuals directly responsible for implementing the 1-bromopropane WCPP, and to the best of my knowledge and belief, the facility is in compliance with the 1-bromopropane WCPP, including the exposure control plan. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal fines and imprisonment, for knowingly failing to comply with these requirements. If this is the first purchase of 1-bromopropane for this facility, I understand that this certification will serve as a certification that this facility will properly implement and comply with the WCPP for 1-bromopropane consistent with the applicable regulatory timelines.

The self-certification statement must be signed and dated by the owner or operator of the facility, including a name, title, email address, and phone number for the owner or operator who is self-certifying. The self-certification statement must also list the name and address of the facility that is being certified; the condition of use, (e.g., solvent for aerosol spray degreaser/cleaner) and examples of the type of equipment the owner/operator plans to use to meet the WCPP (e.g., closed loop vapor degreaser); and indicate if this is the facility's first purchase of 1-BP, after publication of the final rule. The self-certification statement would be valid for one year, unless the facility has changed processes or there is an indication that exposures to 1-BP have changed.

To ensure distributors are only selling 1-BP to owners or operators of facilities able to implement and comply with the workplace requirements of the WCPP, EPA is proposing to require owners or operators who self-certify to provide a copy of the facility's current self-certification statement to the distributor from whom 1-BP is being purchased, for every purchase of 1-BP. EPA is also proposing for the distributors to collect, maintain, and retain a copy of the self-certification statement. EPA is also proposing to require distributors to keep records, such as invoices, that indicate the name of the purchaser and facility, date of sale, and quantity of 1-BP purchased. Distributors of 1-BP for the uses described in this unit may only

distribute to those facilities that provide the correct self-certification statement for purchasing. EPA realizes that some facilities may not engage in the 1-BP uses listed in this unit at the time this proposed rule is finalized. Owners or operators that may wish to purchase 1-BP after the publication of the final rule would still be required to submit the self-certification statement to the distributor from whom 1-BP was initially purchased in order to purchase 1-BP, certifying that the facility for which 1-BP is being purchased will implement and comply with the WCPP. EPA is also proposing that distributors review the self-certification statement to ensure it is appropriately completed to include the owner or operator's and the facility's information, as outlined in this unit. As proposed, distributors would have to have a completed and valid self-certification statement for each sale of 1-bromopropane for the uses subject to the self-certification requirements. EPA is proposing that the distributors and owners or operators maintain and retain the self-certification statement and related invoices in the most administratively convenient form (electronic or paper) and retain the statement and supporting documentation for five years. EPA is requesting comment on the self-certification requirement for ensuring that only those facilities able to implement and comply with the WCPP are able to purchase 1-BP. Additionally, EPA is interested in hearing if there are other requirements such as a tax identification number, commercial account, or other verification EPA should consider including to ensure that those workplaces that can implement and comply with the WCPP are able to purchase 1-BP while other facilities with the same use who cannot implement the WCPP are unable to do so.

5. Other Requirements

a. Recordkeeping

In addition to the recordkeeping requirements for the WCPP, self-certification, and prescriptive controls outlined in this unit, for conditions of use that are not otherwise prohibited under this proposed regulation, EPA is also proposing that manufacturers, processors, distributors, and industrial and commercial users (except for the commercial use of 1-BP in insulation and insulation products) maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation;

and to maintain such records for a period of 5 years from the date the record is generated. EPA is proposing that this requirement begin on the effective date of the final rule (60 days following publication of the final rule in the **Federal Register**). Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the regulations if necessary. EPA may require more, less, or different documentation in the final rule based on consideration of public comments.

b. Downstream Notification

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of 1-BP and 1-BP-containing products, except for the manufacture, processing, distribution in commerce, use, or disposal of 1-BP in building/construction materials (insulation), provide downstream notification of the prohibitions through the Safety Data Sheets (SDSs) required by OSHA under 29 CFR 191.1200(g) by adding to sections 1(c) and 15 of the SDS the following language:

After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] this chemical/product can only be distributed in commerce to or by retailers for the commercial and consumer use of 1-bromopropane in building/construction materials (insulation). After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product is and can only be distributed in commerce or processed for the following occupational uses: Processing as a reactant/intermediate; Processing into formulation, mixture, or reaction products; Processing for incorporation into articles; Processing by repackaging; Recycling; Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—open-top, in-line vapor degreaser); Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—closed-loop); Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; Industrial and commercial use as solvent in aerosol spray degreaser/cleaner; Industrial and commercial use in other uses in electronic and electronic products and metal products, asphalt extraction, laboratory chemicals, and temperature indicator—coatings; and Disposal.

The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on the use of 1-BP under TSCA as well as provide information to commercial end users about allowable uses of 1-BP.

To provide adequate time to update the SDS and ensure that all affected products in the supply chain include the revised SDS, EPA is proposing a 2-month period for manufacturers and a 6-month period for processors and distributors to implement the proposed SDS changes following publication of the final rule.

EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in this unit.

6. Federal Uses

EPA acknowledges that after the issuance of this rule, once finalized, Federal agencies, their contractors, and other related entities may become aware of important information which indicates a particular use, that would otherwise be prohibited, could meet the criteria of section 6(g) or the requirements of a WCPP. EPA also notes that there are multiple avenues to ask EPA to revisit issues in this TSCA section 6(a) rulemaking, both before and after the mandatory compliance dates that are set consistent with TSCA section 6(d). EPA has the authority under TSCA section 6(g) to consider whether a time limited exemption is appropriate and, consistent with TSCA section 6(g)(1), could expeditiously promulgate such exemptions independently from this rulemaking, including consideration of emergency or interim rulemaking. EPA will initiate a notice of proposed rulemaking for public comment on this topic and will add this to the Spring 2024 Regulatory Agenda. Additionally, any person could petition EPA to request that EPA issue or amend a rule under TSCA section 6.

B. Alternative Regulatory Actions

As indicated by TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA must consider and publish a statement based on reasonably available information with respect to the reasonably ascertainable economic consequences of the rulemaking, including consideration of the costs and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Agency. This unit includes a description of the primary alternative regulatory action and the second alternative regulatory action considered by the Agency. An overview of the proposed regulatory action and two alternative regulatory actions for each condition of use is in Unit IV.C.

1. Primary Alternative Regulatory Action Considered

The primary alternative regulatory action described in this document and considered by EPA combines prohibitions, requirements for a WCPP, self-certification, and prescriptive controls to address the unreasonable risk from 1-BP contributed by the various conditions of use. The primary alternative regulatory action described in this document differs from the proposed regulatory action by considering prescriptive workplace controls and implementation of a PPE program for some conditions of use that would be subject to a WCPP under the proposed regulatory action. The primary alternative regulatory action additionally considers alternative compliance timeframes for prohibitions and implementation of a WCPP and prescriptive controls, as described in this unit. EPA is putting forth only alternative regulatory options that would eliminate the unreasonable risk from 1-BP and notes that TSCA section 6(a) requires that EPA impose regulatory requirements to the extent necessary to address unreasonable risk. Thus, EPA has concluded that it would be most advantageous to put forth and receive public input on alternative regulatory options that the Agency could adopt in a final rule consistent with the requirements of TSCA section 6(a). Where EPA has identified different types of regulatory requirements that would address the unreasonable risk (e.g., a WCPP and prescriptive controls), EPA is seeking public input on each type of regulatory requirement. However, where EPA has identified only one type of regulatory requirement that would address the unreasonable risk (e.g., a prohibition), EPA is seeking public input on the timing for compliance with such a requirement. EPA requests comment on this primary alternative regulatory action and whether any elements of the primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

a. Prohibitions

The primary alternative regulatory action considered by EPA would prohibit the manufacturing, processing, distribution in commerce, and use for the following industrial and commercial uses, which EPA is also proposing to prohibit as part of the proposed

regulatory action: industrial and commercial use in adhesives and sealants; industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers; industrial and commercial use in liquid cleaners (e.g., coin and scissor cleaner); and industrial and commercial use in arts, crafts, hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); and functional fluids (close/open-systems)—refrigerant/cutting oils. Additionally, the primary alternative regulatory action would prohibit the manufacture, processing, and distribution of 1-BP for all consumer use, except in insulation. As shown in Unit IV.C., which presents an overview of the proposed regulatory action and two alternative regulatory actions for each condition of use, the primary alternative action described in this document would prohibit the same occupational and consumer conditions of use as the proposed regulatory action.

Regarding compliance timeframes, the primary alternative regulatory action would include longer timeframes for implementation of the prohibitions than the proposed regulatory action. Under the primary alternative action, the prohibitions would generally take effect 6 months later than in the proposed regulatory action. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the prohibitions for the manufacturing, processing, distribution in commerce, and use of 1-BP for certain occupational conditions of use described in this unit would take effect 12 months for manufacturers, 15 months for processors, 18 months for distributing to retailers, 21 months for all other distributors (including retailers), and 24 months for industrial and commercial users after the publication date of the final rule. With regard to the compliance timeframe for the manufacturing, processing, and distribution in commerce for consumer use (except consumer use in building/construction materials in insulation), under the primary alternative regulatory action, prohibitions described in this unit would take effect in 12 months for manufacturers, 15 months for processors, 18 months for distributing to retailers, and 21 months for all other distributors (including retailers) after the publication date of the final rule.

b. Workplace Chemical Protection Program (WCPP)

The primary alternative regulatory action described in this document would require a WCPP, including

requirements to meet an ECEL, for the following occupational conditions of use: manufacturing (domestic); processing into formulation, mixture, or reaction products; industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; industrial and commercial use as solvent in aerosol spray degreaser/cleaner; and industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals for asphalt extraction; coatings for temperature indicator. EPA requests comment on the ways in which 1-BP may be used in these conditions of use, including whether activities may take place in a closed system and the degree to which users of 1-BP in these sectors could successfully implement an ECEL and ancillary requirements described in Unit IV.A.

As with the compliance timeframes considered as part of the primary alternative action for prohibition, the primary alternative regulatory action also includes longer compliance timeframes for implementation of a 1-BP WCPP by non-Federal owners and operators. The primary alternative regulatory action does not include longer compliance timeframes for implementation of a 1-BP WCPP for Federal agencies and Federal contractors acting for or on behalf of the Federal Government. Under the primary alternative action, the requirements for the WCPP would take effect 6 months later than the proposed regulatory action for non-Federal owners and operators. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the requirements for non-Federal owners and operators to conduct initial baseline monitoring would take effect 12 months after the date of publication of the final rule in the **Federal Register**. Also under the primary alternative action, the requirements for each non-Federal owner or operator to provide respiratory protection to all potentially exposed persons in the regulated area would be within 3 months after receipt of the results of any exposure monitoring or within 15 months after date of publication of the final rule in the **Federal Register**. Non-Federal owners and operators would be required to implement an exposure control plan within 18 months after date of publication of the final rule in the **Federal Register**. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines

identified for the proposed regulatory action in Unit IV.A.

c. Prescriptive Controls

i. Prescriptive Controls—PPE

In contrast to the proposed non-prescriptive requirements of the WCPP, outlined in Unit IV.A.2., including requirements to meet an ECEL, where regulated entities would have the ability to select appropriate controls in accordance with the hierarchy of controls to comply with the performance-based parameters, EPA may also find it appropriate in certain circumstances to require specific prescriptive controls for certain occupational conditions of use. In the 2020 Risk Evaluation for 1-BP, EPA explained how engineering and administrative controls and use of PPE could reduce 1-BP exposures in occupational settings; therefore, EPA considered a combination of required engineering, administrative and PPE controls as the prescriptive approach in the primary alternative regulatory action for the following conditions of use: industrial and commercial use of solvent for cleaning and degreasing in vapor degreasers (batch vapor degreaser—open-top and, in-line vapor degreaser); and industrial and commercial use of solvent for cleaning and degreasing in vapor degreasers (batch vapor degreaser—closed-loop). Under the proposed regulatory action, these two conditions of use would be regulated under the WCPP.

When considering the use of required prescriptive engineering controls, administrative controls and PPE, EPA expects that such controls will be fully and properly implemented. Merely having the specified controls present is not sufficient to consider them “fully and properly” implemented. Rather, the regulated entities would be required to ensure that the controls are present and maintained, and that employees understand the proper use of those controls and use them accordingly. Examples of practices that would demonstrate that the regulated entities are in compliance with the controls would include proper installation and maintenance of the equipment according to manufacturer’s instructions, timely replacement of filters and other similar parts, regular documented inspections to ensure equipment is operating properly, maintaining the required flow rates, and regular documented training to ensure proper use of controls.

For the condition of use of industrial and commercial use as solvent for cleaning and degreasing in vapor

degreaser (batch vapor degreaser—open-top, inline vapor degreaser) EPA described in section 2.3.1.11 of the risk evaluation a local exhaust ventilation system for an open-top vapor degreaser (lateral exhaust hoods installed on two sides of the tank) that can reduce worker exposure. There are several limitations regarding use of ventilation systems, including uncertainties regarding the type of model used and the lack of monitoring data. Additionally, local exhaust ventilation systems may increase the volatilization of the solvent, leading to an increase in the use of solvent and the cost of operating the vapor degreaser. Also, a local ventilation system might require a Title V operating permit under the Clean Air Act and could require additional controls, such as the use of a carbon adsorber, to avoid emissions to the environment. As discussed in the proposed regulatory action (Unit IV.A.1.), EPA is proposing to require pollution prevention and source reduction wherever possible when making decisions about what control techniques to install. In addition, as indicated in the risk evaluation, a 90% reduction of 1-BP workplace emissions by using a local exhaust ventilation system is not enough to address the unreasonable risk to workers and occupational non-users. Additional controls would be needed, such as respirators with an APF of 50. Workers would also need gloves to reduce dermal exposures.

In Section 2.3.1.12 of the risk evaluation, EPA also identified a study indicating that air emissions can be reduced by 98% or more when a closed-loop degreaser is used instead of an open-top vapor degreaser (Ref. 1). Also, in the risk evaluation, EPA indicated that the unreasonable risk to workers when using a closed-loop degreaser could be addressed by using respirators with an APF of 10, but additional controls would be needed to reduce inhalation exposures to occupational non-users.

Therefore, under this primary alternative regulatory action, for the industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—open-top, inline vapor degreaser), EPA considered requirements to demonstrate reductions of emissions based on engineering controls and achieve an exposure concentration of less than 2.5 ppm (50 times the proposed ECEL value of 0.05ppm) as an 8-hour time-weighted average, isolate the vapor degreaser with controlled access to a “regulated area” where only workers who are wearing

PPE to minimize exposures to 1-BP, and use of respirators with APF of 50 for any worker operating the vapor degreaser, would be permitted to go. EPA also considered requirements for use of gloves made of supported polyvinyl alcohol or a multiple-layer laminated material. EPA also considered requiring periodic monitoring (personal breathing zone or representative sample) every 3 months to determine that the respirators used are of a sufficient protection factor to be adequate to protect workers. In addition, EPA considered requiring that the regulated entity implement all aspects of a respiratory protection program (*e.g.*, training, fitting, medical surveillance, etc.), as outlined in Unit IV.A.2.c., and referred to 29 CFR 1910.132, 29 CFR 1910.133, and 29 CFR 1910.134 for requirements on selection and use of PPE.

Also as a primary alternative regulatory option, for the industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—closed-loop) EPA considered requiring regulated entities to: use closed-loop vapor degreasers with the adequate maintenance and a ventilation system or other engineering controls to achieve an exposure concentration of less than 0.5 ppm as an 8-hour time-weighted average; require isolation of the vapor degreaser in a “regulated area” with controlled access to minimize exposures to 1-BP; and require the use of respirators with APF of 10 for any worker in the vicinity of the vapor degreaser within the regulated area. EPA also considered requiring use of gloves made of supported polyvinyl alcohol or a multiple-layer laminated material. EPA also considered requiring periodic monitoring (personal breathing zone or representative sample) every 3 months to determine that the respirators used are adequate to protect workers. In addition, EPA considered requiring that the regulated entity implement all aspects of a respiratory protection program (*e.g.*, training, fitting, medical surveillance, etc.), as outlined in Unit IV.A.2.c., and refers to 29 CFR 1910.132, 29 CFR 1910.133, and 29 CFR 1910.134 for requirements on selection and use of PPE.

EPA also considered requiring the use of closed-loop vapor degreasers instead of open-top or inline vapor degreasers. EPA recognizes that using only closed-loop vapor degreasers can present several challenges to the regulated entities, depending on the size of the parts, the configuration of their operation and the time required to complete the cleaning operation. In addition, closed-loop vapor degreasers

can be expensive. Therefore, EPA is also seeking comments on an alternative regulatory approach where facilities would be required to use only closed-loop vapor degreasers for any batch vapor degreasing, and use ventilation systems and engineering controls that achieve exposure concentrations of less than 0.5 ppm as an 8-hour time-weighted average, isolate the vapor degreaser in a “regulated area” with controlled access to minimize exposures to 1-BP, and require the use of respirators with APF of 10 for any worker in the regulated area of the vapor degreaser, and the use of gloves made of supported polyvinyl alcohol or a multiple-layer laminated material. This alternative also considered requiring periodic monitoring (personal breathing zone or representative sample) every 3 months to determine that the respirators used are adequate to protect workers, and requiring that the regulated entity implement all aspects of a respiratory protection program (e.g., training, fitting, medical surveillance, etc.), as outlined in Unit IV.A.2.c., including referring to 29 CFR 1910.132, 29 CFR 1910.133, and 29 CFR 1910.134 for requirements on selection and use of PPE.

For batch vapor degreasing (open-top and inline vapor degreasers) and cold cleaning, EPA also considered requiring engineering controls similar to the requirements set by the National Emission Standards for Halogenated Solvent Cleaning (40 CFR part 63, subpart T), which currently apply to other halogenated solvents but not 1-BP. EPA would expect that requirements under 40 CFR part 63, subpart T most likely would not reduce the 1-BP concentrations to 0.05 ppm as an 8-hour time-weighted average. Even if facilities were to install control measures to meet the requirements of 40 CFR part 63, subpart T, EPA believes that additional controls and PPE would be needed, including the use of gloves made of supported polyvinyl alcohol or a multiple-layer laminated material. Therefore, EPA is seeking comments regarding how the requirements of 40 CFR part 63, subpart T could be applied for 1-BP, as well as any additional information on how effective these requirements would be to reduce 1-BP air concentrations and additional controls needed to reduce 1-BP exposure to workers to 0.05 ppm as an 8-hour time-weighted average.

Under this primary alternative regulatory option, EPA considered requiring that the regulated entity engaged in any uses of 1-BP outlined in this Unit IV.B.1.c. develop an exposure control plan, as outlined in Unit

IV.A.2.d.i., as well as comply with monitoring requirements, as outlined in Unit IV.2.A.b.ii., and recordkeeping requirements, as outlined in Unit IV.2.A.d.iv.

EPA also considered requiring that within 15 working days after receipt of the results of any exposure monitoring, the regulated entity must notify each person whose exposure is represented by that monitoring in writing, either individually to each person or by posting the information in an appropriate and accessible location. The notice would identify the exposure monitoring results, and any corresponding respiratory protection required. Also, the notice would be required to include a description of the actions taken by the regulated entity to reduce inhalation exposures or refer to a document available to the person which states the actions to be taken to reduce exposures.

ii. Prescriptive Controls—Gloves

Under the primary alternative regulatory action, EPA would apply prescriptive controls to reduce dermal exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to 1-BP. Specifically, EPA is proposing that the owner or operator require the use of gloves for the following conditions of use: manufacturing (import); processing as a reaction; processing as incorporation into articles; repackaging, recycling; and disposal. As shown in Unit IV.C., which presents an overview of the proposed regulatory action and two alternative regulatory actions for each condition of use, the primary alternative action described in this document would subject the same occupational conditions of use to prescriptive dermal controls as the proposed regulatory action.

Regarding compliance timeframes, the primary alternative regulatory action would include longer timeframes for implementation of glove use by non-Federal owners and operators than the proposed regulatory action. Under the primary alternative action, prescriptive controls would generally take effect for non-Federal owners and operators 6 months later than in the proposed regulatory action. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the prescriptive controls for certain occupational conditions of use of 1-BP described in this unit would take effect for non-Federal owners and operators 12 months after the publication date of the final rule. The primary alternative regulatory action does not include longer compliance timeframes for

implementation of these prescriptive controls for Federal agencies and Federal contractors acting for or on behalf of the Federal Government.

d. Self-Certification

The primary alternative regulatory action considered by EPA would also require self-certification, as outlined in Unit IV.A.4., for the following occupational conditions of use: processing for incorporation into a formulation, mixture, or reaction products; industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—open-top, in-line); industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—closed-loop); industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; industrial and commercial use as solvent in aerosol spray degreaser/cleaner; industrial and commercial use in other uses in electronic and electronic products and metal products, laboratory chemicals and asphalt extraction, and in coatings for temperature indicators. As shown in Unit IV.C., which presents an overview of the proposed regulatory action and two alternative regulatory actions for each condition of use, the primary alternative action described in this document would subject the same occupational conditions of use to self-certification requirements as the proposed regulatory action. While similar in most ways to the proposed regulatory action, the primary alternative regulatory action differs from the proposed regulatory action by requiring prescriptive controls rather a WCPP for two industrial and commercial conditions of use: industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—open-top, in-line); industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser—closed-loop). If the primary alternative regulatory action is chosen rather than the proposed regulatory action, EPA will update the self-certification statement to better align with whichever regulatory action is chosen.

2. Second Alternative Regulatory Action Considered

a. Prohibitions

The second alternative regulatory action described in this document and considered by EPA is to prohibit all occupational uses of 1-BP and the manufacture, processing, and

distribution in commerce of 1-BP for all consumer uses, except for the consumer use of 1-BP in building/construction materials (insulation) and distribution in commerce for non-prohibited uses, to address the unreasonable risk from 1-BP contributed by the various conditions of use. While similar in some ways to the proposed regulatory action, the second alternative regulatory action differs from the proposed regulatory action by prohibiting the conditions of use that would have requirements for a WCPP, self-certification, and/or prescriptive controls under the proposed regulatory action. Regarding the compliance timeframes, the second alternative regulatory action would include a longer timeframe for implementation of prohibition than the proposed regulatory action. Additionally, EPA would not stagger the compliance dates for manufacturers, processors, and distributors. The prohibitions for the manufacturing, processing, distribution in commerce, and use for the occupational conditions of use, except for the commercial use of 1-BP in insulation, would take effect 3 years after the publication date of the final rule. With regard to the compliance timeframe for the manufacturing, processing, and distribution in commerce for consumer use, except the consumer use of 1-BP in insulation, the prohibitions would take effect 3 years after the publication date of the final rule (Ref. 32). EPA requests

comment on this second alternative regulatory action and whether any elements of this second alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

b. Recordkeeping and Downstream Notification

The second alternative regulatory action also would include a requirement that manufacturers, processors and distributors maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of the second alternative regulatory action; and to maintain such records for a period of 5 years from the date the record is generated. The recordkeeping requirements associated with this second alternative regulatory action would take effect 90 days after the effective date of the final rule.

Also, under this second alternative regulatory action, EPA would require that manufacturers, processors, and distributors, excluding retailers, of 1-BP provide downstream notification of the prohibitions through SDS by adding to sections 1(c) and 15 of the SDS the following language:

As of [DATE 90 DAYS AFTER OF PUBLICATION OF THE FINAL RULE], this chemical/product can only be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for use in insulation for building/construction materials.

The downstream notification requirements associated with this alternative approach would take effect 90 days after the effective date of the final rule in order to provide adequate time to undertake the changes to the SDS and ensure that all products in the supply chain include the revised SDS.

C. Overview of Conditions of Use, Proposed Regulatory Action and Alternative Regulatory Actions

Table 2 is a side-by-side depiction of the proposed regulatory action with the primary and secondary alternative regulatory actions that EPA considered for each condition of use identified as driving the unreasonable risk (Ref. 2). The purpose of this table is to succinctly convey to the public certain differences between the proposed regulatory action and the alternative regulatory actions; as such the actions in each column are truncated and do not reflect all the details of the proposed and alternative regulatory actions, including differences in timeframes, as outlined in Units IV.A. and B. The proposed action and the alternative regulatory actions that EPA considered are described more fully in Units IV.A. and B.

TABLE 2—OVERVIEW OF CONDITIONS OF USE DRIVING UNREASONABLE RISK AND PROPOSED REGULATORY ACTION AND ALTERNATIVE REGULATORY ACTION

Conditions of use	Action		
	Proposed regulatory action	Primary alternative action ²	Secondary alternative action
Industrial and commercial use as solvent for open-top batch and in-line vapor degreasing.	1-BP WCPP + self-certification.	Prescriptive Controls + self-certification.	Prohibit.
Industrial and commercial use as solvent for closed-loop batch vapor degreasing.	1-BP WCPP + self-certification.	Prescriptive Controls + self-certification.	Prohibit.
Industrial and commercial use as solvent for cold cleaning	1-BP WCPP + self-certification.	1-BP WCPP + self-certification.	Prohibit.
Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner.	1-BP WCPP + self-certification.	1-BP WCPP + self-certification.	Prohibit.
Industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals; asphalt extraction.	1-BP WCPP + self-certification.	1-BP WCPP + self-certification.	Prohibit.
Industrial and commercial use in adhesives and sealants	Prohibit	Prohibit	Prohibit.
Industrial and commercial use in other uses in arts, crafts, hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); functional fluids (close/open-systems)—refrigerant/cutting oils.	Prohibit	Prohibit	Prohibit.
Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers.	Prohibit	Prohibit	Prohibit.
Industrial and commercial use in coin and scissor cleaner (liquid, aerosol, or spray cleaners).	Prohibit	Prohibit	Prohibit.
Consumer use as solvent in aerosol degreasers/cleaners	Prohibit ¹	Prohibit ¹	Prohibit. ¹

TABLE 2—OVERVIEW OF CONDITIONS OF USE DRIVING UNREASONABLE RISK AND PROPOSED REGULATORY ACTION AND ALTERNATIVE REGULATORY ACTION—Continued

Conditions of use	Action		
	Proposed regulatory action	Primary alternative action ²	Secondary alternative action
Consumer use in spot cleaners and stain removers	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Consumer use in liquid cleaners (<i>e.g.</i> , coin and scissor cleaner) and liquid aerosol/spray cleaners.	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Consumer use in liquid spray/aerosol cleaners	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Consumer use in arts, crafts, and hobby materials (adhesive accelerant).	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Consumer use in automotive care products (refrigerant flush)	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Consumer use in anti-adhesive agents (mold cleaning and release products).	Prohibit ¹	Prohibit ¹	Prohibit. ¹
Manufacturing (Domestic manufacturing)	1-BP WCPP	1-BP WCPP	Prohibit.
Manufacturing (Import)	Prescriptive Controls	Prescriptive Controls	Prohibit.
Processing: processing as a reactant	Prescriptive Controls	Prescriptive Controls	Prohibit.
Processing: incorporation into a formulation, mixture, or reaction product.	1-BP WCPP + self-certification.	1-BP WCPP + self-certification.	Prohibit.
Processing: incorporation into articles	Prescriptive Controls	Prescriptive Controls	Prohibit.
Processing: repackaging	Prescriptive Controls	Prescriptive Controls	Prohibit.
Processing: recycling	Prescriptive Controls	Prescriptive Controls	Prohibit.
Disposal	Prescriptive Controls	Prescriptive Controls	Prohibit.

¹ Prohibit manufacture (including import), processing, and distribution in commerce for the consumer use. Except in insulation.

² Different timeframes are applicable to the primary and secondary alternative regulatory actions considered, in comparison to the proposed regulatory action.

V. Rationale for the Proposed Regulatory Action and Alternative Regulatory Actions

This unit describes how the considerations described in Unit III.B.3. were applied when selecting among the TSCA section 6(a) requirements to arrive at the proposed and alternative regulatory actions described in Unit IV.

A. Consideration of Risk Management Requirements Available Under TSCA Section 6(a)

1. Proposed Regulatory Action

a. Prohibition

EPA considered a prohibition as a regulatory option and is proposing it for certain occupational conditions of use (Unit IV.A.). As described in this unit, EPA determined prohibition was appropriate for certain occupational conditions of use after taking into consideration other combinations of controls such as self-certification, a non-prescriptive WCPP, or prescriptive controls (*i.e.*, engineering controls, administrative controls, and PPE).

EPA also considered the potential for 1-BP use to increase in particular sectors, such as dry cleaning solvents, where it has largely been phased out because of its well-established hazard (Refs. 26, 3). In order to prevent the potential for use of 1-BP to increase in a sector that has already moved away from it, use of 1-BP for certain conditions of use would be prohibited under the proposed regulatory and

alternative regulatory actions. Such uses of 1-BP include, but are not limited to, use as dry cleaning solvents, use in adhesives and sealants, and use in liquid cleaners and liquid spray/aerosol cleaners.

EPA determined prohibition would not be appropriate for the remaining occupational conditions of use, such as manufacturing (domestic manufacturing and import), processing as a reactant, processing for incorporation into articles, recycling, and repackaging; processing into a formulation, mixture, or reaction product; and industrial and commercial uses as a solvent for cleaning and degreasing in vapor degreasers, in aerosol spray degreaser/cleaner, in electronic and electronic products and metal products, in laboratory use for asphalt extraction, and in coating for temperature indicators. EPA made this determination based on compelling reasons, as described below, to not prohibit the activity and to identify a different regulatory action that would address the unreasonable risk. For example, prohibition may not be appropriate for conditions of use where EPA identified strict workplace controls could be implemented to address the unreasonable risk as described in Unit V.A.1.b. Additionally, prohibition may not be appropriate for conditions of use where alternative substances to 1-BP are more or equally hazardous (in particular some of the other solvents

undergoing risk evaluation and risk management under TSCA section 6).

For these conditions of use, EPA determined restrictions under a 1-BP WCPP, self-certification requirements, prescriptive controls, or a combination of such requirements were more appropriate for addressing the unreasonable risk to the extent necessary so that 1-BP no longer presents such risk, while also allowing for regulated entities to continue operations, as described in this unit and in Unit IV.A.

Regarding industrial, commercial, and consumer uses of 1-BP, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture “for a particular use” to ensure that a chemical substance no longer presents unreasonable risk. For this rulemaking, EPA proposes that “for a particular use” includes consumer use more broadly, as well as industrial and commercial use, which encompasses all known, intended, and reasonably foreseen uses of 1-BP. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for 1-BP for all industrial, commercial, and consumer conditions of use (except in insulation), and noting that those conditions of use encompass all known, intended, and reasonably foreseen use of 1-BP, EPA proposes that prohibiting manufacture (including importing),

processing, and distribution in commerce of 1-BP for some industrial and commercial use and all consumer conditions of use, except for the consumer and commercial use of 1-BP in building materials/construction (insulation), is reasonable and necessary to eliminate the unreasonable risk of 1-BP from industrial, commercial, and consumer use. This includes precluding retailers from selling 1-BP and products containing 1-BP, except insulation, to consumers for unspecified end-uses. EPA believes that any retailer selling products containing 1-BP, except insulation, to consumers for unspecified end-uses would be selling products for use by consumers for one of the consumer uses EPA evaluated in the 2020 Risk Evaluation for 1-BP and found to contribute to the unreasonable risk for 1-BP in the 2022 revised risk determination. EPA's proposed requirements to address unreasonable risk to consumers and bystanders to consumer use are described in Unit IV.A.

A key consideration regarding consumer uses is the role of retailers and other distributors. A retailer, as EPA has defined in 40 CFR 751.103 (and proposes to define in CFR 751.5), is any entity that makes available a chemical substance or mixture to consumer end users, including through e-commerce internet sales or distribution. Previously, in the 2019 methylene chloride TSCA section 6(a) risk management rule addressing consumer use of methylene chloride in paint and coating removal (Ref. 34), EPA prohibited retailers from distributing in commerce paint and coating removers containing methylene chloride (see 40 CFR 751.105(b) and (c)). To meet the same goal of protecting consumers from accessing products containing 1-BP that could pose unreasonable risks, for a broader range of consumer use, EPA considered and is proposing a similar provision to ensure that retailers will not be able to purchase 1-BP for sale or distribution to consumers and will not be able to sell or distribute 1-BP to consumers, including making available to consumers products containing 1-BP, except insulation. For these reasons, as described in Unit IV.A., EPA's proposal to address unreasonable risk from 1-BP includes prohibition on the distribution in commerce of 1-BP to and by retailers, except for the use of 1-BP in insulation.

b. Workplace Chemical Protection Program (WCPP)

One option EPA considered for occupational conditions of use was establishing a requirement for a 1-BP WCPP, which would include a

combination of requirements to the extent necessary to address unreasonable risk contributed by inhalation and dermal exposures in the workplace. A 1-BP WCPP would encompass restrictions on certain occupational conditions of use and could include provisions for an ECEL and ancillary requirements to support implementation of these exposure limits. Due to the low exposure level and stringent requirements in the 1-BP WCPP that would be necessary to address the unreasonable risk from 1-BP, EPA identified those conditions of use where the Agency expected a 1-BP WCPP could be successfully implemented.

i. Existing Chemical Exposure Limit (ECEL)

One requirement considered by EPA to include in a 1-BP WCPP to address unreasonable risk contributed by inhalation exposures to 1-BP for occupational conditions of use was establishing an ECEL and related implementation measures, such as exposure monitoring. As described in Unit IV.A., the 1-BP WCPP would be non-prescriptive, in the sense that regulated entities would not be required to use specific controls prescribed by EPA to achieve the exposure concentration limit. Rather, it would be a performance-based exposure limit that would enable owners or operators to determine how to most effectively meet the exposure limit based on conditions at their workplace, consistent with the hierarchy of controls.

A central component of the 1-BP WCPP is the exposure limit. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health from occupational inhalation exposures for those conditions of use subject to the WCPP.

In the case of 1-BP, EPA has calculated the ECEL to be 0.05 parts per million (ppm) (0.25 mg/m³) for inhalation exposures as an 8-hour TWA in workplace settings, based on the chronic cancer inhalation unit risk (IUR) at a risk level of 1×10^{-4} . This is the concentration at which an adult human, including a member of a potentially exposed or susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime (Ref. 12). EPA chose the chronic cancer inhalation endpoint for 1-BP as the basis for this exposure limit because it is the most protective of the endpoints identified for occupational settings, and therefore will be protective of both acute and chronic cancer and chronic non-

cancer inhalation endpoints over the course of a working day and lifetime, as described in Unit IV.A.2.b.

In deciding whether an ECEL and related required implementation measures would appropriately address the unreasonable risk contributed by occupational inhalation exposures for specific conditions of use, EPA considered factors related to work activities that may make it difficult to comply with an ECEL, particularly at the low air concentration level EPA has identified. Once EPA identified the appropriate risk-based inhalation limit to address identified unreasonable risk, EPA carefully considered the appropriateness of such an exposure control program for each occupational condition of use of 1-BP, in the context of the unreasonable risk. Examples include conditions of use with work activities that may take place in the field, making it challenging to establish a regulated area and conduct monitoring; work activities that may take place in open systems that require manual contact with the chemical substance; work activities that may take place in small, enclosed spaces, creating challenges for implementing engineering controls or using respiratory PPE; work activities that require a high range of motion or for some other reason create challenges for the implementation of respiratory PPE; and the type of PPE that would be needed under the 1-BP WCPP to meet the ECEL in the absence of, or in addition to, other feasible exposure controls, based on analysis in the 2020 Risk Evaluation for 1-BP describing expected exposures with and without use of PPE.

