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Executive Order 14299 of May 23, 2025

The President

## Deploying Advanced Nuclear Reactor Technologies for National Security

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

**Section 1. *Background.*** The United States faces a critical national security imperative to ensure a resilient, secure, and reliable energy supply for critical defense facilities designated under section 8240–1(c) of title 16, United States Code, and other mission capability resources. Advanced computing infrastructure for artificial intelligence (AI) capabilities and other mission capability resources at military and national security installations and national laboratories demands reliable, high-density power sources that cannot be disrupted by external threats or grid failures. These facilities and resources' vulnerability to energy disruption represents a strategic risk that must be addressed.

Advanced nuclear reactors include nuclear energy systems like Generation III+ reactors, small modular reactors, microreactors, and stationary and mobile reactors that have the potential to deliver resilient, secure, and reliable power to critical defense facilities and other mission capability resources. However, despite its promise, such technology has not been utilized in the United States at the scale or speed necessary to meet the Nation's urgent national security requirements, while our adversaries are rapidly exporting and deploying such technology around the world.

The Federal Government must utilize its full authority to accelerate the secure and responsible development, demonstration, deployment, and export of United States designed advanced nuclear technologies to bolster readiness and enhance American technological superiority. Additionally, the United States must further enhance our ability to export our nuclear technology to our allies and commercial partners, strengthening our shared ability to combat reliance on foreign adversaries through the use of safe, secure, and safeguarded nuclear technologies. Therefore, we must unleash the domestic nuclear industrial base and position American nuclear companies as the partners of choice for future energy growth throughout the world.

**Sec. 2. *Policy.*** It is the policy of the United States to:

(a) ensure the rapid development, deployment, and use of advanced nuclear technologies to support national security objectives, such as the protection and operation of critical infrastructure, critical defense facilities, and other mission capability resources;

(b) enable private sector investment, innovation, development, and use of advanced nuclear technologies in the United States, recognizing their benefit to national security, by aligning incentives across the Federal Government to fully leverage federally owned uranium and plutonium resources declared excess to defense needs, related nuclear material, supply chain components, and research and development infrastructure; and

(c) coordinate regulatory efforts across the Department of Defense and the Department of Energy, ensuring that these agencies optimize resources and risk allocation in accordance with their respective missions sets.

**Sec. 3. *Deployment and Use of Advanced Nuclear Reactor Technologies at Military Installations.*** (a) The Secretary of Defense, through the Secretary of the Army, shall establish a program of record for the utilization of nuclear

energy for both installation energy and operational energy. The Secretary of Defense, through the Secretary of the Army, shall commence the operation of a nuclear reactor, regulated by the United States Army, at a domestic military base or installation no later than September 30, 2028. The Secretary of Defense shall designate the Secretary of the Army as the executive agent for both installation and operational nuclear energy across the Department of Defense.

(b) The Secretary of Energy shall provide technical advice, as requested, to the Secretary of Defense on the design, construction, and operation of any advanced nuclear reactor on a military installation pursuant to this order.

(c) The Secretary of State shall provide advice to the Secretary of Defense on any international legal requirements, or any necessary modification to international agreements or arrangements, relevant to this order.

(d) Within 240 days of the date of this order, the Secretary of Defense shall, in coordination with the Secretary of Energy, the Director of the Office of Management and Budget (OMB), and the Secretaries of the military departments, prepare and submit to the Assistant to the President for National Security Affairs recommendations for legislative proposals and regulatory actions regarding the distribution, operation, replacement, and removal of advanced nuclear reactors and spent nuclear fuel on military installations.

**Sec. 4. *Deployment and Use of Advanced Nuclear Reactor Technologies at Department of Energy Facilities.*** (a) The Secretary of Energy shall initiate the process for designating AI data centers within the 48 contiguous States and the District of Columbia, in whole or in part, that are located at or operated in coordination with Department of Energy facilities, including as support for national security missions, as critical defense facilities, where appropriate. The electrical infrastructure, including both nuclear and non-nuclear power generation infrastructure, needed to operate such shall be considered defense critical electric infrastructure, for purposes of this order and subsequently across all applicable statutes, regulations, and directives or other non-regulatory statements of policy, as appropriate and consistent with applicable law.

(b) Within 90 days of the date of this order, the Secretary of Energy shall designate one or more sites owned or controlled by the Department of Energy within the United States, including national laboratories, for the use and deployment of advanced nuclear reactor technologies.

(c) The Secretary of Energy shall utilize all available legal authorities to site, approve, and authorize the design, construction, and operation of privately funded advanced nuclear reactor technologies at Department of Energy-owned or controlled sites for the purpose of powering AI infrastructure, other critical or national security needs, supply chain items, or on-site infrastructure. The Secretary of Energy shall prioritize early site preparation and authorization activities with a goal of operating an advanced nuclear reactor at the first site no later than 30 months from the date of this order.

**Sec. 5. *Uranium and Related Materials for Reactors Referenced in this Order.***

(a) Within 90 days of the date of this order, the Secretary of Energy shall identify all useful uranium and plutonium material within the Department of Energy's inventories that may be recycled or processed into nuclear fuel for reactors in the United States.

(b) The Secretary of Energy shall release into a readily available fuel bank not less than 20 metric tons of high assay low-enriched uranium (HALEU) for any project from the private sector which receives authorization to construct and operate at a Department of Energy-owned or controlled site and that is regulated by the Department of Energy for the purpose of powering AI and other infrastructure. The Secretary of Energy shall retain such stockpiles of fuel as are necessary for tritium production, naval propulsion, and nuclear weapons as well as other existing national security obligations and therefore draw from other caches of Department of Energy-owned

material to provide HALEU for the fuel bank pursuant to this section. To the extent feasible, the Secretary of Energy shall implement plans to ensure that a long-term supply of enriched uranium is available for the continued operation of the projects referenced in this first sentence of this subsection, including through the establishment of domestic fuel fabrication and supply chains to reduce reliance on foreign sources of fuel.

(c) The Secretary of Defense and the Secretary of Energy shall utilize all available legal authorities to site, approve, and authorize the design, construction, and operation of privately-funded nuclear fuel recycling, reprocessing, and reactor fuel fabrication technologies at identified sites controlled by their respective agencies for the purpose of fabricating fuel forms for use in national security reactors, commercial power reactors, and non-power research reactors.

**Sec. 6. *Interagency Coordination.*** The Secretary of Defense and the Secretary of Energy shall execute any useful contract or agreement under any of their respective authorities to support implementation of this order, including contracts or agreements for technical advisory support from the Department of Energy at Department of Defense installations for research, development, design, acquisition, specification, construction, inspection, installation, certification, testing, overhaul, refueling, operation, maintenance, supply support, and disposition of advanced nuclear reactor technologies in support of mission assurance objectives for critical infrastructure and to ensure military readiness and support from the Department of Defense to identify novel uses of advanced nuclear reactor technologies for defense applications and testing at Department of Energy-owned or controlled sites.

**Sec. 7. *National Environmental Policy Act Compliance.*** The Secretary of Defense and the Secretary of Energy shall consult with the Chairman of the Council on Environmental Quality regarding:

(a) applying the Department of Defense's and the Department of Energy's established categorical exclusions under the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, for the construction of advanced nuclear reactor technologies on certain Federal sites within the United States and for any other appropriate measures for the purposes of implementing this order;

(b) adopting other executive departments and agencies' (agencies) categorical exclusions for the same purposes;

(c) establishing new categorical exclusions for the same purposes;

(d) seeking to utilize other agencies' emergency and other permitting procedures for the siting and construction of advanced nuclear reactor technologies; and

(e) developing alternative arrangements for compliance with NEPA in emergency situations as appropriate for the same purposes.

**Sec. 8. *Promoting American Nuclear Exports.*** (a) The Secretary of State or the Secretary of State's designee shall:

(i) lead diplomatic engagement and negotiations for Agreements for Peaceful Nuclear Cooperation pursuant to section 123 of the Atomic Energy Act of 1954, 42 U.S.C. 2153 (123 Agreements);

(ii) aggressively pursue at least 20 new 123 Agreements by the close of the 120th Congress to enable the United States nuclear industry to access new markets in partner countries;

(iii) aggressively renegotiate 123 Agreements set to expire within the next decade;

(iv) fully leverage the resources of the Federal Government to promote the United States nuclear industry in the development of commercial civil nuclear projects globally; and

(v) lead engagement with the Congress regarding the progress and reporting of negotiating 123 Agreements.

(b) The Secretary of Energy shall expeditiously review and, subject to the concurrence of the Secretary of State and after consultation with the Nuclear Regulatory Commission, the Department of Commerce, and the Department of Defense, adjudicate export authorization requests to facilitate United States technological leadership. The Secretary of Energy, subject to the concurrence of the Secretary of State and after consultation with the Nuclear Regulatory Commission, the Department of Commerce, and the Department of Defense, shall approve or deny each technology transfer export authorization request within 30 days of receipt of a complete application and completion by the Department of Energy of the required accompanying analysis, excluding any time period waiting for (i) concurrence from the Department of State; and (ii) retransfer and nonproliferation assurances to be received from the government of the country where the export is proposed to be sent.

(c) Within 90 days of the date of this order, the Director of the Office of Science and Technology Policy and the Assistant to the President for Economic Policy shall, in consultation with the Secretary of State, the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Energy, the Director of OMB, the Assistant to the President for National Security Affairs, and the Chair of the National Energy Dominance Council, determine a strategy which addresses:

(i) optimizing the value of the United States International Development Finance Corporation to provide equity and other financing of American nuclear energy technology;

(ii) increasing the effectiveness of the United States Trade and Development Agency, as consistent with law, by expanding grant financing for United States nuclear technology pilots, fuel supplies, and project preparation to recently graduated high income economies of national strategic interest;

(iii) leveraging the Export-Import Bank of the United States and other relevant agencies to increase financing for projects utilizing United States civil nuclear technology exports throughout the project lifecycle;

(iv) holding trade missions and reverse trade missions and leveraging other trade promotion tools to remove trade barriers and increase the market competitiveness of the United States nuclear industry; and

(v) achieving competitive parity in the global market for high-level advocacy and representation from the Federal Government to foreign governments of potential import countries to include alignment on nuclear-related bilateral issues, focusing on countries with the highest probability of nuclear deployment within the next 4 years based on industry assessment and established commercial criteria such as the strength of the country's financial and regulatory system.

(d) Within 90 days of the date of this order, the Secretary of the Treasury shall, in consultation with the Secretary of State, the Secretary of Commerce, the Secretary of Energy, the Director of OMB, the Director of the Office of Science and Technology Policy, the Chair of the National Energy Dominance Council, and the Assistant to the President for Economic Policy, determine a strategy that:

(i) leverages United States participation in the multilateral development banks to support client country access to financial and technical assistance for the generation and distribution of nuclear energy and a reliable fuel supply; and

(ii) supports such assistance at relevant institutions to make financial support available on competitive terms, strengthen the capacity of such institutions to assess, implement, and evaluate nuclear energy projects, and support adoption of nuclear energy technologies and fuel supply chains that meet or exceed the quality standards in the United States or a country allied with the United States.

(e) Within 90 days of the date of this order, the Secretary of State or his designee shall, in consultation with the Secretary of Commerce and

the Secretary of Energy, and after review by the Director of the Office of Science and Technology Policy and the Assistant to the President for Economic Policy, implement a program to enhance the global competitiveness of American nuclear suppliers, investors, and lenders to compete for nuclear projects around the globe, including actions to:

- (i) expedite the conclusion of intergovernmental agreements on nuclear energy and the fuel supply chain with potential export countries;
- (ii) promote broad adherence to the Convention on Supplementary Compensation for Nuclear Damage;
- (iii) identify statutory and regulatory burdens on exports of American nuclear technology, fuel supplies, equipment, and services that are not addressed by this or other Executive Orders and recommend appropriate remedial action; and
- (iv) encourage favorable decisions by potential import countries on the use of American nuclear technology, fuel supplies, equipment, and services.

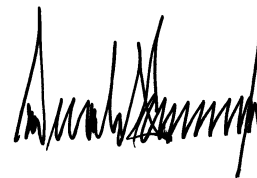
**Sec. 9. *Prioritization of Nuclear Clearances.*** The Secretary of Defense, through the Defense Counterintelligence and Security Agency and in consultation with the Secretary of Energy, shall prioritize the issuance as appropriate of Department of Energy and Department of Defense security clearances including “L”, “Q”, “SECRET”, “TOP SECRET”, “RD”, “CNWDI”, and “SCI” to support the rapid distribution and use of nuclear energy and fuel cycle technologies.

**Sec. 10. *Other Provisions.*** Nothing in this order shall be construed to impair or otherwise affect OMB functions related to procurement actions and related policy. This order shall be carried out subject to the budgetary, legislative, and procurement processes and requirements established by the Director of OMB, and coordinated with OMB, as appropriate, prior to the initiation of any new program, obligation, or commitment of Federal funds or submission of any legislative or procurement proposal arising from this order. This order shall be carried out in a manner which adheres to applicable legal requirements, conforms with nonproliferation obligations, and meets the highest safeguards and safety and security standards.

**Sec. 11. *General Provisions.*** (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
  - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations;
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Department of Energy shall provide funding for publication of this order in the *Federal Register*.

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THE WHITE HOUSE,  
May 23, 2025.

[FR Doc. 2025-09796  
Filed 5-28-25; 8:45 am]  
Billing code 6450-01-P

## Presidential Documents

Executive Order 14300 of May 23, 2025

### Ordering the Reform of the Nuclear Regulatory Commission

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

**Section 1. Purpose.** Abundant energy is a vital national- and economic-security interest. In conjunction with domestic fossil fuel production, nuclear energy can liberate America from dependence on geopolitical rivals. It can power not only traditional manufacturing industries but also cutting-edge, energy-intensive industries such as artificial intelligence and quantum computing.

Between 1954 and 1978, the United States authorized the construction of 133 since-completed civilian nuclear reactors at 81 power plants. Since 1978, the Nuclear Regulatory Commission (NRC) has authorized only a fraction of that number; of these, only two reactors have entered into commercial operation. The NRC charges applicants by the hour to process license applications, with prolonged timelines that maximize fees while throttling nuclear power development. The NRC has failed to license new reactors even as technological advances promise to make nuclear power safer, cheaper, more adaptable, and more abundant than ever.