EPA also considered the feasibility of exposure reduction sufficient to address the unreasonable risk, including in facilities complying with recommended OELs such as the ACGIH TLV. This creates a degree of uncertainty as to whether facilities engaging in some industrial and commercial conditions of use could meet the ECEL (and associated action level) and whether they could do so without relying primarily on the use of PPE (which is the least preferred option in the hierarchy of controls), and, therefore, whether exposures could be reduced in a manner aligned with the hierarchy of controls.

EPA understands that this uncertainty extends to the feasibility of respirators to address unreasonable risk from 1-BP as well. Although respirators, specifically SCBAs, could reduce exposures to levels that protect against non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function

due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. OSHA requires that a determination regarding the ability to use a respirator be made by a physician or other licensed health-care professional, and annual fit testing is required for tight-fitting, full-face piece respirators to provide the required protection. Individuals with facial hair, such as beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, “improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer’s safety or health.” (63 FR 1189 through 1190).

ii. Personal Protective Equipment (PPE) Program

Another requirement considered by EPA to include in a 1-BP WCPP to address unreasonable risk driven by exposures to 1-BP for occupational conditions of use was requiring a prescriptive PPE program. The requirements under this prescriptive program are a process-based set of provisions to address unreasonable risk driven by workplace exposures to 1-BP. In order to address workplace exposures to 1-BP, requirements would include use of prescriptive PPE, including dermal PPE. EPA’s description for how the requirements related to this prescriptive PPE program would address the unreasonable risk resulting from workplace exposures and the rationale for this regulatory approach is outlined in Units III.B.3. and V.A.

Similar to the ECEL, under prescriptive PPE requirements, EPA is proposing to require owners and operators to implement respiratory controls in accordance with the hierarchy of controls, as outlined in Unit IV.A.2.c. EPA also recommends and encourages the use of pollution prevention as a means of controlling exposures whenever practicable.

In contrast to the proposed non-prescriptive requirements of the ECEL, EPA is proposing to require owners and operators to implement specific prescriptive controls for those occupational conditions of use subject to a 1-BP WCPP. Specifically, EPA is proposing to require the use of

chemically resistant gloves made of supported polyvinyl alcohol or a multiple-layer laminated material, in combination with specific activity training (e.g., procedure for glove removal and disposal) for tasks where dermal exposure can be expected to occur.

In consideration of the whole of the 2020 Risk Evaluation for 1-BP, including the uncertainties, EPA has preliminarily determined that preventing workplace exposure to 1-BP through prescriptive PPE requirements, including the use of respirators and/or gloves, workplace specific training, and PPE training, as described in Unit IV.A.2.c., for certain occupational conditions of use would address the unreasonable risk from 1-BP exposures in the workplace driven by these conditions of use for potentially exposed persons.

iii. 1-BP WCPP

Taking into account these considerations, EPA is proposing that certain conditions of use would be allowed to continue if regulated entities could ensure exposures remain at or below the ECEL and other requirements are met in the 1-BP WCPP. In contrast to considerations that would weigh against the likelihood that a facility within a condition of use to successfully implement a WCPP, there are certain considerations that indicate a facility engaged in a condition of use would likely be able to achieve effective risk management via WCPP. Based on reasonably available information, including monitoring data process descriptions, and information related to considerations described previously in this unit, EPA’s confidence that requirements to meet an ECEL can be implemented is highest in highly standardized and industrialized settings, such as where 1-BP is used in a closed system (Ref. 32). For example, two industry commenters provided EPA with closed system process and exposure monitoring information that indicate circumstances where the requirements to meet an ECEL could be successfully implemented (Ref. 32).

Pursuant to TSCA section 6(c)(2)(A)(i), EPA is considering reasonably available information regarding the adverse effects of 1-BP on human health and the magnitude of exposure of human beings to 1-BP. EPA recognizes that people at workplaces that manufacture, process, use, or dispose of 1-BP may live in the fenceline communities surrounding these facilities and consequently may be potentially exposed to 1-BP through ambient air outside of working hours. In

addition, the Agency understands that certain engineering controls can reduce exposure to people inside the workplace but may lead to increased ventilation of 1-BP outside of the workplace, thereby increasing risks to people in fenceline communities of adverse health effects from exposure to 1-BP in ambient air. Therefore, pursuant to TSCA section 6(c)(2)(B), EPA is considering the potential adverse effects on health of people in fenceline communities posed by emissions of 1-BP to ambient air described in Unit VI. as a factor when proposing to prohibit increased releases of 1-BP to outdoor air associated with the implementation of the WCPP. This proposed requirement is intended to avoid unintended increases in exposures to people from 1-BP emissions to ambient air. The proposed rule would require owners and operators to attest in their WCPP exposure control plan that engineering controls selected to address worker risk do not increase emissions of 1-BP to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of 1-BP to ambient air.

Details of the proposed 1-BP WCPP, including provisions for the ECEL and ancillary required implementation measures, requirements for demonstrating compliance, and requirements for distributors, are described in more detail in Unit IV.A. EPA requests comment on all aspects of this proposal to allow certain conditions of use to continue under the WCPP, including the likelihood that the provisions of the WCPP, including exposure monitoring, engineering and administrative controls, PPE, and the exposure control plan, could be successfully implemented for the identified conditions of use, including, for example, the industrial and commercial use as a solvent for aerosol spray degreaser/cleaner.

c. Prescriptive Controls

In addition to the considerations addressed in Unit V.A.1.b., EPA is also proposing prescriptive controls to reduce dermal exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to 1-BP. Specifically, EPA is proposing the use of chemically resistant gloves, either made of supported polyvinyl alcohol or a multiple-layer laminated material, supplied by the owner or operator, for certain occupational conditions of use where dermal exposure is expected to result in unreasonable risk, but for which there is no unreasonable risk

from inhalation exposure. In the 2020 Risk Evaluation for 1-BP, EPA identified that only the use of such gloves is needed to reduce dermal exposures to 1-BP to address the unreasonable risk contributed by dermal exposures from these conditions of use. Details of the proposed prescriptive controls are described in more detail in Unit IV.A.

d. Self-Certification

Since it is unlikely that all industrial or commercial facilities with occupational exposures engaged in one or more uses of 1-BP as listed in Unit IV.A.2. have the ability to implement a WCPP, EPA is including a point-of-sale self-certification requirement in order to purchase 1-BP for certain uses. EPA is proposing that this self-certification would be required for the conditions of use, other than domestic manufacturing, that would be allowed to continue for regulated entities under the WCPP. This would allow only those entities within those conditions of use that could ensure that exposures remain at or below the ECEL and meet other requirements of the 1-BP WCPP to continue to process or use 1-BP for those particular conditions of use. EPA estimates that most, but not all, workplaces under the conditions of use that would be subject to the WCPP as a proposed regulatory action are capable of implementing the ECEL and other aspects of the WCPP as part of an industrial hygiene program (existing or newly established for 1-BP), since many of these facilities would have the ability to implement process changes to reduce exposures, have equipment in place to control ventilation rates, and have or can implement a monitoring program to demonstrate compliance. However, EPA does not expect that all workplaces would be able to implement fully all the controls and monitoring necessary to comply with the WCPP to reduce the risks from 1-BP so that they are no longer unreasonable. Subjecting facilities to self-certification would ensure that only those facilities that are able to implement the ECEL and other requirements of the WCPP would be able to continue to purchase 1-BP for a condition of use subject to the 1-BP WCPP.

Under a self-certification requirement, entities would submit a self-certification to the distributor each time 1-BP is purchased. The self-certification would consist of a statement indicating that the facility is implementing a WCPP that would include an ECEL, PPE requirements, and ancillary requirements; the self-certification would be signed and presented to the

distributor by the facility owner or operator or person authorized to do so. In this way, distributors of 1-BP for the specified conditions of use would be able to identify clearly the entities engaging in the specified conditions of use who should be able to purchase 1-BP. Additionally, while not required to be reported to EPA, the self-certification records would be retained for 5 years and would also provide important information to EPA during any verification of compliance with the WCPP.

Details of the proposed self-certification, including ancillary recordkeeping requirements, requirements for demonstrating compliance and requirements for distributors, are described in more detail in Unit IV.A.

2. Alternative Regulatory Actions

EPA acknowledges that, for two of the occupational conditions of use (industrial and commercial use in batch vapor degreasing—open-top and in-line; industrial and commercial use in batch vapor degreasing—closed-loop) that EPA is proposing to subject to a WCPP, there may be some activities or facilities that could conceivably implement prescriptive controls to ensure that exposures remain below an ECEL. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. As described in Unit IV.B.1.b., under a 1-BP WCPP owners and operators would have more ability to implement risk reduction measures that may be better suited for their facility rather than subjecting facilities to specific required prescriptive controls that may not be the most suitable for all. Therefore, as a primary alternative regulatory action, described in Unit IV.B., EPA is considering and requesting comment on prescriptive controls and the implementation of a PPE program. Additionally, EPA is requesting any existing monitoring data that could inform whether a WCPP or prescriptive controls with a PPE program is a more appropriate regulatory action for these two conditions of use of 1-BP.

EPA understands that some of the workplaces engaged in a condition of use may already have stringent engineering controls, administrative controls, and PPE in place to reduce inhalation and dermal exposures to 1-BP, such as vapor degreasing. As part of the primary alternative regulatory action, EPA considered prescribed engineering controls, administrative controls, and PPE for the two occupational conditions of use. In contrast to the proposed non-

prescriptive requirements of the WCPP where regulated entities would have flexibility to select controls in accordance with the hierarchy of controls to comply, EPA understands that requiring specific prescriptive controls for certain occupational conditions of use may provide greater certainty to some facilities that they are addressing the unreasonable risk. However, as summarized in this unit, EPA has uncertainty regarding the feasibility of exposure reductions through specified engineering controls, administrative controls, and/or PPE to address unreasonable risk across all workplaces engaged in certain conditions of use. Prescribing specific engineering controls, administrative controls, or PPE does not consider distinctions in processes, equipment, or workplace layout in all facilities, which may result in varying levels and types of controls needed to reduce inhalation exposures to below the ECEL. Additionally, as described in Unit V.A.1.b., there is a degree of uncertainty regarding applicability of respirators, including their feasibility and consistency of proper use, especially when exposure monitoring is not regularly conducted. However, as part of the primary alternative regulatory action, EPA is considering PPE and soliciting comment on prescribing specific engineering and administrative controls for some occupational conditions of use. In the 2020 Risk Evaluation for 1-BP, EPA identified PPE that could reduce exposures and therefore considered requiring PPE, including respiratory protection and dermal protection, as part of the primary alternative regulatory action for those certain conditions of use where the proposed regulatory action is a 1-BP WCPP. Turning to the use of PPE, however, does not consider other more preferable controls in the hierarchy of controls, including elimination, substitution, engineering, and administrative controls. As part of the primary alternative regulatory action, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use.

EPA also considered a prohibition as a second alternative regulatory option for all manufacturing (including import), processing, industrial and commercial use, and disposal of 1-BP, except for the use of 1-BP and products containing 1-BP in building/construction materials (insulation). EPA

considered determining that prohibition, as a second alternative regulatory option, would be suitable for all conditions of use (except in insulation) after taking into consideration other combinations of controls as described in this unit and Unit IV. Ultimately, a prohibition would result in elimination of unreasonable risk from the use of 1-BP, rather than allowing 1-BP use to continue in perpetuity.

EPA acknowledges that, for some conditions of use for which it is considering prohibition under the second alternative regulatory option, there may be some activities or facilities that would need longer compliance timeframes in order to appropriately transition. Therefore, the second alternative regulatory action also considered providing for additional time under a prohibition to provide the flexibility for facilities to comply, for example, to account for issues affecting the supply chain, such as the ready availability of alternatives to reformulate products. In selecting among the TSCA section 6(a) requirements for the second alternative regulatory action for use of 1-BP-containing products, EPA considered risk-related factors, including but not limited to, the population exposed and the severity of the hazard of 1-BP and, separately, for other alternative solvents, which are undergoing risk evaluation and risk management under TSCA section 6, such as PCE (as part of a separate rulemaking). For example, there may be instances where PCE and 1-BP may be desired because they are non-flammable solvents used as cleaning agents for use in vapor degreasing. In these instances, additional time may be needed to identify an alternative chemical or process to avoid flammability concerns.

Details of the primary alternative regulatory action and second alternative regulatory action are described in more detail in Unit IV.B.

3. Risk Management Requirements Considered But Not Proposed

EPA considered but is not proposing to regulate the weight fraction of 1-BP in products for industrial and commercial or consumer use because 1-BP is the main constituent (*e.g.*, cleaning component) of the majority of 1-BP-containing product formulations and EPA understands that decreasing the concentration of 1-BP decreases the efficacy of the product.

EPA's proposed requirements to address unreasonable risk to workers, ONUs, and consumers and bystanders to

consumer use are described in Unit IV.A.

Additional Considerations

After considering the different regulatory options under TSCA section 6(a), alternatives (described in Unit V.B.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit IV.A. to address the unreasonable risk from 1-BP to the extent necessary so that the risk is no longer unreasonable. To ensure successful implementation of this proposed regulatory action, EPA considered other section 6(a) requirements to support compliance with the proposed regulations, such as requiring monitoring and recordkeeping to demonstrate compliance with the 1-BP WCPP and downstream notification regarding the prohibition on manufacturing, processing, distribution in commerce, and use of 1-BP, including products containing 1-BP, for certain conditions of use. These proposed requirements are described in Unit IV.A.

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the final rule (except in the case of a use exempted under TSCA section 6(g) or for full implementation of ban or phase-out requirements). For ban or phase-out requirements, EPA must specify mandatory compliance dates for the start of ban or phase-out requirements, which must be as soon as practicable but no later than 5 years after the date of promulgation of the final rule. These compliance dates are detailed in Unit IV.A. and IV.B. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments. Following Panel recommendations in the SBAR report, and described in Unit IV., EPA considered reasonable compliance timeframes in response to SER input and other appropriate factors, such as capital costs for new equipment, and ongoing regulations and rulemakings, including the addition of 1-BP to the list of (HAPs under the Clean Air Act (January 5, 2022; 87 FR 393) (Ref. 20). Additionally, following Panel recommendations in the SBAR report, EPA considered compliance timelines based on the availability of technically and economically feasible alternatives, as well as any information provided by other agencies that may set requirements for certification or standards relevant to degreasing, parts

cleaning, or other uses of 1-BP.

Following Panel recommendations in the SBAR report, EPA is requesting comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for degreasing and other industries, as well as differing compliance or reporting requirements or timetables that account for the resources available to small entities.

B. Consideration of Alternatives in Deciding Whether To Prohibit or Substantially Restrict 1-BP

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to an Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 35).

For this assessment, EPA identified and analyzed alternatives to 1-BP in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted, even if such restrictions are not anticipated to substantially prevent the condition of use. Based on reasonably available information, including information submitted by the industry, EPA understands viable alternatives to 1-BP may not be available for several conditions of use—for example, processing 1-BP as a raw material in chemical reactions for the manufacturing of another chemical substance or product—and considered that information to the extent practicable in the development of the regulatory options as described in Unit III.B.3. For some conditions of use, EPA was unable to identify products currently available for sale that contain 1-BP. EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain 1-BP at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such use of 1-BP. These conditions of use are detailed in the Alternatives Assessment (Ref. 35).

In deciding whether to propose prohibition or other significant restrictions on a condition of use of 1-BP and in proposing an appropriate transition period for any such action, EPA has therefore, pursuant to TSCA section 6(c)(2)(C), considered, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use proposed to be prohibited or restricted, would be reasonably available as a substitute when a proposed prohibition or other significant restriction would become effective. EPA is additionally requesting comment on the Alternatives Assessment as a whole.

VI. TSCA Section 6(c)(2) Considerations

A. Health Effects of 1-BP and the Magnitude of Human Exposure to 1-BP

EPA's analysis of the health effects of 1-BP and the magnitude of human exposure to 1-BP are in the 2020 Risk Evaluation for 1-BP (Ref. 1). A summary is presented here.

The 2020 Risk Evaluation for 1-BP identified potential health effects of 1-BP including non-cancer adverse health effects such as liver toxicity, kidney toxicity, reproductive toxicity, developmental toxicity, and neurotoxicity. Relative to cancer effects, the risk evaluation identified cancer hazards from genotoxicity, a recognized mechanism of cancer, and site-specific cancers, particularly for skin, intestinal, and lung tumors. EPA has determined that protecting at the cancer endpoint would also address the risk for other acute or chronic non-cancer endpoints.

For acute inhalation and dermal exposure scenarios, EPA identified non-cancer developmental effects as the most sensitive endpoint. For chronic inhalation and dermal exposure scenarios, EPA identified the following health effects: liver (increased hepatocellular vacuolization), kidney (increased pelvic mineralization), reproductive system (decreased seminal vesicle weight), developmental effects (decreased live litter size and post-implantation loss), and nervous system (decreased traction time) as the most sensitive endpoints. By the criteria presented in EPA's Guidelines for Carcinogen Risk Assessment (Ref. 30), 1-BP is characterized as "likely to be carcinogenic to humans by all routes of exposure" based on the positive findings for carcinogenicity in more than one test species, together with positive findings for the direct reactivity of 1-BP with DNA and suggestive but inconclusive evidence for genetic toxicity. In a two-year cancer bioassay

with 1-BP exposures via the inhalation route, increases in the incidence of skin tumors (keratoacanthoma/squamous cell carcinomas) in male F344 rats, rare large intestine adenomas in female F344 rats, and alveolar/bronchiolar adenomas or carcinomas (combined) in female B6C3F1 mice were observed (Ref.1).

Regarding the magnitude of human exposure, one factor EPA considers for the conditions of use that contribute to unreasonable risk is the size of the exposed population which, for 1-BP, EPA estimates that, annually, there are between approximately 4,147 and 8,131 workers and between 2,310 and 4,709 ONUs at between 716 and 1,627 commercial operations either processing or using products containing 1-BP (Ref. 3). The number of consumers that use products containing 1-BP each year is likely to be few because EPA found that products containing 1-BP aren't typically marketed to consumers and several products that might have been marketed to consumers are being discontinued.

For the conditions of use that contribute to the unreasonable risk for 1-BP, PESS include workers, ONUs, consumer users, and bystanders to consumers using products containing 1-BP. PESS also includes the following life stages: people of reproductive age, pregnant women, infants, and children.

In addition to workers, ONUs, consumers, and bystanders to consumer use directly exposed to 1-BP, EPA recognizes there is exposure to the general population from the ambient air pathway for 1-BP, including fenceline communities. As mentioned in Unit II.D., EPA has separately conducted a screening approach to assess whether there may be potential risks to the general population from this exposure pathway. While the use of this screening approach indicates that EPA is not able to quantify reduced risk or find that there are no potential risks to fenceline communities, the screening approach was not designed to facilitate the making of an unreasonable risk determination for these communities. This unit summarizes the results of that fenceline analysis. EPA is not making a determination of unreasonable risk based on the fenceline screening analysis, however, the proposed regulatory action described in Unit IV., in combination with EPA's designation of 1-BP as a HAP (87 FR 393) and subsequent CAA-required NESHAPs, particularly for vapor degreasing, is expected to reduce risk.

As described in Unit II.D., EPA's fenceline analysis methodology was presented to the SACC peer review panel in March 2022, and EPA

considered SACC feedback (including the SACC recommendation to EPA to consider multiple years of release data to estimate exposures and associated risks) and made decisions regarding how to assess general population exposures. For 1-BP, EPA recognizes that a key input into the fenceline analysis for the ambient air pathway was data on releases from the most recent Toxics Release Inventory (TRI) reporting year and that the use of more than one year of data could result in different conclusions. Accordingly, in this unit EPA presents the results of its ambient air pathway fenceline analysis based on 1-BP releases reported to TRI over a single reporting year as well as over multiple years. Additionally, analysis of the facilities identified with risk show no co-located facilities (Ref. 36).

EPA's fenceline analysis for the air pathway for 1-BP indicates that EPA is not able to conclude that there are no potential risks to fenceline communities, described further in this unit. Additionally, based on the fenceline analysis for the ambient air pathway for 1-BP, including the strengths, limitations, and uncertainties associated with the information used to inform the analysis, EPA is unable to determine with this analysis whether those risks contribute to the unreasonable risk of injury to health presented by 1-BP. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, 1×10^{-6} to 1×10^{-4}) depending on the subpopulation exposed. For example, when setting standards under section 112(f)(2) of the CAA, EPA uses a two-step process, with "an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand" (Ref. 37). In this screening level fenceline analysis for the ambient air pathway for 1-BP, estimates of risk to fenceline communities were calculated with reference to a 1×10^{-6} benchmark for cancer risk. While the screening fenceline analysis for 1-BP indicates risk to fenceline communities, EPA is unable to determine, based on that analysis, whether risks to the general population contribute to the unreasonable risk (Ref. 36). The benchmark values are not a bright line, and the Agency considers a number of factors when determining unreasonable risk, such as the endpoint under

consideration, the reversibility of effect, and exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or size of population exposed). EPA is working on improving the fenceline assessment methodology for future chemicals based on feedback from SACC and public comments. The evolving approach for evaluating risks to fenceline communities was in EPA's Draft Supplement to the Risk Evaluation for 1,4-Dioxane, <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0011>.

In this unit, EPA presents the results of its ambient air pathway fenceline analysis and the uncertainties associated with the analysis. EPA also describes how the proposal to prohibit the manufacturing (include importing), processing, and distribution in commerce of 1-BP for certain industrial and commercial use and all consumer use, and to prohibit some industrial and commercial use of 1-BP, is expected to reduce the potential risks identified in the screening analysis to fenceline communities close to facilities engaging in 1-BP use. This unit also describes how EPA believes the proposed WCPP requirements may reduce exposures to the general population for facilities identified in the fenceline analysis with expected exposures to fenceline communities that are associated with conditions of use EPA is not proposing to prohibit. EPA also believes that with the proposed prohibitions of some conditions of use, risk is expected to be reduced for certain fenceline communities. EPA therefore does not intend to revisit the air pathway for 1-BP as part of a supplemental risk evaluation.

In January 2022, 1-BP was added to the HAP list under the CAA (87 FR 393), which also requires EPA to list source categories of HAPs, set standards for all HAPs that are emitted from each source category, and review and revise these standards, if necessary, to account for improvements in air pollution controls and/or prevention, including addition of any recently added HAPs that may be applicable to the standard being reviewed. As NESHAPs continue to be reviewed, and as the majority of facilities assessed, and those which indicate potential risk, in the fenceline analysis were vapor degreasing facilities, the NESHAPs process under the CAA will assess risk to the general population at the fenceline and regulate as necessary.

There are some uncertainties associated with the fenceline analysis for the air pathway for 1-BP. The TRI dataset used for the single- and the multi-year fenceline analysis and land

use analysis does not include actual release point locations, which can affect the estimated concentrations of the chemical at varying distances modeled. To identify the release location for each facility, EPA used a local-coordinate system based on latitude/longitude coordinates reported in TRI. The latitude/longitude coordinates may represent the mailing address location of the office building associated with a very large facility or some other area of the facility rather than the actual release location (e.g., a specific process stack). This discrepancy between the coordinates reported in TRI and the actual release point could result in an exposure concentration that does not represent the actual distance where fenceline communities may be exposed. The fenceline analysis also evaluated the most "conservative exposure scenario" that consists of a facility that operates year-round (365 days per year, 24 hours per day, 7 days per week) in a South Coastal meteorologic region and a rural topography setting (Ref. 36). Therefore, the modeled exposures to people may be overestimated if there are fewer exposure days per year or hours per day. Additionally, the ambient air fenceline analysis organizes facilities and associated risks by OES and generally crosswalks each OES with the associated condition of use of 1-BP (Ref. 36). For some OES, EPA identified the associated conditions of use to the category level in the August 2020 Risk Evaluation for 1-BP but was unable to identify the conditions of use to the subcategory level due to limited information on activities and use of 1-BP reported under TRI. Therefore, some OES indicating increased cancer risk from ambient air exposures to 1-BP in the air fenceline analysis may be associated with one or more conditions of use of 1-BP.

EPA's single year fenceline analysis for the ambient air pathway, based on methods presented to the SACC, evaluated 1-BP releases to TRI over the 2019 reporting year. This single year fenceline analysis identified 71 facilities with some indication of releases and potential exposure with associated cancer risk to people within select distances evaluated from 5 to 1,000 meters from the respective releasing facility. Separately, following SACC feedback, EPA applied a slightly modified pre-screening methodology to evaluate 5 years of 1-BP release data (2016 through 2020 TRI data as well as the 5-year average of that data) rather than a single year of data for facilities with reported releases in TRI. The multi-year fenceline analysis identified

105 facilities with some indication of releases and potential exposures and associated cancer risk in excess of 1×10^{-6} at a distance of 100 meters from the releasing facility (Ref. 36). Based on the multi-year fenceline analysis, 47 of these 105 facilities may have cancer risks above 1×10^{-6} at distances farther out than 100 meters when compared to the single year analysis or are facilities that were not captured in the single-year analysis (e.g., did not report in 2019 TRI). Although the multi-year analysis identified several additional facilities whose operations may result in fenceline community risks above 1×10^{-6} for cancer farther out when compared to the single year analysis or that were not captured in the single-year analysis, the results of overall risk profiles (i.e., OES and corresponding conditions of use with risk estimates above the benchmark for cancer at the distances evaluated) for the single year and multi-year fenceline analyses are the same.

EPA conducted a land use analysis to determine if EPA can reasonably expect an exposure to fenceline communities to occur within the modeled distances for facilities where there was an indication of risk in the single year or multi-year fenceline analysis. This review consisted of a visual analysis using aerial imagery and interpreting land/use zoning practices spaces are present within those radial distances indicating risk (as opposed to uninhabited areas), as well as whether the radial distances lie outside the boundaries of the facility. The land use analysis identified 49 facilities indicating risk in the single-year fenceline analysis and identified 35 out of the 49 facilities with expected exposure to fenceline communities. The land use analysis of the 34 additional facilities indicating risk in the multi-year fenceline analysis (i.e., facilities where cancer risk estimates were above 1×10^{-6} at distances farther out when compared to the single-year analysis or facilities that were not captured in the single year analysis) identified 30 additional facilities with expected exposure to fenceline communities. Overall, the land use analysis identified a total of 49 facilities, associated with 11 conditions of use of 1-BP, with expected exposure to fenceline communities (Ref. 36). Those conditions of use of 1-BP are: degreasing (batch open-top degreasing; batch closed-loop degreasing; conveyorized vapor degreasing; web vapor degreasing; cold cleaning); incorporation into formulation, mixture, or reaction product; import; manufacturing (domestic manufacturing); other

industrial uses—cutting oils; repackaging; and recycling and disposal (Ref. 36).

Under the proposed regulatory action described in Unit IV.A., most of the conditions of use with an indication of potential risk to fenceline communities would be subject to requirements of the 1-BP WCPP, including: manufacturing; several processing conditions of use; and several industrial conditions of use. EPA is also proposing to prohibit certain conditions of use that may be associated with 2 of the 47 facilities analyzed with an indication of potential risk to fenceline communities in the fenceline analysis, including: dry cleaning and functional fluids. As a result, exposures to any fenceline communities from these facilities would be addressed under the prohibitions in the proposed rulemaking.

The remaining facilities with expected exposure to fenceline communities may be associated with the following conditions of use that EPA is not proposing to prohibit: manufacturing (domestic manufacture); processing as a reactant; processing for incorporation into formulation, mixture, or reaction products; processing for incorporation into articles; industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser—closed loop; industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser—open-top, inline vapor degreaser; and, industrial and commercial use as solvent for cleaning and degreasing in cold cleaners. For these conditions of use that may be associated with facilities that indicate expected exposure to fenceline communities, the proposed rule would require strict workplace exposure controls via implementation of a WCPP as described in Unit IV.A.2. Under the proposed WCPP requirements, facilities would need to monitor 1-BP air concentrations by taking personal breathing zone air samples of potentially exposed persons, which would allow facilities to better understand and manage the total releases of 1-BP within the facility and potentially stack and fugitive emissions. Furthermore, as part of the proposed controls outlined in Unit IV., EPA is proposing to prohibit increased releases of 1-BP to outdoor air associated with the implementation of the WCPP to avoid unintended increases in exposures to people (in the workplace and fenceline communities) from 1-BP emissions to ambient air by requiring owners to attest in their WCPP exposure control plan that engineering controls selected do not increase emissions of 1-BP to ambient air outside of the

workplace, keep records of that statement as part of the WCPP exposure control plan, and document in their exposure control plan whether additional equipment was installed to capture or otherwise prevent increased emissions of 1-BP to ambient air. EPA is requesting comment on best practices to remove and reduce fugitive emissions of 1-BP from relevant operations including, but not limited to, chemical manufacturing, vapor degreasing, electronics degreasing, cold cleaning, and adhesives manufacturing. EPA is requesting comment on the types and costs of technologies firms would adopt to comply with the prohibition on increased releases of 1-BP to outdoor air associated with engineering controls used in the implementation of the WCPP. In addition, EPA requests comment on whether and to what extent certain technologies, including technologies that might be implemented pursuant to applicable regulatory authority (such as emission standards resulting from possible future NESHAP requirements), would reduce 1-BP emissions to ambient air at facilities that adopt them below emissions levels that may have existed prior to implementation of the WCPP.

Finally, in the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that that may result in more 1-BP being ventilated outside, EPA believes this potential additional exposure would be limited as a result of anticipated revisions to NESHAP requirements following the designation of 1-BP as a HAP under the CAA.

EPA expects that this proposed action, in combination with the emissions standards resulting from anticipated revisions to NESHAP requirements following the designation of 1-BP as a HAP, would reduce risk sufficiently to the general population and fenceline communities. EPA does not intend at this time to revisit the air pathway for 1-BP as part of a supplemental risk evaluation. EPA is seeking comment on its conclusions, and whether, consistent with TSCA section 9(b), any other statutory authorities administered by EPA should be used to take additional regulatory action identified as necessary to protect against such risk. EPA is also soliciting comment on whether EPA should require ambient air monitoring, including fenceline monitoring, at fenceline locations or facility emissions source monitoring to demonstrate compliance with the proposed requirement that engineering controls implemented as part of a WCPP under

this rulemaking would not result in the ventilation of more 1-BP outside. The Agency recognizes that owners and operators may have difficulty distinguishing between emission increases due to implementation of the WCPP and emissions increases resulting from other factors such as increased manufacturing, processing, or use of 1-BP, although monitoring at both upwind and downwind locations could help them do so. In addition, EPA understands the difficulty in distinguishing between background levels of 1-BP and emissions from facilities. Therefore, EPA is soliciting comment on the need for and associated costs of ambient air monitoring at fenceline locations and facility emissions source monitoring, as well as information on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule (such as a detection limit for 1-BP). EPA is also requesting comment on methods to inform fenceline communities of any increases of 1-BP emissions to ambient air. EPA is also soliciting comment on whether, if EPA does not finalize the proposed prohibition on increased releases of 1-BP to ambient air outside of the workplace associated with implementation of the WCPP, EPA should require monitoring to alert EPA to any increased emissions to ambient air associated with WCPP implementation so that the Agency may take appropriate action.

B. Environmental Effects of 1-BP and the Magnitude of Exposure of the Environment to 1-BP

EPA's analysis of the environmental effects of 1-BP and the magnitude of exposure of the environment to 1-BP are in the 2020 Risk Evaluation for 1-BP (Ref. 1). The unreasonable risk determination for 1-BP is based solely on risks to human health; based on the TSCA 2020 Risk Evaluation for 1-BP, EPA determined that exposures to the environment did not contribute to the unreasonable risk from 1-BP. A summary is presented here.

EPA considered the effects of 1-BP on aquatic, sediment dwelling, and terrestrial organisms. EPA found that there were no exceedances of benchmarks to aquatic organisms from exposures to 1-BP. Based on a consideration of the physical-chemical properties and uses of 1-BP, exposure to aquatic species is the only route of exposure to the environment that was quantitatively assessed in the risk evaluation. Risks to terrestrial and sediment-dwelling aquatic species were qualitatively evaluated by considering

physical-chemical and environmental fate properties of 1-BP, which indicate that there is a low potential for exposure to terrestrial and sediment-dwelling aquatic species. The quantitative assessment of water column-dwelling aquatic species was updated in the final risk evaluation to incorporate the Ecological Structure Activity Relationships (ECOSAR) modeling results for environmental hazards to reduce uncertainty about the limited environmental hazard data available for 1-BP. EPA conducted a screening-level assessment of the available environmental hazards and release information to calculate RQs to quantify potential risks to the environment from 1-BP. The RQ values associated with acute and chronic exposures are <0.01 and 0.12, respectively, based on the best available science (Risk Evaluation, Table 4-2) and are less than the concentrations that would cause an effect to organisms in the aquatic pathways. The RQ values for risks from acute and chronic exposure to 1-BP are <1, based on a comparison of all available data characterizing exposure and hazard to aquatic species. These values indicate that risks to the environment are not identified based on the conditions of use within the scope of the risk evaluation.

EPA considered uncertainties in its determination of unreasonable risk for 1-BP to the environment. While EPA has determined that sufficient data are reasonably available to characterize the overall environmental hazards of 1-BP under the conditions of use, there are uncertainties regarding the available environmental hazard data for 1-BP. High volatility (Vapor Pressure = 110 mm Hg and Henry's Law constant of 7.3×10^{-3} atm-m³/mole), and a consideration of the conditions of use of the chemical, indicate that 1-BP will only be present in terrestrial environmental compartments as a transient vapor. No specific conditions of use were identified that resulted in systematic, significant airborne exposures that overlap with terrestrial habitats, so this is not considered a relevant route of exposure for 1-BP under the conditions of use of the risk evaluation. Additionally, 1-BP is not expected to bioaccumulate and therefore, exposure to terrestrial species through ingestion of prey is negligible.

C. Benefits of 1-BP for Various Uses

1-BP has a wide range of uses, including as a solvent for cleaning and degreasing (*i.e.*, vapor degreasing, cold cleaning, and aerosol degreasing). A variety of consumer and commercial products use 1-BP as adhesives and

sealants, in furniture care products, in dry cleaning, spot cleaning and other liquid, spray, and aerosol cleaners, and in automotive care products. 1-BP is also used in insulation for building and construction materials. 1-BP is subject to federal and state regulations and reporting requirements, as further described in Unit VIII. According to data collected in EPA's 2016 Chemical Data Reporting (CDR) Rule, 25.9 million pounds of 1-BP were manufactured in or imported into the United States in 2015. Data publicly reported indicate that there are two domestic manufacturers and eight importers of 1-BP in the United States. Total production volume (domestic manufacture plus import) of 1-BP increased from 2012 to 2015. 1-BP's volume has increased because it has been an alternative to ozone-depleting substances and chlorinated solvents. Import volumes for 1-BP reported to the 2016 CDR are between 10 million and 25 million pounds per year.