This failure stems from a fundamental error: Instead of efficiently promoting safe, abundant nuclear energy, the NRC has instead tried to insulate Americans from the most remote risks without appropriate regard for the severe domestic and geopolitical costs of such risk aversion. The NRC utilizes safety models that posit there is no safe threshold of radiation exposure and that harm is directly proportional to the amount of exposure. Those models lack sound scientific basis and produce irrational results, such as requiring that nuclear plants protect against radiation below naturally occurring levels. A myopic policy of minimizing even trivial risks ignores the reality that substitute forms of energy production also carry risk, such as pollution with potentially deleterious health effects.

Recent events in Europe, such as the nationwide blackouts in Spain and Portugal, underscore the importance of my Administration's focus on dispatchable power generation—including nuclear power—over intermittent power. Beginning today, my Administration will reform the NRC, including its structure, personnel, regulations, and basic operations. In so doing, we will produce lasting American dominance in the global nuclear energy market, create tens of thousands of high-paying jobs, and generate American-led prosperity and resilience.

**Sec. 2. Policy.** It is the policy of the United States to:

- (a) Reestablish the United States as the global leader in nuclear energy;
- (b) Facilitate increased deployment of new nuclear reactor technologies, such as Generation III+ and IV reactors, modular reactors, and microreactors, including by lowering regulatory and cost barriers to entry;
- (c) Facilitate the expansion of American nuclear energy capacity from approximately 100 GW in 2024 to 400 GW by 2050;
- (d) Employ emerging technologies to safely accelerate the modeling, simulation, testing, and approval of new reactor designs;

(e) Support the continued operation of, and facilitate appropriate operational extensions for, the current nuclear fleet, as well as the reactivation of prematurely shuttered or partially completed nuclear facilities; and

(f) Maintain the United States' leading reputation for nuclear safety.

**Sec. 3. *Reforming the NRC's Culture.*** The Congress has mandated that the NRC's "licensing and regulation of the civilian use of radioactive materials and nuclear energy be conducted in a manner that is efficient and does not unnecessarily limit—(1) the civilian use of radioactive materials and deployment of nuclear energy; or (2) the benefits of civilian use of radioactive materials and nuclear energy technology to society." Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, Public Law 118–67, sec. 501(a). Just as the Congress directed, the NRC's mission shall include facilitating nuclear power while ensuring reactor safety. When carrying out its licensing and related regulatory functions, the NRC shall consider the benefits of increased availability of, and innovation in, nuclear power to our economic and national security in addition to safety, health, and environmental considerations.

**Sec. 4. *Reforming the NRC's Structure.*** (a) The current structure and staffing of the NRC are misaligned with the Congress's directive that the NRC shall not unduly restrict the benefits of nuclear power. The NRC shall, in consultation with the NRC's DOGE Team (as defined in Executive Order 14158 of January 20, 2025 (Establishing and Implementing the President's "Department of Government Efficiency")), and consistent with its governing statutes, reorganize the NRC to promote the expeditious processing of license applications and the adoption of innovative technology. The NRC shall undertake reductions in force in conjunction with this reorganization, though certain functions may increase in size consistent with the policies in this order, including those devoted to new reactor licensing. The NRC shall also create a dedicated team of at least 20 officials to draft the new regulations directed by section 5 of this order.

(b) The personnel and functions of the Advisory Committee on Reactor Safeguards (ACRS) shall be reduced to the minimum necessary to fulfill ACRS's statutory obligations. Review by ACRS of permitting and licensing issues shall focus on issues that are truly novel or noteworthy.

**Sec. 5. *Reforming and Modernizing the NRC's Regulations.*** The NRC, working with its DOGE Team, the Office of Management and Budget, and other executive departments and agencies as appropriate, shall undertake a review and wholesale revision of its regulations and guidance documents, and issue notice(s) of proposed rulemaking effecting this revision within 9 months of the date of this order. The NRC shall issue final rules and guidance to conclude this revision process within 18 months of the date of this order. In conducting this wholesale revision, the NRC shall be guided by the policies set forth in section 2 of this order and shall in particular:

(a) Establish fixed deadlines for its evaluation and approval of licenses, license amendments, license renewals, certificates of compliance, power uprates, license transfers, and any other activity requested by a licensee or potential licensee, as directed under the Nuclear Energy Innovation and Modernization Act, rather than the nonbinding "generic milestone schedules" guidelines the NRC has already adopted. Those deadlines shall be enforced by fixed caps on the NRC's recovery of hourly fees. The deadlines shall include: (1) a deadline of no more than 18 months for final decision on an application to construct and operate a new reactor of any type, commencing with the first required step in the regulatory process, and (2) a deadline of no more than 1 year for final decision on an application to continue operating an existing reactor of any type, commencing with the first required step in the regulatory process. The regulations should not provide for tolling those deadlines except in instances of applicant failure, and must allow a reasonably diligent applicant to navigate the licensing process successfully in the time allotted. Moreover, these are maximum time periods; the NRC shall adopt shorter deadlines tailored to particular reactor types or licensing pathways as appropriate.

(b) Adopt science-based radiation limits. In particular, the NRC shall reconsider reliance on the linear no-threshold (LNT) model for radiation exposure and the “as low as reasonably achievable” standard, which is predicated on LNT. Those models are flawed, as discussed in section 1 of this order. In reconsidering those limits, the NRC shall specifically consider adopting determinate radiation limits, and in doing so shall consult with the Department of Defense (DOD), the Department of Energy (DOE), and the Environmental Protection Agency.

(c) Revise, in consultation with the Council on Environmental Quality, NRC regulations governing NRC’s compliance with the National Environmental Policy Act to reflect the Congress’s 2023 amendments to that statute and the policies articulated in sections 2 and 5 of Executive Order 14154 of January 20, 2025 (Unleashing American Energy).

(d) Establish an expedited pathway to approve reactor designs that the DOD or the DOE have tested and that have demonstrated the ability to function safely. NRC review of such designs shall focus solely on risks that may arise from new applications permitted by NRC licensure, rather than revisiting risks that have already been addressed in the DOE or DOD processes.

(e) Establish a process for high-volume licensing of microreactors and modular reactors, including by allowing for standardized applications and approvals and by considering to what extent such reactors or components thereof should be regulated through general licenses.

(f) Establish stringent thresholds for circumstances in which the NRC may demand changes to reactor design once construction is underway.

(g) Revise the Reactor Oversight Process and reactor security rules and requirements to reduce unnecessary burdens and be responsive to credible risks.

(h) Adopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments focus on credible, realistic risks.

(i) Reconsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.

(j) Streamline the public hearings process.

**Sec. 6. General Provisions.** (a) Nothing in this order shall be construed to impair or otherwise affect:

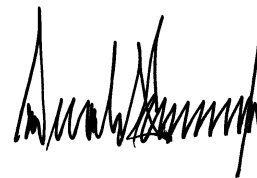
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Nuclear Regulatory Commission shall provide funding for publication of this order in the *Federal Register*.

A handwritten signature in black ink, appearing to be a stylized name, possibly 'Donald Trump', written in a cursive style.

THE WHITE HOUSE,  
May 23, 2025.

[FR Doc. 2025-09798  
Filed 5-28-25; 8:45 am]  
Billing code 7590-01-P

## Presidential Documents

Executive Order 14301 of May 23, 2025

### Reforming Nuclear Reactor Testing at the Department of Energy

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

**Section 1. Purpose.** The United States led the development of civilian nuclear power through the Atomic Energy Commission, the National Reactor Testing Station (now known as Idaho National Laboratory), and several other Federal Government entities. This work produced safe and abundant energy. But in the decades since, commercial deployment of new nuclear technologies has all but stopped. The Idaho National Laboratory has principal responsibility for constructing and testing new reactor designs; it concluded construction of new reactors in the 1970s. Our proud history of innovation has succumbed to overregulated complacency.

As I stated in Executive Order 14156 of January 20, 2025 (Declaring a National Energy Emergency), the United States needs a reliable, diversified, and affordable supply of energy to drive development of advanced technologies, manufacturing, transportation, agriculture, and defense industries, and to sustain modern life and national security. Nuclear energy both is vital to this effort and has never held so much promise. Decades of research and engineering have produced prototypes of advanced nuclear technologies that incorporate passive safety mechanisms, improve the physical architecture of reactor designs, increase reactor operational flexibility and performance, and reduce risk in fuel disposal. Advanced reactors—including microreactors, small modular reactors, and Generation IV and Generation III+ reactors—have revolutionary potential. They will open a range of new applications to support data centers, microchip manufacturing, petrochemical production, healthcare, desalination, hydrogen production, and other industries.

The United States cultivated the effort to design and build the first Generation IV reactor for commercial use, but the Federal Government has effectively throttled the domestic deployment of advanced reactors, ceding the initiative to foreign nations in building this critical technology. That changes today. It is the policy of my Administration to foster nuclear innovation and bring advanced nuclear technologies into domestic production as soon as possible.

**Sec. 2. Definitions.** For purposes of this order:

(a) The term “advanced reactor” has the same meaning as the term “advanced nuclear reactor” in 42 U.S.C. 16271(b)(1).

(b) The term “Department” means the Department of Energy.

(c) The term “qualified test reactor” means an advanced reactor that satisfies thresholds established by the Department sufficient to demonstrate that, from the perspective of technical development and financial backing, the reactor may feasibly be operational within 2 years from the date a substantially complete application is submitted.

(d) The term “Secretary” means the Secretary of Energy.

**Sec. 3. Findings.** With some rare and arguable exceptions, no advanced reactors have yet been deployed in America. I find that design, construction, operation, and disposition of such reactors under the auspices of the Department—and not to produce commercial electric power—would be for research

purposes, rather than “for the purpose of demonstrating the suitability for commercial application of . . . a reactor” within the meaning of 42 U.S.C. 5842. The purpose of testing these reactors at this stage in America’s industrial evolution is to establish fundamental technological viability. Thus, at least for the foreseeable future, advanced reactors over which the Department exercises sufficient control and that do not produce commercial electric power, including those “under contract with and for the account of the [Department],” 42 U.S.C. 2140(a)(2), fall within the jurisdiction of the Department, which has authority to foster research and development in nuclear reactors. Nothing in this section alters the authority or jurisdiction of the Department of Defense.

**Sec. 4. *Reforming the National Laboratory Process for Reactor Testing.*** (a) Within 60 days of the date of this order, the Secretary shall issue guidance regarding what counts as a qualified test reactor for purposes of this order.

(b) Within 90 days of the date of this order, the Secretary shall take appropriate action to revise the regulations, guidance, and procedures and practices of the Department, the National Laboratories, and any other entity under the Department’s jurisdiction to significantly expedite the review, approval, and deployment of advanced reactors under the Department’s jurisdiction. The Secretary shall ensure that the Department’s expedited procedures enable qualified test reactors to be safely operational at Department-owned or Department-controlled facilities within 2 years following the submission of a substantially complete application.

(c) Upon finding that an applicant has submitted a substantially complete application for a qualified test reactor, the Secretary shall establish a team consisting of representatives from the Secretary’s office, the relevant National Laboratory or Laboratories, the Department’s Office of General Counsel, and any other entities within the Department that possess the authority to deconflict, oppose, or approve the application. The team shall provide assistance to the applicant to ensure expeditious processing of its application. For these purposes, each member shall report directly to the Secretary.

(d) The Secretary shall prioritize qualified test reactor projects for processing, as consistent with applicable law.

**Sec. 5. *Establishing a Pilot Program Outside the National Laboratories.*** (a) The Secretary shall create a pilot program for reactor construction and operation outside the National Laboratories, pursuant to the Atomic Energy Act’s authorization of reactors under the Department’s sufficient control, including reactors “under contract with and for the account of” the Department, in accordance with 42 U.S.C. 2140. The Secretary shall approve at least three reactors pursuant to this pilot program with the goal of achieving criticality in each of the three reactors by July 4, 2026.

(b) Upon approval of an application for this pilot program, the Secretary shall assign a team to provide assistance to the applicant as specified in subsection 4(c) of this order.

**Sec. 6. *Streamlining Environmental Reviews.*** (a) The Secretary shall, in consultation with the Chair of the Council on Environmental Quality, take action to reform the Department’s rules governing compliance with the National Environmental Policy Act (NEPA) no later than June 30, 2025, consistent with the policies articulated in sections 2 and 5 of Executive Order 14154 of January 20, 2025 (Unleashing American Energy), and with applicable law.

(b) The Secretary shall, consistent with applicable law, use all available authorities to eliminate or expedite the Department’s environmental reviews for authorizations, permits, approvals, leases, and any other activity requested by an applicant or potential applicant. In addition to the measures outlined in section 7 of the Executive Order of May 23, 2025 (Deploying Advanced Nuclear Reactor Technologies for National Security), such measures shall include determining which Department functions are not subject to NEPA, creating categorical exclusions as appropriate for reactors within certain

parameters (or relying on existing categorical exclusions), relying on supplemental analyses where reactors will be located on existing sites, or utilizing alternative procedures under NEPA.

**Sec. 7. Implementation.** The Secretary shall work with the DOGE Team Lead at the Department, as defined in Executive Order 14158 of January 20, 2025 (Establishing and Implementing the President's "Department of Government Efficiency"), with the Director of the Office of Management and Budget, and with the Director of the Office of Science and Technology Policy to implement this order.

**Sec. 8. General Provisions.** (a) Nothing in this order shall be construed to impair or otherwise affect:

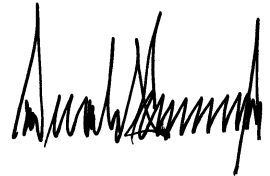
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Department of Energy shall provide funding for publication of this order in the *Federal Register*.

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THE WHITE HOUSE,  
May 23, 2025.

## Presidential Documents

Executive Order 14302 of May 23, 2025

### Reinvigorating the Nuclear Industrial Base

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

**Section 1. Purpose.** The United States originally pioneered nuclear energy technology during a time of great peril. We now face a new set of challenges, including a global race to dominate in artificial intelligence, a growing need for energy independence, and access to uninterrupted power supplies for national security.

It took nearly 40 years for the United States to add the same amount of nuclear capacity as another developed nation added in 10 years. Further, as American deployment of advanced reactor designs has waned, 87 percent of nuclear reactors installed worldwide since 2017 are based on designs from two foreign countries. At the same time, the Nation's nuclear fuel cycle infrastructure has severely atrophied, leaving the United States heavily dependent on foreign sources of uranium as well as uranium enrichment and conversion services. These trends cannot continue.

Swift and decisive action is required to jumpstart America's nuclear energy industrial base and ensure our national and economic security by increasing fuel availability and production, securing civil nuclear supply chains, improving the efficiency with which advanced nuclear reactors are licensed, and preparing our workforce to establish America's energy dominance and accelerate our path towards a more secure and independent energy future.