D. Reasonably Ascertainable Economic Consequences of the Proposed Rule

1. Likely Effect of the Rule on the National Economy, Small Business, Technological Innovation, the Environment, and Public Health

The reasonably ascertainable economic consequences of this proposed rule include several components, all of which are described in the Economic Analysis for this proposed rule (Ref. 3). With respect to the anticipated effects of this proposed rule on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers and did not find that there would be an impact on the national economy (Ref. 3). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP). Given the current GDP, this is equivalent to a cost of \$40 billion to \$80 billion. Therefore, because EPA has estimated that the monetized cost of the proposed rule would range from \$14.8 million annualized over 20 years at a 3% discount rate and \$15.5 million annualized over 20 years at a 7% discount rate, EPA has concluded that it is highly unlikely this proposed rule would result in any measurable effect on the national economy (Ref. 3). In addition, EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but

EPA expects the short-term and longer-term employment effects would be small.

There are an estimated 931 small entities affected by the proposed option with a per firm and total estimated cost impact of \$13 thousand and \$12 million, respectively. Of the small businesses potentially impacted by this proposed rule, 88% are expected to have impacts of less than 1% of their firm revenues, 7% are expected to have impacts between 1 and 3% of their firm revenues, and 5% are expected to have impacts greater than 3% of their firm revenues.

Users of 1-BP in vapor degreasing could be strongly impacted because they may have no economical alternative to the use of 1-BP.

No incremental costs beyond the cost of rule familiarization are estimated for users of 1-BP products that are prohibited under the proposed rule. Users are assumed to switch to alternatives with similar costs and efficacy. As noted in section 7.12 of the EA, there may be some applications where 1-BP is more effective, reducing labor time and wait time, and this analysis was unable to quantify those costs. For example, there may be some safety-critical applications where alternatives would need to undergo extensive safety review and testing before they could replace the 1-BP products. The impact of a prohibition of 1-BP for these uses could potentially result in important negative impacts of the proposed option, but EPA was unable to quantify any of these potential impacts, so cost impacts to potentially affected small businesses could not be estimated.

With respect to this proposed rule's effect on technological innovation, EPA expects this action to spur more innovation than it will hinder. A prohibition or significant restriction on the manufacture, processing, and distribution in commerce of 1-BP for uses covered in this proposed rule may increase demand for safer chemical substitutes. This proposed rule is not likely to have significant effects on the environment because 1-BP does not present an unreasonable risk to the environment, though this proposed rule does present the potential for small reductions in air emissions associated with improper disposal of products containing 1-BP. The effects of this proposed rule on public health are estimated to be positive, due to the reduced risk of cancer and other non-cancer endpoints from exposure to 1-BP.

2. Costs and Benefits of the Proposed Regulatory Action and of the One or More Primary Alternative Regulatory Actions Considered by the Administrator

The costs and benefits that can be monetized for this proposed rule are described at length in the Economic Analysis (Ref. 3). The monetized costs for this proposed rule are estimated to range from \$14.8 million annualized over 20 years at a 3% discount rate and \$15.5 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be \$27.2 million annualized over 20 years at a 3% discount rate and \$12.9 million annualized over 20 years at a 7% discount rate.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce alternative regulatory actions. The primary and second alternative regulatory actions are described in detail in Unit IV.B. The estimated annualized costs of the primary alternative regulatory action are \$14.4 million at a 3% discount rate and \$15.0 million at a 7% discount rate over 20 years (Ref. 3). The estimated annualized costs of the second alternative regulatory action are \$181.2 million at a 3% discount rate and \$250.1 million at a 7% discount rate over 20 years. The monetized benefits of the primary alternative action are estimated to be \$27.2 million annualized over 20 years at a 3% discount rate and \$12.9 million annualized over 20 years at a 7% discount rate (Ref. 3). The monetized benefits of the second alternative action are estimated to be \$27.2 million annualized over 20 years at a 3% discount rate and \$13.0 million annualized over 20 years at a 7% discount rate. For the proposed rule, as described in the Economic Analysis, EPA assumes that all vapor degreasing and batch cold cleaning users can comply with a WCPP. However, some users may require supplied air respirators to comply with the WCPP and it may be impractical for some workers to perform their jobs using these types of respirators. Since we estimate substitution away from 1-BP to be much more expensive than complying with a WCPP, our estimated costs could be several times higher than our current estimate if a WCPP is impractical for many users.

This proposal is expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. EPA believes that the balance of costs and

benefits of this proposal cannot be fairly described without considering the additional, non-monetized benefits of mitigating the cancer and non-cancer adverse effects. These effects may include liver toxicity, kidney toxicity, reproductive effects possibly including reduction in fertility, developmental effects possibly including fetal loss and low birth weight, and neurotoxicity including peripheral neuropathy (Ref. 1). Peripheral neuropathy has been documented in workers chronically exposed to high levels of 1-BP in spray adhesives.

Fetal loss, also referred to as fetal death or fetal mortality, includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs. The impacts of fetal death, including miscarriage or stillbirth, include mental health impacts, such as depression and anxiety on the woman experiencing the death of a fetus, and can also impact partners and spouses (Ref. 3). Mental health research has consistently identified both miscarriage (defined as fetal death occurring before the 20th week of gestation) and stillbirth (defined as fetal death occurring after the 20th week of gestation) as a significant emotional burden exhibited as anxiety and depression that can persist; research suggests women and men feel effects for more than a year, women can feel effects nearly three years following the event of fetal death and after the birth of a healthy child, which emphasizes effects can persist significantly longer beyond the event (Ref. 3).

EPA also identified risks of reduction in fertility as an effect resulting from exposures to 1-BP (Ref. 1). While impacts from 1-BP exposure on fertility and fecundity cannot be quantified at this time with available data, for couples seeking treatment for infertility, costs of such treatment are often significant both financially and emotionally. The most comprehensive and appropriate value for benefit-cost analysis is willingness to pay. There are few studies for the reduced risk of infertility, but a recent study estimates a willingness to pay of \$102,000 per statistical case of infertility avoided (Ref. 3). EPA also identified risks of low-birth weight by women of child-bearing age exposed to 1-BP as another health effect of concern. Low birth weight can have significant impacts on childhood development and the incidence of future diseases; reduced birth weight can cause serious health problems for some children, as well as long-term impacts on their lives as adults (Ref. 3).

The multitude of adverse effects from 1-BP exposure can profoundly impact

an individual's quality of life, as discussed in Units II.A. (overview), III.B.2. (description of the unreasonable risk), and VI.A. (discussion of the health effects), as well as the 2020 Risk Evaluation for 1-BP. Chronic adverse effects of 1-BP exposure include both cancer and the non-cancer effects addressed in Unit VI.A. Acute effects of 1-BP exposure could be experienced for a shorter portion of life but are nevertheless significant in nature. The incremental improvements in health outcomes achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with 1-BP exposure, and therefore cannot be converted into monetized benefits. The qualitative discussion throughout this rulemaking and in the Economic Analysis highlights the importance of these non-cancer effects. These effects include willingness-to-pay to avoid illness, which includes cost of illness and other personal costs such as pain and suffering. Considering only monetized benefits underestimates the impacts of 1-BP adverse outcomes and therefore underestimates the benefits of this proposed rule. EPA requests comment on how EPA might best quantify and monetize non-cancer endpoints described in the 2020 Risk Evaluation for 1-BP for economic analysis.

3. Cost Effectiveness of the Proposed Regulatory Action and of One or More Primary Alternative Regulatory Actions Considered by the Administrator

Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. A goal of this proposed regulatory action is to prevent unreasonable risk resulting from exposure to 1-BP. The proposed regulatory action would cost \$3.2 million per potential prevented cancer case while the primary alternative regulatory action would cost \$3.1 million (using the 3% discount rate) and the second alternative regulatory action would cost \$38.8 million to achieve the same goals. At a 7% discount rate, the proposed regulatory action would cost \$3.3 million per potential prevented cancer case while the primary alternative regulatory action would cost \$3.2 million, and the second alternative regulatory action would cost \$53.6 million to achieve the same goals. While the proposed regulatory action is higher in cost compared to the primary alternative action, the difference is small (Ref. 3).

VII. TSCA Section 9 Analysis, Section 14, and Section 26 Considerations

A. TSCA Section 9(a) Analysis

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. Section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency following submission of any such report. As discussed in this unit, for this proposed rule, the Administrator proposes to exercise discretion not to determine that the unreasonable risk from 1-BP under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

In addition, TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burdens of duplicative requirements. For this proposed rule, EPA has and continues to coordinate with appropriate Federal executive departments and agencies including OSHA and the Consumer Product Safety Commission (CPSC) to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to 1-BP, which are summarized in this unit.

OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education and assistance. However, gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. Health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only "to the extent feasible." 29 U.S.C. 655(b)(5). To set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). But under TSCA section 6(a), EPA's substantive burden is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being

determined without consideration of costs or other nonrisk factors. Thus, if OSHA were to initiate a new action to establish a PEL for 1-BP, the difference in standards between the OSH Act and TSCA may well result in the OSHA PEL being set at a higher level than the exposure limit that EPA determined would be sufficient to address the unreasonable risk under TSCA.

In addition, OSHA may set exposure limits for workers, but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals, and thus OSHA cannot address the unreasonable risk from 1-BP under all of its conditions of use, which include consumer uses. OSHA also does not have direct authority over State and local employees, and it has no authority over the working conditions of State and local employees in States that have no OSHA-approved State Plan under 29 U.S.C. 667.

CPSC, under authority provided to it by Congress in the CPSA, protects the public from unreasonable risks of injury or death associated with the use of consumer products. Under the CPSA, CPSC has the authority to regulate 1-BP in consumer products, but not in other sectors such as automobiles, industrial and commercial products, or aircraft, for example. Further, a consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs," 15 U.S.C. 2058(f)(3)(E), whereas EPA must apply TSCA risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a), (c)(2). Additionally, the 2016 amendments to TSCA reflect Congressional intent to "delete the paralyzing 'least burdensome' requirement," 162 Cong. Rec. S3517 (June 7, 2016), a reference to TSCA section 6(a) as originally enacted, which required EPA to use "the least burdensome requirements" that protect "adequately" against unreasonable risk, 15 U.S.C. 2605(a) (1976). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action CPSC may take under the Federal Hazard Substances Act (FHSA) relative to action EPA may take under TSCA. 15 U.S.C. 1262. EPA's substantive burden

under TSCA section 6(a) is to apply requirements to the extent necessary so that the chemical substance no longer present the unreasonable risk that was determined in accordance with TSCA section 6(b)(4)(A) without consideration of cost or other non-risk factors.

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of 1-BP to a sufficient extent across the range of conditions of use, exposures and populations of concern. This unreasonable risk can be addressed in a more coordinated, efficient and effective manner under TSCA than under different laws implemented by different agencies. Moreover, the timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations cannot be estimated, while TSCA requires a much more accelerated 2-year statutory timeframe for proposing and finalizing regulatory requirements to address unreasonable risk. Further there are key differences between the finding requirements of TSCA and those of the OSH Act, CPSA, and FHSA. For these reasons, in the Administrator's discretion, the Administrator proposes not to determine that unreasonable risk from 1-BP may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA. However, EPA is requesting public comment on this issue (*i.e.*, the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce a risk to health or the environment, TSCA section 9(b) instructs EPA to use these other authorities to protect against that risk unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: "the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk."

Although several EPA statutes could be used to limit 1-BP exposure (Ref. 6), regulations under those EPA statutes would have limitations with respect to addressing the unreasonable risk of injury to human health presented by 1-BP as identified in the 2020 Risk Evaluation because they largely regulate

releases to the environment, rather than occupational or consumer exposures, and risk to the environment does not contribute to the unreasonable risk from 1-BP identified by EPA under TSCA.

The primary exposures and unreasonable risk to consumers, bystanders, workers, and ONUs would be addressed by EPA's proposed prohibitions and restrictions under TSCA section 6(a). In January 2022, EPA added 1-BP to the HAP list under the CAA (87 FR 393). Section 112 of the CAA requires that EPA identify categories of sources that emit HAPs and then promulgate emission standards that address the emissions of all HAPs emitted from the source category. Section 112 also requires EPA to review promulgated standards at least every 8 years and to revise such standards, if necessary, to account for improvements in air pollution controls and/or pollution prevention. Technology reviews typically include an evaluation of developments in HAP control technologies or other methods of reducing HAP emissions, adjustments to emissions testing and monitoring approaches, and updates to ensure that rules are consistent with recent court decisions and other relevant issues related to the CAA section 112 rulemaking program. Further, CAA section 112 requires EPA to conduct a residual risk review to assess human health and environmental risks associated with the HAP emitted from the source category being reviewed. It is intended to ensure that public health is protected with an ample margin of safety. EPA has generally treated the risk review as a one-time requirement for each source category, but EPA has authority to conduct subsequent reviews, and sometimes does so, for example, if new information, such as a new toxicological assessment showing the increased potency of a chemical, warrants a new residual risk assessment. As part of these reviews, the EPA is required to set standards for any unregulated HAPs emitted from the source category under review, including any newly listed HAP. Since the listing of 1-BP in 2022, EPA has conducted reviews of the standards promulgated for some source categories and has looked for potential emissions of 1-BP. None of these categories were found to emit 1-BP and, therefore, EPA has not yet promulgated standards for 1-BP under CAA section 112. As other NESHAP reviews continue as part of the 8-year review cycle, including for the halogenated solvents source category for vapor degreasing facilities that constitute the majority of facilities

assessed in the 1-BP fenceline analysis, the NESHAPs process under the CAA will assess risk to the general population, including people living in near proximity to facilities in the source categories. These reviews are intended to provide an ample margin of safety to protect public health consistent with statutory requirements. All source categories will be reviewed and EPA will set CAA section 112 standards that regulate 1-BP if it is found to be emitted from the source category under review. This includes the halogenated solvents source category. This rulemaking under TSCA is more appropriate to address the unreasonable risk of injury to human health and the environment presented by 1-BP as identified in the 2020 Risk Evaluation. None of EPA's other statutes (e.g., RCRA, CAA, CWA) can adequately address exposures to workers and ONUs related to the specific activities that result in occupational exposures. EPA therefore concludes that TSCA is the most appropriate regulatory authority to prevent or reduce risks of 1-BP to a sufficient extent across the range of conditions of use, exposures, and populations of concern.

For these reasons, the Administrator does not determine that unreasonable risk from 1-BP under the conditions of use evaluated in the 2020 TSCA Risk Evaluation for 1-BP could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. TSCA Section 14 Requirements

EPA is also providing notice to manufacturers, processors, and other interested parties about potential impacts to CBI that may occur if this action is finalized as proposed. Under TSCA section 14(b)(4), if EPA promulgates a rule pursuant to TSCA section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any CBI regarding that chemical substance and submitted pursuant to TSCA will be "presumed to no longer apply," subject to the limitations identified in TSCA section 14(b)(4)(B)(i) through (iii). If this action is finalized as proposed, then pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure would apply only to information about the specific conditions of use that this rulemaking would prohibit or phase out. Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would need to be

submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange (CDX).

D. TSCA Section 26 Considerations

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. As in the case of the unreasonable risk determination, risk management decisions for this proposed rule, as discussed in Unit III.B.3. and Unit V., were based on a risk evaluation that was subject to public comment and independent, expert peer review, and was developed in a manner consistent with the best available science and based on the weight of the scientific evidence as required by TSCA sections 26(h) and (i) and 40 CFR 702.43 and 702.45.

In particular, the ECEL value incorporated into the WCPP is derived from the analysis in the 2020 Risk Evaluation for 1-BP; it likewise represents decisions based on the best available science and the weight of the scientific evidence (Refs. 12, 38, 39). The ECEL value of 0.05 ppm as an 8-hour TWA is based on the chronic cancer inhalation unit risk (IUR) at a risk level of 1×10^{-4} identified in the 2020 Risk Evaluation for 1-BP, which is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rulemaking. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found at EPA's risk evaluation docket at EPA-HQ-OPPT-2016-0741 (Ref. 32).

VIII. Requests for Comment

EPA is requesting public comment on all aspects of this proposal, including the proposed and alternative regulatory actions and all individual elements of these, and all supporting analysis. Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this

section summarizes those specific requests for comment.

1. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions.

2. EPA is requesting comment on all elements of the IRFA, and, in particular the flexibilities that EPA has identified following input from the SERs during the SBAR process.

3. EPA is requesting public comment regarding the need for exemptions from the proposed requirement (and under what specific circumstances) pursuant to the provisions of TSCA section 6(g).

4. EPA requests public comment on whether EPA should promulgate definitions for the conditions of use covered by the 2020 Risk Evaluation for 1-BP that would not be prohibited, and, if so, whether the descriptions in Unit II.B. are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for 1-BP and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation if EPA were to promulgate a regulation that contains a list of the industrial and commercial conditions of use evaluated in the 2020 Risk Evaluation for 1-BP. Additionally, EPA is requesting comment regarding the number of businesses or other entities that could potentially close, as well as associated costs, with a prohibition of 1-BP for certain industrial and commercial conditions of use identified in this proposed rule.

5. EPA also requests comment on whether, rather than just excluding the consumer and commercial uses of 1-BP in insulation from the prohibitions and other requirements in this risk management rulemaking, EPA should more broadly exclude the use of articles under TSCA section 6(c)(2)(E), which would also exclude the use of 1-BP in articles that were not specifically evaluated in the 2020 Risk Evaluation for 1-BP, and if so, whether and how to define “article” for the purposes of this rulemaking.

6. EPA requests comment on the proposed compliance dates for prohibitions of 1-BP manufacturing, processing, distribution in commerce, and use and whether additional time is needed, for example, for products to clear the channels of trade, or for implementing substitutes; comments should include documentation such as the specific use of the chemical throughout the supply chain; concrete steps taken to identify, test, and qualify substitutes for those uses (including details on the substitutes tested and the specific certifications that would require updating); and estimates of the time

required to identify, test, and qualify substitutes with supporting documentation. EPA also requests comment on whether these are the appropriate types of information for use in evaluating compliance requirements, and whether there are other considerations that should apply.

7. EPA would also like comment on whether it should consider a de minimis level of 1-BP in formulations for certain continuing industrial and commercial uses to account for impurities when finalizing these prohibitions, and, if so, what process and product formulations should be considered when evaluating a de minimis calculation to ensure exposure risk is removed.

8. EPA is requesting comment on commercial distribution channels or systems that would allow for distribution to commercial users while preventing retailers from making these products available to consumers, or feasible distribution channels for commercial users that have been developed in analogous situations, including information on whether there are market barriers to such systems.

9. EPA is soliciting comment regarding an ECEL action level that is lower than the ECEL and any associated provisions related to the ECEL action level.

10. EPA requests comment on the feasibility of complying with and monitoring for an ECEL of 0.05 ppm and an ECEL action level of 0.03 ppm, including occupational exposure monitoring and associated analytical methods. In particular, EPA requests comment on changes that may be needed in order to meet such a standard, for example changes related to elimination or substitution of 1-BP, engineering controls, process changes, or monitoring frequency. EPA is also interested in the information on the availability of laboratory capacity needed to meet the proposed standard, and the costs associated with such testing.

11. EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving 1-BP where exposures may approach the ECEL.

12. EPA requests comment on the timeframes for periodic monitoring outlined in Table 1 of Unit IV.A.2.

13. EPA requests comment on workplace monitoring for implementation of an ECEL. EPA is soliciting information related to the frequency of monitoring, initial monitoring, and periodic monitoring that would be needed to demonstrate workplace exposure levels. Specifically,

when this may impact the frequency of periodic monitoring where initial monitoring shows that employee exposures are above the level that would initiate requirements for compliance with the ECEL.

14. EPA is requesting comment on the proposed timeframe of within 30 days to conduct additional exposure monitoring after there has been a change in the production, process, control equipment, personnel or work practices that may reasonably be expected to result in new or additional exposures at or above the ECEL action level, or when the owner or operator has any reason to believe that new or additional exposures at or above the ECEL action level have occurred.

15. EPA is also requesting comment on the proposed timeframe to conduct additional exposure monitoring after the cleanup of the spill or repair of the leak, rupture or other breakdown, as outlined in Unit IV.A.2.

16. EPA is requesting comment on how the proposed requirement that owners or operators attest that the engineering controls selected do not increase emissions of 1-BP to ambient air outside of the workplace may impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

17. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA’s General Industry Standard for Beryllium.

18. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA’s General Industry Standard for 1,3-Butadiene, or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA’s General Industry Standard for Benzene.

19. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program. EPA is also requesting comment on whether EPA should include designated representatives who can also be permitted to observe exposure monitoring and have regular access to exposure-related information at the request of potentially exposed persons.

20. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within the timeframes identified in this proposed rule, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined

in this proposed rule, including establishment of a respiratory protection program and development of an exposure control plan.

21. EPA also requests comment on whether additional time is needed to implement all aspects of the WCPP or if there are available substitutes for these applications.

22. EPA is soliciting comments on the requirements proposed for appropriate PPE selection. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate.

23. EPA requests comment on establishing a self-certification requirement, and/or reporting requirements, for purchasing and continued use of 1-BP or products containing 1-BP for certain conditions of use. For example, EPA seeks comment on whether, in future rulemakings, it should require reporting to EPA of the type of records specified in 40 CFR 751.815.

24. EPA requests comment on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing 1-BP; implementation of new engineering or administrative controls; changes to labels, SDSs, and packaging; implementation of new PPE requirements, including training and monitoring practices; and supply chain management challenges. EPA also requests comment on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

25. EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in this proposed rule.

26. EPA requests comment on the primary alternative regulatory action (a combination of prohibitions, requirements for a WCPP, prescriptive controls, self-certification, and glove use) and whether any elements of this primary alternative regulatory action described in this proposed rule should be considered as EPA develops the final regulatory action. In particular, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation

exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use. EPA also requests comment on any advantages or drawbacks for the timelines outlined in Unit IV.B. compared to the timelines identified for the proposed regulatory action in Unit IV.A.

27. EPA is requesting comment on the ways in which 1-BP may be used in the following conditions of use: manufacturing (domestic); processing into formulation, mixture, or reaction products; industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; industrial and commercial use as solvent in aerosol spray degreaser/cleaner; and industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals for asphalt extraction; coatings for temperature indicator, including whether activities may take place in a closed system and the degree to which users of 1-BP in these sectors could successfully implement an ECEL and ancillary requirements described in Unit IV.A.

28. EPA requests comment on the second alternative regulatory action (prohibition of all uses of 1-BP, except for the commercial and consumer uses in insulation) and whether any elements of this second alternative regulatory action described in Unit IV.B. should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in Unit IV.B. compared to the timelines identified for the proposed regulatory action in Unit IV.A.

29. Each non-Federal owner or operator would be required to provide respiratory protection to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring or within 9 months after date of publication of the final rule in the **Federal Register**. Non-Federal regulated entities would be required to implement an exposure control plan within 12 months after date of publication of the final rule in the **Federal Register**. EPA requests comment on any advantages or drawbacks for the timelines outlined in Unit IV.B. compared to the timelines identified for the proposed regulatory action in Unit IV.A.

30. EPA requests comment on the amount of time needed, for example, for vapor degreasers, to transition to an alternative process or solvent. EPA also requests comment regarding the number of entities that could potentially close as identified in the proposed rule.

31. EPA is seeking comments regarding how the requirements of 40 CFR part 63, subpart T could be applied for 1-BP, as well as any additional information on how effective these requirements would be to reduce 1-BP air concentrations and additional controls needed to reduce 1-BP exposure to workers to 0.05 ppm as an 8-hour time-weighted average.

32. EPA is requesting comment on the second alternative regulatory action and whether any elements of this second alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

33. EPA requests comment on providing an option of either complying with the ECEL or implementing various administrative and engineering controls, such as those uses employed in a closed-loop system. EPA also requests information on how a small business can demonstrate that such controls eliminate the unreasonable risk for uses of 1-BP in closed-loop systems, or other types of vapor degreasers.

34. EPA requests comment on all aspects of the proposal to allow certain conditions of use to continue under the WCPP, including the likelihood that the provisions of the WCPP, including exposure monitoring, engineering and administrative controls, PPE, and the exposure control plan, could be successfully implemented for the identified conditions of use, including, for example, the industrial and commercial use as a solvent for aerosol spray degreaser/cleaner.

35. EPA is requesting comment on specific controls that would mitigate the unreasonable risk from 1-BP and that could be included as part of a prescriptive workplace controls requirement, which could be considered as EPA develops the final regulatory action. Specifically, EPA is soliciting comment on combinations of specific engineering controls, administrative controls, and PPE that would reduce inhalation exposures to at or below the ECEL of 0.05 ppm as an 8-hour TWA for all workplaces where such controls would be required. EPA also is soliciting comment on the extent to which such requirements could reduce inhalation exposures to at or below the ECEL of 0.05 ppm as an 8-hour TWA. EPA is requesting comment on the compliance timeframe needed to implement engineering controls, administrative controls, and PPE that reduce inhalation exposures to at or

below the ECEL of 0.05 ppm as an 8-hour TWA for all regulated entities. Additionally, EPA is requesting any existing monitoring data that could inform whether a WCPP or prescriptive controls with a PPE program is a more appropriate regulatory action for industrial and commercial use of 1-BP in batch vapor degreasing.

36. EPA is soliciting comments on whether, for those product types relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or significantly restricted, where EPA was unable to identify products currently available for sale that contain 1-BP, there are products in use or available for sale relevant to these conditions of use that contain 1-BP at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such use of 1-BP.

37. EPA is requesting comment on the Alternatives Assessment as a whole.

38. EPA is requesting comment on the types and costs of technologies firms would adopt to comply with the prohibition on increased releases of 1-BP to outdoor air associated with engineering controls used in the implementation of the WCPP. Additionally, EPA requests comment on whether and to what extent certain control technologies, including technologies that might be implemented pursuant to applicable regulatory authority (such as emission standards resulting from possible future NESHAP requirements), would reduce 1-BP ambient air emissions at facilities that adopt them below emissions levels that existed prior to implementation of the WCPP.

39. EPA is requesting public comment on its TSCA Section 9(a) Analysis described in Unit VII.A., (*i.e.*, the sufficiency of an action taken under a Federal law not administered by EPA).

40. EPA is requesting comment on the need for and associated costs of ambient air monitoring, including fenceline monitoring, at fenceline locations; or facility emissions source monitoring, as well as information on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule (such as a detection limit for 1-BP). EPA is also requesting comment on methods to inform fenceline communities of any increases of 1-BP emissions to ambient air.

41. EPA is requesting comment on whether, if EPA does not finalize the proposed prohibition on increased releases of 1-BP to ambient air outside of the workplace associated with

implementation of the WCPP, EPA should require monitoring to alert EPA to any increased emissions to ambient air associated with WCPP implementation so that the Agency may take appropriate action.

42. EPA requests comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased releases of 1-BP to ambient air from the workplace, and keep records of that statement as part of the WCPP exposure control plan.

43. EPA is requesting comment on best practices for controlling fugitive emissions and associated costs of monitoring and controlling facility emissions to eliminate or reduce fenceline releases. This can include best workplace hazard control practices that EPA should consider including as requirements in the final rule.

44. EPA requests comment on how EPA might best quantify and monetize non-cancer endpoints described in the 2020 Risk Evaluation for 1-BP for economic analysis.

45. Following Panel report recommendations and in response to input provided by SERs, EPA is requesting comment on the following topics as outlined in the SBAR Panel Report (Ref. 23):

- EPA requests public comment on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements.

- EPA requests comment on the methodology and inputs for the ECEL value that are directly derived from the peer reviewed analysis in the August 2020 Risk Evaluation.

- EPA requests comment on reasonable compliance timeframes for small businesses.

- EPA requests comment on differing compliance or reporting requirements or timetables that account for the resources available to small entities.

- EPA requests public comment about the feasibility of entities complying with and monitoring for a potential ECEL of 0.05 ppm. Specifically, EPA aims to obtain more information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations.

- EPA requests comment on providing an option of either complying with the ECEL or implementing various administrative and engineering controls, such as those employed in a closed-loop

system, including information on how a small business can demonstrate that such controls eliminate the unreasonable risk for that use.

- EPA requests public comment about the feasibility of the use of alternatives to 1-BP and their availability for conditions of use that contribute to the unreasonable risk.

- EPA requests comment on temporary work practices to allow for limited circumstances, including but not limited to equipment failure or maintenance activity, where monitoring may not be feasible to comply with an ECEL. EPA requests information on the extent to which 1-BP may be used in the same facility for TSCA and non-TSCA uses.

IX. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Risk Evaluation for 1-Bromopropane. August 2020.
2. EPA. Final Revised Unreasonable Risk Determination for 1-Bromopropane (1-BP) December 19, 2022.
3. EPA. Economic Analysis of the Proposed Regulation of 1-Bromopropane Under TSCA Section 6(a). July 2024.
4. EPA. Chemical Data Reporting. 2016.
5. EPA. Chemical Data Reporting. 2020.
6. EPA. Regulatory Actions Pertaining to 1-Bromopropane. July 2024.
7. OSHA. Standard Interpretations: 8-hour total weight average (TWA) permissible exposure limit (PEL).
8. NIOSH. Hierarchy of Controls.
9. EPA. 1-Bromopropane (1-BP); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register*. 87 FR 43265, July 20, 2022 (FRL-9944-01-OCSP).
10. U.S. Army Public Health Command. Information Regarding 1-Bromopropane and the Adopted Notice of Intended Change (Threshold Limit Value Decrease from 10 ppm to 0.1 ppm).
11. OSHA. Enforcement Policy for Respiratory Hazards Not Covered by OSHA Permissible Exposure Limits. November 2, 2018.
12. EPA. Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1-Bromopropane (1-BP). March 2, 2021.
13. G. Ichihara, et al. Neurologic Abnormalities in Workers of a 1-Bromopropane Factory. *Environmental Health Perspectives*. 112(13): 1319-1325.

September 2004. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1247523/>.

14. NIOSH. Hazard Alert. October 2014.

15. EPA. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021.

16. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 20, 2021).

17. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021).

18. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).

19. EPA. Science Advisory Committee on Chemicals 1-Bromopropane Meeting Minutes and Final Report. September 10–12, 2019.

20. EPA. Notes from Federalism Consultation on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). October 22, 2020.

21. EPA. Notes from Tribal Consultations on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). November 12 & 17, 2020.

22. EPA. Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a). November 16 & 19, 2020.

23. Small Business Advocacy Review Panel. Small Business Advocacy Review Panel on EPA's Planned Proposed Rule under the Toxic Substances Control Act (TSCA) Section 6(a) for 1-Bromopropane (1-BP). December 16, 2021.

24. EPA. Initial Regulatory Flexibility Analysis for 1-Bromopropane; Regulation under the Toxic Substances Control Act (TSCA); Proposed Rule; RIN 2070-AK73. August 2023.

25. EPA. Materials for September 2020 1-Bromopropane Risk Management Webinar.

26. EPA. Stakeholder Meeting List for Proposed Rulemaking for 1-Bromopropane under TSCA Section 6(a).

27. EPA. 2021 Policy on Children's Health. October 5, 2021.

28. EPA. Problem Formulation of the Risk Evaluation for 1-Bromopropane. May 2018.

29. EPA. Supplemental Information on Occupational Exposure Assessment. August 2019.

30. EPA. Guidelines for Carcinogen Risk Assessment. March 2005.

31. OSHA. Occupational Exposure to Methylene Chloride. **Federal Register**. 62 FR 7, January 10, 1997.

32. EPA. Summary of External Peer Review and Public Comments and Disposition for 1-Bromopropane (n-Propyl Bromide). August 2020.

33. OSHA. Personal Protective Equipment. 2004. <https://www.osha.gov/sites/default/files/publications/osha3151.pdf>.

34. EPA. Final Rule. Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a). **Federal Register**. 84 FR 11420, March 27, 2019 (FRL-9989-29).

35. EPA. Alternatives Assessment for Use of 1-Bromopropane. July 2023.

36. EPA. 1-Bromopropane: Fenceline Technical Support—Ambient Air Pathway. June 16, 2023.

37. EPA. Final Rule. National Emission Standards for Hazardous Air Pollutants; Benzene Emissions From Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke ByProduct Recovery Plants. **Federal Register**. 54 FR 38044, September 14, 1989.

38. EPA. 1-Bromopropane (1-BP): Risk Management Support Documents. [DATE].

39. EPA. Risk Management for 1-Bromopropane Supplemental File: Consumer Risk Calculator. [DATE].

40. EPA. Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA); Regulation of 1-Bromopropane under TSCA Section 6(a) (Proposed Rule). EPA ICR No. 2785.01; OMB Control No. 2070-NEW. [DATE].

41. Kevin Ashley. Harmonization of NIOSH Sampling and Analytical Methods with Related International Voluntary Consensus Standards. *Journal of Occupational and Environmental Hygiene*. 12(7):D107–15. 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589148/>.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866 (58 FR 51735 October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to OMB for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an economic analysis (Ref. 3) of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Unit VI.D.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR Number 2785.01 (Ref. 40). You can find a copy of the ICR in the docket for this proposed rule, and it is briefly summarized here.

There are four primary provisions of the proposed rule that may increase burden under the PRA. The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of 1-BP, who would provide notice to companies downstream upon shipment of 1-BP about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies. The second primary provision of the proposed rule that may increase burden under the PRA is WCPP-related information generation, recordkeeping, and notification requirements (including development of exposure control plans; exposure level monitoring and related recordkeeping; development of documentation for a PPE program and related recordkeeping; development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program documentation). The third primary provision of the rule that may increase burden under the PRA are requirements related to prescriptive controls recordkeeping and notification (including development and retention of records necessary for implementing use of prescriptive controls (e.g., gloves), providing workplace notification to potentially exposed persons, and serving as a reference for EPA or authorized entities). The fourth primary provision of the proposed rule that may increase burden under the PRA is self-certification-related information generation, recordkeeping, and notification requirements (including development and documentation of those requirements under the WCPP and related recordkeeping; development of documentation of a self-certification statement and related recordkeeping; and notification of self-certification).

Respondents/affected entities: Persons that manufacture, process, use, distribute in commerce, or dispose of 1-BP or products containing 1-BP, except for the use of 1-BP and products containing 1-BP in building/construction materials (insulation). See also Unit I.A.

Respondent's obligation to respond: Mandatory (TSCA section 6(a) and 40 CFR part 751).

Estimated number of respondents: 1,143.

Frequency of response: On occasion.

Total estimated burden: 73,401 hours (per year). Burden is defined as 5 CFR 1320.3(b).

Total estimated cost: \$8,955,764 (per year), includes \$4,371,126 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. EPA will respond to ICR-related comments in the final rulemaking. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. OMB must receive comments no later than September 9, 2024.

C. Regulatory Flexibility Act (RFA)

As required by section 609(b) of the RFA, 5 U.S.C. 601 *et seq.*, EPA convened a SBAR Panel to obtain advice and recommendations from SERs that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an initial regulatory flexibility analysis (IRFA). A copy of the full SBAR Panel Report (Ref. 23) is available in the rulemaking docket.

Pursuant to section 603 of the RFA, EPA prepared an IRFA (Ref. 24) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. Need for the Rule

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a PESS identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements listed in TSCA section 6(a)

to the extent necessary so that the chemical substance or mixture no longer presents such risk. 1-BP was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in August 2020. In addition, in December 2022, EPA issued a revised unreasonable risk determination that 1-BP as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that 1-BP no longer presents such risk.

2. Objectives and Legal Basis

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. EPA has determined through a TSCA section 6(b) risk evaluation that 1-BP presents an unreasonable risk under the conditions of use.

3. Description and Number of Small Entities to Which the Rule Will Apply

The proposed rule potentially affects small manufacturers (including importers), processors, distributors, retailers, users of 1-BP or of products containing 1-BP, and entities engaging in disposal. EPA estimates that the proposal would affect approximately 931 small entities. End users with economic and technologically feasible alternatives available do not have estimated cost impacts beyond rule familiarization costs.

4. Projected Compliance Requirements

To address the unreasonable risk EPA has identified, EPA is proposing to: prohibit the manufacture (including import), processing, and distribution in commerce of 1-BP for all consumer use, excluding the use of 1-BP in insulation; prohibit certain industrial and commercial uses and the manufacture (including import), processing and distribution in commerce of 1-BP for those uses; require a 1-BP WCPP, which would include requirements to meet an inhalation exposure concentration limit, for certain conditions of use; require self-certification for certain occupational conditions of use; require the use of gloves for certain occupational conditions of use; and establish recordkeeping and downstream notification requirements. There are an estimated 931 small entities affected by the proposed option

with a per firm cost of \$13 thousand with a total estimated cost impact of \$12 million. This includes \$12.0 million for WCPP use and \$0.1 million for uses that are prohibited. No incremental costs beyond the cost of rule familiarization are estimated for users of 1-BP products that are prohibited under the proposed rule. Users are assumed to switch to alternatives with similar costs and efficacy. As noted in section 7.12 of the EA, there may be some applications where 1-BP is more effective, reducing labor time and wait time, and this analysis was unable to quantify those costs. For example, there may be some safety-critical applications where alternatives would need to undergo extensive safety review and testing before they could replace the 1-BP products. The impact of a prohibition of 1-BP for these uses could potentially result in important negative impacts of the proposed option, but EPA was unable to quantify any of these potential impacts, so cost impacts to potentially affected small businesses could not be estimated.

EPA is proposing to prohibit certain conditions of use. For most other conditions of use that contribute to the unreasonable risk determination for 1-BP, EPA proposes to address the unreasonable risk with a 1-BP WCPP, which would include a combination of requirements to address unreasonable risk contributed by inhalation. A 1-BP WCPP would encompass restrictions on certain occupational conditions of use and could include provisions for an ECEL, a PPE program, and ancillary requirements to support implementation of these restrictions.

As described in Unit IV.A., the 1-BP WCPP would be non-prescriptive, in the sense that regulated entities would not be required to use specific controls prescribed by EPA to achieve the exposure concentration limit. Rather, it would be a performance-based exposure limit that would enable owners or operators to determine how to most effectively meet the exposure limit based on conditions at their workplace.

A central component of the 1-BP WCPP is the exposure limit. Exposures remaining at or below the ECEL would address any unreasonable risk of injury to health contributed by inhalation exposures for occupational conditions of use. EPA's proposed requirements include the specific exposure limits that would be required to meet the TSCA section 6(a) standard to apply one or more requirements to the substance so that it no longer presents unreasonable risk, and also include ancillary requirements necessary for the ECEL's

successful implementation as part of a WCPP.

Regarding recordkeeping requirements, three primary provisions of the proposed rule relate to recordkeeping. The first is recordkeeping of general records: all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of 1-BP or products containing 1-BP, except for the use of 1-BP in insulation, must maintain ordinary business records, such as invoices and bills-of-lading related to compliance with the prohibitions, restrictions, and other provisions of the regulation.

The second is recordkeeping related to WCPP compliance: under the proposed regulatory action, facilities complying with the rule through WCPP would be required to develop and maintain records associated with ECEL exposure monitoring (including measurements, compliance with Good Laboratory Practice Standards, and information regarding monitoring equipment); ECEL compliance (including the exposure control plan, PPE program implementation, and workplace information and training); and workplace participation. To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP retain compliance records for five years.

EPA is also proposing to require self-certification for certain occupational conditions of use. To further support and demonstrate compliance, EPA is proposing to require owners or operators to self-certify with a self-certification statement and provide that statement to distributors of 1-BP, as described in Unit IV.A. EPA is also proposing that each owner or operator of a facility subject to self-certification, and distributors of 1-BP to such facilities, retain compliance records for five years.

a. Classes of Small Entities Subject to the Compliance Requirements

The small entities that would be potentially directly regulated by this rulemaking are small entities that manufacture (including import), process, distribute in commerce, use, or dispose of 1-BP, including retailers of 1-BP for end-consumer uses.

b. Professional Skills Needed To Comply

Entities that would be subject to this proposal that manufacture (including import), process, or distribute 1-BP in commerce for consumer use (except for the use of 1-BP in insulation) would be required to cease under the proposed

rule. The entity would be required to modify their SDS to inform their customers of the prohibition on manufacture, processing, and distribution of 1-BP for consumer use (except for the consumer use of 1-BP in building/construction materials (insulation)). They would also be required to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation. These are all routine business tasks that do not require specialized skills or training.

Entities that use 1-BP in any industrial and commercial capacity that is proposed to be prohibited would be required to cease under the proposed rule. Restriction or prohibition of these uses will likely require the implementation of an alternative chemical or the cessation of use of 1-BP in a process or equipment that may require persons with specialized skills, such as engineers or other technical experts. Instead of developing an alternative method themselves, industrial and commercial users of 1-BP may choose to contract with another entity to do so.

Certain entities that would be permitted to continue to manufacture, process, distribute, use, or dispose of 1-BP would be required to implement a WCPP and would have to meet the provisions of the program for continued use of 1-BP. A transition to a WCPP may require persons with specialized skills such as an engineer or health and safety profession. Instead of implementing the WCPP themselves, entities that use 1-BP may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP, as applicable. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills, such as an industrial hygienist.

Certain entities that would be permitted to continue to manufacture, process, distribute, use, or dispose of 1-BP would be required to self-certify and would have to meet the provisions of self-certification for continued purchase of 1-BP. Records would have to be maintained for compliance with self-certification, as applicable. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills, such as an industrial hygienist, engineers, or other technical experts.

5. Relevant Federal Rules

EPA has issued numerous rules and notices pertaining to 1-BP under its various authorities. 1-BP manufacturing (including importing), processing, and use information is reported under the Chemical Data Reporting (CDR) rule (85 FR 20122, April 9, 2020; see 40 CFR part 711). 1-BP is also a listed substance subject to Toxics Release Inventory (TRI) reporting requirements pursuant to section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA), effective as of January 1, 2016 (40 CFR 372.65).

Relative to releases to air, in 2010 and 2011, EPA received petitions from the Halogenated Solvents Industry Alliance and the New York State Department of Environmental Conservation to list 1-BP as a hazardous air pollutant (HAP) under Section 112(b)(1) of the Clean Air Act (80 FR 6676, February 6, 2015). On January 9, 2017, EPA published a draft notice on the rationale for granting the petitions to add 1-BP to the list of HAPs (82 FR 2354, January 9, 2017), and subsequently issued a final notice granting the petitions to add 1-BP to the list of HAPs contained in Section 112(b)(1) of the CAA, 42 U.S.C. 7412 (85 FR 36851, June 18, 2020). On January 5, 2022, EPA published a final rule adding 1-BP to the list of HAPs (87 FR 393), effective February 4, 2022. In addition, 1-BP is listed under the National Volatile Organic Compound (VOC) Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E).

The listing of 1-BP as a HAP also triggered the addition of 1-BP as a hazardous substance under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (87 FR 20721, April 8, 2022), so that releases of 1-BP in excess of one pound must be reported (40 CFR 302).

Under EPA's Significant New Alternatives Policy (SNAP) program, EPA evaluated 1-BP as an acceptable substitute for ozone-depleting substances. In 2007, EPA listed 1-BP as an acceptable substitute for chlorofluorocarbon (CFC)-113 and methyl chloroform in the solvent and cleaning sector of industrial equipment for metals cleaning, electronics cleaning, and precision cleaning. EPA recommended the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing when using 1-BP (72 FR 30142, May 30, 2007). In 2007, the Agency also proposed to list 1-BP as an unacceptable substitute for CFC-113, hydrochlorofluorocarbon (HCFC)-141b

and methyl chloroform when used in adhesives or in aerosol solvents due to unacceptable risks to human health when compared with other available alternatives for these uses; and as an acceptable substitute in the coatings end use (subject to use conditions) (72 FR 30168, May 30, 2007). This proposed rule under SNAP has not been finalized by the Agency.

While OSHA has not issued a PEL for 1-BP, OSHA and NIOSH have issued a Hazard Alert, which indicates a recommended time-weighted average threshold limit value (TWA-TLV) of 10 ppm by the American Conference of Governmental Industrial Hygienists (Ref. 10). However, since then, ACGIH has recommended 0.10 ppm as the TWA-TLV value for 1-BP (Ref. 10). The U.S. Department of Transportation (DOT) regulates specific bromopropanes as a hazardous material, e.g., “UN2344, Bromopropanes, 3, PG II” and “UN2344, Bromopropanes, 3, PG III” and therefore, are subject to certain requirements under the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) such as marking, labeling, and placarding—among others. The HMR derives its authority from the Federal Hazardous Materials Transportation Law (49 U.S.C. 5101 *et seq.*). As such, section 5103(b) authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.

6. Significant Alternatives to the Proposed Rule

EPA analyzed alternative regulatory approaches to identify which would be feasible, reduce burden to small businesses, and achieve the objective of the statute (*i.e.*, applying one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents an unreasonable risk). As described in more detail in Unit V., EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: the effects of 1-BP on health and the environment, the magnitude of exposure to 1-BP of human beings and the environment, the benefits of 1-BP for various uses, and the reasonably ascertainable economic consequences of the proposed rule. EPA also considered input provided by the SERs in selecting among possible TSCA section 6(a) requirements as part of the proposed regulatory action and alternative

regulatory actions. Additionally, as a part of this analysis, EPA considered—in addition to prohibition, WCPP, and self-certification described earlier—a wide variety of control measures to address the unreasonable risk from 1-BP such as weight fractions. As discussed in Unit V.A.3., EPA considered limiting the weight fraction of 1-BP in industrial/commercial and consumer products and conducted an analysis to estimate to what extent this would reduce risks from conditions of use that contribute to the unreasonable risk for 1-BP. EPA’s analysis of these risk management approaches is detailed in Unit V.A.3. In general, EPA determined that this approach alone would either not be able to address the unreasonable risk, or would result in a product containing so little 1-BP that it would not be efficacious for the intended purpose.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action would affect entities that use 1-BP. It is not expected to affect state, local, or Tribal governments because the use of 1-BP by government entities is minimal. The costs involved in this action are estimated not to exceed \$183 million in 2023\$ (\$100 million in 1995\$ adjusted for inflation using the GDP implicit price deflator) or more in any one year.

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulations under TSCA section 6(a) may preempt State law. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risks presented by a chemical substance has the potential to trigger preemption of laws, criminal penalties, or administrative actions by a State or political subdivision of a State that are: (1) Applicable to the same chemical substance as the rule under TSCA section 6(a); and (2) Designed to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3) applies that preemption only to the “hazards, exposures, risks, and uses or conditions of use” of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following preliminary federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included background presentation on September 9, 2020, and a consultation meeting on October 22, 2020. EPA invited the following national organizations representing State and local elected officials to these meetings: Association of State Drinking Water Administrators, National Association of Clean Water Agencies, Western States Water Council, National Water Resources Association, American Water Works Association, Association of Metropolitan Water Agencies, Association of Clean Water Administrators, Environmental Council of the States, National Association of Counties, National League of Cities, County Executives of America, U.S. Conference of Mayors, and National Association of Attorneys General. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 20). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. This rulemaking would not have substantial direct effects on Tribal governments because 1-BP is not manufactured, processed, or distributed in commerce by Tribes. 1-BP is not regulated by Tribes, and this rulemaking would not impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action. Nevertheless, EPA met with Tribal officials during the development of this action consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, which EPA applies more broadly than Executive Order 13175.

As described in Unit III.A.1., EPA met with Tribal officials via teleconferences on November 12, 2020, and November 17, 2020, concerning the prospective regulation of the 1-BP under TSCA

section 6, (Ref. 21). During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for 1-BP, types of information to inform risk management, principles for transparency during risk management, and types of information EPA is seeking from Tribes (Ref. 21). EPA briefed Tribal officials on the Agency's risk management considerations and encouraged Tribal officials to provide additional comments after the teleconferences. Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings. (Ref. 21)

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. While the environmental health or safety risks addressed by this action present a disproportionate risk to children because the most sensitive adverse health effects are in early life stages, this action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866.

However, EPA's *Policy on Children's Health* applies to this action. Information on how the Policy was applied is available in Units III.A.3., III.B.2., VI.A. and VI.B., and the 2020 Risk Evaluation for 1-BP and the Economic Analysis for this proposed rulemaking (Refs. 1, 3).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

I. National Technology Transfer and Advancement Act (NTTAA)

Pursuant to the NTTAA section 12(d), 15 U.S.C. 272, the Agency has determined that this rulemaking involves environmental monitoring or measurement, specifically for

occupational inhalation exposures to 1-BP. Consistent with the Agency's Performance Based Measurement System (PBMS), the Agency proposes not to require the use of specific, prescribed analytic methods. Rather, the Agency plans to allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

For this rulemaking, the key consideration for the PBMS approach is the ability to accurately detect and measure airborne concentrations of 1-BP at the ECEL and the ECEL action level. Some examples of methods which meet the criteria are included in appendix B of the ECEL memo (Ref. 12). EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria (Ref. 41). EPA requests comments on whether it should incorporate such voluntary consensus standards in the final rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the proposed rule in lieu of the PBMS approach.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that the human health and environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns. As described more fully in the Economic Analysis, EPA conducted an analysis to characterize the baseline conditions faced by communities and workers affected by the regulation to identify the potential for disproportionate impacts on communities with environmental justice concerns. The baseline characterization suggests that workers in affected industries and regions, as well as residents of nearby communities, are more likely to be people of color than the general population in affected states, although this varied by use assessed.

EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with environmental justice concerns. While the regulatory options are anticipated to address the unreasonable risk from exposure to 1-BP to the extent necessary so that it is no longer unreasonable, EPA is not able to quantify the distribution of the change in risk across affected workers, communities, or demographic groups. EPA is also unable to quantify the changes in risks to workers, communities, and demographic groups from non-1-BP-using technologies or practices that firms may adopt in response to the regulation to determine whether any such changes could pose EJ concerns. Data limitations prevent EPA from conducting a more comprehensive analysis that would identify the incremental impacts of the regulatory options and assess the extent to which they mitigate or exacerbate any disproportionate impacts in communities with EJ concerns. These data limitations are summarized in the Economic Analysis (Ref. 3).

EPA additionally identified and addressed EJ concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to 1-BP, such as communities with environmental justice concerns. On November 16 and 19, 2020, EPA held public meetings as part of this consultation. (Ref. 22). See also Unit III.A.1.

The information supporting the review under Executive Order 12898 and Executive Order 14096 is contained in Units I.E., II.D., III.A.1., VI.A., and in the Economic Analysis (Ref. 3). EPA's presentations and fact sheets for the EJ consultations related to this rulemaking, are available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/environmental-justice-consultations-methylene-chloride>. These materials and a summary of the consultation are also available in the public docket for this rulemaking (Ref. 22).

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Michael S. Regan,
Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 751 as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

■ 2. Amend § 751.5 by adding in alphabetical order definitions for “ECEL” and “Exposure group”, to read as follows:

§ 751.5 Definitions

* * * * *

ECEL is an Existing Chemical Exposure Limit and means an airborne concentration generally calculated as an eight (8)-hour time-weighted average (TWA).

* * * * *

Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.

* * * * *

■ 3. Add subpart I to read as follows:

Subpart I—1-Bromopropane

751.801 General.

751.803 Definitions.

751.805 Prohibitions of manufacturing, processing, distribution in commerce, and use.

751.807 Workplace Chemical Protection Program (WCPP).

751.809 Prescriptive controls.

751.811 Self-certification requirements.

751.813 Downstream notification.

751.815 Recordkeeping requirements.

§ 751.801 General.

This subpart establishes prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of 1-bromopropane (CASRN 106–94–5), also known as n-propyl bromide, to prevent unreasonable risks of injury to health in accordance with TSCA section 6(a).

§ 751.803 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply to this subpart:

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.813 and 751.815.

ECEL action level means a concentration of airborne 1-

bromopropane of 0.03 parts per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA).

§ 751.805 Prohibitions of manufacturing, processing, distribution in commerce, and use.

(a) *Applicability.* The provisions of this section apply to the following conditions of use of 1-bromopropane as indicated in each paragraph of this section:

(1) All manufacturing, processing, and distribution in commerce for consumer use, excluding use of 1-bromopropane in building/construction materials (insulation).

(2) All manufacturing (including import), processing, and distribution in commerce of 1-bromopropane for industrial or commercial use, other than for the conditions of use addressed under §§ 751.807(a) and 751.809(a) of this subpart.

(3) All commercial or industrial use of 1-bromopropane, other than the conditions of use addressed under §§ 751.807(a) and 751.809(a) of this subpart.

(b) *Prohibitions.*

(1) After [DATE 6 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from manufacturing (including importing) 1-bromopropane for the uses listed in paragraph (a) of this section.

(2) After [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from processing 1-bromopropane, including any 1-bromopropane-containing products, for the uses listed in paragraph (a) of this section.

(3) After [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from distributing in commerce or making available 1-bromopropane, including any 1-bromopropane-containing products, to retailers for any use except in insulation.

(4) After [DATE 15 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all retailers are prohibited from distributing in commerce or making available 1-bromopropane, including any 1-bromopropane-containing products, for any use except in insulation.

(5) After [DATE 15 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from distributing in commerce or making available 1-bromopropane,

including any 1-bromopropane containing products, for the uses described in paragraph (a) of this section.

(6) After [DATE 18 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons are prohibited from industrial or commercial use of 1-bromopropane, including any 1-bromopropane containing products, for the conditions of use listed in paragraph (a)(3) of this section.

§ 751.807 Workplace Chemical Protection Program (WCPP).

(a) *Applicability.* The provisions of this section apply to the following conditions of use of 1-bromopropane, unless otherwise indicated in this section, except to the extent the conditions of use are prohibited by § 751.805:

(1) Manufacturing (domestic manufacturing);

(2) Processing into formulation, mixture or reaction products;

(3) Industrial and commercial use as solvent for open-top and in-line batch vapor degreasing;

(4) Industrial and commercial use as solvent for closed-loop batch vapor degreasing;

(5) Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners;

(6) Industrial and commercial use as solvent in aerosol spray degreaser/cleaner; and

(7) Industrial and commercial uses in other uses, in electronic and electronic products and metal products; asphalt extraction; laboratory chemicals; temperature indicator—coatings

(b) *Existing chemical exposure limit (ECEL).*

(1) *Eight-hour time-weighted average (TWA) ECEL.* Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, or beginning 4 months after introduction of 1-bromopropane into the workplace if 1-bromopropane use commences after [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the owner or operator must ensure that no person is exposed to an airborne concentration of 1-bromopropane in excess of 0.05 parts of 1-bromopropane per million parts of air (0.05 ppm) as an

eight (8)-hour TWA, consistent with requirements of paragraphs (c)(1) and, if necessary, paragraph (e)(1) of this section.

(2) *Exposure monitoring.*

(i) *General.*

(A) Owners or operators must determine each potentially exposed person's exposure by either:

(1) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(2) Taking personal breathing zone air samples that are representative of the 8-hour TWA of each exposure group.

(B) Personal breathing zone air samples are representative of the 8-hour TWA of all potentially exposed persons in an exposure group if the samples are of at least one person's full-shift exposure who represents the highest potential 1-bromopropane exposures in that exposure group.

(C) Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice

Standards in 40 CFR part 792 or a laboratory accredited by the American Industrial Hygiene Association (AIHA) or another industry-recognized program.

(D) Owners or operators must ensure that methods used to perform exposure monitoring produce results that are accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of 1-bromopropane.

(E) Owners and operators must re-monitor within 15 working days after receipt of any exposure monitoring when results indicate non-detect or air monitoring equipment malfunction, unless an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.

(ii) *Initial monitoring.* By [DATE 33 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the

Federal Government, [DATE 6 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, or within 30 days of introduction of 1-bromopropane into the workplace, whichever is later, each owner or operator covered by this section must perform initial monitoring of potentially exposed persons. Where the owner or operator has monitoring results from monitoring conducted within five years prior to [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] and the monitoring satisfies all other requirements of this section, the owner or operator may rely on such earlier monitoring results to satisfy the requirements of this paragraph.

(iii) *Periodic monitoring.* The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to 1-bromopropane in accordance with Table 1.

TABLE 1 TO PARAGRAPH (b)(2)(iii)—PERIODIC MONITORING REQUIREMENTS

Air concentration condition	Periodic monitoring requirement
If initial exposure monitoring is below ECEL action level (< 0.03 ppm 8-hour TWA).	Periodic exposure monitoring is required at least once every five years.
If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (>0.05 ppm 8-hour TWA).	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level but at or below the ECEL (≥ 0.03 ppm 8-hour TWA, ≤ 0.05 ppm 8-hour TWA).	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart within a 6 month period, indicate exposure is below the ECEL action level (< 0.03 ppm 8-hour TWA).	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which the ECEL is required but does not manufacture, process, use, or dispose of 1-bromopropane in that condition of use over the entirety of time since the last required monitoring event.	The owner or operator may forgo the next periodic monitoring event. However, documentation of cessation of use of 1-bromopropane is required; and periodic monitoring would be required immediately when the owner or operator resumes the condition of use.

(iv) *Additional monitoring.*

(A) The owner or operator must conduct the exposure monitoring required by paragraph (b)(2)(ii) of this section within 30 days after there has been a change in the production, process, control equipment, personnel or work practices that may reasonably be expected to result in new or additional exposures above the ECEL action level or when the owner or operator has any reason to believe that new or additional exposures above the ECEL action level have occurred.

(B) Whenever start-ups or shutdowns, or spills, leaks, ruptures or other breakdowns or unexpected releases occur that may lead to exposure to potentially exposed persons, the owner or operator must conduct the exposure monitoring required by paragraph (b)(2)(ii) of this section within 30 days

after the conclusion of the start-up or shutdown and/or the cleanup of the spill or repair of the leak, rupture or other breakdown.

(v) *Observation of monitoring.*

(A) The owner or operator must provide potentially exposed persons an opportunity to observe any monitoring of occupational exposure to 1-BP that is conducted under this section and is designed to characterize the potentially exposed person's exposure.

(B) When monitoring observation requires entry into a regulated area, the owner or operator must provide the observers with the required PPE in accordance with paragraph (b)(3)(iv).

(vi) *Notification of monitoring results.*

(A) The owner or operator must inform each person whose exposures are monitored or who is part of a monitored exposure group of any represented by

the monitoring of the monitoring results within 15 working days of receipt of monitoring results.

(B) This notification must include the following:

- (1) Exposure monitoring results;
- (2) Identification and explanation of the ECEL and ECEL action level;
- (3) Statement of whether the monitored airborne concentration of 1-bromopropane exceeds the ECEL action level or ECEL;
- (4) If the ECEL is exceeded per paragraph (b)(2)(vi)(B) of this section, descriptions of any exposure controls implemented by the owner or operator to reduce exposures to or below the ECEL, as required by paragraph (c)(1) of this section;
- (5) Explanation of any respiratory protection provided in accordance with

paragraphs (b)(3)(iv), (c)(1)(ii), and (e) of this section;

(6) Quantity of 1-bromopropane in use at the time of monitoring;

(7) Location(s) of 1-bromopropane use at the time of monitoring;

(8) Manner of 1-bromopropane use at the time of monitoring; and

(9) Identified releases of 1-bromopropane.

(C) Notice must be written, in plain language, and either provided to each potentially exposed person individually in a language that the person understands, or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(3) *Regulated areas.*

(i) *Establishment.* By [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, or beginning 4 months after introduction of 1-bromopropane into the workplace if 1-bromopropane use commences after [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], the owner or operator must establish and maintain a regulated area wherever airborne concentrations of 1-bromopropane exceeds or can reasonably be expected to exceed the ECEL.

(ii) *Access.* The owner or operator must limit access to regulated areas to authorized persons.

(iii) *Demarcation.* The owner or operator must demarcate regulated areas from the rest of the workplace in a manner that adequately establishes and alerts persons to the boundaries of the area and minimizes the number of authorized persons exposed to 1-bromopropane within the regulated area.

(iv) *Provision of respirators.*

(A) The owner or operator must ensure that each person who enters a regulated area is supplied with a respirator selected in accordance with paragraph (e) of this section and must ensure that all persons within the regulated area are using the provided respirators whenever 1-bromopropane exposures may exceed the ECEL.

(B) An owner or operator who has implemented all feasible controls as

required in paragraph (c)(1) of this section, and who has established a regulated area as required by paragraphs (b)(3)(i) and (iii) of this section where 1-bromopropane exposure can be reliably predicted to exceed the ECEL only on certain days (for example, because of work or process schedule) must have persons use respirators in that regulated area on those days.

(vi) The owner or operator must ensure that, within a regulated area, persons do not engage in non-work activities which may increase 1-bromopropane exposure.

(vii) The owner or operator must ensure that while persons are wearing respirators in the regulated area, they do not engage in activities which interfere with respirator seal or performance.

(c) *Exposure control procedures and plan.*

(1) *Methods of compliance.*

(i) By [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, the owner or operator must institute one or a combination of elimination, substitution, engineering controls or administrative controls to reduce exposure to or below the ECEL except to the extent that the owner or operator can demonstrate that such controls are not feasible, in accordance with the hierarchy of controls.

(ii) If the feasible controls required under paragraph (c)(1)(i) of this section that can be instituted do not reduce exposures for potentially exposed persons to or below the ECEL, then the owner or operator must use such controls to reduce exposure to the lowest levels achievable by these controls and must supplement those controls with the use of respiratory protection that complies with the requirements of paragraph (e) of this section.

(iii) Where an owner or operator cannot demonstrate that exposure to 1-bromopropane has been reduced to or below the ECEL through the use of controls required under paragraphs (c)(1)(i) and (ii) of this section, and has not demonstrated that it has appropriately supplemented with respiratory protection that complies with the requirements of paragraph (e) of this section, this will constitute a failure to comply with the ECEL.

(iv) For the Department of Defense and Federal contractors acting for or on

behalf of the Department of Defense, in the event that ongoing or planned construction is necessary to implement the feasible controls required by paragraph (c)(1)(i) of this section such that no one is exposed above the ECEL, the deadlines in paragraph (c)(1)(i) of this section are extended to [DATE 60 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**]. Ongoing or planned construction efforts to address exposures above the ECEL must be documented in the exposure control plan required by paragraph (c)(2) of this section.

(2) *Exposure control plan.* By [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, each owner and operator must establish and implement an exposure control plan.

(i) *Exposure control plan contents.* The exposure control plan must include documentation of the following:

(A) Identification of exposure controls that were considered, including those that were used or not used to meet the requirements of paragraph (c)(1)(i) of this section, in the following sequence: elimination, substitution, engineering controls and administrative controls;

(B) For each exposure control considered, a rationale for why the exposure control was selected or not selected based on feasibility, effectiveness, and other relevant considerations;

(C) A description of actions the owner or operator must take to implement exposure controls selected, including proper installation, regular inspections, maintenance, training or other actions;

(D) A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;

(E) Description of activities conducted by the owner or operator to review and update the exposure control plan in compliance with paragraph (c)(2)(ii)(C) of this section to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls;

(F) Attestation that exposure controls selected do not increase emissions of 1-bromopropane to ambient air outside of the workplace and whether additional equipment was installed to capture or

otherwise prevent increased emissions of 1-bromopropane to ambient air.

(ii) *Exposure control plan requirements.*

(A) The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(B) The owner or operator must maintain the effectiveness of any controls instituted under this paragraph (c).

(C) The exposure control plan must be reviewed and updated as necessary, but at least every 5 years, to reflect any significant changes in the status of the owner or operator's approach to compliance with paragraphs (b) and (c) of this section.

(iii) *Availability of exposure control plan.*

(A) Owners or operators must make the exposure control plan and associated records available to potentially exposed persons.

(B) Owners or operators must notify potentially exposed persons of the availability of the exposure control plan and associated records within 30 days of the date that the exposure control plan is completed and at least annually thereafter.

(C) Notice of the availability of the exposure control plan and associated records must be provided in plain language writing to each potentially exposed person in a language that the person understands or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(d) *Workplace information and training.*

(1) By [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, the owner or operator must institute a training program and ensure that persons potentially exposed to 1-bromopropane participate in the program according to the requirements of this paragraph (d).

(2) The owner or operator must ensure that each potentially exposed person is trained prior to or at the time of a potential exposure to 1-bromopropane.

(3) The owner or operator must ensure that information and training is presented in a manner that is

understandable to each person required to be trained.

(4) The following information and training must be provided to all persons potentially exposed to 1-bromopropane:

(i) The requirements of this section, as well as how to access or obtain a copy of these requirements in the workplace;

(ii) The quantity, location, manner of use, release, and storage of 1-bromopropane and the specific operations in the workplace that could result in exposure to 1-bromopropane, particularly noting where each regulated area is located;

(iii) Methods and observations that may be used to detect the presence or release of 1-bromopropane in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of 1-bromopropane when being released);

(iv) The acute and chronic health hazards of 1-BP as detailed on relevant Safety Data Sheets; and

(v) The principles of safe use and handling of 1-bromopropane and measures potentially exposed persons can take to protect themselves from 1-bromopropane, including specific procedures the owner or operator has implemented to protect potentially exposed persons from exposure to 1-bromopropane, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(5) The owner or operator must re-train each potentially exposed person annually to ensure that each such person maintains the requisite understanding of the principles of safe use and handling of 1-bromopropane in the workplace.

(6) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, that increase exposure, and where such exposure exceeds or can reasonably be expected to exceed the ECEL action level, the owner or operator must update the training and ensure that each potentially exposed person is re-trained.

(e) *Personal Protective Equipment (PPE).*

(1) *Respiratory protection.*

(i) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, or within 3 months after

receipt of any exposure monitoring that indicates exposures exceeding the ECEL, or that indicates non-detect or air monitoring equipment malfunction resulting in an unknown concentration, if an owner or operator is required to provide respiratory protection pursuant to paragraph (b)(3)(iv) or (c)(1)(ii), the owner or operator must ensure that each potentially exposed person is provided with a respirator according to the requirements of this section.

(ii) For the purposes of this paragraph (e)(1), cross-referenced provisions in 29 CFR 1910.134 applying to an "employee" apply equally to potentially exposed persons and cross-referenced provisions applying to an "employer" also apply equally to owners or operators. Other terms in cross-referenced provisions in 29 CFR 1910.134 that are defined in 29 CFR 1910.134(b) have the meaning assigned to them in that paragraph.

(iii) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, or within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL, or that indicates non-detect or air monitoring equipment malfunction resulting in an unknown concentration, if an owner or operator is required to provide respiratory protection pursuant to paragraph (b)(3)(iv) or (c)(1)(ii), the owner or operator must develop and administer a written respiratory protection program consistent with the requirements of 29 CFR 1910.134(c)(1), (c)(3) and (c)(4).

(iv) Owners and operators must select respiratory protection required by paragraph (e)(1)(i) based on a medical evaluation consistent with the requirements of 29 CFR 1910.134(e), 1910.134 App. C. If a potentially exposed person cannot use a negative-pressure respirator that would otherwise be required by paragraph (e)(1)(i), then the owner or operator must provide that person with an alternative respirator. The alternative respirator must have less breathing resistance than the negative-pressure respirator and provide equivalent or greater protection. If the person is unable to use an alternative respirator, then the person must not be permitted to enter the regulated area.

(v) Owners and operators must select respiratory protection that properly fits each affected person and communicate

respirator selections to each affected person consistent with the requirements of 29 CFR 1910.134(f), 1910.134 App. A.

(vi) Owners and operators must provide, ensure use of, and maintain (in a sanitary, reliable, and undamaged condition) respiratory protection that is of safe design and construction for the applicable condition of use consistent with the requirements of 29 CFR 1910.134(g) through (j), 1910.134 App. B-1 to B-2.

(vii) Prior to or at the time of initial assignment to a job involving potential exposure to 1-bromopropane, owners and operators must provide training to all persons required to use respiratory protection consistent with 29 CFR 1910.134(k), 1910.134 App. D.

(viii) Owners and operators must retrain all persons required to use PPE at least annually, or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE, or when changes in the workplace or in PPE to be used render the previous training obsolete.

(ix) Owners or operators must select and provide to persons appropriate respirators as indicated by the most recent monitoring results as follows:

(A) If the measured exposure concentration is at or below 0.05 ppm: no respiratory protection is required.

(B) If the measured exposure concentration is above 0.05 ppm and less than or equal to 0.5 ppm (10 times ECEL): Any NIOSH Approved® air-purifying half mask respirator equipped with organic vapor cartridges or canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in demand mode equipped with a half mask; or any NIOSH-certified Self-Contained Breathing Apparatus (SCBA) in demand mode equipped with a half mask [APF 10].

(C) If the measured exposure concentration is above 0.5 ppm and less than or equal to 1.25 ppm (25 times ECEL): Any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) equipped with a loose-fitting facepiece or hood/helmet equipped with organic vapor cartridges or canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood [APF 25].

(D) If the measured exposure concentration is above 1.25 ppm and less than or equal to 2.5 ppm (50 times ECEL): Any NIOSH Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges

or canisters; any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a pressure-demand or other positive pressure mode with a half mask; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a half mask; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a pressure-demand or other positive pressure mode with a half mask; or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet/hood [APF 50].

(E) If the measured exposure concentration is above 2.5 ppm and less than or equal to 50 ppm (1,000 times ECEL): Any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) equipped with a full facepiece equipped with organic vapor cartridges or canisters; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with full facepiece; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply [APF 1,000]; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a helmet or hood and has been tested to demonstrate performance at a level of a protection of APF 1,000 or greater.

(F) If the measured exposure concentration is greater than 50 ppm (1,000 times ECEL): Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or helmet/hood [APF 10,000].

(G) If the exposure concentration is unknown: Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or helmet/hood [APF 10,000].

(x) Owners and operators must select and provide respirators as required in paragraph (e)(1)(ix) of this section consistent with the requirements of 29 CFR 1910.134(d)(1)(iv), and with consideration of workplace and user factors that affect respirator performance and reliability.

(xi) Owners and operators who select air-purifying respirators must either:

(A) Select respirators that have an end-of-service-life indicator (ESLI) that

is NIOSH-certified for 1-bromopropane; or

(B) Implement a change schedule for canisters and cartridges based on objective information or data that ensures that canisters and cartridges are changed before the end of their service life. The written respiratory protection program required by paragraph (e)(1)(iii) of this section must include a description of the information and data relied upon, the basis for reliance on the information and data, and the basis for the canister and cartridge change schedule.