**Sec. 2. Policy.** It is the policy of the United States to expedite and promote to the fullest possible extent the production and operation of nuclear energy to provide affordable, reliable, safe, and secure energy to the American people, to power advanced nuclear reactor technologies, as defined in 42 U.S.C. 16271(b)(1)(A), and to build associated supply chains that secure our global industrial and digital dominance, achieve our energy independence, protect our national security, and maximize the efficiency and effectiveness of nuclear fuel through recycling, reprocessing, and reinvigorating the commercial sector.

**Sec. 3. Strengthening the Domestic Nuclear Fuel Cycle.** (a) Within 240 days of the date of this order, the Secretary of Energy, in coordination with the Secretary of Defense, the Secretary of Transportation, and the Director of the Office of Management and Budget (OMB), shall prepare and submit to the President, through the Chair of the National Energy Dominance Council and the Director of the Office of Science and Technology Policy, a report that includes:

- (i) a recommended national policy to support the management of spent nuclear fuel and high-level waste and the development and deployment of advanced fuel cycle capabilities to establish a safe, secure, and sustainable long-term fuel cycle;
- (ii) a review of relevant statutory authorities to identify any legislative changes necessary or desirable to achieve the national policy recommended under subsection (a)(i) of this section;
- (iii) an evaluation of the reprocessing and recycling of spent nuclear fuel from the operation of Department of Defense and Department of Energy reactors and other spent nuclear fuel managed by the Department of Energy, along with a discussion of steps the Department of Defense

and the Department of Energy are taking or must take to improve such reprocessing and recycling processes;

(iv) an analysis of legal, budgetary, and policy considerations relevant to efficiently transferring spent nuclear fuel from reactors to a government-owned, privately operated reprocessing and recycling facility;

(v) recommendations for the efficient use of the uranium, plutonium, and other products recovered through recycling and reprocessing;

(vi) recommendations for the efficient disposal of the wastes generated by recycling or reprocessing through a permanent disposal pathway;

(vii) a recommended process for evaluating, prior to disposal, nuclear waste materials for isotopes of value to national security, or medical, industrial, and scientific sectors;

(viii) a reevaluation of historic and current nuclear reprocessing, separation, and storage facilities slated for decommissioning and that are identified as having valuable materials, isotopes, equipment, licenses, operations, or experienced workers, and that may have potential fuel cycle or national security benefits if operations are continued or increased; and

(ix) a program to develop methods and technologies to transport, domestically and overseas, used and unused advanced nuclear fuels and advanced nuclear reactors containing such fuels in a safe, secure, and environmentally sound manner, including any legislation required to support this initiative.

(b) Within 120 days of the date of this order, the Secretary of Energy, in consultation with the Chair of the Nuclear Regulatory Commission and the Director of OMB, shall develop a plan to expand domestic uranium conversion capacity and expand enrichment capabilities sufficient to meet projected civilian and defense reactor needs for low enriched uranium (LEU), high enriched uranium (HEU) and high assay, low enriched uranium (HALEU), subject to retention of such stockpiles as are necessary for tritium production, naval propulsion, and nuclear weapons. The plan shall be implemented based on the timeframes set forth in the plan.

(c) The Secretary of Energy shall halt the surplus plutonium dilute and dispose program except with respect to the Department of Energy's legal obligations to the State of South Carolina. In place of this program, the Secretary of Energy shall establish a program to dispose of surplus plutonium by processing and making it available to industry in a form that can be utilized for the fabrication of fuel for advanced nuclear technologies.

(d) Within 90 days of the date of this order, the Secretary of Energy, in consultation with the Secretary of Defense as appropriate, shall update the Department of Energy's excess uranium management policy to align with the policy objectives of this order and the Nuclear Fuel Security Act, factoring in the national security need to modernize the United States nuclear weapon stockpile. The Secretary of Energy shall prioritize contracting for the development of fuel fabrication facilities that demonstrate the technical and financial feasibility to supply fuel to qualified test reactors or pilot program reactors within 3 years from the date of such applications.

(e) Within 30 days of the date of this order, the Secretary of Energy, in coordination with the Attorney General and the Chairman of the Federal Trade Commission, shall utilize the authority provided to the President in section 708(c)(1) of the Defense Production Act of 1950 (DPA) (50 U.S.C. 4558(c)(1)), which has been delegated to the Secretary of Energy pursuant to Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness), to seek voluntary agreements pursuant to section 708 of the DPA with domestic nuclear energy companies. The Secretary of Energy should prioritize agreements with those companies that have achieved objective milestones (e.g., Department of Energy-approved conceptual safety design reports, the ability to privately finance their fuel, or the demonstrated technology capability) for the cooperative procurement of LEU and HALEU,

including as needed by the Federal Government for tritium production, naval propulsion, and nuclear weapons.

(f) The Secretary of Energy, the Attorney General, and the Chairman of the Federal Trade Commission shall take all necessary and appropriate steps under sections 708(c), (d), (e), and (f)(1)(A) of the DPA (50 U.S.C. 4558(c), (d), (e), (f)(1)(A)), for the Secretary of Energy to form agreements pursuant to subsection (e) of this section.

(g) The Attorney General shall, after consultation with the Chairman of the Federal Trade Commission, consider whether to make the finding described in section 708(f)(1)(B) of the DPA (50 U.S.C. 4558(f)(1)(B)), with respect to any agreement and, no later than 30 days after any voluntary agreement is reached, shall publish such finding as appropriate.

(h) Such voluntary agreements shall further allow consultation with domestic nuclear energy companies to discuss and implement methods to enhance the capability to manage spent nuclear fuel, including the recycling and reprocessing of spent nuclear fuel, to ensure the continued reliable operation of the Nation's nuclear reactors. Such voluntary agreements shall also allow industry consultation to establish consortia and plans of action to ensure that the nuclear fuel supply chain capacity, including milling, conversion, enrichment, deconversion, fabrication, recycling, or reprocessing, is available to enable the continued reliable operation of the Nation's existing, and future, nuclear reactors. The Secretary of Energy, consistent with applicable law, is authorized to provide procurement support, forward contracts, or guarantees to such consortia as a means to ensure offtake for newly established domestic fuel supply, including conversion, enrichment, reprocessing, or fabrication capacity.

**Sec. 4. *Funding for Restart, Completion, Uprate, or Construction of Nuclear Plants.*** (a) To maximize the speed and scale of new nuclear capacity, the Department of Energy shall prioritize work with the nuclear energy industry to facilitate 5 gigawatt of power uprates to existing nuclear reactors and have 10 new large reactors with complete designs under construction by 2030. To help achieve these objectives, the Secretary of Energy, through the Department of Energy Loan Programs Office, shall, subject to the requirements of the Federal Credit Reform Act and other applicable law and OMB Circular A-11, prioritize activities that support nuclear energy, including actions to make available resources for restarting closed nuclear power plants, increasing power output of operating nuclear power plants, completing construction of nuclear reactors that was prematurely suspended, constructing new advanced nuclear reactors, and improving all associated aspects of the nuclear fuel supply chain.

(b) The Secretary of Energy shall also coordinate with the Secretary of Defense to assess the feasibility of restarting or repurposing closed nuclear power plants as energy hubs for military microgrid support, consistent with applicable law, focusing initially on installations with insufficient power resilience or grid fragility.

(c) Within 180 days of the date of this order, the Secretary of Energy, in coordination with the Administrator of the Small Business Administration, shall, subject to the availability of appropriations, prioritize funding for qualified advanced nuclear technologies through grants, loans, investment capital, funding opportunities, and other Federal support. Priority shall be given to those companies demonstrating the largest degrees of design and technological maturity, financial backing, and potential for near-term deployment of their technologies.

**Sec. 5. *Expanding the Nuclear Energy Workforce.*** (a) Nuclear engineering and other careers and education pathways that support the nuclear energy industry shall be considered areas of focus and priority pursuant to Executive Order 14278 of April 23, 2025 (Preparing Americans for High-Paying Skilled Trade Jobs of the Future).

(b) Within 120 days of the date of this order, the Secretary of Labor and the Secretary of Education shall seek to increase participation in nuclear

energy-related Registered Apprenticeships and Career and Technical Education programs by:

(i) using apprenticeship intermediary contracts and allocating existing discretionary funds, as appropriate and consistent with applicable law, to engage industry organizations and employers to perform a gap analysis of apprenticeship programs, and facilitate the development of Registered Apprenticeship programs, in nuclear energy-related occupations that are underrepresented;

(ii) encouraging States and grantees to use funding provided under the Workforce Innovation and Opportunity Act (Public Law 113–128), as amended, to develop nuclear engineering and other nuclear energy-related skills and to support work-based learning opportunities, including issuing related guidance to State and local workforce development boards and others regarding use of such funds for such purposes; and

(iii) consistent with applicable law, establishing nuclear engineering and other nuclear energy-related skills training and work-based learning as a grant priority in Employment and Training Administration and Office of Career, Technical, and Adult Education discretionary grant programs.

(c) Within 120 days of the date of this order, all executive departments and agencies that provide educational grants shall, as appropriate and consistent with applicable law, consider nuclear engineering and other nuclear energy-related careers as a priority area for investment.

(d) Within 120 days of the date of this order, the Secretary of Energy shall take steps to increase access to research and development infrastructure, workforce, and expertise at Department of Energy National Laboratories for college and university students studying nuclear engineering and other nuclear energy-related fields, and Department of Defense personnel affiliated with nuclear energy programs.

**Sec. 6. *Other Provisions.*** Nothing in this order shall be construed to impair or otherwise affect OMB functions related to procurement actions and related policy. This order shall be carried out subject to the budgetary, legislative, and procurement processes and requirements established by the Director of OMB, and coordinated with OMB, as appropriate, prior to the initiation of any new program, obligation, or commitment of Federal funds, or submission of any legislative or procurement proposal arising from this order. This order shall be carried out in a manner which adheres to applicable legal requirements, conforms with nonproliferation obligations, and meets the highest safeguards, safety, and security standards.

**Sec. 7. *General Provisions.*** (a) Nothing in this order shall be construed to impair or otherwise affect:

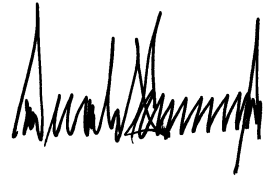
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Department of Energy shall provide funding for publication of this order in the *Federal Register*.

A handwritten signature in black ink, appearing to be a stylized name, located in the upper right quadrant of the page.

THE WHITE HOUSE,  
May 23, 2025.

[FR Doc. 2025-09801  
Filed 5-28-25; 8:45 am]  
Billing code 6450-01-P

## Presidential Documents

### Executive Order 14303 of May 23, 2025

### Restoring Gold Standard Science

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 7301 of title 5, United States Code, it is hereby ordered:

**Section 1. *Policy and Purpose.*** Over the last 5 years, confidence that scientists act in the best interests of the public has fallen significantly. A majority of researchers in science, technology, engineering, and mathematics believe science is facing a reproducibility crisis. The falsification of data by leading researchers has led to high-profile retractions of federally funded research.

Unfortunately, the Federal Government has contributed to this loss of trust. In several notable cases, executive departments and agencies (agencies) have used or promoted scientific information in a highly misleading manner. For example, under the prior Administration, the Centers for Disease Control and Prevention issued COVID-19 guidance on reopening schools that incorporated edits by the American Federation of Teachers and was understood to discourage in-person learning. This guidance's restrictive and burdensome reopening conditions led many schools to remain at least partially closed, resulting in substantial negative effects on educational outcomes—even though the best available scientific evidence showed that children were unlikely to transmit or suffer serious illness or death from the virus, and that opening schools with reasonable mitigation measures would have only minor effects on transmission.

The National Marine Fisheries Service justified a biological opinion by adopting an admitted “worst-case scenario” projection of the North Atlantic right whale population that it believed was “very likely” wrong. The agency's proposed actions could have destroyed the historic Maine lobster fishery. The D.C. Circuit Court of Appeals subsequently overturned that opinion because the agency's decision to seek out the worst-case scenario skewed its approach to the evidence.

Similarly, agencies have used Representative Concentration Pathway (RCP) scenario 8.5 to assess the potential effects of climate change in a “higher” warming scenario. RCP 8.5 is a worst-case scenario based on highly unlikely assumptions like end-of-century coal use exceeding estimates of recoverable coal reserves. Scientists have warned that presenting RCP 8.5 as a likely outcome is misleading.

Actions taken by the prior Administration further politicized science, for example, by encouraging agencies to incorporate diversity, equity, and inclusion considerations into all aspects of science planning, execution, and communication. Scientific integrity in the production and use of science by the Federal Government is critical to maintaining the trust of the American people and ensuring confidence in government decisions informed by science.

My Administration is committed to restoring a gold standard for science to ensure that federally funded research is transparent, rigorous, and impactful, and that Federal decisions are informed by the most credible, reliable, and impartial scientific evidence available. We must restore the American people's faith in the scientific enterprise and institutions that create and apply scientific knowledge in service of the public good. Reproducibility, rigor, and unbiased peer review must be maintained. This order restores the scientific integrity policies of my first Administration and ensures

that agencies practice data transparency, acknowledge relevant scientific uncertainties, are transparent about the assumptions and likelihood of scenarios used, approach scientific findings objectively, and communicate scientific data accurately. Agency use of Gold Standard Science, as set forth in this order, will spur innovation, translate discovery to success, and ensure continued American strength and global leadership in technology.

**Sec. 2. Definitions.** For the purposes of this order:

(a) “Employee” has the meaning given that term in 5 U.S.C. 2105.

(b) “Scientific information” means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, physical sciences, or probability and statistics. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.

(c) “Scientific misconduct” means fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting the results of scientific research, but does not include honest error or differences of opinion. For the purposes of this definition:

(i) “fabrication” is making up data or results and recording or reporting them;

(ii) “falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record; and

(iii) “plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

(d) “Senior appointee” means an individual appointed by the President (or an individual performing the functions and duties of an individual appointed by the President) or a non-career member of the Senior Executive Service.

(e) “Weight of scientific evidence” means an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data.

**Sec. 3. Restoring Gold Standard Science.** (a) Within 30 days of the date of this order, the Director of the Office of Science and Technology Policy (OSTP Director) shall, in consultation with the heads of relevant agencies, issue guidance for agencies on implementation of “Gold Standard Science” in the conduct and management of their respective scientific activities. For the purposes of this order, Gold Standard Science means science conducted in a manner that is:

(i) reproducible;

(ii) transparent;

(iii) communicative of error and uncertainty;

(iv) collaborative and interdisciplinary;

(v) skeptical of its findings and assumptions;

(vi) structured for falsifiability of hypotheses;

(vii) subject to unbiased peer review;

(viii) accepting of negative results as positive outcomes; and

(ix) without conflicts of interest.

(b) Upon publication of the guidance prescribed in subsection (a), each agency head, as necessary and appropriate and in consultation with the

Director of the Office of Management and Budget (OMB Director) and the OSTP Director, shall promptly update applicable agency policies governing the production and use of scientific information, including scientific integrity policies, to implement the OSTP Director's guidance on Gold Standard Science and ensure that agency scientific activities are conducted in accordance with this order.

(c) Each agency head shall, to the extent practicable, incorporate the OSTP Director's guidance on Gold Standard Science and the requirements of this order into the processes by which their agency conducts, manages, interprets, communicates, and uses scientific or technological information prior to the finalization of the updated policies under this section.

(d) Within 60 days of the publication of the guidance prescribed in section 3(a), agency heads shall report to the OSTP Director on the actions taken to implement Gold Standard Science at their agency.

**Sec. 4. *Improving the Use, Interpretation, and Communication of Scientific Data.*** No later than 30 days after the date of this order, agency heads and employees shall adhere to the following rules governing the use, interpretation, and communication of scientific data, unless otherwise provided by law:

(a) Employees shall not engage in scientific misconduct nor knowingly rely on information resulting from scientific misconduct.

(b) Except as prohibited by law, and consistent with relevant policies that protect national security or sensitive personal or confidential business information, agency heads shall in a timely manner and, to the extent practicable and within the agency's authority:

(i) subject to paragraph (ii), make publicly available the following information within the agency's possession:

(A) the data, analyses, and conclusions associated with scientific and technological information produced or used by the agency that the agency reasonably assesses will have a clear and substantial effect on important public policies or important private sector decisions (influential scientific information), including data cited in peer-reviewed literature; and

(B) the models and analyses (including, as applicable, the source code for such models) the agency used to generate such influential scientific information. Employees may not invoke exemption 5 to the Freedom of Information Act (5 U.S.C. 552(b)(5)) to prevent disclosure of such models unless authorized in writing to do so by the agency head following prior notice to the OSTP Director.

(ii) risk models used to guide agency enforcement actions or select enforcement targets are not information that must be disclosed under this subsection.

(c) When using scientific information in agency decision-making, employees shall transparently acknowledge and document uncertainties, including how uncertainty propagates throughout any models used in the analysis.

(d) Where employees produce or use scientific information to inform policy or legal determinations they must use science that comports with the legal standards applicable to those determinations, including when agencies evaluate the realistic or reasonably foreseeable effects of an action.

(e) Employees shall be transparent about the likelihood of the assumptions and scenarios used. Highly unlikely and overly precautionary assumptions and scenarios should only be relied upon in agency decision-making where required by law or otherwise pertinent to the agency's action.

(f) When scientific or technological information is used to inform agency evaluations and subsequent decision-making, employees shall apply a "weight of scientific evidence" approach.

(g) Employees' communication of scientific information shall be consistent with the results of the relevant analysis and evaluation and, to the extent

that uncertainty is present, the degree of uncertainty should be communicated. Communications involving a scientific model or information derived from a scientific model should include reference to any material assumptions that inform the model's outputs.

(h) Once the guidance on Gold Standard Science is established and promulgated pursuant to section 3 of this order, it shall, among other things, form the basis for employees' evaluation of all scientific and technological information called for in this order except where otherwise required by law.

**Sec. 5. *Interim Scientific Integrity Policies.*** (a) Until the issuance of updated agency scientific integrity policies pursuant to section 3 of this order, and except where required by law:

(i) scientific integrity policies in each agency shall be governed by the scientific integrity policies that existed within the executive branch on January 19, 2021, except that in the event of a conflict between such policies and the policies and requirements of this order, the policies and requirements of this order control; and

(ii) agency heads shall take all necessary actions to reevaluate and, where necessary, revise or rescind scientific integrity policies or procedures, or amendments to such policies or procedures, issued between January 20, 2021, and January 20, 2025.

(iii) each agency head shall promptly revoke any organizational or operational changes, designations, or documents that were issued or enacted pursuant to the Presidential Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking), which was revoked pursuant to Executive Order 14154 and shall conduct applicable agency operations in the manner and revert applicable agency organization to the same form as would have existed in the absence of such changes, designations, or documents.

(b) In updating applicable scientific integrity policies pursuant to section 3 of this order, agencies should ensure they:

(i) encourage the open exchange of ideas;

(ii) provide for consideration of different or dissenting viewpoints; and

(iii) protect employees from efforts to prevent or deter consideration of alternative scientific opinions.

(c) Agencies, unless prohibited by law, shall review agency actions taken between January 20, 2021, and January 20, 2025, including regulations, guidance documents, policies, and scientific evaluations and take all appropriate steps, consistent with law, to ensure alignment with the policies and requirements of this order.

**Sec. 6. *Scope and Applicability.*** (a) The policies and rules set forth in this order apply to all employees involved in the generation, use, interpretation, or communication of scientific information, regardless of job classification, and to all agency decision-making, except where precluded by law.

(b) Agency heads and employees shall, to the extent practicable and consistent with applicable law, require agency contractors to adhere to these policies and rules as though they were agency employees.

(c) The policies and rules set forth in this order govern the use of science that informs agency decisions but they are not applicable to non-scientific aspects of agency decision-making.

**Sec. 7. *Enforcement and Oversight.*** (a) Each agency head shall establish internal processes to evaluate alleged violations of the requirements of this order and other applicable agency policies governing the generation, use, interpretation, and communication of scientific information. Such processes shall be the responsibility, and administered under the direction, of a senior appointee designated by the agency head and shall provide for taking appropriate measures to correct scientific information in response to violations, consistent with the requirements and procedures of section 515 of the statute

commonly known as the Information Quality Act, Public Law 106–554, appendix C (114 Stat. 2763A–153). The designated senior appointee may also forward potential violations to the relevant human resources officials for discipline to the extent the potential violation also violates applicable agency policies and procedures. The designated senior appointee may consult appropriate officials with scientific expertise when establishing such processes.

(b) The processes created under this section are, unless otherwise required by applicable law, the sole and exclusive means of evaluating and, as applicable, addressing alleged violations of this order and other agency policies governing the use, interpretation, and communication of scientific information.

**Sec. 8. *Waivers.*** (a) An agency head may request in writing that the OMB Director, in consultation with the OSTP Director, waive any of the requirements of this order for good cause shown. Such request must explain how the requested waiver is consistent with the policies and purposes of this order.

(b) Notwithstanding any other provision of this order, the policies and requirements of this order shall apply to agency actions that pertain to foreign or military affairs, or to a national security or homeland security function of the United States, only to the extent that the applicable agency head, in his or her sole and exclusive discretion, determines they should apply.

**Sec. 9. *General Provisions.*** (a) Nothing in this order shall be construed to impair or otherwise affect:

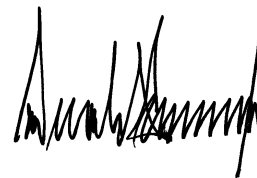
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Office of Management and Budget shall provide funding for publication of this order in the *Federal Register*.

A handwritten signature in black ink, appearing to be a stylized name, possibly 'Donald Trump', written in a cursive style.

THE WHITE HOUSE,  
May 23, 2025.

[FR Doc. 2025-09802  
Filed 5-28-25; 8:45 am]  
Billing code 3110-01-P

# Rules and Regulations

Federal Register

Vol. 90, No. 102

Thursday, May 29, 2025

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.

The Code of Federal Regulations is sold by the Superintendent of Documents.

## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

#### 7 CFR Part 3

[Docket No. USDA–2025–0007]

RIN 0503–AA83

#### Civil Monetary Penalty Inflation Adjustments for 2025

**AGENCY:** Office of the Secretary, USDA.  
**ACTION:** Final rule.

**SUMMARY:** This final rule amends the U.S. Department of Agriculture’s civil monetary penalty regulations by making inflation adjustments as mandated by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

**DATES:** Effective May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael Poe, Office of the General Counsel, USDA, 1400 Independence Avenue SW, Washington, DC 20250–1400, (202) 769–8247.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990, was signed into law to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act requires agencies to adjust for inflation annually.

This rule amends 7 CFR part 3 to update the amount of civil monetary penalties that may be levied by U.S. Department of Agriculture (USDA) agencies to reflect inflationary adjustments for 2025 in accordance with the 2015 Act. As required by the 2015 Act, the annual adjustment was made for inflation based on the Consumer Price Index for the month of October 2024 and rounded to the nearest dollar

after an initial adjustment. The civil monetary penalties are listed according to the applicable administering agency.

##### II. Notice and Comment Not Required

This rule is required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, with no issue of policy discretion. Accordingly, pursuant to the administrative procedure provisions in 5 U.S.C. 553, we find upon good cause that prior notice and other public procedure with respect to this action are not necessary. We also find good cause for making this action effective less than 30 days after publication in the **Federal Register**.

##### III. Procedural Requirements

###### *Executive Orders 12866 and 14192*

The Office of Management and Budget (OMB) has determined that this regulatory action does not meet the criteria for significant regulatory action pursuant to Executive Order 12866, Regulatory Planning and Review.

This rule contains inflation adjustments in compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The great majority of individuals, organizations, and entities participating in the programs affected by this regulation do not engage in prohibited activities and practices that would result in civil monetary penalties being incurred. Accordingly, we believe that any aggregate economic impact of this revised regulation will be minimal, affecting only the limited number of program participants that may engage in prohibited behavior in violation of the statutes. Moreover, USDA has determined that this revised regulation is expressly exempt from the requirements of Executive Order 14192, Unleashing Prosperity Through Deregulation, because it pertains to agency organization and management.

###### *Regulatory Flexibility Act*

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this final rule because USDA was not required to publish notice of proposed rulemaking under 5 U.S.C. 553 or any other law. Accordingly, a regulatory flexibility analysis is not required.

##### *Paperwork Reduction Act*

This final rule imposes no new reporting or recordkeeping requirements necessitating clearance by OMB.

##### List of Subjects in 7 CFR Part 3

Administrative practice and procedure, Claims, Government employees, Income taxes, Loan programs—agriculture, Penalties, Reporting and recordkeeping requirements, Wages.

Accordingly, we are amending 7 CFR part 3, subpart I, as follows:

#### PART 3—DEBT MANAGEMENT

##### Subpart I—Adjusted Civil Monetary Penalties

■ 1. The authority citation for part 3, subpart I, continues to read as follows:

**Authority:** 28 U.S.C. 2461 note.

■ 2. Section 3.91 is amended by revising paragraphs (a)(2) and (b) to read as follows:

##### § 3.91 Adjusted civil monetary penalties.

(a) \* \* \*

(2) *Timing.* Any increase in the dollar amount of a civil monetary penalty listed in paragraph (b) of this section applies only to violations occurring after May 29, 2025.

\* \* \* \* \*

(b) *Penalties*—(1) *Agricultural Marketing Service.* (i) Civil penalty for improper record keeping codified at 7 U.S.C. 136i–1(d), has: A maximum of \$1,182 in the case of the first offense, and a minimum of \$2,296 in the case of subsequent offenses, except that the penalty will be less than \$2,296 if the Secretary determines that the person made a good faith effort to comply.

(ii) Civil penalty for a violation of the unfair conduct rule under the Perishable Agricultural Commodities Act, in lieu of license revocation or suspension, codified at 7 U.S.C. 499b(5), has a maximum of \$6,435.

(iii) Civil penalty for violation of the licensing requirements under the Perishable Agricultural Commodities Act, codified at 7 U.S.C. 499c(a), has a maximum of \$2,054 for each such offense and not more than \$513 for each day it continues, or a maximum of \$513 for each offense if the Secretary determines the violation was not willful.

(iv) Civil penalty in lieu of license suspension under the Perishable Agricultural Commodities Act, codified at 7 U.S.C. 499h(e), has a maximum penalty of \$4,108 for each violative transaction or each day the violation continues.

(v) Civil penalty for a violation of the Export Apple Act, codified at 7 U.S.C. 586, has a minimum of \$187 and a maximum of \$18,767.

(vi) Civil penalty for a violation of the Export Grape and Plum Act, codified at 7 U.S.C. 596, has a minimum of \$358 and a maximum of \$35,910.

(vii) Civil penalty for a violation of an order issued by the Secretary under the Agricultural Adjustment Act, reenacted with amendments by the Agricultural Marketing Agreement Act of 1937, codified at 7 U.S.C. 608c(14)(B), has a maximum of \$3,592. Each day the violation continues is a separate violation.

(viii) Civil penalty for failure to file certain reports under the Agricultural Adjustment Act, reenacted by the Agricultural Marketing Agreement Act of 1937, codified at 7 U.S.C. 610(c), has a maximum of \$358.

(ix) Civil penalty for a violation of a seed program under the Federal Seed Act, codified at 7 U.S.C. 1596(b), has a minimum of \$122 and a maximum of \$2,449.

(x) Civil penalty for failure to collect any assessment or fee for a violation of the Cotton Research and Promotion Act, codified at 7 U.S.C. 2112(b), has a maximum of \$3,592.

(xi) Civil penalty for failure to pay, collect, or remit any assessment or fee for a violation of a program under the Potato Research and Promotion Act, codified at 7 U.S.C. 2621(b)(1), has a minimum of \$1,610 and a maximum of \$14,847.

(xii) Civil penalty for failure to obey a cease-and-desist order under the Potato Research and Promotion Act, codified at 7 U.S.C. 2621(b)(3), has a maximum of \$1,610. Each day the violation continues is a separate violation.

(xiii) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Egg Research and Consumer Information Act, codified at 7 U.S.C. 2714(b)(1), has a minimum of \$1,861 and a maximum of \$18,611.

(xiv) Civil penalty for failure to obey a cease-and-desist order under the Egg Research and Consumer Information Act, codified at 7 U.S.C. 2714(b)(3), has a maximum of \$1,861. Each day the violation continues is a separate violation.

(xv) Civil penalty for failure to remit any assessment or fee or for a violation of a program under the Beef Research and Information Act, codified at 7 U.S.C. 2908(a)(2), has a maximum of \$14,519.

(xvi) Civil penalty for failure to remit any assessment or for a violation of a program regarding wheat and wheat foods research, codified at 7 U.S.C. 3410(b), has a maximum of \$3,592.

(xvii) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Floral Research and Consumer Information Act, codified at 7 U.S.C. 4314(b)(1), has a minimum of \$1,691 and a maximum of \$16,899.