(xii) Owners and operators must ensure that respirators are used in compliance with the terms of the respirator's NIOSH certification.

(xiii) Owners and operators must conduct regular evaluations of the workplace, including consultations with potentially exposed persons using respiratory protection, consistent with the requirements of 29 CFR 1910.134(l), to ensure that the provisions of the written respiratory protection program required under paragraph (e)(1)(iii) of this section are being effectively implemented.

(xiv) The respiratory protection requirements in this paragraph represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(2) *Dermal protection.*

(i) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 9 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, the owner or operator must provide to and ensure appropriate use of gloves by each potentially exposed person in accordance with § 751.809(b)(1) through (3).

(ii) The owner or operator must provide training and retraining to all persons required to use gloves consistent with § 751.809(b)(4) and (5).

§ 751.809 Prescriptive Controls.

(a) *Applicability.*

The provisions of this section apply to workplaces engaged in the following conditions of use of 1-bromopropane, unless otherwise indicated:

- (1) Manufacturing (import);
- (2) Processing as a reactant;
- (3) Processing for incorporation into articles;
- (4) Processing as repackaging;

- (5) Processing as recycling; and
(6) Disposal.

(b) *Glove requirements.*

(1) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 6 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**] for other owners and operators, the owner or operator is required to provide and ensure the use of gloves that are chemically-resistant to 1-bromopropane, made of supported polyvinyl alcohol or a multiple-layer laminated materials, by all persons likely to be dermally exposed to 1-bromopropane (including products containing 1-bromopropane).

(2) Owners and operators must select gloves that properly fit each affected person and communicate glove selections to each affected person.

(3) Owners and operators must provide, ensure use of, and maintain (in a sanitary, reliable, and undamaged condition) gloves that are of safe design and construction for the work to be performed.

(4) Owners or operators must provide training in accordance with 29 CFR 1910.132(f) to all persons required to use gloves prior to or at the time of initial assignment to a job involving exposure to 1-bromopropane. For the purposes of this paragraph (b), provisions in 29 CFR 1910.132(f) applying to an “employee” also apply equally to potentially exposed persons, and provisions applying to an “employer” also apply equally to owners or operators.

(5) Owners and operators must retrain each person required to use gloves at least annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use gloves, or when changes in the workplace or in gloves to be used render the previous training obsolete.

§ 751.811 Self-certification.

(a) *Applicability.*

The provisions of this section apply to the following conditions of use of 1-bromopropane, unless otherwise indicated:

- (1) Processing into a formulation, mixture, or reaction product;
(2) Industrial and commercial use as a solvent in open-top and in-line batch vapor degreasing;
(3) Industrial and commercial use as a solvent in closed-loop vapor degreasing;

(4) Industrial and commercial use as a solvent for cleaning and degreasing in cold cleaners;

(5) Industrial and commercial use as a solvent in aerosol spray degreaser/cleaner; and

(6) Industrial and commercial use in other uses in electronic and electronic products and metal products; laboratory chemicals; asphalt extraction; and coatings for temperature indicators.

(b) *Self-certification requirements.*

(1) The owner or operator purchasing 1-bromopropane for one or more of the conditions of use listed in (a) must comply with the requirements of § 751.807.

(2) The owner or operator, or authorized person, must self-certify each facility engaging in one or more uses listed in paragraph (a) of this section are in compliance with requirements of § 751.807 of this subpart with the following written statement:

I certify each of the following statements, under penalty of law., This document was prepared under my direction and supervision. I further certify that this facility’s implementation of the Workplace Chemical Protection Program (WCPP) for 1-bromopropane was evaluated by qualified personnel with industrial hygiene qualifications or similar experience and that this facility has implemented and complies with the WCPP for 1-bromopropane. Based on my inquiry of the individual or individuals who manage the facility and/or those individuals directly responsible for implementing the 1-bromopropane WCPP, and to the best of my knowledge and belief, the facility is in compliance with the 1-bromopropane WCPP, including the exposure control plan. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal fines and imprisonment, for knowingly failing to comply with these requirements. If this is the first purchase of 1-bromopropane for this facility, I understand that this certification will serve as a certification that this facility will properly implement and comply with the WCPP for 1-bromopropane consistent with the applicable regulatory timelines.

(i) The statement must include the following:

(A) Printed name and signature, job classification, title, email address and phone number of the owner or operator, or authorized person, who is self-certifying;

(B) Date of self-certification;

(C) Name and address of the facility;

(D) Lists the condition of use, (e.g., solvent for aerosol spray degreaser/cleaner);

(E) Examples of the type of equipment the owner or operator plans to use to meet the WCPP (e.g., closed loop vapor degreaser); and

(F) Indication of whether this is the facility’s first purchase of 1-bromopropane after [DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

(ii) Owners and operators must provide a current self-certification statement for each facility to the distributor from whom 1-bromopropane is being purchased for every purchase.

(iii) The self-certification statement is valid for one year, unless the facility has changed processes or there is an indication that exposures to 1-BP have changed.

(iv) Distributors of 1-bromopropane must review the self-certification statement to ensure it is appropriately completed to include the owner or operator’s and the facility’s information, as required by this section.

(v) Distributors of 1-bromopropane must have a complete and valid self-certification statement in accordance with this section for each sale of 1-bromopropane for a use described in paragraph (a) of this section. If the distributor obtains knowledge that the purchaser of 1-BP has failed to comply with the WCPP for 1-BP, the distributor must immediately cease to supply the substance to that purchaser, and may only commence supplying to the purchaser upon, unless the distributor has received written notification from EPA that permits its distribution.

§ 751.813 Downstream notification.

(a) Beginning on [DATE 2 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], each person who manufactures (including imports) 1-bromopropane for any use must, prior to or concurrent with the shipment, notify companies to whom 1-bromopropane is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

(b) Beginning on [DATE 6 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], each person who processes or distributes in commerce 1-bromopropane or any 1-bromopropane-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom 1-bromopropane is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

(c) The notification required under paragraphs (a) and (b) of this section must occur by inserting the following text in sections 1(c) and 15 of the Safety Data Sheet (SDS) provided with the 1-bromopropane or with any product

containing 1-bromopropane, except for the manufacture, processing, distribution in commerce, use, or disposal of 1-bromopropane in building/construction materials (insulation):

After [DATE 18 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product can only be distributed in commerce to or by retailers for the commercial and consumer use of 1-bromopropane in building/construction materials (insulation). After [DATE 21 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], this chemical/product is and can only be distributed in commerce to non-retailers or processed for the following purposes: Processing as a reactant; Processing into formulation, mixture, or reaction product; Processing for incorporation into articles; Processing for repackaging; Recycling; Industrial and commercial use as solvent for cleaning and degreasing in open-top and in-line batch vapor degreaser; Industrial and commercial use as solvent for cleaning and degreasing in closed-loop batch vapor degreaser; Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; Industrial and commercial use as solvent in aerosol spray degreaser/cleaner; Industrial and commercial uses in electronic and electronic products and metal products; asphalt extraction; laboratory chemicals; and temperature indicator—coatings; and Disposal.

§ 751.815 Recordkeeping requirements.

(a) General records.

After [DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of 1-bromopropane or 1-bromopropane-containing products, except for the use of 1-bromopropane in insulation, must maintain ordinary business records, such as invoices and bills-of-lading related to compliance with the prohibitions, restrictions, and other provisions of this subpart.

(b) Workplace Chemical Protection Program (WCPP) compliance.

(1) *ECEL exposure monitoring.* For each monitoring event, owners or operators subject to the ECEL described in § 751.807(b) must retain records of:

- (i) Dates, duration, and results of each sample taken;
- (ii) The quantity, location(s) and manner of 1-bromopropane in use at the time of each monitoring event;
- (iii) All measurements that may be necessary to determine the conditions that may have affected the monitoring results;
- (iv) Name, workplace address, work shift, job classification, work area, and

type of respiratory protection (if any) of each monitored person;

(v) Identification of all potentially exposed persons that a monitored person is intended to represent if using a representative sample, consistent with § 751.807(b)(2)(i)(A) and (B);

(vi) Sampling and analytical methods used as described in § 751.807(b)(2)(i)(D);

(vii) Compliance with the Good Laboratory Practice Standards in 40 CFR part 792, or use of a laboratory accredited by the AIHA or another industry-recognized program, as required by § 751.807(b)(2)(i)(C);

(viii) Information regarding air monitoring equipment, including: type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions; and

(xi) Notification of exposure monitoring results in accordance with § 751.801(b)(2)(v).

(2) *ECEL compliance.* Owners or operators subject to the ECEL described in § 751.807(b) must retain records of:

(i) Exposure control plan as described in § 751.807(c)(2);

(ii) Implementation of the exposure control plan described in § 751.807(c)(2), including:

(A) Any regular inspections, evaluations, and updating of the exposure controls to maintain effectiveness;

(B) Confirmation that all persons are implementing the exposure controls; and

(C) Each occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes an exceedance of the ECEL and any subsequent corrective actions taken by the owner or operator during the start-up, shutdown, or malfunctions to mitigate exposures to 1-bromopropane.

(iii) Respiratory protection used by each potentially exposed person and PPE program implementation as described in § 751.807(e), including:

(A) The name, workplace address, work shift, job classification, and work area of each potentially exposed person, and the type of respiratory protection provided to each potentially exposed person;

(B) The basis for the specific PPE selection in accordance with § 751.807(e); and

(C) Fit testing and training in accordance with § 751.807(e).

(iv) Information and training provided as required in § 751.807(d).

(3) *Workplace participation.* Owners or operators must document the notice to and ability of any potentially exposed person that may reasonably be affected by 1-bromopropane inhalation exposure

to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to 1-bromopropane exposure in the workplace.

(c) Dermal protection.

Owners and operators subject to the dermal protection requirements described in § 751.807(e)(2) or § 751.809 of this subpart must maintain records of the following information:

(1) Dermal protection used by each potentially exposed person and PPE program implementation as described in § 751.809(b), including the name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle 1-bromopropane or handle equipment or materials on which 1-bromopropane may present;

(2) Appropriately sized gloves and the type of glove being used at the facility, either supported polyvinyl alcohol, multiple-layer laminates, or other gloves as provided under subsequent guidance of this rule; and

(3) Training in accordance with § 751.809(b)(4) and (5).

(d) Self-certification.

(1) Owners and operators who self-certify as required under § 751.811 must document and retain records of each self-certification statement for each facility that is self-certifying, including:

(i) Printed name and signature, job classification, email address and phone number of the owner or operator who is self-certifying;

(ii) Date of self-certification;

(iii) Name and address of the facility; and

(iv) All records required under paragraphs (a) and (b) of this section.

(2) Distributors of 1-bromopropane must collect, maintain, and retain records relating to self-certification statements received under § 751.811 that include the following:

(i) Name of facility;

(ii) Name of owner or operator who is self-certifying;

(iii) Date of sale;

(iv) Quantity of 1-bromopropane being purchased; and

(v) Self-certification statement for each purchase of 1-bromopropane.

(e) Retention.

Persons required to maintain records required under this section must maintain the records for a period of 5 years from the date that such records were generated.

[FR Doc. 2024–17204 Filed 8–7–24; 8:45 am]

BILLING CODE 6560–50–P



FEDERAL REGISTER

Vol. 89

Thursday,

No. 153

August 8, 2024

Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Endangered Species
Status for Cedar Key Mole Skink and Designation of Critical Habitat;
Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R4-ES-2024-0053;
FXES1111090FEDR-245-FF09E21000]

RIN 1018-BH41

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Cedar Key Mole Skink and Designation of Critical Habitat**AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Cedar Key mole skink (*Plestiodon egregius insularis*), a lizard subspecies from the Cedar Keys, Florida, as an endangered species under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing this subspecies is warranted. We also propose to designate critical habitat for the Cedar Key mole skink under the Act. In total, approximately 2,713 acres (1,098 hectares) in Levy County, Cedar Keys, Florida, fall within the boundaries of the proposed critical habitat designation. In addition, we announce the availability of an economic analysis of the proposed designation of critical habitat for the Cedar Key mole skink. If we finalize this rule as proposed, it would extend the Act's protections to this subspecies and its designated critical habitat.

DATES: We will accept comments received or postmarked on or before October 7, 2024. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by September 23, 2024.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter FWS-R4-ES-2024-0053, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment."

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R4-ES-2024-0053, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Supporting materials, such as the species status assessment report, are available on the Service's website at <https://www.fws.gov/office/florida-ecological-services/library> and at <https://www.regulations.gov> at Docket No. FWS-R4-ES-2024-0053. For the proposed critical habitat designation, the coordinates or plot points or both from which the maps are generated are included in the decision file for this critical habitat designation and are available at <https://www.regulations.gov> at Docket No. FWS-R4-ES-2024-0053 and on the Service's website at <https://www.fws.gov/office/florida-ecological-services/library>.

FOR FURTHER INFORMATION CONTACT:

Lourdes Mena, Division Manager, Classification and Recovery, Florida Ecological Services Field Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256-7517; lourdes_mena@fws.gov; telephone 352-749-2462. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please see Docket No. FWS-R4-ES-2024-0053 on <https://www.regulations.gov> for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:**Executive Summary**

Why we need to publish a rule. Under the Act (16 U.S.C. 1531 *et seq.*), a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species

promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that the Cedar Key mole skink meets the Act's definition of an endangered species; therefore, we are proposing to list it as endangered and proposing a designation of its critical habitat. Both listing a species as an endangered or threatened species and making a critical habitat designation can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. We propose to list the Cedar Key mole skink as an endangered species under the Act, and we propose the designation of critical habitat for the subspecies.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the Cedar Key mole skink is endangered due to threats associated with climate change, specifically sea level rise, increased high tide flooding, and increased intensity of storm events (Factor E).

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary), to the maximum extent prudent and determinable, concurrently with listing designate critical habitat for the species. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

- (1) The subspecies' biology, range, and population trends, including:
 - (a) Biological or ecological requirements of the subspecies, including habitat requirements for feeding, breeding, and sheltering;
 - (b) Genetics and taxonomy;
 - (c) Historical and current range, including distribution patterns and the locations of any additional populations of this subspecies;
 - (d) Historical and current population levels, and current and projected trends; and
 - (e) Past and ongoing conservation measures for the subspecies, its habitat, or both.
- (2) Threats and conservation actions affecting the subspecies, including:
 - (a) Factors that may be affecting the continued existence of the subspecies, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or humanmade factors;
 - (b) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this subspecies; and
 - (c) Existing regulations or conservation actions that may be addressing threats to this subspecies.
- (3) Additional information concerning the historical and current status of this subspecies.
- (4) Specific information on:
 - (a) The amount and distribution of Cedar Key mole skink habitat;
 - (b) Any additional areas occurring within the range of the subspecies, the Cedar Keys in Levy County, Florida, that should be included in the critical habitat designation because they (i) are occupied at the time of listing and contain the physical or biological feature that is essential to the conservation of the subspecies and that may require special management considerations or protection, or (ii) are unoccupied at the time of listing and are essential for the conservation of the subspecies;
 - (c) Special management considerations or protection that may be

needed in the critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) Whether areas not occupied at the time of listing qualify as habitat for the species and are essential for the conservation of the species.

(5) Land use designations and current or planned activities and their possible impacts on proposed critical habitat.

(6) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the related benefits of including or excluding specific areas.

(7) Information on the extent to which the description of probable economic impacts in the economic analysis is a reasonable estimate of the likely economic impacts and any additional information regarding probable economic impacts that we should consider.

(8) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. If you think we should exclude any additional areas, please provide information supporting a benefit of exclusion.

(9) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available, and section 4(b)(2) of the Act directs that the Secretary shall designate critical habitat on the basis of the best scientific data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in

ADDRESSES. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on <https://www.regulations.gov>.

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as any information that may become available after the publication of this proposal. Based on the new information we receive (and, if relevant, any comments on that new information), we may conclude that the subspecies is threatened instead of endangered, or we may conclude that the subspecies does not warrant listing as either an endangered species or a threatened species. For critical habitat, our final designation may not include all areas proposed, may include some additional areas that meet the definition of critical habitat, or may exclude some areas if we find the benefits of exclusion outweigh the benefits of inclusion and exclusion will not result in the extinction of the subspecies. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public

hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On July 11, 2012, we received a petition from the Center for Biological Diversity to list the Cedar Key mole skink as an endangered or threatened species under the Act. On July 1, 2015, we published in the **Federal Register** (80 FR 37568) a 90-day finding that the petition provided substantial information indicating that listing the Cedar Key mole skink may be warranted. On December 19, 2018, we published in the **Federal Register** (83 FR 65127) a 12-month finding that the Cedar Key mole skink did not warrant listing under the Act. On January 26, 2022, the Center for Biological Diversity filed suit against the Service, alleging the Service did not use the best available scientific data regarding sea level rise and its impacts to Cedar Key mole skink habitat in its 12-month finding. In May 2022, the Service agreed to submit a new finding to the **Federal Register** by July 31, 2024. This finding and proposed rule reflect the updated assessment of the status of the Cedar Key mole skink based on the best available science, including an updated species status assessment for the subspecies (Service 2023, entire).

Peer Review

A species status assessment (SSA) team prepared an SSA report for the Cedar Key mole skink. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the subspecies, including the impacts of past, present, and future factors (both negative and beneficial) affecting the subspecies.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review in listing and recovery actions under the Act, we solicited independent scientific review of the information contained in the Cedar Key mole skink SSA report. We sent the SSA report to six independent peer reviewers and received one response. Results of this structured peer review process can be found at <https://www.regulations.gov> and <https://www.fws.gov/office/florida-ecological-services>. In preparing this proposed rule, we incorporated the results of this review, as appropriate, into the SSA report, which is the foundation for this proposed rule.

Summary of Peer Reviewer Comments

As discussed in Peer Review above, we received comments from one peer reviewer on the draft SSA report. We reviewed the comments for substantive issues and new information regarding the contents of the SSA report. The peer reviewer generally concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions, including clarifications in terminology and other editorial suggestions.

The peer reviewer suggested that our statement that “rafting is rare, but does occur” was inappropriate. The peer reviewer noted that there is no evidence that rafting occurs in the Cedar Key mole skink (or any mole skink subspecies) and that, in fact, genetic evidence suggests the opposite (that there is no movement of mole skinks among islands). We updated the SSA report to indicate that rafting is unlikely.

The peer reviewer also commented that our analysis of “potential habitat” on the two developed islands, Way Key and Airstrip Island, was an overrepresentation of the amount of habitat truly available to the Cedar Key mole skink. In our initial analysis, we included high intensity and low intensity urban data layers for these islands as part of our calculation of potential habitat available because skinks have been found in backyards, in parking lots, along roadsides, and in other disturbed or developed areas. However, these data layers also included roads, buildings, and other developed areas, which are not considered habitat for the Cedar Key mole skink. As a result, our use of these data layers increased what we had identified as potential habitat on Airport Island from 1.00 acre (0.40 hectares) to 52.43 acres (21.0 hectares), and on Way Key from 2.65 acres (1.07 hectares) to 266.14 acres (107.70 hectares). We agree with the peer reviewer that the use of the urban areas in our analysis overestimated the amount of habitat truly available to the Cedar Key mole skink. Thus, we restricted our analysis of these two islands to only include the preferred habitat data layers that included beaches, dunes, and coastal hammock. We included the additional analysis focused on high-intensity and low-intensity urban areas on Way Key and Airport Island as part of appendix A in the SSA report.

I. Proposed Listing Determination Background

A thorough review of the taxonomy, life history, and ecology of the Cedar

Key mole skink (*Plestiodon egregius insularis*) is presented in the SSA report (Service 2023, pp. 2–16). The Cedar Key mole skink is one of five distinct subspecies of mole skinks in Florida, all in the genus *Plestiodon* (previously *Eumeces*) (Brandley et al. 2005, pp. 387–388), and is endemic to the Cedar Keys, Florida. This subspecies represents a unique genetic lineage that is distinct from the other four mole skink subspecies (Brandley et al. 2005, pp. 387–388; Parkinson et al. 2016, entire). The Cedar Key mole skink is the largest of the five subspecies, approaching 15 centimeters (5.9 inches), with the tail accounting for two-thirds of the length.

The Cedar Key mole skink is semi-fossorial (adapted to digging, burrowing, and living underground) and cryptic in nature. The Cedar Key mole skink is a cold-blooded reptile and therefore highly dependent air and soil temperature to thermoregulate (maintain body core temperature) (Mount 1963, p. 362). Ground cover moderates soil temperatures and provides shade to assist in the skinks’ thermoregulation in hot climate. The optimum temperature range for the mole skink species (*Plestiodon egregius*) is 26 to 34 degrees Celsius (C) (78.8 to 93.2 degrees Fahrenheit (F)) with a mean of 29.5 C (85.1 F) (Mount 1963, p. 363). Mole skinks are considered thermoconformers, lacking the capacity to adjust or regulate to changes in temperature outside of this stable and relatively narrow thermal range in which it occurs (Gallagher et al 2015, p. 62).

The specific diet of Cedar Key mole skink is unknown, but in general, skinks in the genus *Plestiodon* are known to eat ants, spiders, crickets, beetles, termites, small bugs, mites, and butterfly larva (Hamilton and Pollack 1958, p. 26). Native snakes are considered natural predators of mole skinks (Hamilton and Pollack 1958, p. 28, Mount 1963, p. 356) and domestic and feral cats on some islands in the Cedar Keys are known to prey on skink populations (Florida Fish and Wildlife Commission (FWC) 2013, p.5). The Cedar Key mole skink relies on dry, unconsolidated soils for movement, cover, and nesting, and it needs detritus, leaves, wrack, and other ground cover for shelter, temperature regulation, and food (insects and arthropods found in ground cover).

The Cedar Keys are a coastal complex of islands, tidal creeks, bays, and salt marsh, located along 10 miles (16 kilometers) of Florida’s central Gulf of Mexico coast in Levy County. The Cedar Key mole skink has been found in small numbers on 10 islands of the Cedar

Keys archipelago (see figure 1, below). Eight of these islands are currently considered occupied (skink detections documented between 2000 to 2022), and two of these islands are considered to have uncertain status (skink detections

documented prior to 1999, but not resurveyed) (Mount 1963, entire; Mount 1965 entire; FWC 2023, entire). In total, 215 Cedar Key mole skinks have been detected, with 62 individuals documented since 2000. Within this

limited range, the Cedar Key mole skink is found most frequently in sand beach and coastal dune habitats. The estimated home range of a Cedar Key mole skink is approximately a 328-ft (100-meter) radius (Service 2023, p. 12).

Cedar Key Mole Skink (*Plestiodon egregius insularis*) Distribution

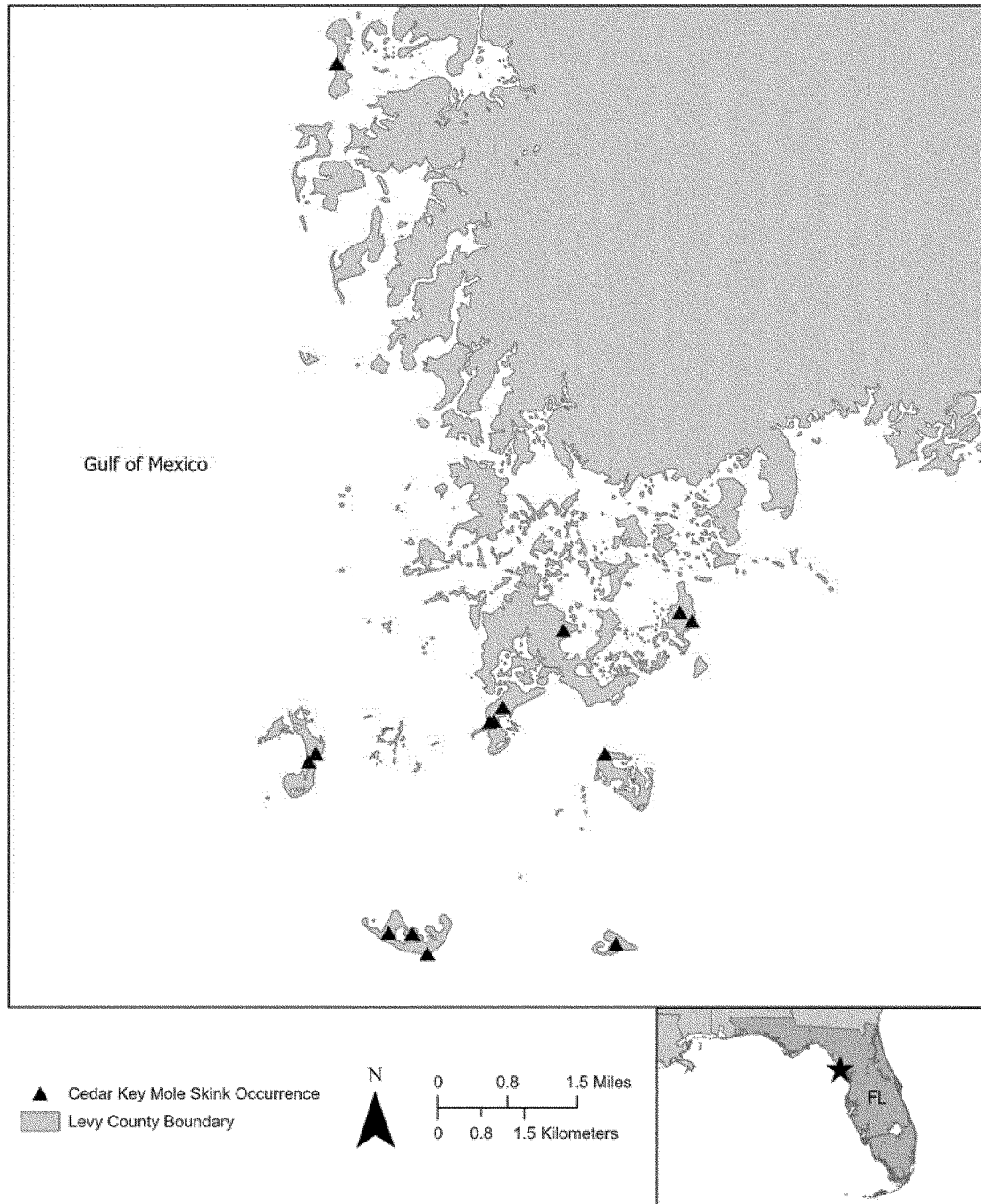


Figure 1—Distribution and occurrences of the Cedar Key mole skink.

The Cedar Keys archipelago is a relatively small coastal ecosystem of 30 or more, mostly undeveloped islands of varying size and elevations. Of the eight current islands with known Cedar Key mole skink occurrence, only one island, Airstrip Island, is developed. Deer Island, also occupied by the Cedar Key mole skink, is privately owned with one dwelling and could be further developed with a small number of (off-the-grid) dwellings. Way Key, the largest island within the Cedar Keys, where the City of Cedar Key is located, is mostly developed, but the Cedar Key mole skink population status there is uncertain. The remaining islands with known populations of the Cedar Key mole skink are undeveloped and largely protected as part of the Cedar Keys National Wildlife Refuge. There are other islands of the Cedar Keys archipelago that contain suitable habitat and soils for the Cedar Key mole skink, but they have unknown occupancy due to lack of survey efforts. Many of these islands are also protected as conservation lands, and some are privately owned (all or in part) but remain undeveloped.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for endangered and threatened species. On April 5, 2024, jointly with the National Marine Fisheries Service, we issued a final rule that revised the regulations in 50 CFR part 424 regarding how we add, remove, and reclassify endangered and threatened species and what criteria we apply when designating listed species' critical habitat (89 FR 24300). On the same day, we published a final rule revising our protections for endangered species and threatened species at 50 CFR 17 (89 FR 23919). These final rules are now in effect and are incorporated into the current regulations.

The Act defines a "species" as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines an "endangered species" as a species that is in danger of extinction throughout all or a significant portion of its range, and a "threatened species" as a species that is likely to become an

endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
- (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an "endangered species" or a "threatened species" only

after conducting this cumulative analysis and describing the expected effect on the species.

The Act does not define the term "foreseeable future," which appears in the statutory definition of "threatened species." Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis, which is further described in the 2009 Memorandum Opinion on the foreseeable future from the Department of the Interior, Office of the Solicitor (M-37021, January 16, 2009; "M-Opinion," available online at <https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/M-37021.pdf>). The foreseeable future extends as far into the future as the U.S. Fish and Wildlife Service and National Marine Fisheries Service (hereafter, the Services) can make reasonably reliable predictions about the threats to the species and the species' responses to those threats. We need not identify the foreseeable future in terms of a specific period of time. We will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat projection timeframes, and environmental variability. In other words, the foreseeable future is the period of time over which we can make reasonably reliable predictions. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction, in light of the conservation purposes of the Act.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent our decision on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies.

To assess the Cedar Key mole skink's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency is the ability of the subspecies to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years);

redundancy is the ability of the subspecies to withstand catastrophic events (for example, droughts, large pollution events); and representation is the ability of the subspecies to adapt to both near-term and long-term changes in its physical and biological environment (for example, climate conditions, pathogens). In general, the subspecies' viability will increase with increases in resiliency, redundancy, and representation. Using these principles, we identified the subspecies' ecological requirements for survival and reproduction at the individual, population, and subspecies levels, and described the beneficial and risk factors influencing the subspecies' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the subspecies' individual and population life-history needs. The next stage involved an assessment of the historical and current condition of the subspecies' demographics and habitat characteristics, including an explanation of how the subspecies arrived at its current condition. The final stage of the SSA involved making predictions about the subspecies' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of the subspecies to sustain populations in the wild over time, which we then used to inform our regulatory decision.

The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS-R4-ES-2024-0053 on <https://www.regulations.gov> and at <https://www.fws.gov/office/florida-ecological-services/library>.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the subspecies and its resources, and the threats that influence the subspecies' current and future condition, in order to assess the subspecies' overall viability and the risks to that viability.

Subspecies Needs

The SSA report contains a detailed discussion of the Cedar Key mole skink's individual and population requirements (Service 2023, pp. 2–16); we provide a summary here. Based upon the best available scientific and commercial information, and acknowledging existing ecological uncertainties, the resource and demographic needs for breeding,

feeding, sheltering, and dispersal of the Cedar Key mole skink are characterized as:

- Beaches, dunes, and coastal hammock habitats that provide ground cover in the form of leaf litter and wrack material, that the Cedar Key mole skink needs for nesting, arthropod and insect food sources, and cover; and
- Dry, loose, sandy, permeable, or friable (crumbly in texture) soils for digging of nest cavities and movement, as all portions of the Cedar Key mole skink's life cycle occur within or on the surface of the soil.

The Cedar Key mole skink's abundance, distribution, and life-history behaviors (e.g., nesting, breeding) are limited to, and defined by, the availability of these resources in the areas of beach, dune, and coastal hammock habitats.

Threats

The main threats affecting the Cedar Key mole skink are related to shifts in climate as a result of increasing greenhouse gas emissions. Sea level rise, more frequent tidal flooding (increase of tides above the mean high tide), and increasing intensity of storm events (such as hurricanes) are the predominant threats to the Cedar Key mole skink and its habitat. We also evaluated existing regulatory mechanisms and ongoing conservation measures. In the SSA report, we considered additional threats: habitat loss and degradation that result from development and habitat disturbance; overutilization due to recreational, educational, and scientific use; disease; oil spills; and nonnative species. We concluded that, as indicated by the best available scientific and commercial information, these additional threats are currently having little to no impact on the Cedar Key mole skink, and thus their overall effect now and into the future is expected to be minimal. For full descriptions of all threats and how they impact the Cedar Key mole skink, please see the SSA report (Service 2023, pp. 16–31).

Climate Change

The predominant threats currently affecting the Cedar Key mole skink and its habitat are the rapid and intense shifts in climate occurring as a result of increasing greenhouse gas emissions. The entire Cedar Key archipelago is being affected by sea level rise, more frequent high tide flooding, and increased intensity of tropical storms and hurricanes. In the SSA report and this proposed rule, we discuss the effects of climate change on the Cedar Key mole skink in terms of increasing

sea level rise, more frequent tidal flooding, and increased intensity of storm events.

Sea level rise—Within Florida, sea level rise is increasing at a faster rate than globally, making this subspecies especially vulnerable to impacts from sea level rise across its entire range (Carter et al. 2014, pp. 401–403; Park and Sweet 2015, entire; Sweet et al. 2017, p. 25). Accelerated sea level rise in Florida is attributed to shifts in the Florida Current due to added ocean mass brought on by the melting Antarctic and Greenland ice packs and thermal expansion from warming oceans (Park and Sweet 2015, entire; Rahmstorf et al. 2015, entire; Deconto and Pollard 2016, p. 596; Sweet et al. 2017, p. 14). Tidal gauges around Florida have shown approximately 25 centimeters (10 inches) of sea level rise since 1920. However, from 2006 to 2016 alone, there was a 12-centimeter (5-inch) sea level rise in southeast Florida (Sweet et al. 2017, p. 41; *SeaLevelRise.org* 2023, p. 1).

The majority of the Cedar Keys are low-lying sandy islands (see table 1, below), making them highly susceptible to erosion and flooding, and at risk of inundation and saltwater intrusion (Florida Department of Environmental Protection (FDEP) 2012, p. 12; U.S. Geological Survey (USGS) 2017, unpaginated). As sea level rises, Cedar Key mole skink habitat becomes inundated and unusable due to saturation of the soils or direct loss of habitat. The Cedar Key mole skink utilizes coastal beach habitat and coastal maritime hammock habitat during all of its life stages, making it especially vulnerable to current and projected sea level rise across its entire range. The effects of rising sea levels (loss of beach habitat, coastal flooding, and saltwater intrusion) are currently being experienced along Florida's Gulf Coast, including the Cedar Keys, and these effects are projected to continue (see table 1, below; Carter et al. 2014, pp. 398–400, 403; Wadlow 2016, entire; *SeaLevelRise.org* 2023, p. 1).

High tide flooding—One of the most noticeable impacts from sea level rise is the increased frequency of high tide flooding (Sweet et al. 2020, p. v). High tide flooding begins when coastal water levels exceed the mean higher high-water level (increase of tides above the mean high tide) (Sweet et al. 2014, entire). Frequent flooding above the high tide line causes flooded areas to become unusable to the Cedar Key mole skink (individuals cannot easily move through wet sand; individuals or nests will be washed away). High tide flooding can result in beach erosion and

salinization of soils, even if high tide flooding is infrequent (Saha et al. 2011a, pp. 181–182; Saha et al. 2011b, pp. 82–84; Sweet et al. 2020, pp. 1–4). Over time, habitat that is frequently impacted by high tide flooding is degraded as it becomes more intertidal, even prior to sea level rise inundation. Thus, high tide flooding is likely to result in removal of habitat, displacement of individuals landward to less suitable habitat, and potential loss of individual Cedar Key mole skinks due to drowning. Cedar Key mole skink populations are especially vulnerable when these impacts occur repeatedly without time to recover. Currently, the national high tide flooding frequency is estimated at 5 days per year and is projected to increase to 7 to 15 days by 2030, and to 25 to 75 days by 2050, in much of coastal Florida and the Cedar Keys (Sweet et al. 2021, pp. 9–10).