(xviii) Civil penalty for failure to obey a cease-and-desist order under the Floral Research and Consumer Information Act, codified at 7 U.S.C. 4314(b)(3), has a maximum of \$1,691. Each day the violation continues is a separate violation.

(xix) Civil penalty for violation of an order under the Dairy Promotion Program, codified at 7 U.S.C. 4510(b), has a maximum of \$3,124.

(xx) Civil penalty for pay, collect, or remit any assessment or fee or for a violation of the Honey Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 4610(b)(1), has a minimum of \$939 and a maximum of \$9,624.

(xxi) Civil penalty for failure to obey a cease-and-desist order under the Honey Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 4610(b)(3), has a maximum of \$961. Each day the violation continues is a separate violation.

(xxii) Civil penalty for a violation of a program under the Pork Promotion, Research, and Consumer Information Act of 1985, codified at 7 U.S.C. 4815(b)(1)(A)(i), has a maximum of \$2,905.

(xxiii) Civil penalty for failure to obey a cease-and-desist order under the Pork Promotion, Research, and Consumer Information Act of 1985, codified at 7 U.S.C. 4815(b)(3)(A), has a maximum of \$1,453. Each day the violation continues is a separate violation.

(xxiv) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Watermelon Research and Promotion Act, codified at 7 U.S.C. 4910(b)(1), has a minimum of \$1,453 and a maximum of \$14,519.

(xxv) Civil penalty for failure to obey a cease-and-desist order under the Watermelon Research and Promotion Act, codified at 7 U.S.C. 4910(b)(3), has a maximum of \$1,453. Each day the

violation continues is a separate violation.

(xxvi) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Pecan Promotion and Research Act of 1990, codified at 7 U.S.C. 6009(c)(1), has a minimum of \$2,364 and a maximum of \$23,634.

(xxvii) Civil penalty for failure to obey a cease-and-desist order under the Pecan Promotion and Research Act of 1990, codified at 7 U.S.C. 6009(e), has a maximum of \$2,362.

(xxviii) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Mushroom Promotion, Research, and Consumer Information Act of 1990, codified at 7 U.S.C. 6107(c)(1), has a minimum of \$1,149 and a maximum of \$11,489.

(xxix) Civil penalty for failure to obey a cease-and-desist order under the Mushroom Promotion, Research, and Consumer Information Act of 1990, codified at 7 U.S.C. 6107(e), has a maximum of \$1,149. Each day the violation continues is a separate violation.

(xxx) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of the Lime Research, Promotion, and Consumer Information Act of 1990, codified at 7 U.S.C. 6207(c)(1), has a minimum of \$1,149 and a maximum of \$11,489.

(xxxi) Civil penalty for failure to obey a cease-and-desist order under the Lime Research, Promotion, and Consumer Information Act of 1990, codified at 7 U.S.C. 6207(e), has a maximum of \$1,149. Each day the violation continues is a separate violation.

(xxxii) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Soybean Promotion, Research, and Consumer Information Act, codified at 7 U.S.C. 6307(c)(1)(A), has a maximum of \$2,364.

(xxxiii) Civil penalty for failure to obey a cease-and-desist order under the Soybean Promotion, Research, and Consumer Information Act, codified at 7 U.S.C. 6307(e), has a maximum of \$11,767. Each day the violation continues is a separate violation.

(xxxiv) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Fluid Milk Promotion Act of 1990, codified at 7 U.S.C. 6411(c)(1)(A), has a minimum of \$1,149 and a maximum of \$11,489, or in the case of a violation that is willful, codified at 7 U.S.C. 6411(c)(1)(B), has a minimum of \$22,576 and a maximum of \$229,739.

(xxxv) Civil penalty for failure to obey a cease-and-desist order under the Fluid Milk Promotion Act of 1990, codified at 7 U.S.C. 6411(e), has a maximum of \$11,823. Each day the violation continues is a separate violation.

(xxxvi) Civil penalty for knowingly labeling or selling a product as organic except in accordance with the Organic Foods Production Act of 1990, codified at 7 U.S.C. 6519(c), has a maximum of \$22,974.

(xxxvii) Civil penalty for failure to pay, collect, or remit any assessment or fee or for a violation of a program under the Fresh Cut Flowers and Fresh Cut Greens Promotion and Information Act of 1993, codified at 7 U.S.C. 6808(c)(1)(A)(i), has a minimum of \$1,083 and a maximum of \$10,831.

(xxxviii) Civil penalty for failure to obey a cease-and-desist order under the Fresh Cut Flowers and Fresh Cut Greens Promotion and Information Act of 1993, codified at 7 U.S.C. 6808(e)(1), has a maximum of \$10,831. Each day the violation continues is a separate violation.

(xxxix) Civil penalty for a violation of a program under the Sheep Promotion, Research, and Information Act of 1994, codified at 7 U.S.C. 7107(c)(1)(A), has a maximum of \$2,111.

(xl) Civil penalty for failure to obey a cease-and-desist order under the Sheep Promotion, Research, and Information Act of 1994, codified at 7 U.S.C. 7107(e), has a maximum of \$1,055. Each day the violation continues is a separate violation.

(xli) Civil penalty for a violation of an order or regulation issued under the Commodity Promotion, Research, and Information Act of 1996, codified at 7 U.S.C. 7419(c)(1), has a minimum of \$1,992 and a maximum of \$19,939 for each violation.

(xlii) Civil penalty for failure to obey a cease-and-desist order under the Commodity Promotion, Research, and Information Act of 1996, codified at 7 U.S.C. 7419(e), has a minimum of \$1,992 and a maximum of \$19,939. Each day the violation continues is a separate violation.

(xliii) Civil penalty for a violation of an order or regulation issued under the Canola and Rapeseed Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 7448(c)(1)(A)(i), has a maximum of \$1,992 for each violation.

(xliv) Civil penalty for failure to obey a cease-and-desist order under the Canola and Rapeseed Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 7448(e), has a maximum of \$9,970. Each day the

violation continues is a separate violation.

(xlv) Civil penalty for violation of an order or regulation issued under the National Kiwifruit Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 7468(c)(1), has a minimum of \$998 and a maximum of \$9,970 for each violation.

(xlvi) Civil penalty for failure to obey a cease-and-desist order under the National Kiwifruit Research, Promotion, and Consumer Information Act, codified at 7 U.S.C. 7468(e), has a maximum of \$998. Each day the violation continues is a separate violation.

(xlvii) Civil penalty for a violation of an order or regulation under the Popcorn Promotion, Research, and Consumer Information Act, codified at 7 U.S.C. 7487(a), has a maximum of \$1,992 for each violation.

(xlviii) Civil penalty for certain violations under the Egg Products Inspection Act, codified at 21 U.S.C. 1041(c)(1)(A), has a maximum of \$11,489 for each violation.

(xlix) Civil penalty for violation of an order or regulation issued under the Hass Avocado Promotion, Research, and Information Act of 2000, codified at 7 U.S.C. 7807(c)(1)(A)(i), has a minimum of \$1,812 and a maximum of \$18,124 for each violation.

(l) Civil penalty for failure to obey a cease-and-desist order under the Hass Avocado Promotion, Research, and Information Act of 2000, codified at 7 U.S.C. 7807(e)(1), has a maximum of \$18,141 for each offense. Each day the violation continues is a separate violation.

(li) Civil penalty for violation of certain provisions of the Livestock Mandatory Reporting Act of 1999, codified at 7 U.S.C. 1636b(a)(1), has a maximum of \$18,767 for each violation.

(lii) Civil penalty for failure to obey a cease-and-desist order under the Livestock Mandatory Reporting Act of 1999, codified at 7 U.S.C. 1636b(g)(3), has a maximum of \$18,767 for each violation. Each day the violation continues is a separate violation.

(liii) Civil penalty for failure to obey an order of the Secretary issued pursuant to the Dairy Product Mandatory Reporting program, codified at 7 U.S.C. 1637b(c)(4)(D)(iii), has a maximum of \$18,141 for each offense.

(liv) Civil penalty for a willful violation of the Country of Origin Labeling program by a retailer or person engaged in the business of supplying a covered commodity to a retailer, codified at 7 U.S.C. 1638b(b)(2), has a maximum of \$1,458 for each violation.

(lv) Civil penalty for violations of the Dairy Research Program, codified at 7

U.S.C. 4535 and 4510(b), has a maximum of \$3,124 for each violation.

(lvi) Civil penalty for a packer or swine contractor violation, codified at 7 U.S.C. 193(b), has a maximum of \$35,904.

(lvii) Civil penalty for a livestock market agency or dealer failure to register, codified at 7 U.S.C. 203, has a maximum of \$2,448 and not more than \$122 for each day the violation continues.

(lviii) Civil penalty for operating without filing, or in violation of, a stockyard rate schedule, or of a regulation or order of the Secretary made thereunder, codified at 7 U.S.C. 207(g), has a maximum of \$2,449 and not more than \$122 for each day the violation continues.

(lix) Civil penalty for a stockyard owner, livestock market agency, or dealer, who engages in or uses any unfair, unjustly discriminatory, or deceptive practice or device in connection with determining whether persons should be authorized to operate at the stockyards, or with receiving, marketing, buying, or selling on a commission basis or otherwise, feeding, watering, holding, delivery, shipment, weighing, or handling of livestock, codified at 7 U.S.C. 213(b), has a maximum of \$35,904.

(lx) Civil penalty for a stockyard owner, livestock market agency, or dealer, who knowingly fails to obey any order made under the provisions of 7 U.S.C. 211, 212, or 213, codified at 7 U.S.C. 215(a), has a maximum of \$2,449.

(lxi) Civil penalty for live poultry dealer violations, codified at 7 U.S.C. 228b–2(b), has a maximum of \$104,446.

(lxii) Civil penalty for a violation, codified at 7 U.S.C. 86(c), has a maximum of \$350,870.

(lxiii) Civil penalty for failure to comply with certain provisions of the U.S. Warehouse Act, codified at 7 U.S.C. 254, has a maximum of \$45,354 per violation if an agricultural product is not involved in the violation.

(2) *Animal and Plant Health Inspection Service.* (i) Civil penalty for a violation of the imported seed provisions of the Federal Seed Act, codified at 7 U.S.C. 1596(b), has a minimum of \$122 and a maximum of \$2,449.

(ii) Civil penalty for a violation of the Animal Welfare Act, codified at 7 U.S.C. 2149(b), has a maximum of \$14,575, and knowing failure to obey a cease-and-desist order has a civil penalty of \$2,185.

(iii) Civil penalty for any person that causes harm to, or interferes with, an animal used for the purposes of official inspection by USDA, codified at 7

U.S.C. 2279e(a), has a maximum of \$18,141.

(iv) Civil penalty for a violation of the Swine Health Protection Act, codified at 7 U.S.C. 3805(a), has a maximum of \$36,461.

(v) Civil penalty for any person that violates the Plant Protection Act (PPA), or that forges, counterfeits, or, without authority from the Secretary, uses, alters, defaces, or destroys any certificate, permit, or other document provided for in the PPA, codified at 7 U.S.C. 7734(b)(1), has a maximum of the greater of: \$90,708 in the case of any individual (except that the civil penalty may not exceed \$1,813 in the case of an initial violation of the PPA by an individual moving regulated articles not for monetary gain), \$453,537 in the case of any other person for each violation, \$728,765 for all violations adjudicated in a single proceeding if the violations do not include a willful violation, and \$1,457,528 for all violations adjudicated in a single proceeding if the violations include a willful violation; or twice the gross gain or gross loss for any violation, forgery, counterfeiting, unauthorized use, defacing, or destruction of a certificate, permit, or other document provided for in the PPA that results in the person deriving pecuniary gain or causing pecuniary loss to another.

(vi) Civil penalty for any person (except as provided in 7 U.S.C. 8309(d)) that violates the Animal Health Protection Act (AHPA), or that forges, counterfeits, or, without authority from the Secretary, uses, alters, defaces, or destroys any certificate, permit, or other document provided under the AHPA, codified at 7 U.S.C. 8313(b)(1), has a maximum of the greater of: \$87,055 in the case of any individual, except that the civil penalty may not exceed \$1,741 in the case of an initial violation of the AHPA by an individual moving regulated articles not for monetary gain, \$435,273 in the case of any other person for each violation, \$728,765 for all violations adjudicated in a single proceeding if the violations do not include a willful violation, and \$1,457,528 for all violations adjudicated in a single proceeding if the violations include a willful violation; or twice the gross gain or gross loss for any violation, forgery, counterfeiting, unauthorized use, defacing, or destruction of a certificate, permit, or other document provided under the AHPA that results in the person's deriving pecuniary gain or causing pecuniary loss to another person.

(vii) Civil penalty for any person that violates certain regulations under the Agricultural Bioterrorism Protection Act of 2002 regarding transfers of listed

agents and toxins or possession and use of listed agents and toxins, codified at 7 U.S.C. 8401(i)(1), has a maximum of \$435,273 in the case of an individual and \$870,550 in the case of any other person.

(viii) Civil penalty for violation of the Horse Protection Act, codified at 15 U.S.C. 1825(b)(1), has a maximum of \$7,183.

(ix) Civil penalty for failure to obey Horse Protection Act disqualification, codified at 15 U.S.C. 1825(c), has a maximum of \$14,037.

(x) Civil penalty for knowingly violating, or, if in the business as an importer or exporter, violating, with respect to terrestrial plants, any provision of the Endangered Species Act of 1973, any permit or certificate issued thereunder, or any regulation issued pursuant to section 9(a)(1)(A) through (F), (a)(2)(A) through (D), (c), (d) (other than regulations relating to record keeping or filing reports), (f), or (g), as specified at 16 U.S.C. 1540(a)(1), has a maximum of \$65,656 for each violation.

(xi) Civil penalty for knowingly violating, or, if in the business as an importer or exporter, violating, with respect to terrestrial plants, any other regulation under the Endangered Species Act of 1973, as specified at 16 U.S.C. 1540(a)(1), has a maximum of \$31,441 for each violation.

(xii) Civil penalty for violating, with respect to terrestrial plants, the Endangered Species Act of 1973, or any regulation, permit, or certificate issued thereunder, as specified at 16 U.S.C. 1540(a)(1), has a maximum of \$1,657 for each violation.

(xiii) Civil penalty for knowingly and willfully violating 49 U.S.C. 80502 with respect to the transportation of animals by any rail carrier, express carrier, or common carrier (except by air or water), a receiver, trustee, or lessee of one of those carriers, or an owner or master of a vessel, codified at 49 U.S.C. 80502(d), has a minimum of \$206 and a maximum of \$1,055.