Storm events—Habitat for the Cedar Key mole skink can be degraded or removed by extreme storm events such as hurricanes, storm surges, and floods. Storm events are a natural part of the Cedar Keys ecosystem and can provide indirect benefits to Cedar Key mole skink habitat. Storms can deposit wrack and other debris that provide habitat for the subspecies' prey and shelter for Cedar Key mole skinks. However, hurricane activity has increased since the Atlantic Multi-Decadal Oscillation (the natural variability of the sea surface temperature in the Atlantic Ocean) went into its warm phase around 1992 (National Oceanic and Atmospheric Administration (NOAA) 2019, p. 1), and the increased intensity of storms over the last several decades has likely had negative impacts on the Cedar Key mole skink's resiliency, representation, and redundancy.

Information on direct impacts of hurricanes to the Cedar Key mole skink are lacking. However, there is information on impacts to habitat from recent hurricanes and other strong storms that have occurred in the region. Hurricane Hermine (Category 1) passed by the Cedar Keys in September 2016, causing widespread overwash and erosion to beach and coastal hammock habitats. Vegetation became buried, and the ground cover was greatly reduced from the resulting storm surge (Enge et al. 2017, entire). As a result of Hurricane Hermine, the beachfront of North Key lost most of the vegetative cover required for the Cedar Key mole skink (Enge et al. 2017, entire). In August 2023, Hurricane Idalia (Category 3) made landfall in the Cedar Keys and caused a storm surge of up to 7 feet (2.1 meters), causing complete overwash of many islands. For example, Seahorse

Key lost 20 to 30 feet (6 to 9 meters) of beach and the remaining sand was left compacted (Thomas 2023, pers. comm.). Overtime, the vegetative cover will likely return to beach and coastal hammock habitats, but when these storm impacts occur repeatedly, there is less time for Cedar Key mole skink populations to recover from any single event (e.g., temporary inundation of soils, loss of shelter and food resource, drowning), thus reducing overall resiliency when impacts by extreme and repetitive storm events occur (Service 2017, p. 7).

The severity and duration of hurricane impacts to the Cedar Key mole skink and its habitat vary based on the intensity and scale of storm events. Localized impacts can vary greatly depending upon not only the strength of the storm but the direction of its approach and how quickly it moves through the area. Storm surges and their intensity can also vary depending on location. The increased intensity of storm events over the last several decades has likely led to a reduction in Cedar Key mole skink populations, thereby reducing overall population resiliency and the subspecies' redundancy.

In summary, impacts from climate change have the potential to reduce survival of the Cedar Key mole skink at the individual, population, and subspecies level. Sea level rise can degrade existing habitat that supports the Cedar Key mole skink, reducing the habitat features that the subspecies needs and thus reducing population resiliency. Increased high tide flooding and increased intensity of storm events have the potential to further degrade Cedar Key mole skink habitat. Increased high tide flooding and storm events also have the potential to kill skinks directly or to reduce individual survival, which could then lead to a reduction in population resiliency and the subspecies' redundancy. An increase in the intensity of storms or a direct hit from a strong hurricane could significantly reduce subspecies abundance (reducing population resiliency) and potentially extirpate populations (limiting redundancy). There are no regulatory mechanisms or conservation measures that address the impacts of sea level rise, high tide flooding, or increased intensity of storm events.

Conservation Efforts and Regulatory Mechanisms

Several local, State, and Federal government plans provide conservation actions that directly or indirectly benefit the Cedar Key mole skink and its

habitat. Levy County has several plans for coastal management, emergency management, and land use management, including their Comprehensive Plan (Frank et al. 2014, entire; Levy County 2017, entire). Levy County has policies to limit incompatible future growth and development in coastal areas subject to flooding (Frank et al. 2014, p. 69), which are areas where the Cedar Key mole skink's habitat occurs. The Comprehensive Plan also contains coastal setback guidelines, standards for construction near or on the shoreline, and policies for protecting environmentally sensitive land (Frank et al. 2014, p. 69; Levy County 2017, p. 13). The Levy County Code of Ordinances (Levy County 2023, pp. 6–12) requires the protection of environmentally sensitive lands and coordination with Florida Fish and Wildlife Commission and the Service regarding potential impacts to endangered or threatened species or their habitats.

The City of Cedar Key has a variety of land uses: residential, conservation, recreation, marsh, mixed use, commercial, and public (City of Cedar Key 2018, p. 145). City Code 4–3.2 states that “the City shall protect native vegetation, including but not limited to trees, mangroves, and marsh grasses, and cooperate with Levy County in identifying, conserving, protecting or preserving unique vegetative communities in contiguous areas to assure that development does not degrade the environment, impair aesthetics, damage coastal resources or deny reasonable property rights and uses” (City of Cedar Key 2018, p. 169). City Code 4–8.1 states, “a minimum coastal construction setback line of 50 feet (15 meters) from the mean high-water line will be maintained on any land adjoining all surface waters. In addition to the 50 feet (15 meters) setback line, an additional setback may be required to protect water-dependent vegetation located landward of the coastal construction setback line” (City of Cedar Key 2018, p. 172). These setbacks from beach habitat allow Cedar Keys mole skink habitat along the shoreline to remain intact. The city also has plans to manage and protect all ecological and wildlife communities (City of Cedar Key 2018, pp. 271–273).

The Florida Gulf Coast Mitigation Bank (Mitigation Bank) consists of approximately 1,587 acres (642 hectares) of habitat in Levy County owned and managed by the Mitigation Banking Group, Incorporated. The Mitigation Bank is characterized by coastal habitats, including maritime hammocks, coastal scrub, and both

freshwater and saltwater wetlands. The entire property is covered by a conservation easement. Habitat for several federally listed species (Florida salt marsh vole (*Microtus pennsylvanicus*, listed as *Microtus pennsylvanicus dukecampbelli*), Florida scrub-jay (*Aphelocoma coerulescens*), and wood stork (*Mycteria americana*)) is protected by the Mitigation Bank. Restoration and management activities include mechanical treatment, prescribed fire, and road removal to improve natural hydroperiods. Three of the proposed critical habitat units (see II. Critical Habitat, below) for the Cedar Key mole skink are located on Mitigation Bank property, and the protection and management of these areas will provide benefits to the Cedar Key mole skink.

Florida's Nature Coast Conservancy (Conservancy) is a nonprofit land trust dedicated to acquiring land for preservation, conservation, and/or public recreation. The Conservancy has protected at least 11 properties throughout the Cedar Keys and ensures sustainable land management protocols are in place for each. Two of the proposed critical habitat units (see II. Critical Habitat, below) for the Cedar Key mole skink are within the Conservancy's properties, and the protection and management of these areas will provide benefits to the Cedar Key mole skink.

The Cedar Key mole skink also occurs within three State Parks, including Cedar Key Museum State Park, Cedar Key Scrub Wildlife Management Area, and Cedar Key Scrub State Reserve. Active management of these parks provides indirect benefits to the Cedar Key mole skink by protecting and providing habitat through beach

restoration and nourishment and nonnative plant and animal control. Part of the active management of these parks includes the Florida Parks Service conducting nonnative plant and animal control that benefits Cedar Key mole skinks.

The Cedar Key mole skink occurs within two National Wildlife Refuges: the Lower Suwannee and Cedar Keys National Wildlife Refuges. Specific management or conservation objectives for the Cedar Key mole skink are not identified in the management plans for these National Wildlife Refuges lands; however, ongoing management activities, including habitat restoration and nonnative species control, provide benefits to the Cedar Key mole skink and its habitat.

Cumulative Effects

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have analyzed the cumulative effects of identified threats and conservation actions on the subspecies. To assess the current and future condition of the subspecies, we evaluate the effects of all the relevant factors that may be influencing the subspecies, including threats and conservation efforts. Because the SSA framework not only considers the presence of the factors, but to what degree they collectively influence risk to the entire subspecies, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

Current Condition

Resiliency

Due to the semi-fossorial and cryptic nature of the Cedar Key mole skink,

abundance data are lacking, and no population trend data exist for this subspecies. There are also no data available regarding the population structure or demographics of the Cedar Key mole skink. There have been 215 detections of Cedar Key mole skinks on 10 islands, with 62 individuals documented on 8 islands since 2000. Two of these island populations are considered to have uncertain status given the last detections were in 1988 and 1993. In total, 191 acres (77 hectares) of preferred habitats (this includes sand, beach, and coastal dune habitats) are currently estimated on all ten islands where Cedar Key mole skinks have been detected.

Table 1, below, provides a summary of the projected magnitude of change in resiliency for populations of the Cedar Key mole skink for the 3-foot (ft) (0.9-meter) sea level rise scenario in 2040. In the "Population status" column of table 1, "current" means occupied in 2000–2022, and "uncertain" means occupied prior to 1999. In the "Year 2040 (3-ft sea level rise)" column, we use symbols as follows:

- ↓ means a slight decrease in population resiliency (more than 10 percent but less than or equal to 50 percent);
- ↓↓ means a moderate decrease in population resiliency (more than 50 percent but less than or equal to 75 percent);
- ↓↓↓ means a large decrease in population resiliency (more than 75 percent but less than or equal to 90 percent); and
- X means extirpated, based on more than 90 percent of the potential habitat being impacted regardless of population resiliency.

TABLE 1—PROJECTED MAGNITUDE OF CHANGE IN RESILIENCY FOR POPULATIONS OF THE CEDAR KEY MOLE SKINK FOR THE 3-FT SEA LEVEL RISE SCENARIO IN THE NEAR FUTURE

[Year 2040]

Island group	Current habitat (acres) *	Island elevation (feet)	Population status	Number of skinks	Year 2040 (3-ft sea level rise)
Airstrip Island	1	15	current	15	↓
Atsena Otie Key	26	20	current	2	X
Cedar Point	8	10	current	2	↓↓
Deer Island	9	10	current	2	X
Dog Island	2	10	uncertain	0	X
North Key	49	15	current	22	X
Scale Key	24	5	current	1	↓
Seahorse Key	55	50	current	17	↓↓↓
Snake Key	14	5	current	1	X
Way Key	3	35	uncertain	0	↓
Total	191			62	

* Totals may not sum due to rounding.

To date, sea level rise has resulted in the direct loss of habitat, as beaches have become inundated for long periods of time. Repeated high tide flooding has resulted in additional loss of habitat as frequently flooded areas become unusable to the Cedar Key mole skink (individuals cannot easily move through wet sand; individuals or nests are washed away). Within the near term (by 2040 or sooner), five of the eight current populations are projected to lose 75 to 90 percent or more of preferred habitat due to continued increases in sea level rise and high tide flooding (table 1). In addition, recent hurricanes (Hurricane Hermine in 2016 and Hurricane Idalia in 2023) have resulted in direct loss of habitat as well as higher storm surge and coastal flooding that has further reduced availability and quality of Cedar Key mole skink habitat. Future projections indicate an increase in the severity of these storms.

Given the current impacts of sea level rise, high tide flooding, and hurricanes, and given the limited available habitat, the relatively low number of individuals documented, and the potential for repeated catastrophic storm events, the overall resiliency of the Cedar Key mole skink is considered low.

Redundancy

Redundancy is the ability of a species to withstand catastrophic events. In the Cedar Keys, tropical storms and hurricanes are regular and common events. However, catastrophic events may include particularly strong or intense hurricanes or storms and the resulting winds, waves, and storm surges associated with these events. Increased intensity of such storms associated with climate change could further reduce the ability of Cedar Key mole skink populations to recover and could cause catastrophic impacts to the subspecies.

Land mass in the Cedar Keys in general is limited, thus providing less redundancy or “backup” for the available habitat such that natural expansion of the subspecies is not possible. Given its small geographic range (eight islands within a length of 10 miles (16 kilometers)), the entire subspecies is vulnerable to potential catastrophic events such as a storm or hurricane that would likely impact all islands.

Representation

The Cedar Key mole skink has limited representation. There is no evidence of morphological or behavioral differences (or “types”) among populations. The Cedar Key mole skink occurs across a narrow geographic and ecological range;

there is no variation in habitat types across distance or elevations. Furthermore, dispersal of individuals across islands is considered very rare, and genetic evidence shows little to no sign of interbreeding between the identified island populations (Parkinson et al. 2016, entire).

As part of the SSA, we also developed sea level rise and high tide flooding future condition scenarios projected out until the year 2100. Our scenarios included intermediate, intermediate-high, and high scenarios, which are aligned with emissions-based, conditional probabilistic and global model projections of global mean sea level rise (Service 2023, p. 42). Because we determined that the current condition of the Cedar Key mole skink is consistent with an endangered species (see Determination of Cedar Key Mole Skink’s Status, below), we are not presenting the detailed results of the future scenarios in this proposed rule. Please refer to the SSA report (Service 2023, pp. 41–50) for the full analysis of future scenarios.

Determination of Cedar Key Mole Skink’s Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an “endangered species” as a species in danger of extinction throughout all or a significant portion of its range, and a “threatened species” as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We presented summary evaluations of the primary threats analyzed in the SSA report including climate change, specifically sea level rise, increased high tide flooding, and increased intensity of storm events (Factor E). We also evaluated existing regulatory mechanisms (Factor D) and ongoing conservation measures. In the SSA report, we also considered additional threats: habitat loss and degradation that

results from development (Factor A); overutilization due to recreational, educational, and scientific use (Factor B); disease (Factor C); oil spills (Factor E); and nonnative species (Factor E). We concluded that, as indicated by the best available scientific and commercial information, these additional threats currently have little to no impact on the Cedar Key mole skink and its habitat such that the overall effect now and into the future is expected to be minimal. However, we consider each of these threats in the determination for the subspecies, because although they may have low impacts on their own, combined with impacts of other threats, they could further reduce the already low number of Cedar Key mole skinks.

Status Throughout All of Its Range

After evaluating threats to the subspecies and assessing the cumulative effect of the threats under the Act’s section 4(a)(1) factors, we have determined that the Cedar Key mole skink has limited resiliency, redundancy, and representation to maintain viability over time. Only 62 skinks have been documented on eight islands in the last 20 years. Given the historical and current impacts from sea level rise, high tide flooding, and hurricanes, habitat for the Cedar Key mole skink is limited. In total, approximately 191 acres (77 hectares) of preferred habitat are currently estimated on islands where the Cedar Key mole skink has been detected. Because the subspecies is limited to a relatively small area (eight islands within a length of 10 miles (16 kilometers)), the subspecies is considered to have little redundancy. A single catastrophic event, such as a severe storm or hurricane, could result in the extinction of the subspecies. Additionally, given the subspecies’ narrow range and limited-to-no island dispersal capabilities, we consider the subspecies to have low representation. The current and future projected increase in sea level rise, high tide flooding, and storm events exacerbates the current condition for the Cedar Key mole skink. We do not find that the Cedar Key mole skink meets the Act’s definition of a threatened species because it already has shown declines in available habitat, has limited abundance, and its population’s exhibit low resiliency. Because of the Cedar Key mole skink’s low redundancy and limited representation, the subspecies is vulnerable to catastrophic storm events. Thus, after assessing the best available information, we conclude that the Cedar Key mole skink is in danger of extinction throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. We have determined that the Cedar Key mole skink is in danger of extinction throughout all of its range and accordingly did not undertake an analysis of any significant portion of its range. Because the Cedar Key mole skink warrants listing as endangered throughout all of its range, our determination does not conflict with the decision in *Center for Biological Diversity v. Everson*, 435 F. Supp. 3d 69 (D.D.C. 2020), because that decision related to significant portion of the range analyses for species that warrant listing as threatened, not endangered, throughout all of their range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Cedar Key mole skink meets the Act's definition of an endangered species. Therefore, we propose to list the Cedar Key mole skink as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition as a listed species, planning and implementation of recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, foreign governments, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies, including the Service, and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The goal of this

process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

The recovery planning process begins with development of a recovery outline made available to the public soon after a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions while a recovery plan is being developed. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) may be established to develop and implement recovery plans. The recovery planning process involves the identification of actions that are necessary to halt and reverse the species' decline by addressing the threats to its survival and recovery. The recovery plan identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened ("downlisting") or removal from protected status ("delisting"), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery outline, draft recovery plan, final recovery plan, and any revisions will be available on our website as they are completed (<https://www.fws.gov/program/endangered-species>), or from our Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their ranges may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this subspecies is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and

nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Florida would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Cedar Key mole skink. Information on our grant programs that are available to aid species recovery can be found at: <https://www.fws.gov/service/financial-assistance>.

Although the Cedar Key mole skink is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this subspecies. Additionally, we invite you to submit any new information on this subspecies whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7 of the Act is titled, "Interagency Cooperation," and it mandates all Federal action agencies to use their existing authorities to further the conservation purposes of the Act and to ensure that their actions are not likely to jeopardize the continued existence of listed species or adversely modify critical habitat. Regulations implementing section 7 are codified at 50 CFR part 402.

Section 7(a)(2) states that each Federal action agency shall, in consultation with the Secretary, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Each Federal agency shall review its action at the earliest possible time to determine whether it may affect listed species or critical habitat. If a determination is made that the action may affect listed species or critical habitat, formal consultation is required (50 CFR 402.14(a)), unless the Service concurs in writing that the action is not likely to adversely affect listed species or critical habitat. At the end of a formal consultation, the Service issues a biological opinion, containing its determination of whether the Federal action is likely to result in jeopardy or adverse modification.

In contrast, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. Although the conference procedures are required only when an action is likely to result in jeopardy or adverse modification,

action agencies may voluntarily confer with the Service on actions that may affect species proposed for listing or critical habitat proposed to be designated. In the event that the subject species is listed or the relevant critical habitat is designated, a conference opinion may be adopted as a biological opinion and serve as compliance with section 7(a)(2) of the Act.

Examples of discretionary actions for the Cedar Key mole skink that may be subject to conference and consultation procedures under section 7 are land management or other landscape-altering activities on Federal lands administered by the Service as well as actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation. Federal agencies should coordinate with the local Service Field Office (see **FOR FURTHER INFORMATION CONTACT**) with any specific questions on section 7 consultation and conference requirements.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, and the Service's implementing regulations codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or to cause to be committed any of the following acts with regard to endangered wildlife: (1) import into, or export from, the United States; (2) take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct) within the United States, within the territorial sea of the United States, or on the high seas; (3) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such wildlife that has been taken illegally; (4) deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or (5) sell or offer for sale in interstate or foreign commerce. Certain exceptions to these

prohibitions apply to employees or agents of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits for endangered wildlife are codified at 50 CFR 17.22, and general Service permitting regulations are codified at 50 CFR part 13. With regard to endangered wildlife, a permit may be issued: for scientific purposes, for enhancing the propagation or survival of the species, or for take incidental to otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

II. Critical Habitat Background

Critical habitat is defined in section 3 of the Act as:

- (1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features
 - (a) Essential to the conservation of the species; and
 - (b) Which may require special management considerations or protection; and
- (2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.*, migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement,

habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that each Federal action agency ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect an area designated as critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal agency would have already been required to consult with the Service even absent the designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement "reasonable and prudent alternatives" to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as

space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2)

regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define “physical or biological features essential to the conservation of the species” as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting,

symbiotic fungi, or absence of a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the Cedar Key mole skink from studies of the subspecies' habitat, ecology, and life history as described above. Additional information can be found in the SSA report (Service 2023, entire; available on <https://www.regulations.gov> under Docket No. FWS–R4–ES–2024–0053). We have determined that the following physical or biological feature is essential to the conservation of the Cedar Key mole skink: Natural habitats (including, but not limited to, beaches, dunes, and coastal hammocks) along the coast or within the interior of the Cedar Keys that contain:

(a) Suitable soils (dry, loose, sandy, permeable, or friable soils) for movement and nesting; and

(b) Sufficient, appropriate ground cover (including, but not limited to, tidal wrack deposited above the mean high-water line, leaf litter, and vegetative debris) for protection from predators and temperature extremes, sources of food (e.g., insects and arthropods), and areas for reproduction.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the subspecies at the time of listing contain features which are essential to the conservation of the subspecies and which may require special management

considerations or protection. The feature essential to the conservation of the Cedar Key mole skink may require special management considerations or protection to reduce threats posed by climate change (sea level rise, more frequent tidal flooding, and increasing intensity of storm events); recreational activities (beach cleaning to remove wrack and other vegetative material); and human-caused disasters and response activities. For an in-depth discussion of threats, see Summary of Biological Status and Threats, above, and the SSA report (Service 2023, pp. 16–31).

Management activities that could ameliorate these threats include (but are not limited to): maintaining and protecting suitable habitat within occupied areas; identifying areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implementing nourishment or restoration/protection activities; conducting restoration and debris cleanup after storms, while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establishing protocols and agreements to allow storm-enhanced habitats (storms can create berms and dunes and can redeposit sand and wrack, which are all beneficial to the Cedar Key mole skink) to persist; coordinating with landowners and local managers to implement best management practices during regular beach cleaning activities; conducting public outreach and education at all occupied areas; and preparing disaster response plans and conducting trainings that consider Cedar Key mole skinks and their habitat.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat.

We are proposing to designate critical habitat in areas within the geographical area occupied by the subspecies at the time of listing. We also are proposing to designate specific areas outside the geographical area occupied by the subspecies because we have determined that those areas are essential for the

conservation of the subspecies. By the year 2040, five out of eight islands currently occupied by the Cedar Key mole skink are projected to lose 75 to 90 percent or more of their preferred habitat under the lowest projected sea level rise scenario of 3.0 feet (0.9 meters) (see table 1, above). We identified suitable habitat on islands within the Cedar Keys that meet the definition of critical habitat and are considered essential to provide for subspecies redundancy into the future. These islands are considered areas with high resiliency to sea level rise (*i.e.*, islands with higher elevation that are projected to have habitat remaining at 5.0 feet (1.5 meters) of sea level rise)). These unoccupied islands contain the physical and biological feature essential to the subspecies and are, therefore, considered habitat for the subspecies. All units (both occupied and unoccupied) are within the range of the subspecies and contain the physical and biological feature essential to the conservation of the subspecies.

We developed the following criteria for determining the specific areas that contain the physical and biological feature essential to the conservation of the subspecies:

(1) Genetic differentiation and geographic extent—To maintain viability in populations of Cedar Key mole skink that represent and conserve any genetic variation that may exist and habitat on each of the eight islands that has current populations (see *Current Condition*, above), critical habitat units should encompass all current populations ensuring that the entire range of the Cedar Key mole skink is represented.

(2) Climate change resilience—To provide sufficient amounts of suitable habitat for the Cedar Key mole skink predicted to be less affected by sea level rise (Service 2023, pp. 41–50), critical habitat should include islands that are less vulnerable to sea level rise within the Cedar Keys.

(3) Structural connectivity—To maintain, enhance, and establish connectivity within Cedar Key mole skink populations (see Summary of Biological Status and Threats, above), critical habitat units should incorporate corridors for connectivity, dispersal, and refuge areas during high tide flooding and storm events.

Sources of data used for the delineation of critical habitat units included:

(1) Confirmed presence data compiled in our Geographic Information System database from 1951 through 2022, and provided by multiple databases maintained by museums, universities,

and State agencies in Florida; State agency reports; and numerous survey reports for projects throughout the subspecies' range.

(2) Habitat and land use cover types from the Cooperative Land Cover map (version 3.5) developed by the Florida Fish and Wildlife Conservation Commission and Florida Natural Areas Inventory (FWC and FNAI 2021, entire) determined to be suitable for the subspecies based on peer-reviewed articles on this subspecies or similar subspecies, and gray literature by researchers involved in wildlife biology and conservation activities.

(3) Levy County soil data layers from the U.S. Department of Agriculture's Natural Resources Conservation Service Web Soil Survey (USDA 2022, entire) determined to be suitable for the subspecies based on their official soil series descriptions.

(4) Shoreline data representing the mean high-water line from the National Oceanic and Atmospheric Administration's Office of Coastal Management (<https://shoreline.noaa.gov/data/index.html>).

(5) Global and regional sea level rise scenarios for the United States from the National Oceanic and Atmospheric Administration's National Ocean Service Center for Operational Oceanographic Products and Services (Sweet et al. 2022, entire).

(6) Environmental Systems Research Institute's (ESRI's) Aeronautical Reconnaissance Coverage Geographical Information System (ArcPro) online basemap aerial imagery (2018 to 2020) to cross-check Cooperative Land Cover data and ensure the presence of the physical or biological feature.

For areas within the geographical area occupied by the Cedar Key mole skink at the time of listing, we delineated critical habitat unit boundaries using the following criteria:

(1) We determined occupied areas for this subspecies by reviewing the best available scientific and commercial data on occurrence records. As discussed above under I. Proposed Listing Determination, Background, Cedar Key mole skinks are cryptic and adapted to living underground. Because of their cryptic nature, we determined that, if suitable habitat containing the physical and biological feature is still present in an area where a Cedar Key mole skink was detected between 2000 and 2022, there is a high likelihood that the subspecies is still present. Therefore, based on the best available information, we defined occupied areas as islands with at least one current occurrence record ranging from 2000 to 2022.

(2) We selected all suitable habitat that contains the physical or biological feature as determined using the data sources listed above on currently occupied islands. When the exact location of an occurrence record could not be determined for an island (a verified record, but only general location information, such as the name of the island, was provided), or the location was accurate but in unsuitable habitat (developed areas), all suitable habitat on the island was selected.

(3) We selected additional suitable habitat within a 328-ft (100-meter) radius (the estimated home range of Cedar Key mole skink; Service 2023, p. 12) on undeveloped islands to include corridors for greater dispersal due to population expansions, localized resource limitations, and sea level rise, storm surge, or tidal flooding refugia areas for the subspecies (*e.g.*, for undeveloped islands, the full island was included).

(4) On developed islands, we constrained the boundary of a critical habitat unit to areas of contiguous suitable habitat. Offshore boundaries of the critical habitat unit were delineated using a simplified buffered shoreline to include the full extent of each island complex, or to the farthest offshore feature (*i.e.*, habitat boundary, mean high-water line, or shoreline visible in aerial imagery).

For areas outside the geographical area currently occupied by the subspecies at the time of listing, we looked at islands considered recently occupied by, or that have an uncertain status (documented before 1999) for, the Cedar Key mole skink. We analyzed these uncertain status islands and all other islands within the Cedar Keys for those that contain suitable habitat and evaluated each site for its potential conservation contribution based on quality of habitat, vulnerability to climate change (specifically sea level rise and high tide flooding), and existing protections and management of the habitat and sites. Based on these criteria, we identified nine islands that

contain appropriate habitat for the subspecies and are essential for the conservation of the subspecies but would be considered unoccupied at the time of listing. For areas outside the geographical area occupied by the Cedar Key mole skink at the time of listing, we delineated critical habitat unit boundaries using the following criteria:

(1) To ensure unoccupied areas would provide skink habitat into the future, we analyzed impacts to potential habitat on each island in the Cedar Keys and included only those that are projected to still have habitat remaining after 5.0 feet (1.5 meters) of sea level rise and high tide flooding by the year 2080 (Service 2023, p. 47).

(2) We selected all suitable habitat that contains the physical or biological feature as determined using Criteria (2)–(4) outlined above for occupied units.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Cedar Key mole skink. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

Seventeen units are proposed for designation based on the physical or biological feature being present to support the Cedar Key mole skink's life-history processes. All units contain the

identified physical or biological feature and support multiple life-history processes.

The proposed critical habitat designation is defined by the maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the proposed critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on <https://www.regulations.gov> at Docket No. FWS-R4-ES-2024-0053 and on our internet site at <https://www.fws.gov/office/florida-ecological-services>.

Proposed Critical Habitat Designation

We are proposing to designate approximately 2,713 acres (1,098 hectares) in 17 units as critical habitat for the Cedar Key mole skink (see table 2, below). The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the Cedar Key mole skink. The 17 areas we propose as critical habitat are: (1) Live Oak Key, (2) Cedar Point, (3) Scale Key, (4) Dog Island, (5) Atsena Otie Key, (6) Snake Key, (7) Seahorse Key, (8) North Key, (9) Airstrip Island, (10) Way Key South, (11) Way Key North, (12) Richards Island, (13) Seabreeze Island, (14) Shell Mound, (15) Raleigh and Horse Islands, (16) Deer Island, and (17) Clark Islands. Most of the units contain highly dynamic barrier beaches and intertidal seashore. This area has the potential to vary year-to-year. In other words, the precise location of the physical and biological feature in some locations may shift over time somewhat because of the intrinsically dynamic nature of shorelines and due to sea level rise and high tide flooding. Table 2 shows the proposed critical habitat units and the approximate area of each unit.

TABLE 2—PROPOSED CRITICAL HABITAT UNITS FOR THE CEDAR KEY MOLE SKINK

[Area estimates reflect all land within critical habitat unit boundaries]

Unit	Occupancy	Ownership * in acres [hectares]					Total area * in acres [hectares]
		Federal	State	Local	Private	Other **	
1. Live Oak Key	No	46 [19]	0	0	49 [20]	14 [6]	109 [44]
2. Cedar Point	Yes	26 [11]	0	0	15 [6]	0	41 [17]
3. Scale Key	Yes	95 [38]	0	0	21 [8]	0	116 [47]
4. Dog Island	No	0	8 [3]	0	0	0	8 [3]
5. Atsena Otie Key ...	Yes	0	116 [47]	0	0	67 [27]	183 [74]
6. Snake Key	Yes	39 [16]	0	0	0	17 [7]	57 [23]
7. Seahorse Key	Yes	118 [48]	0	0	0	47 [19]	165 [67]
8. North Key	Yes	129 [52]	0	0	0	107 [43]	236 [95]

TABLE 2—PROPOSED CRITICAL HABITAT UNITS FOR THE CEDAR KEY MOLE SKINK—Continued

[Area estimates reflect all land within critical habitat unit boundaries]

Unit	Occupancy	Ownership * in acres [hectares]					Total area * in acres [hectares]
		Federal	State	Local	Private	Other **	
9. Airstrip Island	Yes	0	0	19 [8]	10 [4]	0	29 [12]
10. Way Key South ..	No	0	44 [18]	0	0	0	44 [18]
11. Way Key North ...	No	0	9 [4]	15 [6]	0	0	24 [10]
12. Richards Island ..	No	86 [35]	0	0	0	19 [8]	105 [42]
13. Seabreeze Island	No	111 [45]	0	0	0	25 [10]	136 [55]
14. Shell Mound	No	167 [68]	194 [79]	0	688 [278]	0	1,050 [425]
15. Raleigh and Horse Islands.	No	171 [69]	0	0	5 [2]	0	176 [71]
16. Deer Island	Yes	8 [3]	0	0	69 [28]	36 [15]	113 [46]
17. Clark Islands	No	0	0	0	121 [49]	0	121 [49]
Total		996 [403]	371 [150]	34 [14]	978 [396]	332 [134]	2,713 [1,098]

* Totals may not sum due to rounding.

** Includes suitable habitat of unknown or undefined ownership.

We present brief descriptions of all proposed units, and reasons why they meet the definition of critical habitat for the Cedar Key mole skink, below.

Unit 1: Live Oak Key

Unit 1 encompasses approximately 109 acres (44 hectares) of unoccupied habitat in Levy County and includes the entire island of Live Oak Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 46 acres (19 hectares) in Federal ownership, 49 acres (20 hectares) in private ownership, and 14 acres (6 hectares) in other ownership (undefined ownership). The entirety of Unit 1 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot (*Calidris canutus rufa*). Live Oak Key is approximately 2.5 miles (4 kilometers) northeast of Cedar Key within the Gulf of Mexico. The northern portion of the island is managed as the Florida Gulf Coast Mitigation Bank by a private entity and the southern portion is federally owned and managed by the Service as the part of the Cedar Keys National Wildlife Refuge.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated

from one of its currently occupied locations.

Unit 2: Cedar Point

Unit 2 encompasses approximately 41 acres (17 hectares) of occupied habitat in Levy County and includes the entire island of Cedar Point. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 26 acres (11 hectares) in Federal ownership and 15 acres (6 hectares) in private ownership. The entirety of Unit 2 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot. Cedar Point is approximately 1.7 miles (2.7 kilometers) northeast of Cedar Key within the Gulf of Mexico. The Service manages most of the island as the part of the Cedar Keys National Wildlife Refuge. The eastern portion is managed by a private entity as part of the Florida Gulf Coast Mitigation Bank.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change

(e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 3: Scale Key

Unit 3 encompasses approximately 116 acres (47 hectares) of occupied habitat in Levy County and includes the entire island of Scale Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 95 acres (38 hectares) in Federal ownership and 21 acres (8 hectares) in private ownership. The entirety of Unit 3 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot. Scale Key is approximately 1 mile (1.6 kilometers) northeast of Cedar Key within the Gulf of Mexico. The Service manages most of the island as part of the Cedar Keys National Wildlife Refuge. Approximately 14 acres (6 hectares) of the eastern portion are owned by Florida's Nature Coast Conservancy, and 5 acres (2 hectares) of the northern portion are managed by a private entity as part of the Florida Gulf Coast Mitigation Bank.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow

storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 4: Dog Island

Unit 4 encompasses approximately 8 acres (3 hectares) of unoccupied habitat in Levy County and includes the entire Dog Island. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Although Dog Island is currently considered unoccupied, Cedar Key mole skinks were documented here in the past (Enge 2023, pers. comm.; FWC 2023, entire), and it is possible that they are still present.

Dog Island is approximately 1 mile (1.6 kilometers) to the east of Cedar Key within the Gulf of Mexico. Lands within this unit are entirely within State ownership. The entirety of Unit 4 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 5: Atsena Otie Key

Unit 5 encompasses approximately 183 acres (74 hectares) of occupied habitat in Levy County and includes the entire island of Atsena Otie Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 116 acres (47 hectares) in State ownership and 67 acres (27 hectares) in other ownership. Atsena Otie Key is approximately 1 mile (1.6 kilometers) south of Cedar Key within the Gulf of Mexico. The island is owned by the State of Florida and managed as part of the Cedar Keys National Wildlife Refuge through a memorandum of

understanding (MOU) by the Service. The entirety of Unit 5 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 6: Snake Key

Unit 6 encompasses approximately 57 acres (23 hectares) of occupied habitat within Levy County and includes the entire island of Snake Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 39 acres (16 hectares) in Federal ownership and 17 acres (7 hectares) in other ownership. Snake Key is approximately 2.5 miles (4 kilometers) south of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge. The entirety of Unit 6 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to

address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 7: Seahorse Key

Unit 7 encompasses approximately 165 acres (67 hectares) of occupied habitat within Levy County and includes the entire island of Seahorse Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 118 acres (48 hectares) in Federal ownership and 47 acres (19 hectares) in other ownership. Seahorse Key is approximately 3 miles (5 kilometers) south and west of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge. The entirety of Unit 7 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 8: North Key

Unit 8 encompasses approximately 236 acres (95 hectares) of occupied habitat within Levy County and includes the entire island of North Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 129 acres (52 hectares) in Federal ownership and 107 acres (43 hectares) in other ownership. North Key is approximately 3 miles (4.8 kilometers) to the west of Cedar Key within the Gulf of Mexico. The island is

managed by the Service as part of the Cedar Keys National Wildlife Refuge. The entirety of Unit 8 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 9: Airstrip Island

Unit 9 encompasses approximately 29 acres (12 hectares) of occupied habitat within Levy County on the island of Way Key. Lands within this unit include approximately 19 acres (8 hectares) in local government ownership and 10 acres (4 hectares) in private ownership. This unit is composed of the following five separate sections with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies: Airstrip Island Beach, Cedar Key Airport, Airport Island, Piney Point, and Robert Cull Nature Preserve. Airstrip Island Beach is 5 acres (2 hectares) of private shoreline along Daughtry Bayou, encompassing sandy beach from mean higher high-water inland to dense vegetation, hardened structures, or roads, extending from the southern side of the Airport Road bridge to the south for approximately 0.5 miles (0.8 kilometers). Cedar Key Airport includes 16 acres (6 hectares) of unvegetated and vegetated sandy soils on the George T. Lewis Airport (also known as the Cedar Key Airport) that are owned by Levy County. Airport Island is a 2-acre (0.8-hectare), unnamed island southwest of the airport, which is also owned by Levy County. Piney Point is a 3-acre (1-hectare), privately owned, undeveloped, vacant lot on the western side of Piney Point south of the airport. The fifth section is 2 acres (0.8 hectares) of protected land known as the Robert Cull Nature Preserve at the terminus of

Piney Point that are owned and managed by Florida's Nature Coast Conservancy. Approximately 9 acres (4 hectares) of Unit 9 overlap with proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 10: Way Key South

Unit 10 encompasses approximately 44 acres (18 hectares) of unoccupied habitat within Levy County on Way Key. This unit is a series of undeveloped disconnected islands south of Way Key that contain the physical or biological feature essential to the conservation of the subspecies. The largest island, located between the airport and the developed portion of Way Key, is projected to be more resilient to sea level rise (due to its relatively higher elevation) and is composed of coastal scrub habitat with a sandy shoreline fringe. Also included in this unit are several primarily sand islands that occur seaward of the main island. This unit is entirely in State ownership. Approximately 41 acres (17 hectares) of Unit 10 overlap with proposed critical habitat for the rufa red knot.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated

from one of its currently occupied locations.