(xiv) Civil penalty for a violation of the Commercial Transportation of Equine for Slaughter Act, 7 U.S.C. 1901 note, and its implementing regulations in 9 CFR part 88, as specified in 9 CFR 88.6, has a maximum of \$6,240. Each horse transported in violation of 9 CFR part 88 is a separate violation.

(xv) Civil penalty for knowingly violating section 3(d) or 3(f) of the Lacey Act Amendments of 1981, or for violating any other provision provided that, in the exercise of due care, the violator should have known that the plant was taken, possessed, transported, or sold in violation of any underlying law, treaty, or regulation, has a

maximum of \$32,648 for each violation, as specified in 16 U.S.C. 3373(a)(1) (but if the plant has a market value of less than \$436, and involves only the transportation, acquisition, or receipt of a plant taken or possessed in violation of any law, treaty, or regulation of the United States, any Indian Tribal law, any foreign law, or any law or regulation of any State, the penalty will not exceed the maximum provided for violation of said law, treaty, or regulation, or \$32,648, whichever is less).

(xvi) Civil penalty for violating section 3(f) of the Lacey Act Amendments of 1981, as specified in 16 U.S.C. 3373(a)(2), has a maximum of \$816.

(3) *Food and Nutrition Service.* (i) Civil penalty for violating a provision of the Food and Nutrition Act of 2008 (Act), or a regulation under the Act, by a retail food store or wholesale food concern, codified at 7 U.S.C. 2021(a) and (c), has a maximum of \$145,754 for each violation.

(ii) Civil penalty for trafficking in food coupons, codified at 7 U.S.C. 2021(b)(3)(B), has a maximum of \$52,522 for each violation, except that the maximum penalty for violations occurring during a single investigation is \$94,578.

(iii) Civil penalty for the sale of firearms,ammunitions, explosives, or controlled substances for coupons, codified at 7 U.S.C. 2021(b)(3)(C), has a maximum of \$47,289 for each violation, except that the maximum penalty for violations occurring during a single investigation is \$94,578.

(iv) Civil penalty for any entity that submits a bid to supply infant formula to carry out the Special Supplemental Nutrition Program for Women, Infants and Children and discloses the amount of the bid, rebate, or discount practices in advance of the bid opening or for any entity that makes a statement prior to the opening of bids for the purpose of influencing a bid, codified at 42 U.S.C. 1786(h)(8)(H)(i), has a maximum of \$222,610,188.

(v) Civil penalty for a vendor convicted of trafficking in food instruments, codified at 42 U.S.C. 1786(o)(1)(A) and 42 U.S.C. 1786(o)(4)(B), has a maximum of \$19,247 for each violation, except that the maximum penalty for violations occurring during a single investigation is \$76,992.

(vi) Civil penalty for a vendor convicted of selling firearms,ammunition, explosive, or controlled substances in exchange for food instruments, codified at 42 U.S.C. 1786(o)(1)(B) and 42 U.S.C. 1786(o)(4)(B), has a maximum of

\$18,774 for each violation, except that the maximum penalty for violations occurring during a single investigation is \$76,992.

(4) *Food Safety and Inspection Service*. (i) Civil penalty for certain violations under the Egg Products Inspection Act, codified at 21 U.S.C. 1041(c)(1)(A), has a maximum of \$11,489 for each violation.

(ii) [Reserved]

(5) *Forest Service*. (i) Civil penalty for willful disregard of the prohibition against the export of unprocessed timber originating from Federal lands, codified at 16 U.S.C. 620d(c)(1)(A), has a maximum of \$1,182,251 per violation or three times the gross value of the unprocessed timber, whichever is greater.

(ii) Civil penalty for a violation in disregard of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified in 16 U.S.C. 620d(c)(2)(A)(i), has a maximum of \$177,360 per violation.

(iii) Civil penalty for a person that should have known that an action was a violation of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified at 16 U.S.C. 620d(c)(2)(A)(ii), has a maximum of \$118,225 per violation.

(iv) Civil penalty for a willful violation of the Forest Resources Conservation and Shortage Relief Act or the regulations that implement such Act regardless of whether such violation caused the export of unprocessed timber originating from Federal lands, codified in 16 U.S.C. 620d(c)(2)(A)(iii), has a maximum of \$1,182,251.

(v) Civil penalty for a violation involving protections of caves, codified at 16 U.S.C. 4307(a)(2), has a maximum of \$25,838.

(6) [Reserved]

(7) *Federal Crop Insurance Corporation*. (i) Civil penalty for any person who willfully and intentionally provides any false or inaccurate information to the Federal Crop Insurance Corporation or to an approved insurance provider with respect to any insurance plan or policy that is offered under the authority of the Federal Crop Insurance Act, or who fails to comply with a requirement of the Federal Crop Insurance Corporation, codified in 7 U.S.C. 1515(h)(3)(A), has a maximum of the greater of: The amount of the pecuniary gain obtained as a result of

the false or inaccurate information or the noncompliance; or \$15,335.

(ii) [Reserved]

(8) *Rural Housing Service*. (i) Civil penalty for a violation of section 536 of Title V of the Housing Act of 1949, codified in 42 U.S.C. 1490p(e)(2), has a maximum of \$251,321 in the case of an individual, and a maximum of \$2,513,215 in the case of an applicant other than an individual.

(ii) Civil penalty for equity skimming under section 543(a) of the Housing Act of 1949, codified in 42 U.S.C. 1490s(a)(2), has a maximum of \$45,354.

(iii) Civil penalty under section 543b of the Housing Act of 1949 for a violation of regulations or agreements made in accordance with Title V of the Housing Act of 1949, by submitting false information, submitting false certifications, failing to timely submit information, failing to maintain real property in good repair and condition, failing to provide acceptable management for a project, or failing to comply with applicable civil rights laws and regulations, codified in 42 U.S.C. 1490s(b)(3)(A), has a maximum of the greater of: Twice the damages USDA, guaranteed lender, or project that is secured for a loan under Title V suffered or would have suffered as a result of the violation; or \$90,708 per violation.

(9) [Reserved]

(10) *Commodity Credit Corporation*. (i) Civil penalty for willful failure or refusal to furnish information, or willful furnishing of false information under of section 156 of the Federal Agricultural Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$19,940 for each violation.

(ii) Civil penalty for willful failure or refusal to furnish information or willful furnishing of false data by a processor, refiner, or importer of sugar, syrup, and molasses under section 156 of the Federal Agriculture Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$19,940 for each violation.

(iii) Civil penalty for filing a false acreage report that exceeds tolerance under section 156 of the Federal Agriculture Improvement and Reform Act of 1996, codified at 7 U.S.C. 7272(g)(5), has a maximum of \$19,940 for each violation.

(iv) Civil penalty for knowingly violating any regulation of the Secretary of the Commodity Credit Corporation pertaining to flexible marketing allotments for sugar under section 359h(b) of the Agricultural Adjustment Act of 1938, codified at 7 U.S.C. 1359hh(b), has a maximum of \$14,575 for each violation.

(v) Civil penalty for knowing violation of regulations promulgated by the Secretary pertaining to cotton insect eradication under section 104(d) of the Agricultural Act of 1949, codified at 7 U.S.C. 1444a(d), has a maximum of \$17,956 for each offense.

(11) *Office of the Secretary*. (i) Civil penalty for making, presenting, submitting or causing to be made, presented or submitted, a false, fictitious, or fraudulent claim as defined under the Program Fraud Civil Remedies Act of 1986, codified at 31 U.S.C. 3802(a)(1), has a maximum of \$14,309.

(ii) Civil penalty for making, presenting, submitting or causing to be made, presented or submitted, a false, fictitious, or fraudulent written statement as defined under the Program Fraud Civil Remedies Act of 1986, codified at 31 U.S.C. 3802(a)(2), has a maximum of \$14,309.

**Christopher Nelson,**

*Acting Director, United States Department of Agriculture, Office of Budget and Program Analysis.*

[FR Doc. 2025-09614 Filed 5-28-25; 8:45 am]

**BILLING CODE 3410-90-P**

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 29

[Doc. No. AMS-CN-25-0028]

RIN 0581-AE40

#### Tobacco Grading and Inspections Services—Rescission of Tobacco Quota Provisions

**AGENCY:** Agricultural Marketing Service (AMS), Department of Agriculture (USDA)

**ACTION:** Direct final rule.

**SUMMARY:** This direct final rule amends regulations that govern the inspection of tobacco under the national marketing quota system established under the Agricultural Adjustment Act of 1938. The Fair and Equitable Tobacco Reform Act of 2004 eliminated the price support and quota system for tobacco produced in the United States. In alignment with E.O. 14192, AMS is removing and, where appropriate, amending regulations that have expired authorizing statutes and govern non-operational programs.

**DATES:** This direct final rule is effective July 28, 2025, without further action or notice, unless a significant adverse comment is received by June 30, 2025. If a significant adverse comment is

received, AMS will publish in the **Federal Register** a withdrawal of this direct final rule prior to the effective date.

**ADDRESSES:** Comments can be submitted electronically at <https://www.regulations.gov> by searching the docket number listed above. Interested persons are invited to submit written comments concerning this direct final rule. Comments may also be submitted by mail or hand delivery to USDA AMS Cotton and Tobacco Program, 3275 Appling Road, Memphis, TN 38133. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this direct final rule will be included in the record and will be made available to the public at: <https://www.regulations.gov>. Public comments are posted without change. Any identifying information submitted with these comments will also be publicly available.

**FOR FURTHER INFORMATION CONTACT:** Angie Snyder, Deputy Administrator, USDA AMS Cotton and Tobacco Program, 3275 Appling Road, Memphis, TN 38133; Telephone: (901) 384-3000; Email: [angie.snyder@usda.gov](mailto:angie.snyder@usda.gov).

**SUPPLEMENTARY INFORMATION:** Part I of subtitle B of title III of the Agricultural Adjustment Act of 1938 (7 U.S.C. 1311 *et seq.*) authorized the establishment of a national marketing quota program for tobacco to facilitate the orderly marketing of tobacco, thus avoiding abnormally excessive supplies being produced and dumped indiscriminately on the Nation-wide market. However, the Fair and Equitable Tobacco Reform Act of 2004 (sec. 611(b), Pub. L. 108-357, 118 Stat. 1522; Oct. 22, 2004) eliminated the price support and quota system for tobacco produced in the United States as well as mandatory grading of types of tobacco eligible for price support.

AMS's regulations governing tobacco marketed under the quota program are contained in 7 CFR 29. Upon reviewing these regulations in light of changes to the law and in alignment with Executive Order 14192, AMS has determined that regulations in 7 CFR part 29 pertaining to the obsolete market quota program should be removed and, where appropriate, amended.

AMS is removing the statutory authorities listed under this subpart B heading since these authorities are redundant—already cited under the heading for part 29. Paragraph (2) under paragraph (a) of § 29.47a is amended to remove provisions directly related to market quota provisions. Likewise, paragraph (6) under paragraph (a) of

§ 29.47a are removed as they directly pertain to market quota provisions.

AMS is removing redundant and obsolete statutory authorities listed under subpart C heading.

The language in the heading of subpart F is amended to remove references to obsolete market quota program, and the obsolete statutory authorities listed under this subpart heading are being removed. Multiple sections throughout subpart F, including §§ 29.9207, 29.9221, 29.9240, and 29.9261–9262, are being removed as they pertain to the obsolete market quota program. Lastly, §§ 29.9232–9234, and 29.9236, are amended by removing the word “nonquota,” and § 29.9241 is amended by removing the phrase “with no other quota, nonquota.”

Given that AMS has not provided services related to the tobacco quota program in twenty years, there are no known costs or benefits associated with removing AMS's regulations governing tobacco marketed under the quota program. Mandatory inspection and grading of tobacco subject to marketing quota were user-fee based services, which are services paid for by the industry through fees. Fee rates for tobacco inspection and grading services were set such that all costs associated with these services were covered by revenues generated from providing these services. To the extent there is any uncertainty about the costs and benefits of these regulations, it is the policy of USDA to err on the side of deregulation and focus resources on fairly and rationally enforcing a discrete and manageable number of regulations.

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with prior notice and comment for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without first publishing a proposed rule. Removing regulations pertaining to tobacco market quotas and making conforming amendments will provide transparency and may reduce confusion for tobacco producers and other stakeholders. Further, AMS views this action as noncontroversial and anticipates no adverse public comment. This rule will become effective, as published in this document, July 28, 2025 without further action, unless adverse comments are received on or before June 30, 2025. Adverse comments are considered to be those comments that suggest the rule should not be

adopted or suggest the rule should be changed.

If AMS receives adverse comments, we will publish a document in the **Federal Register**, withdrawing this rule before the effective date. AMS will then publish a proposed rule for public comment. Following the close of that comment period, the comments will be considered, and a final rule addressing the comments will be published.

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), AMS certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. AMS has not provided services related to the tobacco quota program in twenty years. The amendments made by the direct final rule will merely conform the CFR with AMS' current operating practices. This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by OMB. There are no current information collections associated with the regulations related to the tobacco market quota program.

USDA has determined that there is no reliance interest in obsolete regulations. Moreover, regardless of the lawfulness, USDA has no interest in maintaining regulations that have expired authorizing statutes or govern non-operational programs. Maintaining regulations pertaining to the obsolete tobacco market quota program in 7 CFR part 29 are not a priority. Therefore, AMS is amending 7 CFR 29 to remove, and where appropriate, references and provisions pertaining to mandatory inspection and grading required by the obsolete market quota program.

#### List of Subjects in 7 CFR Part 29

Administrative practice and procedure, Advisory committees, Government publications, Imports, Pesticides and pests, Reporting and recordkeeping requirements, Tobacco.

For the reasons set forth in the preamble, AMS amends 7 CFR part 29 as follows:

#### PART 29—TOBACCO INSPECTION

- 1. The authority citation for part 29 continues to read as follows:

**Authority:** 7 U.S.C. 511–511s.

#### Subpart B—[Amended]

- 2. Remove the authority citation to subpart B.

#### § 29.74a [Amended]

- 3. Amend § 29.74a by:
  - a. Removing the last sentence of paragraph (a)(2) and;

- b. Removing paragraph (a)(6).

#### Subpart C—[Amended]

- 4. Remove the authority citation to subpart C.

#### Subpart F—Policy Statement and Provisions Governing the Identification and Certification of Tobacco

- 5. Revise the heading to subpart F to read as set forth above.
- 6. Remove the authority citation to subpart F.

#### § 29.9204 [Amended]

- 7. Amend § 29.9204 by removing the word “nonquota.”

#### § 29.9207 [Removed]

- 8. Remove § 29.9207.

#### § 29.9221 [Removed]

- 9. Remove the undesignated heading “POLICY STATEMENT” and § 29.9221.
- 10. Revise § 29.9232 to read as follows:

#### § 29.9232 Where certification is available.

Tobacco may be inspected and certified by class or type, upon request of an interested party, when the tobacco is displayed at an approved receiving station where the tobacco is accessible to the inspector.

#### §§ 29.9233, 29.9234, and 29.9236 [Amended]

- 11. Amend §§ 29.9233, 29.9234, and 29.9236 by removing the word “nonquota” wherever it appears.

#### § 29.9240 [Removed]

- 12. Remove § 29.9240.
- 13. Amend § 29.9241 by revising the second sentence to read as follows:

#### § 29.9241 Accessibility of tobacco.

\* \* \* Each croplot shall be displayed at an approved receiving station in a continuous and orderly sequence with no other producer’s tobacco in between.  
\* \* \*

#### §§ 29.9261 and 29.9262 [Removed]

- 14. Remove §§ 29.9261 and 29.9262.

**Bruce Summers,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2025–09550 Filed 5–28–25; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF AGRICULTURE

### Farm Service Agency

#### 7 CFR Parts 750, 760, 784, and 795

RIN 0560–AI76

#### Removal of Obsolete Regulations

**AGENCY:** Farm Service Agency (FSA), Department of Agriculture.

**ACTION:** Final rule.

**SUMMARY:** FSA is in the process of reviewing all regulations within its purview to reduce regulatory burdens and costs. Pursuant to this review, FSA has identified the following obsolete, unnecessary, and outdated provisions. FSA is removing these provisions to streamline and clarify the dictates of FSA regulations. The changes in this rule will have no impact on past or present FSA customers.

**DATES:** *Effective Date:* This rule is effective May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Sherrie Grimm; telephone: (202) 401–0062; email: *Sherrie.Grimm@usda.gov*. Individuals with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice and text telephone (TTY mode)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone).

#### SUPPLEMENTARY INFORMATION:

##### Background

The President’s Executive Order 14219 of February 19, 2025, *Ensuring Lawful Governance and Implementing the President’s “Department of Government Efficiency” Deregulatory Initiative*, 90 FR 10583, and subsequent implementing memorandum directed all agency heads to review regulations within their purview and rescind those that are, among other things, unlawful or unnecessary. FSA has undertaken such a review and is accordingly rescinding the following provisions from title 7 of the Code of Federal Regulations.

##### Regulatory Certifications

###### *Executive Orders*

This document does not meet the criteria for a significant regulatory action as specified by Executive Order (E.O.) 12866. This action also has no federalism or tribal implications and will not impose substantial unreimbursed compliance costs on States, local governments, or Indian Tribal governments. Therefore, impact

statements are not required under E.O. 13132 or 13175.

###### *Environmental Evaluation*

This rule will have no significant effect on the human environment; therefore, neither an environmental assessment nor impact statement is required.

###### *Paperwork Reduction Act*

This rule does not contain reporting or recordkeeping requirements subject to the Paperwork Reduction Act.

##### Explanation of Provisions

The regulations removed are:

###### *Soil Bank (7 CFR Part 750)*

The regulations at 7 CFR part 750, published at 21 FR 6289 and redesignated by 26 FR 5788, are no longer carried in the CFR. Thus, for the reasons explained in the preamble, FSA is eliminating this part to streamline title 7.

###### *Indemnity Payment Programs (7 CFR Part 760)*

For the reasons described in the preamble, FSA is eliminating the regulations for the Tree Assistance Program (TAP) and the Supplemental Revenue Assistance Payments Program (SURE) codified at 7 CFR part 760 subpart F and subpart G, respectively.

The TAP regulations in 760 subpart F are obsolete as the operative assistance program regulations have been moved to 7 CFR part 1416 subpart E. The regulations in 760 subpart G are obsolete as the time to claim eligible losses under the SURE has passed.

###### *2004 Ewe Lamb Replacement and Retention Payment Program (7 CFR Part 784)*

For the reasons described in the preamble, FSA is eliminating the regulations codified at 7 CFR part 784 related to the 2004 Ewe Lamb Replacement and Retention Payment Program. This 2004 program, authorized by Section 32 of the Act of August 24, 1935, as amended, is no longer available as all funds have been used. The regulations at 7 CFR part 784 implementing the program are therefore obsolete and unnecessary.

###### *Payment Limitations (7 CFR Part 795)*

For the purposes outlined in the preamble, FSA is rescinding the payment limitations codified at 7 CFR Part 795.

Part 795 formerly described the payment limitations applicable to certain FSA programs. However, the current payment limitations are set forth

at 7 CFR part 1400. The regulations in part 795 are accordingly obsolete and unnecessary. Since part 795 is the only part remaining in subchapter E, FSA is also removing and reserving that subchapter.

#### List of Subjects

##### 7 CFR Part 750

Grant programs—agriculture, Grant programs—natural resources, Soil conservation, Water resources, Wildlife.

##### 7 CFR Part 760

Acreage allotments, Dairy products, Indemnity payments, Pesticides and pests, Reporting and recordkeeping requirements.

##### 7 CFR Part 784

Administrative practice and procedure, Agriculture, Livestock, Meat and meat products, Price support programs, Reporting and Recordkeeping Requirements.

##### 7 CFR Part 795

Price support programs, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, and under the authority of 5 U.S.C. 553 and as set forth below, FSA amends 7 CFR chapter VII as follows:

#### Title 7—AGRICULTURE

##### Part 750—[Removed and Reserved]

- 1. Remove and reserve part 750.

##### Part 760—INDEMNITY PAYMENT PROGRAMS

- 2. The authority citation for part 760 continues to read as follows:

**Authority:** 7 U.S.C. 4501 and 1531; 16 U.S.C. 3801, note; 19 U.S.C. 2497; Title III, Pub. L. 109–234, 120 Stat. 474; Title IX, Pub. L. 110–28, 121 Stat. 211; Sec. 748, Pub. L. 111–80, 123 Stat. 2131; Title I, Pub. L. 115–123, 132 Stat. 65; Title I, Pub. L. 116–20, 133 Stat. 871; Division B, Title VII, Pub. L. 116–94, 133 Stat. 2658; Title I, Pub. L. 117–43, 135 Stat. 356; and Division N, Title I, Pub. L. 117–328.

##### Subparts F through G—[Removed and Reserved]

- 3. Remove and reserve subparts F and G.

##### Part 784—[Removed and Reserved]

- 4. Remove and reserve part 784.

##### Subchapter E—[Removed and Reserved]

- 5. Remove and reserve subchapter E.

**William Beam,**

*Administrator, Farm Service Agency.*

[FR Doc. 2025–09617 Filed 5–28–25; 8:45 am]

**BILLING CODE 3411–E2–P**

#### DEPARTMENT OF AGRICULTURE

##### Farm Service Agency

##### 7 CFR Part 760

**RIN 0560–AI73**

**[Docket ID FSA–2025–0005]**

##### Emergency Livestock Relief Program (ELRP) 2023 and 2024

**AGENCY:** Farm Service Agency, U.S. Department of Agriculture (USDA).

**ACTION:** Final rule.

**SUMMARY:** The Secretary of Agriculture is issuing this rule to implement the Emergency Livestock Relief Program (ELRP) 2023 and 2024, which provides payments to eligible livestock producers for losses due to qualifying drought and qualifying wildfire occurring in calendar years 2023 and 2024. This rule specifies the administrative provisions, eligibility requirements, and payment calculation for ELRP 2023 and 2024. The Farm Service Agency (FSA) will calculate payments using data already submitted to FSA by Livestock Forage Disaster Program (LFP) participants; therefore, producers are not required to file an additional application to receive ELRP 2023 and 2024 payments.

**DATES:** This rule is effective on May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Kathy Sayers; telephone: (202) 720–6870; email: [Kathy.Sayers@usda.gov](mailto:Kathy.Sayers@usda.gov).

Individuals with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice and text telephone (TTY mode)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone).

##### SUPPLEMENTARY INFORMATION:

##### Background

Title I of the Disaster Relief Supplemental Appropriations Act, 2025 (Division B of the American Relief Act, 2025; Pub. L. 118–158; referred to as “the Act” in this document) provides \$30,780,000,000, to remain available until expended, for necessary expenses related to losses of revenue, quality or

production of crops (including milk, on-farm stored commodities, crops prevented from planting, and harvested adulterated wine grapes), trees, bushes, and vines, as a consequence of droughts, wildfires, hurricanes, floods, derechos, excessive heat, tornadoes, winter storms, freeze, including a polar vortex, smoke exposure, and excessive moisture occurring in calendar years 2023 and 2024. From that amount, the Act directs the Secretary of Agriculture to use up to \$2 billion to provide assistance to livestock producers, as determined by the Secretary, for losses incurred during calendar years 2023 and 2024 due to drought, wildfires, or floods.

This rule specifies how FSA will implement ELRP 2023 and 2024, which will use approximately \$1 billion of the \$2 billion provided by the Act to provide financial assistance to eligible livestock producers for losses incurred during 2023 and 2024. Payments will be made to offset foregone profits resulting from the loss of quality and quantity of forage due to qualifying drought and qualifying wildfires, using a streamlined process as described below. Livestock producer losses due to flooding which will be addressed in a later rule. If funding remains available after issuing assistance for flooding, FSA may make additional payments to ELRP 2023 and 2024 participants.

According to USDA National Agricultural Statistics Service (NASS) data, average corn prices have steadily decreased and livestock prices have increased since September 2022, meaning that margins have substantially increased.<sup>1</sup> This trend would normally cause producers to maintain or expand their livestock operations. NASS data, however, indicate that livestock inventories, particularly beef cattle, have steadily decreased since 2018.<sup>2</sup>

<sup>1</sup> See the ELRP 2023 and 2024 Cost Benefit Analysis (CBA). To obtain a copy of the ELRP 2023 and 2024 CBA, search by docket number FSA–2025–0005 using the search box on <https://www.regulations.gov/>.

<sup>2</sup> Overall, 2018 represents a stable and typical production year for the livestock sector compared to certain other recent years. Cattle inventories in 2018 were approximately 8 percent higher than in the drought-affected years of 2023–2024, while beef prices were significantly lower, about 50–60 percent less than in 2023–24. This comparison highlights that producers were able to maintain large herd sizes despite relatively moderate price incentives, suggesting that grazing conditions allowed for sustainable herd management. Despite substantially higher beef margins in 2023–24, cattle inventories have not returned to, or surpassed, the high levels of 2018. This is not due to economics, but rather, the diminished grazing capacity resulting from ongoing drought. The reduced availability of pastureland has directly constrained producers’ ability to maintain herd sizes, even in the face of highly favorable market conditions. By choosing 2018 as the baseline, this analysis

despite cattle prices increasing over 60 percent during that period.<sup>3</sup> With limited grazing capacity caused by drought and wildfires, livestock producers were unable to expand and take advantage of increased margins.<sup>4</sup>

Drought and wildfires in the 2023 and 2024 calendar years, particularly in the western United States, have had a significantly negative impact on:

- Forage availability and quality—decreased grazing options equated to reduced carrying capacities and increased expenses for supplemental feed;<sup>5</sup>
- Livestock inventories and retention—the inability to lease or purchase additional grazing land made it more difficult for farmers and ranchers to sustain operations, and producers were forced to cull animals rather than expand their operations;<sup>6</sup> and
- Livestock revenue and production losses—poor forage quality and quantity contributed to a reduction in livestock production, typically through a decline in livestock condition and body weight, which results in lower livestock weaning weights and lower conception rates in breeding livestock.<sup>7</sup>

As explained in the ELRP 2023 and 2024 Cost Benefit Analysis (CBA), persistent and severe drought and wildfire events have significantly impacted forage availability and herd sustainability, underscoring the necessity of federal intervention to stabilize the livestock industry and mitigate economic losses.

ELRP 2023 and 2024 is designed to compensate livestock producers for losses incurred during 2023 and 2024 by making payments in order to offset

emphasizes that the current lower inventories are not due to a lack of economic incentives, but to practical limitations in maintaining livestock numbers due to drought.

<sup>3</sup> See NASS cattle inventory reports, available at <https://usda.library.cornell.edu/concern/publications/h702q636h?locale=en>. Also, the 2023 and 2024 ELRP CBA includes a detailed summary of the change in cattle inventory from 2018 through 2024.

<sup>4</sup> USDA ERS; see Figure 1 in the ELRP 2023 and 2024 CBA. Also, the May 2023 USDA ERS “Livestock, Dairy, and Poultry Outlook” contains extensive analysis, including this sentence: “Despite recent rains, for some producers, the very low hay supplies may not be sufficient to offset poor pastures to sustain herds this summer and allow producers to retain breeding stock to rebuild their herds.” See <https://ers.usda.gov/sites/default/files/laserfiche/outlooks/106571/LDP-M-347.pdf?v=55672>.

<sup>5</sup> See Table 2 in the ELRP 2023 and 2024 CBA.

<sup>6</sup> See Table 2 in the ELRP 2023 and 2024 CBA.

<sup>7</sup> See “Impact of drought on livestock production and health” available at [https://tra.extension.colostate.edu/wp-content/uploads/sites/42/2018/08/3\\_McKensie\\_Effect-of-Heat-Stress-and-Drought-on-Cattle-Production-and-Health\\_Condensed-Drought.pdf](https://tra.extension.colostate.edu/wp-content/uploads/sites/42/2018/08/3_McKensie_Effect-of-Heat-Stress-and-Drought-on-Cattle-Production-and-Health_Condensed-Drought.pdf).

foregone profits due to qualifying drought and qualifying wildfires.<sup>8</sup> Note that foregone profits represent the difference between profits realized by a producer and the profits that could have been achieved by the producer in the absence of certain adverse circumstances. During 2022, feed and grazing costs were extreme, while livestock prices were relatively normal. As a result, livestock production returns were reduced, which became the basis for the ELRP 2022 payment. Since that time, with systemic drought occurring year after year, livestock producers have been forced to reduce the number of cattle grazed per acre as grazing capacity has been woefully short. ELRP 2023 and 2024 compensates for livestock production that would have occurred had there not been extensive drought.