Unit 11: Way Key North

Unit 11 encompasses approximately 24 acres (10 hectares) of unoccupied habitat within Levy County on Way Key. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 9 acres (4 hectares) in State ownership managed as the Cedar Key Museum State Park by the Florida Park Service, and 15 acres (6 hectares) in local government ownership managed as Cemetery Point Park by the City of Cedar Key. Although the unit is currently considered unoccupied, Cedar key mole skinks were documented here in the past (FWC 2023, entire), and it is possible that they are still present. Additionally, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 12: Richards Island

Unit 12 encompasses approximately 105 acres (42 hectares) of unoccupied habitat within Levy County and includes the entirety of Richards Island. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Richards Island is undeveloped and projected to be more resilient to sea level rise due to higher elevation. Lands within this unit include approximately 86 acres (35 hectares) in Federal ownership and 19 acres (8 hectares) in other ownership. Richards Island is approximately 3.3 miles (5.3 kilometers) northwest of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge. Approximately 43 acres (17 hectares) of Unit 12 overlap with proposed critical habitat for the rufa red knot.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the

subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 13: Seabreeze Island

Unit 13 encompasses approximately 136 acres (55 hectares) of unoccupied habitat within Levy County on Seabreeze Island. This unit is composed of protected lands with suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Seabreeze Island is undeveloped and projected to be more resilient to sea level rise. Lands within this unit include approximately 111 acres (45 hectares) in Federal ownership and 25 acres (10 hectares) in other ownership. Seabreeze Island is approximately 4 miles (6 kilometers) northwest of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Lower Suwannee National Wildlife Refuge. Approximately 8 acres (3 hectares) of Unit 13 overlap with proposed critical habitat for the rufa red knot.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 14: Shell Mound

Unit 14 encompasses approximately 1,050 ac (425 hectares) of unoccupied habitat within Levy County on Shell Mound. The unit contains higher elevation lands, is projected to be more resilient to sea level rise, and has suitable habitat containing the physical or biological feature essential to the conservation of the subspecies. This unit extends from Dennis Creek north to Ericson Creek. Lands within this unit include approximately 167 acres (68 hectares) in Federal ownership, 194 acres (79 hectares) in State ownership, and 688 acres (278 hectares) in private ownership. The unit includes portions

of the Cedar Key Scrub State Reserve managed by the Florida Park Service and the Lower Suwannee National Wildlife Refuge managed by the Service.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 15: Raleigh and Horse Islands

Unit 15 encompasses approximately 176 acres (71 hectares) of unoccupied habitat within Levy County on Raleigh and Horse Islands. The unit includes undeveloped islands projected to be more resilient to sea level rise and contains suitable habitat with the physical or biological feature essential to the conservation of the subspecies. Lands within this unit include approximately 171 acres (69 hectares) in Federal ownership and 5 acres (2 hectares) in private ownership. The group of islands is approximately 6 miles (10 kilometers) northwest of Cedar Key within the Gulf of Mexico. The Service manages most of the islands as part of the Lower Suwannee National Wildlife Refuge.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Unit 16: Deer Island

Unit 16 encompasses approximately 113 acres (46 hectares) of occupied habitat within Levy County and includes the entirety of Deer Island. The unit is composed of suitable habitat that contains the physical or biological feature essential to the conservation of the subspecies. Lands within the unit include approximately 8 acres (3 hectares) in Federal ownership, 69 acres

(28 hectares) in private ownership, and 36 acres (15 hectares) in other ownership. Deer Island is approximately 7 miles (11 kilometers) northwest of Cedar Key within the Gulf of Mexico. The entirety of Unit 16 is included in, and thus overlaps with, proposed critical habitat for the rufa red knot.

The physical and biological feature in this unit may require special management considerations or protection to: identify areas where beach erosion is occurring or habitat is succeeding to mangrove swamp or other coastal wetlands due to sea level rise and implement renourishment or restoration/protection activities; conduct restoration and debris cleanup after storms while concurrently minimizing disturbance to Cedar Key mole skinks and their habitat; establish protocols and agreements to allow storm-enhanced habitats to persist; conduct public outreach and education; and prepare disaster response plans and conduct trainings that consider Cedar Key mole skinks and their habitat to address threats from climate change (e.g., sea level rise, high tide flooding, and storm events) and human-caused disasters and response activities (e.g., oil spills).

Unit 17: Clark Islands

Unit 17 encompasses approximately 121 acres (49 hectares) of unoccupied habitat within Levy County on the Clark Islands complex. The unit includes undeveloped islands projected to be more resilient to sea level rise. The entirety of the unit is privately owned. The Clark Islands are approximately 7 miles (11 kilometers) north-northwest of Cedar Key within the Gulf of Mexico.

Although it is currently considered unoccupied, this unit constitutes habitat for the subspecies because it contains the physical or biological feature necessary for the life history of the subspecies. This unit is essential for the conservation of the subspecies because it will provide habitat for potential reintroductions in the case of sea level rise and high tide flooding (Service 2023, pp. 41–50) or stochastic events (such as hurricanes) should other areas of suitable habitat be destroyed or the Cedar Key mole skink be extirpated from one of its currently occupied locations.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of

any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

Compliance with the requirements of section 7(a)(2) of the Act is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define “reasonable and prudent alternatives” (at 50 CFR 402.02) as alternative actions identified during formal consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency’s legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director’s opinion, avoid the likelihood of jeopardizing the continued existence of the listed species or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinstate consultation. Reinitiation of consultation is required and shall be requested by the Federal agency, where discretionary Federal involvement or

control over the action has been retained or is authorized by law and: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action. As provided in 50 CFR 402.16, the requirement to reinstate consultations for new species listings or critical habitat designation does not apply to certain agency actions (*e.g.*, land management plans issued by the Bureau of Land Management in certain circumstances).

Destruction or Adverse Modification of Critical Habitat

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires that our **Federal Register** notices “shall, to the maximum extent practicable also include a brief description and evaluation of those activities (whether public or private) which, in the opinion of the Secretary, if undertaken may adversely modify [critical] habitat, or may be affected by such designation.” Activities that may be affected by designation of critical habitat for the Cedar Key mole skink include those that may affect the physical or biological features of the Cedar Key mole skink’s critical habitat (see Physical or Biological Features Essential to the Conservation of the Species, above).

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the

Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act Improvement Act of 1997 (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. No DoD lands with a completed INRMP are within the proposed critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. Exclusion decisions are governed by the regulations at 50 CFR 424.19 and the Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act (hereafter, the “2016 Policy”; 81 FR 7226, February 11, 2016), both of which were developed jointly with the National Marine Fisheries Service (NMFS). We also refer to a 2008 Department of the Interior Solicitor’s opinion entitled, “The Secretary’s Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act” (M–37016).

In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. In our final rules, we explain any decision to exclude areas, as well as decisions not to exclude, to make clear the rational basis for our decision. We describe below the process that we use for taking into consideration each

category of impacts and any initial analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both “with critical habitat” and “without critical habitat.”

The “without critical habitat” scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (e.g., under the Federal listing as well as other Federal, State, and local regulations). Therefore, the baseline represents the costs of all efforts attributable to the listing of the species under the Act (i.e., conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The “with critical habitat” scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

Executive Order (E.O.) 14094 supplements and reaffirms E.O. 12866 and E.O. 13563 and directs Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements,

our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. Section 3(f) of E.O. 12866 identifies four criteria when a regulation is considered a “significant regulatory action” and requires additional analysis, review, and approval if met. The criterion relevant here is whether the designation of critical habitat may have an economic effect of \$200 million or more in any given year (section 3(f)(1) as amended by E.O. 14094). Therefore, our consideration of economic impacts uses a screening analysis to assess whether a designation of critical habitat for the Cedar Key mole skink is likely to exceed the economically significant threshold.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Cedar Key mole skink (IEc 2023, entire). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographical areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (i.e., absent critical habitat designation) and includes any probable incremental economic impacts where land and water use may already be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. The presence of the listed species in occupied areas of critical habitat means that any destruction or adverse modification of those areas is also likely to jeopardize the continued existence of the species. Therefore, designating occupied areas as critical habitat typically causes little if

any incremental impacts above and beyond the impacts of listing the species. As a result, we generally focus the screening analysis on areas of unoccupied critical habitat (unoccupied units or unoccupied areas within occupied units). Overall, the screening analysis assesses whether the designation of critical habitat is likely to result in any additional management or conservation efforts that may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM constitute what we consider to be our economic analysis of the proposed critical habitat designation for the Cedar Key mole skink and is summarized in the narrative below.

As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the Cedar Key mole skink, first we identified, in the IEM dated August 22, 2023, probable incremental economic impacts associated with the following categories of activities: (1) residential and commercial development; (2) construction activities such as road and bridge construction and maintenance; (3) habitat management activities (such as beach nourishment, shoreline armoring, nonnative species control (including mechanical or herbicide applications), and prescribed fire); and (4) recreational activities and associated developments (such as campgrounds, trails, and visitor facilities), management activities (such as beach raking or other cleaning methods to remove wrack and debris), and airport management activities. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. If we list the subspecies, in areas where the Cedar key mole skink is present, Federal agencies would be required to consult with the Service under section 7 of the Act on activities they authorize, fund, or carry out that may affect the subspecies. If we list the subspecies and also finalize this proposed critical habitat designation, Federal agencies would be required to consider the effects of their actions on the designated habitat, and if

the Federal action may affect critical habitat, our consultations would include an evaluation of measures to avoid the destruction or adverse modification of critical habitat.

In our IEM, we attempted to clarify the distinction between the effects that would result from the subspecies being listed and those attributable to the critical habitat designation (*i.e.*, difference between the jeopardy and adverse modification standards) for the Cedar Key mole skink's critical habitat. Because the designation of critical habitat for the Cedar Key mole skink is being proposed concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the subspecies being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological feature identified for critical habitat are the same features essential for the life requisites of the subspecies, and (2) any actions that would likely adversely affect the essential physical or biological feature of occupied critical habitat are also likely to adversely affect the subspecies itself. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this subspecies. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the Cedar Key mole skink totals approximately 2,713 acres (1,098 hectares) in 17 units in Levy County, Florida (see Proposed Critical Habitat Designation, above). Land ownership across the units includes Federal lands (37 percent), State lands (14 percent), local lands (1 percent), private lands (36 percent), and lands with unknown/undefined ownership (12 percent). Eight of the 17 units are currently occupied by the Cedar Key mole skink; the remaining 9 units are not known to be currently occupied. Approximately 42 percent of the proposed critical habitat for the Cedar Key mole skink overlaps with currently proposed critical habitat for the rufa red knot. Further, 100 percent of the proposed critical habitat for the Cedar Key mole skink intersects with existing ranges for six federally listed species (IEc 2023, p. 8).

When an action is proposed in an area of designated critical habitat, and the

proposed activity has a Federal nexus, the need for section 7 consultation is triggered. Any incremental costs associated with consideration of potential effects to the critical habitat are a result of this consultation process. For all occupied areas, the economic costs of critical habitat designations would most likely be limited to additional administrative efforts to consider adverse modification in section 7 consultations, as the listing of the subspecies is being proposed concurrently with critical habitat designation, and all occupied units would still need to undergo section 7 consultation due to listing regardless of critical habitat designation. While this additional analysis would require time and resources by both the Federal action agency and the Service, it is believed that, in most circumstances, these costs would predominantly be administrative in nature and would not be significant. For the unoccupied units, section 7 consultations would not occur if not for the presence of critical habitat, so additional costs would occur. In unoccupied habitat, the incremental cost associated with a new consultation considering only adverse modification during technical assistances, informal, formal, and programmatic consultations are estimated to be \$1,300, \$8,000, \$17,000, and \$31,000, respectively (IEc 2023, p. 18). These estimates assume that consultation would not occur in the absence of critical habitat designation. In total, the estimated annual, incremental administrative costs for a Cedar Key mole skink critical habitat designation are estimated at \$9,000 annually (IEc 2023, p. 19). Overall, a critical habitat designation for the Cedar Key mole skink is unlikely to generate costs or benefits exceeding \$200 million in a single year. Because of the relatively small size of the critical habitat designation, the landownership (Federal, State, county, or private) of the proposed critical habitat units, the amount of land that is already being managed for conservation, and the significant overlap with the rufa red knot's proposed critical habitat, the numbers of section 7 consultations expected annually are modest (approximately 1 formal, 12 informal, and 5 technical assistance efforts annually across the designation) (IEc 2023, p. 15).

Potential private property value effects are possible due to public perception of impacts to private lands. The designation of critical habitat may cause some developers or landowners to perceive that private lands will be subject to use restrictions or litigation

from third parties, resulting in costs. However, due to the speculative nature of this perception, costs are not able to be quantified. Regardless, only 36 percent of the proposed critical habitat designation is privately owned land, leading to nominal incremental costs arising from changes in public perception of lands included in the designation.

Incremental costs may occur outside of the section 7 consultation process if the designation of critical habitat triggers additional requirements or project modifications under State or local laws, regulations, or management strategies. These types of costs typically occur if the designation increases awareness of the presence of the subspecies or the need for protection of its habitat. Given that the Cedar Key mole skink is covered by existing State protection plans, project proponents may already be aware of the presence of the subspecies. For example, the Cedar Key mole skink is included in the State of Florida's State Wildlife Action Plan as a species of greatest conservation need. The subspecies is further protected through habitat management and conservation under Florida State Park management plans. Therefore, designating critical habitat is unlikely to provide information to State or local agencies that would result in new regulations or actions (IEc 2023, p. 20).

We are soliciting data and comments from the public on the economic analysis discussed above (see Information Requested, above). During the development of a final designation, we will consider the information presented in the economic analysis and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) of the Act, our implementing regulations at 50 CFR 424.19, and the 2016 Policy. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this subspecies.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (*e.g.*, a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section

4(a)(3)(B)(i) of the Act, then national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of “critical habitat.” However, we must still consider impacts on national security, including homeland security, on those lands or areas not covered by section 4(a)(3)(B)(i) because section 4(b)(2) of the Act requires us to consider those impacts whenever we designate critical habitat. Accordingly, if DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns, or we have otherwise identified national-security or homeland-security impacts from designating particular areas as critical habitat, we generally have reason to consider excluding those areas.

However, we cannot automatically exclude requested areas. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland-security impacts, we must conduct an exclusion analysis if the Federal requester provides information, including a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border-security patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act. If the agency requesting the exclusion does not provide us with a reasonably specific justification, we will contact the agency to recommend that it provide a specific justification or clarification of its concerns relative to the probable incremental impact that could result from the designation. If we conduct an exclusion analysis because the agency provides a reasonably specific justification or because we decide to exercise the discretion to conduct an exclusion analysis, we will defer to the expert judgment of DoD, DHS, or another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national-security or homeland-security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary section 4(b)(2) exclusion analysis, we will give great weight to

national-security and homeland-security concerns in analyzing the benefits of exclusion.

In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for the Cedar Key mole skink are not owned or managed by the DoD or DHS, and, therefore, we anticipate no impact on national security or homeland security.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area—such as safe harbor agreements (SHAs), candidate conservation agreements with assurances (CCAAs), or “conservation benefit agreements” or “conservation agreements” (CBAs) (CBAs are a new type of agreement replacing SHAs and CCAAs in use after April 2024 (89 FR 26070; April 12, 2024)) or HCPs—or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, social, or other impacts that might occur because of the designation.

Summary of Exclusions Considered Under 4(b)(2) of the Act

In preparing this proposal, we have determined that no HCPs or other management plans for the Cedar Key mole skink currently exist, and the proposed designation does not include any Tribal lands or trust resources or any lands for which designation would have any economic or national security impacts. Therefore, we anticipate no impact on Tribal lands, partnerships, or HCPs from this proposed critical habitat designation, and, thus, as described above, we are not considering excluding any particular areas on the basis of the presence of conservation agreements or impacts to trust resources.

However, if through this proposed rule’s public comment period (see **DATES** and **Information Requested**, above) we receive information that we determine indicates that there are potential

economic, national security, or other relevant impacts from designating particular areas as critical habitat, then as part of developing the final designation of critical habitat, we will evaluate that information and may conduct a discretionary exclusion analysis to determine whether to exclude those areas under the authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19. If we receive a request for exclusion of a particular area and after evaluation of supporting information we do not exclude, we will fully describe our decision in the final rule for this action.

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order (E.O.) 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open

exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

E.O. 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this proposed rule is not significant.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than \$5 million in annual sales, general and heavy construction businesses with less than \$27.5 million in annual business, special trade contractors doing less than \$11.5 million in annual business, and agricultural businesses with annual sales less than \$750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term “significant economic impact” is meant to apply to a typical small business firm’s business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt the proposed critical habitat designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects “to the extent permitted by law” when undertaking actions identified as significant energy actions (66 FR 28355; May 22, 2001). E.O. 13211 defines a “significant energy action” as an action that (i) is a significant regulatory action under E.O. 12866 or any successor order; and (ii) is likely to have a significant adverse effect on the supply,

distribution, or use of energy. This rule is not a significant regulatory action under E.O. 12866 or E.O. 14094 (88 FR 21879; April 11, 2023). Therefore, this action is not a significant energy action, and there is no requirement to prepare a statement of energy effects for this action.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both “Federal intergovernmental mandates” and “Federal private sector mandates.” These terms are defined in 2 U.S.C. 658(5)–(7). “Federal intergovernmental mandate” includes a regulation that “would impose an enforceable duty upon State, local, or Tribal governments” with two exceptions. It excludes “a condition of Federal assistance.” It also excludes “a duty arising from participation in a voluntary Federal program,” unless the regulation “relates to a then-existing Federal program under which \$500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,” if the provision would “increase the stringency of conditions of assistance” or “place caps upon, or otherwise decrease, the Federal Government’s responsibility to provide funding,” and the State, local, or Tribal governments “lack authority” to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. “Federal private sector mandate” includes a regulation that “would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.”

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions are not likely to destroy or adversely modify critical habitat under section 7. While

non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this proposed rule would significantly or uniquely affect small governments because it would not produce a Federal mandate of \$100 million or greater in any year, that is, it is not a “significant regulatory action” under the Unfunded Mandates Reform Act. Therefore, a small government agency plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Cedar Key mole skink in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the proposed designation of critical habitat for the Cedar Key mole skink, and it concludes that, if adopted, this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the Federal government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that this proposed rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the

Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the physical or biological features essential to the conservation of the species. The proposed areas of critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Regulations adopted pursuant to section 4(a) of the Act are exempt from the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations. In a line of cases starting with *Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir. 1995), the courts have upheld this position.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), the President's memorandum of November 30, 2022 (Uniform Standards for Tribal Consultation; 87 FR 74479, December 5, 2022), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes and Alaska Native Corporations (ANCs) on a government-to-government basis. In accordance with Secretaries' Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for

healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the boundaries of the proposed critical habitat for the Cedar Key mole skink, so no Tribal lands would be affected by the proposed designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <https://www.regulations.gov> and upon request from the Florida Ecological Services Field Office (see FOR FURTHER INFORMATION CONTACT).

Authors

The primary authors of this proposed rule are the staff members of the Fish

and Wildlife Service’s Species Assessment Team and the Florida Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Signing Authority

Martha Williams, Director of the U.S. Fish and Wildlife Service, approved this action on June 14, 2024, for publication. On July 31, 2024, Martha Williams authorized the undersigned to sign the document electronically and submit it to the Office of the Federal Register for publication as an official document of the U.S. Fish and Wildlife Service.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title

50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, in paragraph (h), amend the List of Endangered and Threatened Wildlife by adding an entry for “Skink, Cedar Key mole” in alphabetical order under REPTILES to read as follows:

§ 17.11 Endangered and threatened wildlife.
* * * * *
(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* REPTILES	*	*	*	*
Skink, Cedar Key mole ...	<i>Plestiodon egregius insularis</i> .	Wherever found	E	[Federal Register citation when published as a final rule]; 50 CFR 17.95(c). ^{CH}
*	*	*	*	*

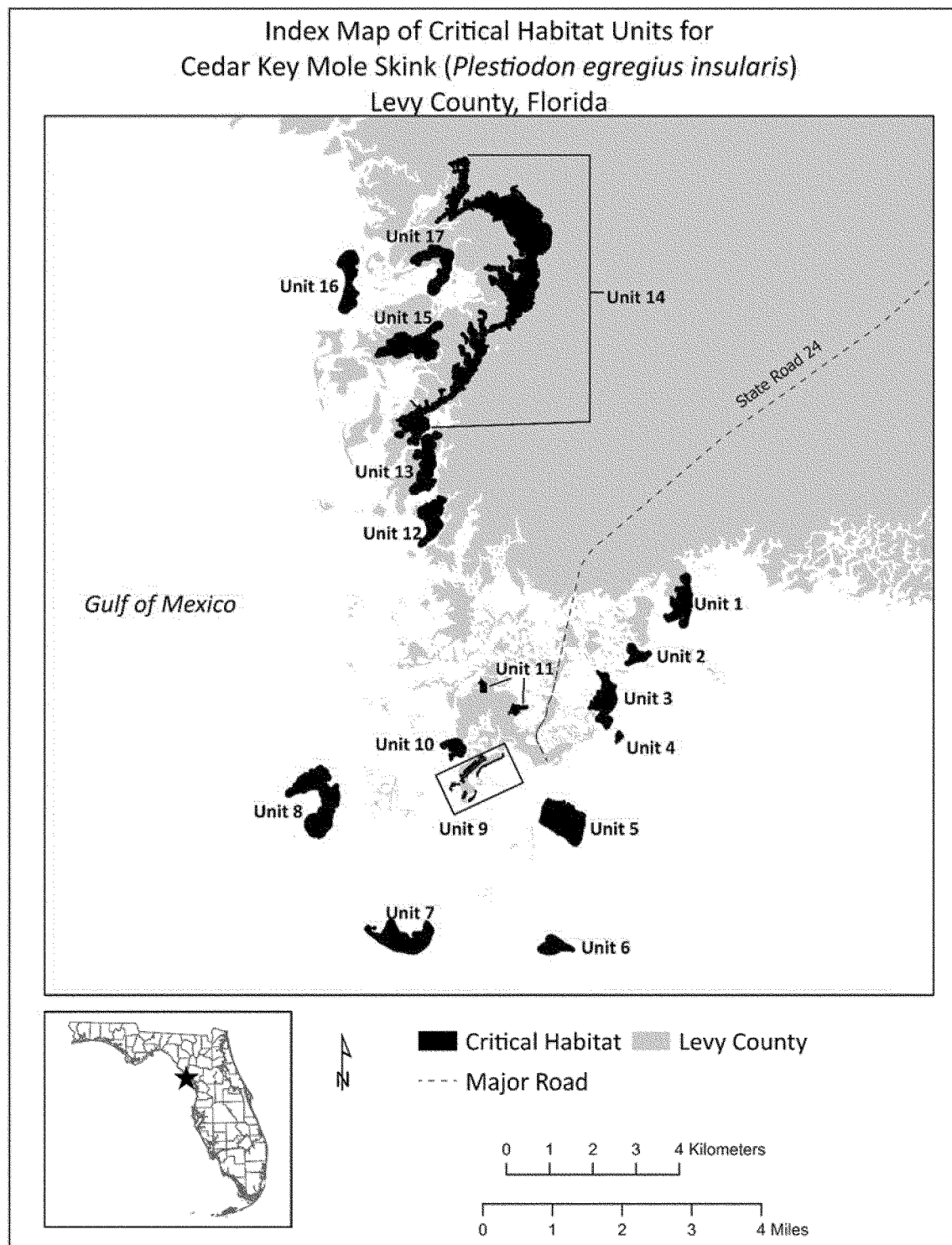
■ 3. In § 17.95, amend paragraph (c) by adding an entry for “Cedar Key Mole Skink (*Plestiodon egregius insularis*)” following the entry for “Loggerhead Sea Turtle, Northwest Atlantic Ocean DPS (*Caretta caretta*)”, to read as follows:

§ 17.95 Critical habitat—fish and wildlife.
* * * * *
(c) Reptiles.
* * * * *

Cedar Key Mole Skink (*Plestiodon egregius insularis*)
(1) Critical habitat units are depicted for Levy County, Florida, on the maps in this entry.
(2) Within these areas, the physical or biological feature essential to the conservation of the Cedar Key mole skink consists of natural habitats (including, but not limited to, beaches, dunes, and coastal hammocks) along the coast or within the interior of the Cedar Keys that contain:
(i) Suitable soils (dry, loose, sandy, permeable, or friable soils) for movement and nesting; and

(ii) Sufficient, appropriate ground cover (including, but not limited to, tidal wrack deposited above the mean high-water line, leaf litter, and vegetative debris) for protection from predators and temperature extremes, sources of food (e.g., insects and arthropods), and areas for reproduction.
(3) Critical habitat does not include human-made structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.
(4) Data layers defining map units were created using Environmental Systems Research Institute’s (ESRI’s) Aeronautical Reconnaissance Coverage Geographical Information System (ArcPro) mapping software along with various spatial data layers. ArcPro was also used to calculate the size of habitat areas. The projection used in mapping and calculating distances and locations within the units was Albers Conical

Equal Area (Florida Geographic Data Library), North American Datum of 1983 (NAD 83) High Accuracy Reference Network (HARN). The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service’s internet site at <https://www.fws.gov/office/florida-ecological-services/library>, at <https://www.regulations.gov> at Docket No. FWS–R4–ES–2024–0053, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.
(5) Index map follows:
Figure 1 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (5)



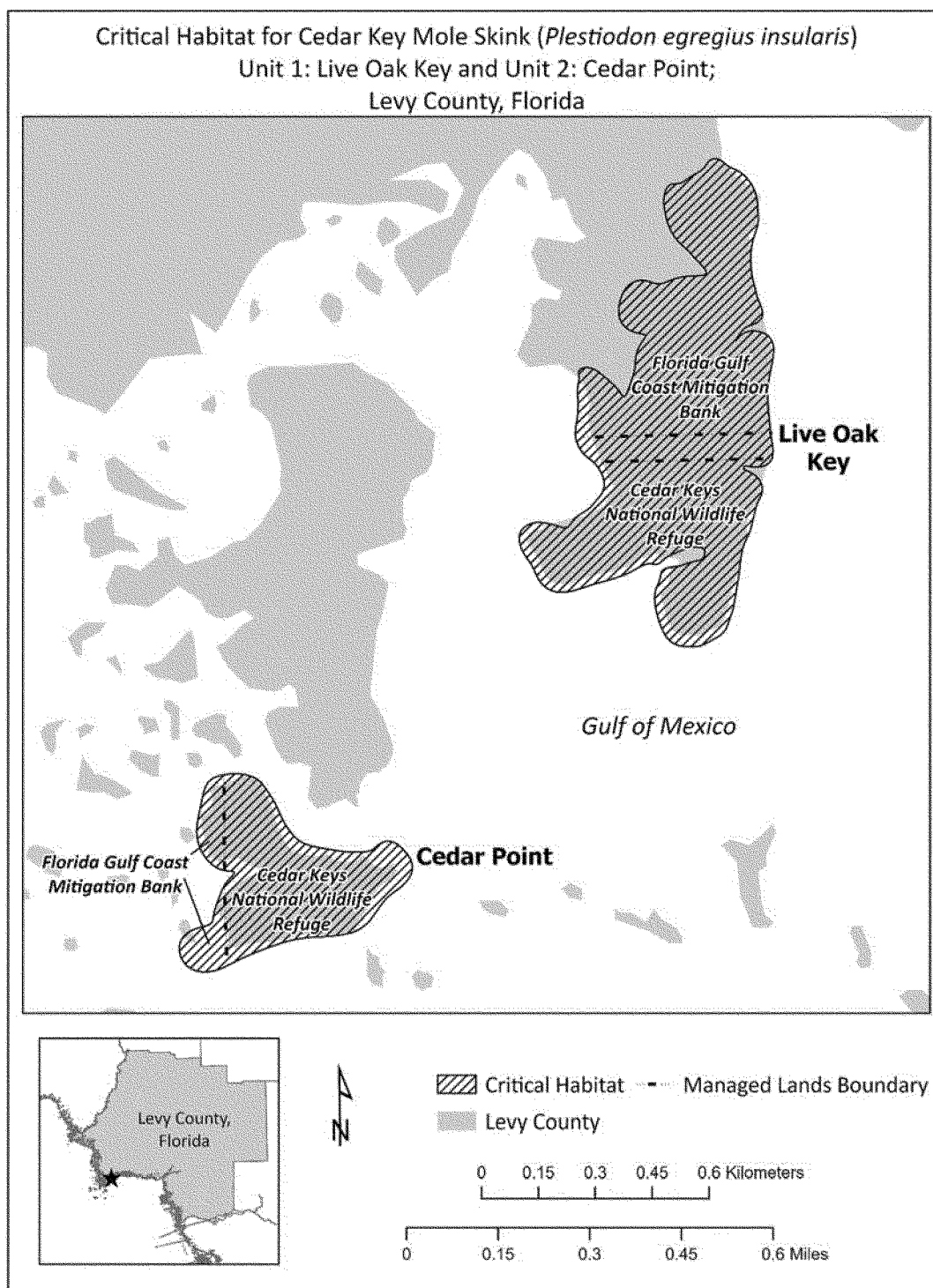
(6) *Unit 1*: Live Oak Key; Levy County, Florida.

(i) *Unit 1* encompasses approximately 109 acres (44 hectares) and includes the entire island of Live Oak Key. Lands within this unit include approximately 46 acres (19 hectares) in Federal ownership, 49 acres (20 hectares) in

private ownership, and 14 acres (6 hectares) in other ownership. Live Oak Key is approximately 2.5 miles (4 kilometers) northeast of Cedar Key within the Gulf of Mexico. The northern portion of the island is managed as the Florida Gulf Coast Mitigation Bank by a private entity and the southern portion

is federally owned and managed by the Service as the part of the Cedar Keys National Wildlife Refuge.

(ii) Map of Units 1 and 2 follow: Figure 2 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (6)(ii)



(7) *Unit 2: Cedar Point; Levy County, Florida.*

(i) Unit 2 encompasses approximately 41 acres (17 hectares) and includes the entire island of Cedar Point. Lands within this unit include approximately 26 acres (11 hectares) in Federal ownership and 15 acres (6 hectares) in private ownership. Cedar Point is approximately 1.7 miles (2.7 kilometers) northeast of Cedar Key within the Gulf

of Mexico. The Service manages most of the island as the part of the Cedar Keys National Wildlife Refuge. The eastern portion is managed by a private entity as part of the Florida Gulf Coast Mitigation Bank.

(ii) Map of Unit 2 is provided at paragraph (6)(ii) of this entry.

(8) *Unit 3: Scale Key; Levy County, Florida.*

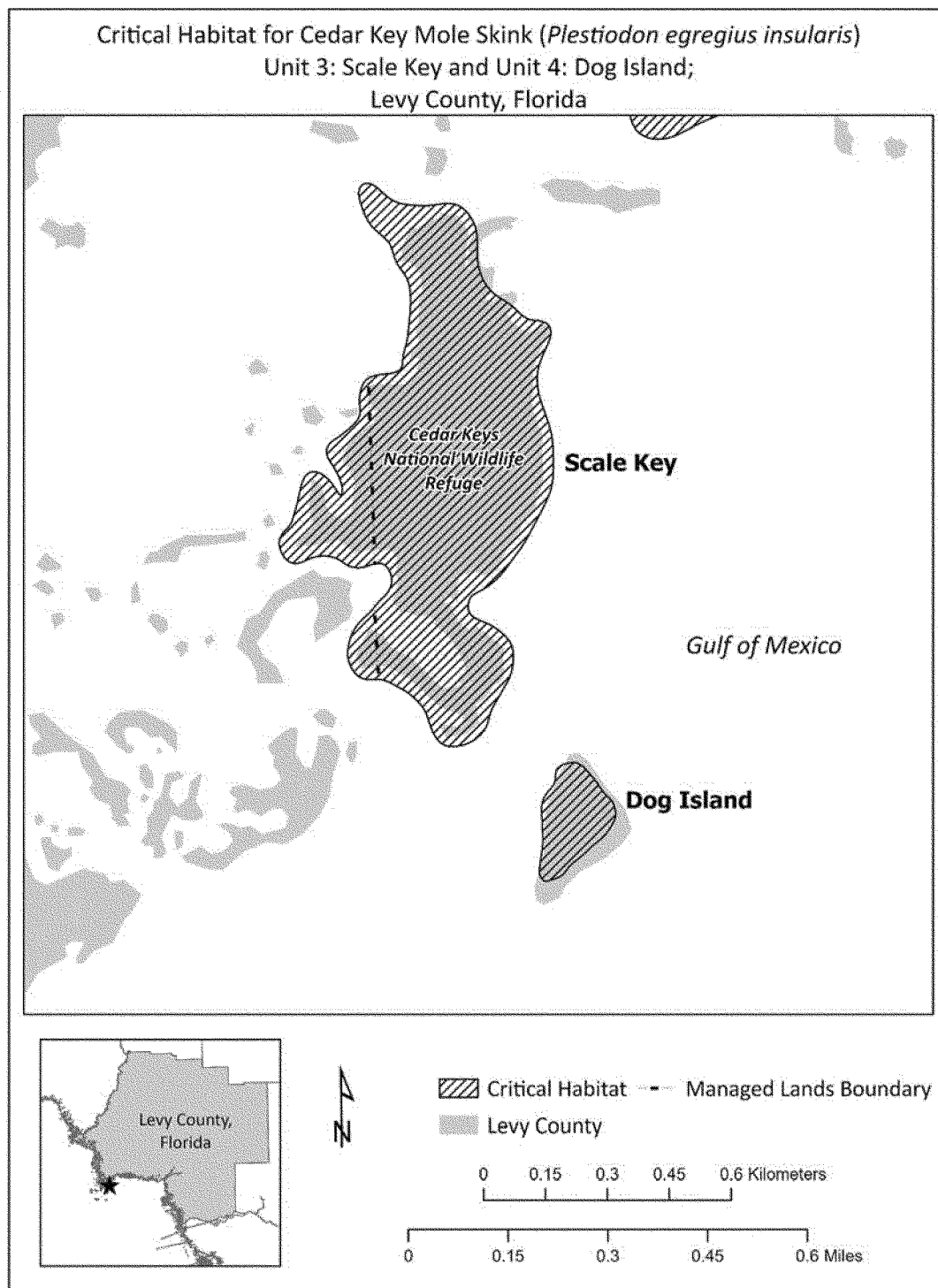
(i) Unit 3 encompasses approximately 116 acres (47 hectares) and includes the entire island of Scale Key. Lands within this unit include approximately 95 acres (38 hectares) in Federal ownership and 21 acres (8 hectares) in private ownership. Scale Key is approximately 1 mile (1.6 kilometers) northeast of Cedar Key within the Gulf of Mexico. The Service manages most of the island as part of the Cedar Keys National

Wildlife Refuge. Approximately 14 acres (6 hectares) of the eastern portion are owned by Florida's Nature Coast Conservancy, and 5 acres (2 hectares) of

the northern portion are managed by a private entity as part of the Florida Gulf Coast Mitigation Bank.

(ii) Map of Units 3 and 4 follows:

Figure 3 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (8)(ii)



(9) *Unit 4*: Dog Island; Levy County, Florida.

(i) *Unit 4* encompasses approximately 8 acres (3 hectares) and includes the entirety of Dog Island. Dog Island is

approximately 1 mile (1.6 kilometers) to the east of Cedar Key within the Gulf of Mexico. Lands within this unit are entirely within State ownership.

(ii) Map of *Unit 4* is provided at paragraph (8)(ii) of this entry.

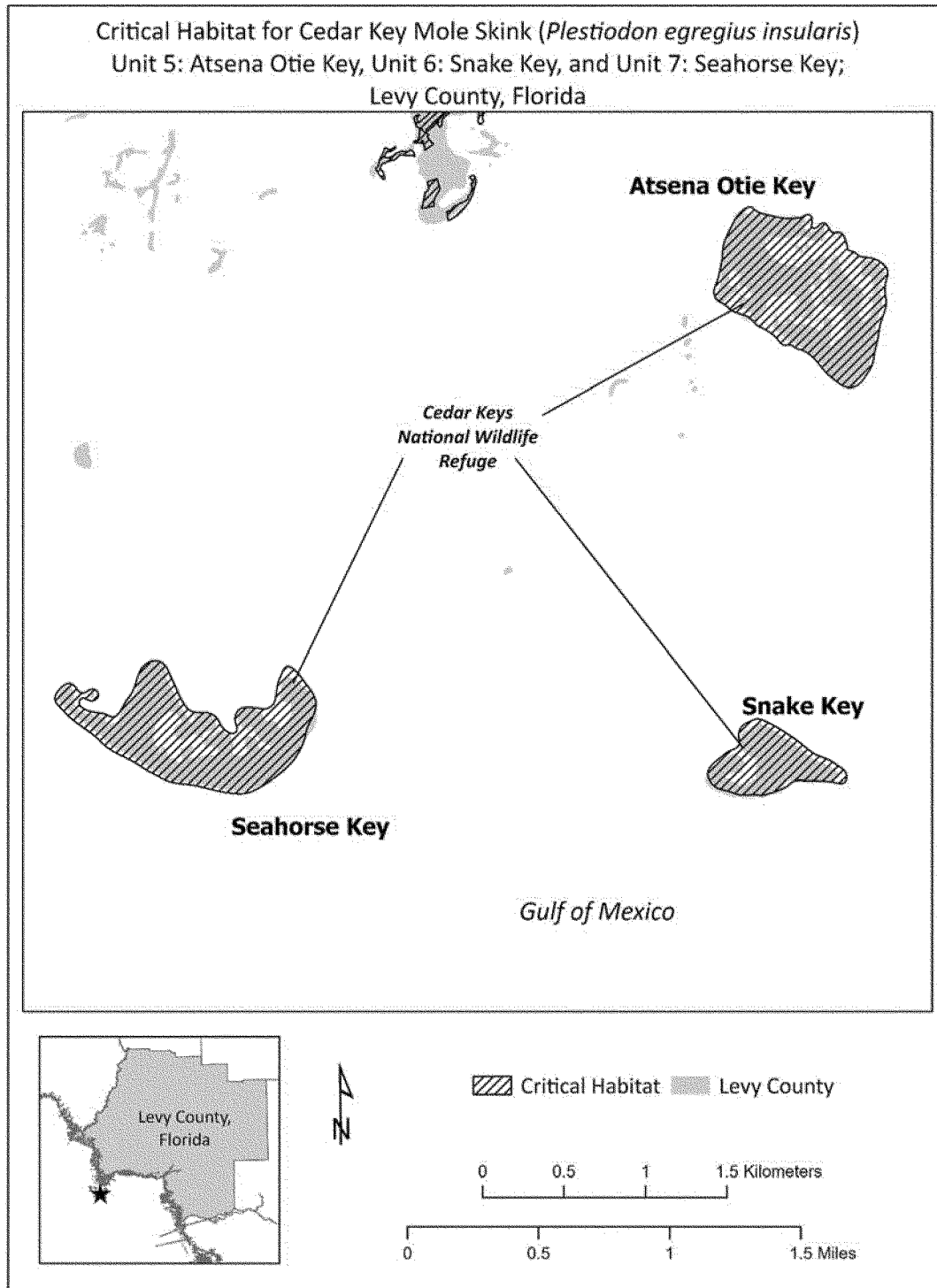
(10) *Unit 5*: Atsena Otie Key; Levy County, Florida.

(i) Unit 5 encompasses approximately 183 acres (74 hectares) and includes the entire island of Atsena Otie Key. Lands within this unit include approximately 116 acres (47 hectares) in State ownership and 67 acres (27 hectares) in other ownership. Atsena Otie Key is

approximately 1 mile (1.6 kilometers) south of Cedar Key within the Gulf of Mexico. The island is owned by the State of Florida and managed as part of the Cedar Keys National Wildlife Refuge through a memorandum of understanding by the Service.

(ii) Map of Units 5, 6, and 7 follows:
Figure 4 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (10)(ii)

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(11) Unit 6: Snake Key; Levy County, Florida.

(i) Unit 6 encompasses approximately 57 acres (23 hectares) and includes the

entire island of Snake Key. Lands within this unit include approximately 39 acres (16 hectares) in Federal ownership and 17 acres (7 hectares) in other ownership. Snake Key is approximately 2.5 miles (4 kilometers) south of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge.

(ii) Map of Unit 6 is provided at paragraph (10)(ii) of this entry.

(12) *Unit 7*: Seahorse Key; Levy County, Florida.

(i) Unit 7 encompasses approximately 165 acres (67 hectares) and includes the

entire island of Seahorse Key. Lands within this unit include approximately 118 acres (48 hectares) in Federal ownership and 47 acres (19 hectares) in other ownership. Seahorse Key is approximately 3 miles (5 kilometers) south and west of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge.

(ii) Map of Unit 7 is provided at paragraph (10)(ii) of this entry.

(13) *Unit 8*: North Key; Levy County, Florida.

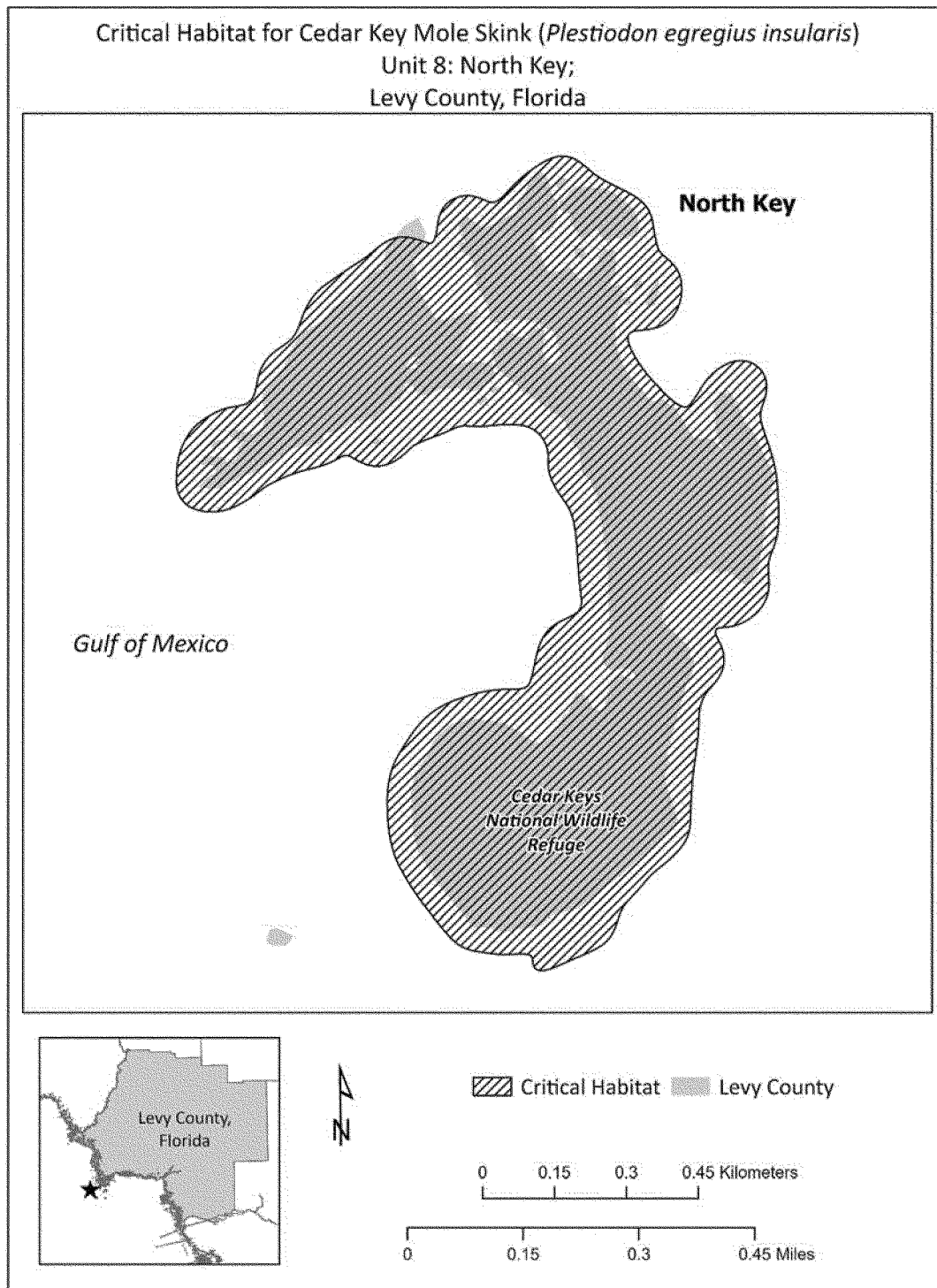
(i) Unit 8 encompasses approximately 236 acres (95 hectares) and includes the

entire island of North Key. Lands within this unit include approximately 129 acres (52 hectares) in Federal ownership and 107 acres (43 hectares) in other ownership. North Key is approximately 3 miles (4.8 kilometers) to the west of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge.

(ii) Map of Unit 8 follows:

Figure 5 to Cedar Key Mole Skink
(*Plestiodon egregius insularis*)
paragraph (13)(ii)

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**BILLING CODE 4333-15-C**

(14) *Unit 9:* Airstrip Island; Levy County, Florida.

(i) Unit 9 encompasses approximately 29 acres (12 hectares) on the island of Way Key. Lands within this unit include approximately 19 acres (8 hectares) in local government ownership and 10 acres (4 hectares) in private ownership. This unit is composed of five separate sections.

(A) Airstrip Island Beach is 5 acres (2 hectares) of private shoreline along Daughtry Bayou, encompassing sandy beach from mean higher high-water inland to dense vegetation, hardened structures, or roads, extending from the southern side of the Airport Road bridge to the south for approximately 0.5 mile (0.8 kilometer).

(B) Cedar Key Airport includes 16 acres (6.5 hectares) of unvegetated and vegetated sandy soils on the George T. Lewis Airport (also known as the Cedar Key Airport) that are owned by Levy County.

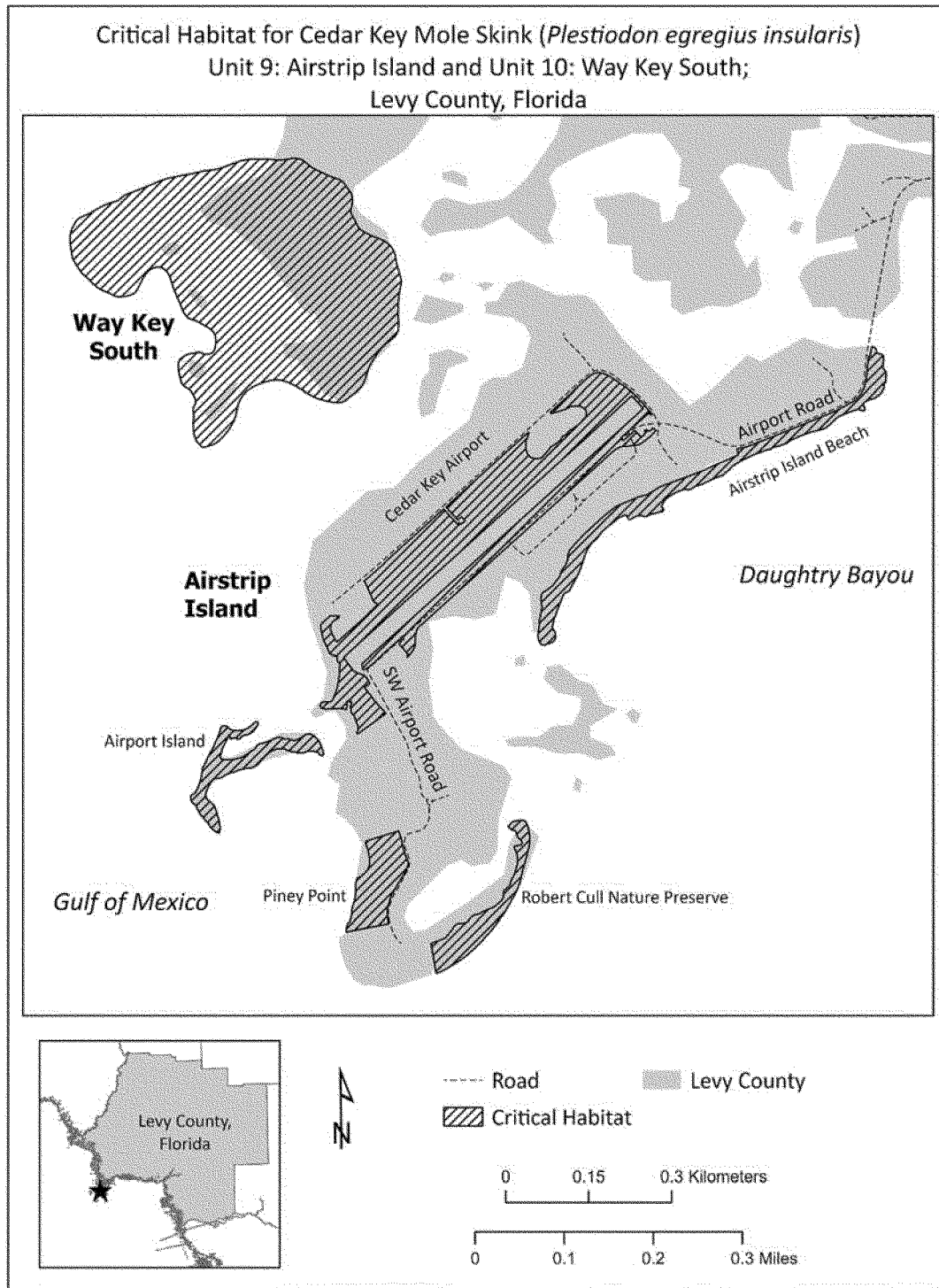
(C) Airport Island is a 2-acre (0.8-hectare), unnamed island southwest of the airport that is owned by Levy County.

(D) Piney Point is a 3-acre (1-hectare), privately owned, undeveloped, vacant lot on the western side of Piney Point south of the airport.

(E) The Robert Cull Nature Preserve is 2 acres (0.8 hectare) of protected land at the terminus of Piney Point that are owned and managed by Florida's Nature Coast Conservancy.

(ii) Map of Units 9 and 10 follows: Figure 6 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (14)(ii)

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BILLING CODE 4333-15-C

(15) *Unit 10: Way Key South; Levy County, Florida.*

(i) Unit 10 encompasses approximately 44 acres (18 hectares) on Way Key. This unit is a series of undeveloped, disconnected islands

south of Way Key. The unit includes a large portion of the island located between the airport and the developed portion of Way Key and several

primarily sand islands that occur seaward of the main island. This unit is entirely in State ownership.

(ii) Map of Unit 10 is provided at paragraph (14)(ii) of this entry.

(16) *Unit 11*: Way Key North; Levy County, Florida.

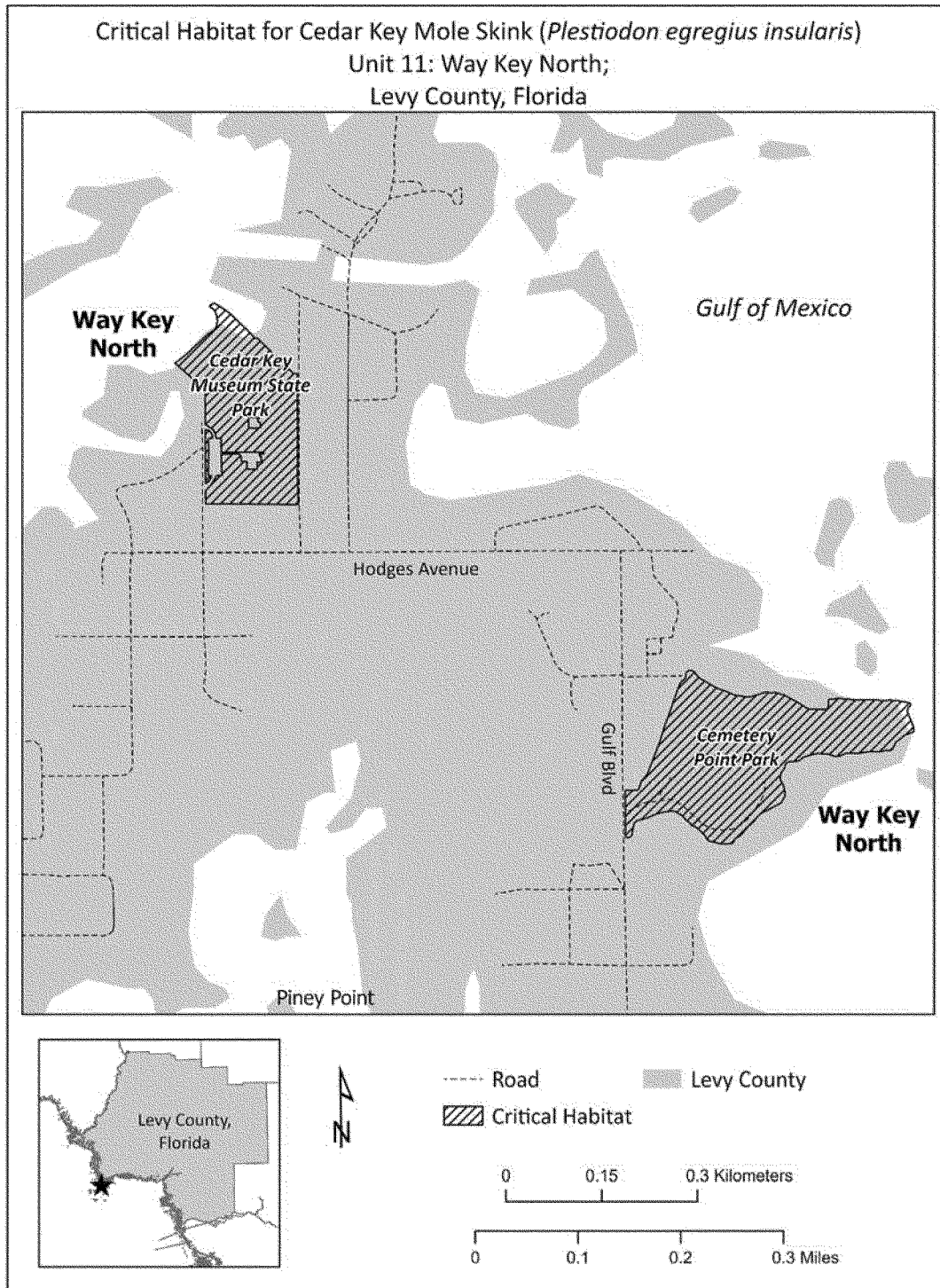
(i) Unit 11 encompasses approximately 24 acres (10 hectares) on Way Key. Lands within this unit include approximately 9 acres (4 hectares) in State ownership, managed as the Cedar Key Museum State Park by the Florida Park Service, and 15 acres (6 hectares) in local government

ownership, managed as Cemetery Point Park by the City of Cedar Key.

(ii) Map of Unit 11 follows:

Figure 7 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (16)(ii)

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(17) *Unit 12*: Richards Island; Levy County, Florida.

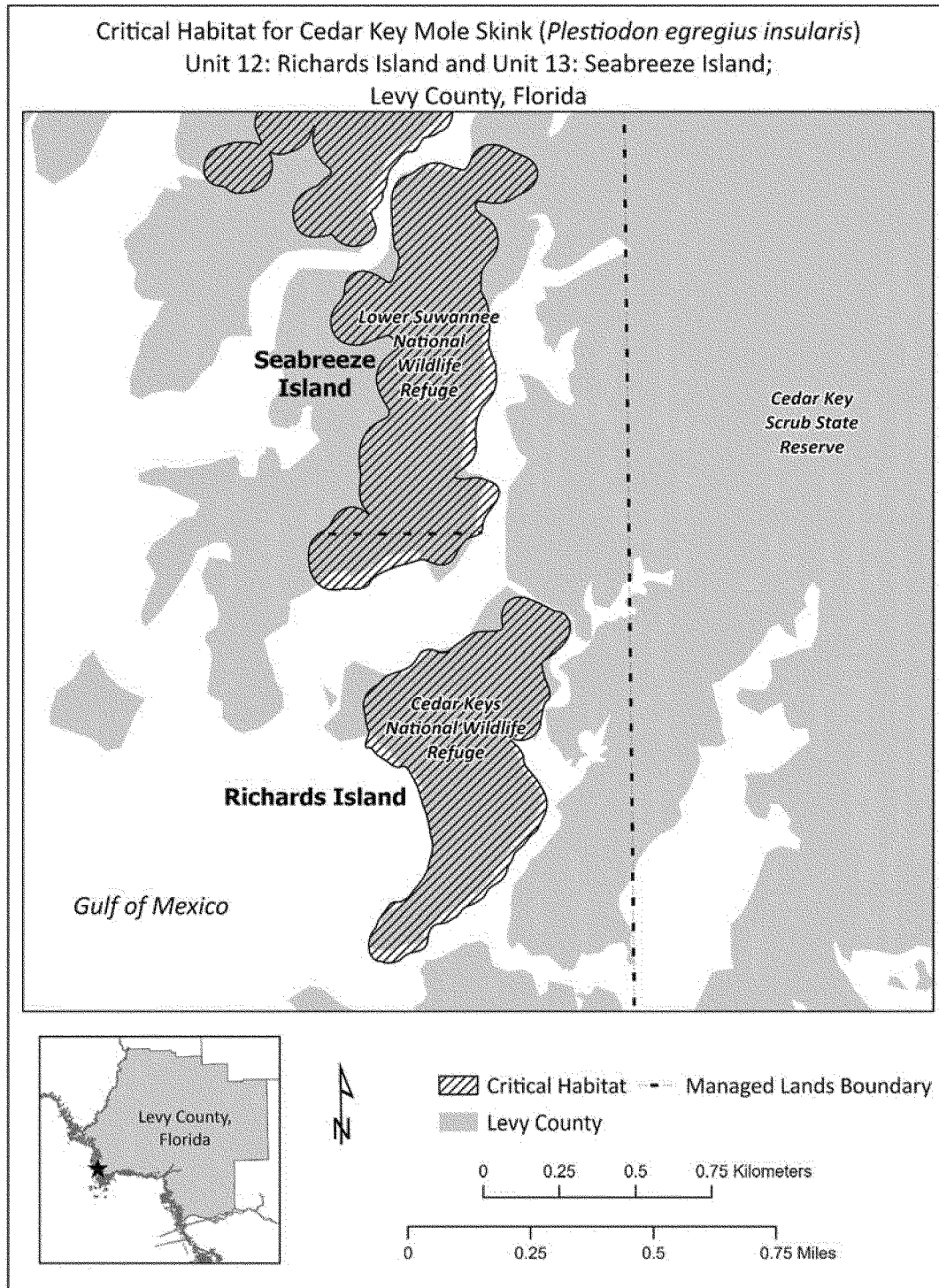
(i) Unit 12 encompasses approximately 105 acres (42 hectares) and includes the entirety of Richards Island. Lands within this unit include approximately 86 acres (35 hectares) in

Federal ownership and 19 acres (8 hectares) in other ownership. Richards Island is approximately 3.3 miles (5.3 kilometers) northwest of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Cedar Keys National Wildlife Refuge.

(ii) Map of Units 12 and 13 follows:

Figure 8 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (17)(ii)

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(18) *Unit 13*: Seabreeze Island; Levy County, Florida.

(i) Unit 13 encompasses approximately 136 acres (55 hectares)

on Seabreeze Island. Lands within this unit include approximately 111 acres (45 hectares) in Federal ownership and 25 acres (10 hectares) in other ownership. Seabreeze Island is approximately 4 miles (6 kilometers) northwest of Cedar Key within the Gulf of Mexico. The island is managed by the Service as part of the Lower Suwannee National Wildlife Refuge.

(ii) Map of Unit 13 is provided at paragraph (17)(ii) of this entry.

(19) *Unit 14*: Shell Mound; Levy County, Florida.

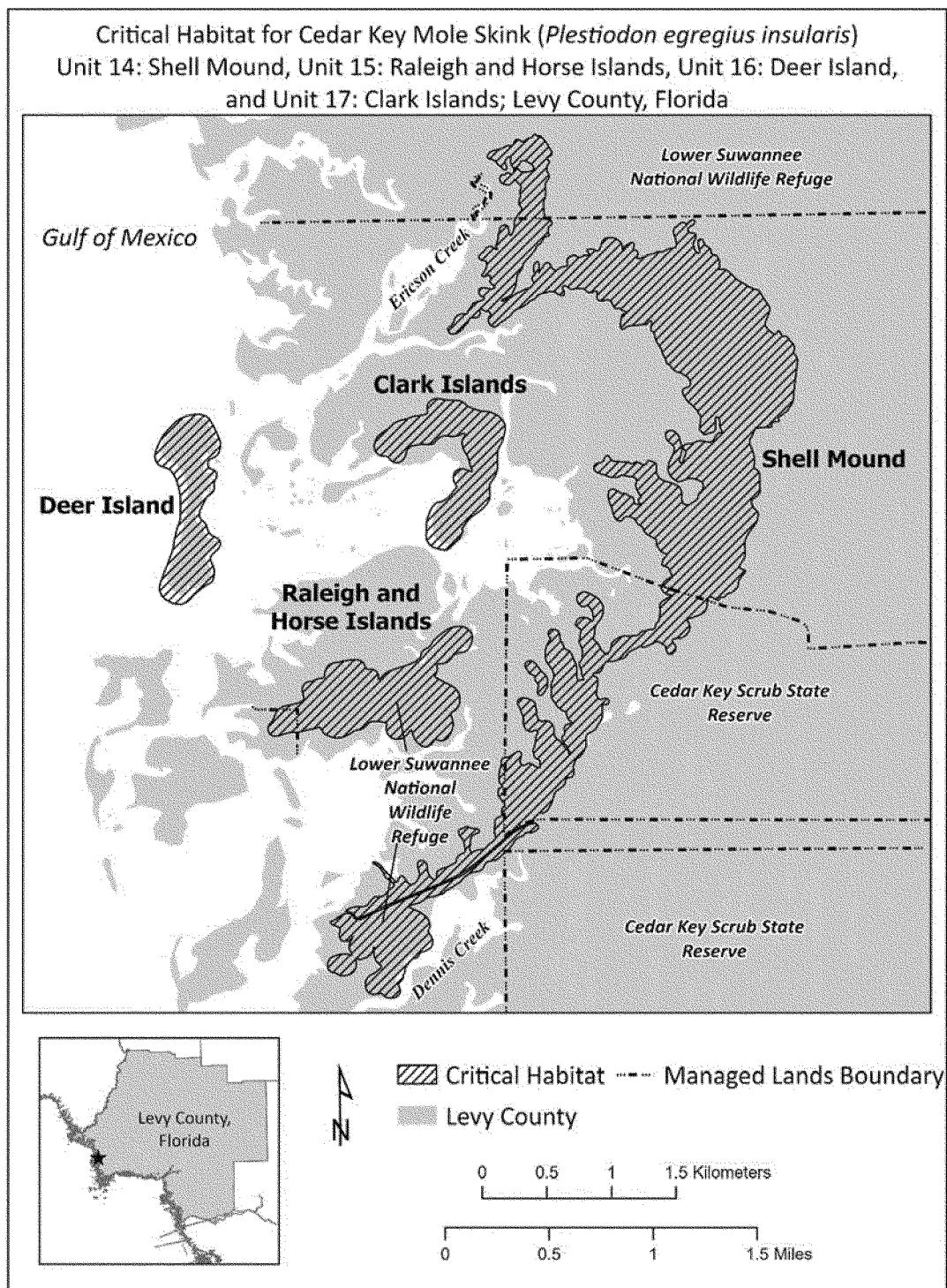
(i) Unit 14 encompasses approximately 1,050 acres (425 hectares) on Shell Mound. This unit extends from Dennis Creek north to Ericson Creek. Lands within this unit include approximately 167 acres (68 hectares) in Federal ownership, 194 acres (79 hectares) in State ownership, and 688 acres (278 hectares) in private ownership. The unit includes portions

of the Cedar Key Scrub State Reserve managed by the Florida Park Service and the Lower Suwannee National Wildlife Refuge managed by the Service.

(ii) Map of Units 14, 15, 16, and 17 follows:

Figure 9 to Cedar Key Mole Skink (*Plestiodon egregius insularis*) paragraph (19)(ii)

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**BILLING CODE 4333-15-C**

(20) *Unit 15:* Raleigh and Horse Islands; Levy County, Florida.

(i) Unit 15 encompasses approximately 176 acres (71 hectares) on Raleigh and Horse Islands. Approximately 171 acres (69 hectares) are in Federal ownership and 5 acres (2 hectares) are in private ownership. The group of islands are approximately 6 miles (10 kilometers) northwest of Cedar

Key within the Gulf of Mexico. The Service manages most of the islands as part of the Lower Suwannee National Wildlife Refuge.

(ii) Map of Unit 15 is provided at paragraph (19)(ii) of this entry.

(21) *Unit 16:* Deer Island; Levy County, Florida.

(i) Unit 16 encompasses approximately 113 acres (46 hectares) and includes the entirety of Deer Island.

Lands within the unit include approximately 8 acres (3 hectares) in Federal ownership, 69 acres (28 hectares) in private ownership, and 36 acres (15 hectares) in other ownership. Deer Island is approximately 7 miles (11 kilometers) northwest of Cedar Key within the Gulf of Mexico.

(ii) Map of Unit 16 is provided at paragraph (19)(ii) of this entry.

(22) *Unit 17*: Clark Islands; Levy County, Florida.

(i) Unit 17 encompasses approximately 121 acres (49 hectares) in the Clark Islands complex. The entirety of the unit is privately owned. The Clark

Islands are approximately 7 miles (11 kilometers) north-northwest of Cedar Key within the Gulf of Mexico.

(ii) Map of Unit 17 is provided at paragraph (19)(ii) of this entry.

* * * * *

Madonna Baucum,
Regulations and Policy Chief, Division of Policy, Economics, Risk Management, and Analytics of the Joint Administrative Operations, U.S. Fish and Wildlife Service.

[FR Doc. 2024–17271 Filed 8–7–24; 8:45 am]

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FEDERAL REGISTER

Vol. 89

Thursday,

No. 153

August 8, 2024

Part V

The President

Notice of August 6, 2024—Continuation of the National Emergency With Respect to the Advancement by Countries of Concern in Sensitive Technologies and Products Critical for the Military, Intelligence, Surveillance, or Cyber-Enabled Capabilities of Such Countries

Presidential Documents

Title 3—

Notice of August 6, 2024

The President

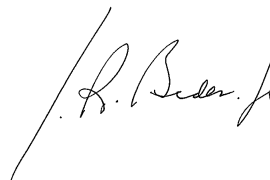
Continuation of the National Emergency With Respect to the Advancement by Countries of Concern in Sensitive Technologies and Products Critical for the Military, Intelligence, Surveillance, or Cyber-Enabled Capabilities of Such Countries

On August 9, 2023, by Executive Order 14105, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security of the United States constituted by the advancement by countries of concern in sensitive technologies and products critical for the military, intelligence, surveillance, or cyber-enabled capabilities of such countries. As described in Executive Order 14105, this threat to the national security of the United States has its source in whole or substantial part outside the United States, and certain United States investments risk exacerbating this threat.

Certain ongoing activities, such as the comprehensive, long-term strategies of countries of concern that direct, facilitate, or otherwise support advancements in sensitive technologies and products that are critical to such countries' military, intelligence, surveillance, or cyber-enabled capabilities, significantly enhance such countries' ability to conduct activities that threaten the national security of the United States. As part of this ongoing strategy of advancing the development of these sensitive technologies and products, countries of concern are exploiting or have the ability to exploit certain United States outbound investments, including certain intangible benefits that often accompany United States investments and that help companies succeed. Such investments risk exacerbating this threat to United States national security.

For this reason, the national emergency declared in Executive Order 14105 of August 9, 2023, must continue in effect beyond August 9, 2024. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 14105 with respect to the threat posed by the advancement by countries of concern in sensitive technologies and products critical for the military, intelligence, surveillance, or cyberenabled capabilities of such countries.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

A handwritten signature in black ink, appearing to read "R. B. Biden", is written over a diagonal line that extends from the bottom left towards the top right.

THE WHITE HOUSE,
August 6, 2024.

[FR Doc. 2024-17846
Filed 8-7-24; 11:15 am]
Billing code 3395-F4-P

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