As an example, a livestock producer with 500 acres of pastureland could normally graze 100 head of cattle, but with continuous annual drought conditions during 2023 and 2024, producers have been forced to reduce their stocking rates or livestock inventories as the availability of grazing and supplemental feed is limited or may be cost prohibitive. As explained above, despite increasing livestock prices and profit margins, many producers were unable to sustain their operations, let alone expand. In addition, drought and wildfire impacted the quality and quantity of forage, which negatively impacted livestock production and profits due to decreased livestock body condition, weights, and breeding conception rates.<sup>9</sup> Without these adverse conditions, producers could have realized significantly higher earnings.

Illustrating the decline in livestock capacity nationally due to drought and wildfires, NASS data on the total

<sup>8</sup> As under ELRP for 2021 and 2022, “qualifying drought” and “qualifying wildfire” for ELRP 2023 and 2024 have the same meaning as “drought” and “fire” in determining eligibility for LFP payments for grazing losses (7 CFR 1416.205). “Qualifying drought” means drought that occurs on land that is native or improved pastureland with permanent vegetative cover or is planted to a crop planted specifically for the purpose of providing grazing for covered livestock, and the land is physically located in a county rated by the U.S. Drought Monitor as having a D2 (severe drought) intensity for at least 8 consecutive weeks or D3 (extreme drought) or D4 (exceptional drought) intensity at any time during the normal grazing period for the specific type of grazing land or pastureland. As under LFP, eligible losses due to qualifying wildfire are limited to losses occurring on rangeland managed by a Federal agency. See 7 CFR 1416.205(c).

<sup>9</sup> See “Impact of drought on livestock production and health” available at [https://tra.extension.colostate.edu/wp-content/uploads/sites/42/2018/08/3\\_McKensie\\_Effect-of-Heat-Stress-and-Drought-on-Cattle-Production-and-Health\\_Condensed-Drought.pdf](https://tra.extension.colostate.edu/wp-content/uploads/sites/42/2018/08/3_McKensie_Effect-of-Heat-Stress-and-Drought-on-Cattle-Production-and-Health_Condensed-Drought.pdf).

inventory of cattle, including calves, was 86.7 million head on January 1, 2025, compared to the pre-pandemic and lower-drought-impact inventory of 94.7 million head on January 1, 2019<sup>10</sup>—a drop of 8.45 percent.<sup>11</sup> In order to estimate losses incurred during 2023 and 2024 as measured by foregone profits, USDA used the average fair market value for non-adult beef cattle weighing over 800 lbs., representing 1 animal unit (AU), which is established for the Livestock Indemnity Program (LIP) and is consistent with Animal Plant Health and Inspection Service programs. The values are \$1,659.50 for 2023 and \$2,187.00 for 2024.<sup>12</sup>

For 2023, the estimated foregone profits due to drought and wildfire are equal to: (2018 inventory of 94.7 million—2023 inventory of 87.2 million) × \$1,659.50 per AU × 10% profit margin<sup>13</sup> = approximately \$1.25 billion or \$165.95 per AU.

For 2024, the estimated foregone profits due to drought and wildfire are equal to: (2018 inventory of 94.7 million—2024 inventory of 86.7 million) × \$2,187.00 per AU × 10% profit margin = approximately \$1.75 billion dollars or \$218.70 per AU.

These calculations result in an average annual foregone profit value of \$192.32 per AU (\$165.90 in 2023 + \$218.70 in 2024, divided by 2), or total foregone profit for 2023 and 2024 of about \$3.0 billion to the nation’s beef cattle industry or \$384.65 per AU.

Similar to previous programs, ELRP 2023 and 2024 will use 2023 and 2024 LFP data already submitted by an eligible producer as a proxy for the payment calculation, representing a percentage of the payment made through LFP for losses incurred during 2023 and 2024 as a direct result of a

<sup>10</sup> See Figure 1 of the ELRP 2023 and 2024 CBA and National Agricultural Statistics Service (NASS) data available at <https://usda.library.cornell.edu/concern/publications/h702q636h?locale=en>.

<sup>11</sup> See Table 2 of the ELRP 2023 and 2024 CBA.

<sup>12</sup> LIP provides benefits to livestock producers for livestock deaths in excess of normal mortality caused by adverse weather or by attacks by animals reintroduced into the wild by the Federal Government. LIP payment rates are equal to 75 percent of the average fair market value of the livestock. See <https://www.fsa.usda.gov/tools/informational/fact-sheets/livestock-indemnity-program-lip>.

<sup>13</sup> Non adult beef cattle over 800 pounds are used as the basis for this analysis because this represents 1 animal unit—the measurement used for LFP payments. All other livestock are converted to animal unit-equivalents according to feed required to sustain them. The 10 percent profit margin used in the calculation is a conservative estimate based on information obtained from conversations with university extension specialists at North Dakota State University, the University of Nebraska, and others. This weight category is the best representation for what livestock producers market annually.

qualifying drought or wildfire that impacted a producer’s foregone profits. This eliminates the requirement for producers to resubmit information to FSA.<sup>14</sup> This approach reduces application burdens for livestock producers by eliminating the need to submit an additional application form, and it streamlines administrative processes for FSA county offices by eliminating the need to process an additional application and enter data into software when the necessary data is already on file with FSA.

Although LFP payments do not compensate livestock producers for their foregone profits, LFP payments directly reflect the severity of the drought or wildfire experienced by an LFP participant.<sup>15</sup> LFP payments are made to eligible owners and contract growers of covered livestock who suffered livestock grazing losses due to qualifying drought or fire, not to exceed five months of assistance during the normal grazing period for drought, based on the documented livestock

inventory eligible for LFP. The gross LFP calculated payment represents a 60 percent reimbursement of monthly feed costs for a maximum of 5 months for drought, or 50 percent of feed costs for the number of days of prohibited grazing due to fire, not to exceed 180 days.<sup>16</sup> In 2023, the LFP monthly payment rate per AU was \$58.12, while in 2024, it decreased to \$52.56. Producers receive drought payments equal to 60 percent of their estimated feed costs, amounting to \$34.87 per AU in 2023 and \$31.54 per AU in 2024 (see Column A in Table 1 below).<sup>17</sup>

FSA has determined the calculated national average foregone profits for livestock producers in 2023 and 2024 were \$165.95 and \$218.70 per AU, respectively (see calculation above). ELRP 2023 and 2024 uses the average of the calculated 2023 and 2024 foregone profits, \$192.32 per AU (see Column E in Table 1 below), as the identified loss to producers that is compensated by ELRP 2023 and 2024. This approach streamlines the payment calculation and

provides a commensurate level of assistance for similar losses. Total payments under ELRP 2023 and 2024, including any subsequent payments if funding remains available, will not exceed 60 percent of the calculated foregone profits per AU for the applicable calendar year.

FSA has determined that the initial ELRP 2023 and 2024 payment factor is 35 percent of the LFP gross calculated payment to stay within the funding amount that will be used for losses due to drought and wildfire and streamline delivery of assistance. Table 1 illustrates the percentage of calculated foregone profits per year per AU that would be covered by the corresponding ELRP 2023 and 2024 payment—32 percent for 2023 and 29 percent for 2024 (see Column F in Table 1). LFP compensates for grazing losses suffered in a calendar year using the drought severity as published by the U.S. Drought Monitor which determines the number of months of assistance provided by LFP.

TABLE 1—CALCULATED ELRP 2023 AND 2024 BENEFIT PER AU AND PERCENT OF CALCULATED FOREGONE PROFITS COMPENSATED BY ELRP 2023 AND 2024

Program year	60 percent of LFP payment rate per 1 AU per month	ELRP 2023 and 2024 payment factor (%)	ELRP 2023 and 2024 calculated benefit per month per eligible AU (A × B)	ELRP calculated benefit per eligible AU (C × 5 LFP payment months)	Average calculated foregone profits for 2023 and 2024 per AU	Percent of foregone profit compensated by ELRP 2023 and 2024 (D ÷ E)
	A	B	C	D	E	F
2023 .....	\$34.87	35	\$12.20	\$61.02	\$192.32	32
2024 .....	31.54	35	11.04	55.20	\$192.32	29

The calculations in Table 1 are based on an LFP payment for D4 (Exceptional Drought) intensity for at least 4 weeks, which results in the maximum LFP payment equal to a five-month payment. The ELRP 2023 and 2024 calculated benefit per AU (Table 1, Column D) and the corresponding percentage of foregone profits (Table 1, Column F) would be lower if the LFP gross payment, used as a proxy, was based on

less than a five-month payment for drought or a payment for wildfire. Table 2 illustrates a situation where a producer received an LFP payment for both 2023 and 2024, representing five months of disaster assistance for each program year. In this example, the producer has 250 head of cattle eligible for 2023 ELRP and 250 head eligible for 2024 ELRP, and received the maximum LFP payment. Therefore, the producer is

also eligible for the maximum ELRP benefit per head. In this example, this producer’s estimated gross 2023 and 2024 ELRP payments, using an ELRP payment factor of 35 percent, are calculated to be \$15,256 for 2023 losses and \$13,799 for 2024 losses (Table 2 Column F), or \$61.02 per AU for 2023 and \$55.20 per AU for 2024 (Table 2 Column G).

<sup>14</sup> FSA has previously used LFP payments as a proxy for losses due to drought and wildfires in calendar years 2021 and 2022. See Notice of Funds Availability for 2021 ELRP Phase 1 (87 FR 19465–19470), Notice of Funds Availability for 2021 ELRP Phase 2 (88 FR 66366–66372), and Notice of Funds Availability for ELRP 2022 (88 FR 66361–66366).

<sup>15</sup> LFP payments for drought are based on both the severity and duration of the drought conditions during the normal grazing period. An eligible producer receives a 1-month LFP payment for D2 (severe drought) intensity for at least 8 consecutive weeks, a 3-month LFP payment for D3 (extreme drought) intensity for any length of time, a 4-month

LFP payment for D3 intensity for at least four weeks or for D4 (exceptional drought) intensity for any length of time, and a 5-month LFP payment for D4 intensity for four weeks during the normal grazing period for the county. See 7 CFR 1416.207(b) through (e).

LFP payments for fire are based on the number of days the producer is restricted from grazing livestock on federally managed land, not to exceed 180 days. See 7 CFR 1416.207(m).

<sup>16</sup> Feed costs are based on a feed grain equivalent that is calculated according to 7 CFR 1416.207, as specified in 7 U.S.C. 9081(c), which uses the higher

of the national average corn price per bushel for the 12- or 24-month period immediately preceding March 1 of the calendar year. For drought, the monthly value of forage resulted in an LFP payment rate of \$58.12 for 2023 and \$52.56 for 2024 per eligible animal unit per month. The rate for fire is based on the number of fire-restricted days, not to exceed 180 days, at a daily animal unit feed rate of \$1.9374 for 2023 and \$1.7521 for 2024.

<sup>17</sup> Additionally, LFP offers an 80 percent compensation factor for eligible livestock that were sold due to drought conditions in one or both of the previous two production years.

TABLE 2—EXAMPLE OF ELRP 2023 AND 2024 PAYMENTS USING A 35 PERCENT ELRP PAYMENT FACTOR

Program year	Number of LFP eligible beef cows (AUs)	LFP rate per 1 AU per month	Maximum gross LFP payment  (A × B × 5 months)	Maximum LFP payment rate per AU  (C ÷ A or B × 5)	ELRP payment factor	Gross ELRP payment  (C × E)	Gross ELRP payment rate per AU  (D × E or F ÷ A)
	A	B	C	D	E	F	G
2023 .....	250	\$34.87	\$43,588	\$174.35	35	\$15,256	\$61.02
2024 .....	250	31.54	39,425	157.70	35	13,799	55.20

Additional ELRP 2023 and 2024 payments may be issued if funding is available after losses for flooding are issued, not to exceed 60 percent of calculated foregone profits.

**Producer Eligibility**

To be eligible for ELRP 2023 and 2024, a livestock producer must have an approved LFP application for the 2023, 2024, or both program years.<sup>18</sup> Eligible producers may receive payment for one or both years. The eligibility criteria applicable to LFP also apply to ELRP 2023 and 2024, excluding the LFP average adjusted gross income (AGI) limitation, consistent with other disaster programs including ELRP, ELRP 2022, the Emergency Relief Program (ERP), ERP 2022, 2017 Wildfire and Hurricane Indemnity Program (WHIP), and WHIP+.

**Payment Calculation**

Because ELRP 2023 and 2024 is based on a producer’s gross LFP calculated payment, the resulting ELRP 2023 and 2024 payments will be based on the following data reported on an eligible livestock producer’s approved CCC–853, Livestock Forage Disaster Program Application, for the 2023 or 2024 program year:

- livestock inventories/AUs,
- forage acreage,
- restricted AUs and grazing days due to fire, and
- qualifying drought and fire information.

Any adjustments made by FSA to the information provided on the CCC–853 will also apply to ELRP 2023 and 2024.

ELRP 2023 and 2024 payments will be calculated separately for each year by multiplying the gross LFP calculated payment for the applicable program year (2023 or 2024) by the ELRP payment factor of 35 percent to determine the

total gross payment for the program year, prior to any applicable payment reductions.

FSA will issue ELRP 2023 and 2024 payments as 2023 and 2024 LFP applications are processed and approved. If a producer becomes eligible for the increased payment limitation described below by filing the FSA–510 form and the accompanying certification by the deadline announced by the Deputy Administrator but after their ELRP 2023 or 2024 payment is issued, FSA will recalculate the ELRP 2023 or 2024 payment and issue the additional amount.

**Payment Limitation**

As required by the Act, ELRP 2023 and 2024 is subject to payment limitations consistent with 7 CFR 760.1507, as in effect on December 21, 2024. Separate payment limitations apply to each year (2023 and 2024). The payment limitation for ELRP 2023 and 2024 is determined by the person’s or legal entity’s average adjusted gross farm income. Specifically, a person or legal entity, other than a joint venture or general partnership, cannot receive, directly or indirectly, more than \$125,000 for each year if their average adjusted gross farm income is less than 75 percent of their average adjusted gross income (AGI) for the applicable base period. If at least 75 percent of the person or legal entity’s average AGI is average adjusted gross farm income and the participant provides the required certification and documentation, as discussed below, the person or legal entity, other than a joint venture or general partnership, is eligible to receive, directly or indirectly, up to \$250,000 for each year.

Average adjusted gross farm income includes income derived from farming, ranching, and forestry operations, which has the same meaning for ELRP 2023 and 2024 as in other recent FSA programs such as ERP, ELRP, and ELRP 2022. If the average adjusted gross farm income derived from the items listed in the definition of “income derived from

farming, ranching, and forestry operations” (7 CFR 760.2002) is at least 66.66 percent of the average adjusted gross income of the person or legal entity, then the average adjusted gross farm income may also take into consideration income or benefits derived from the sale, trade, or other disposition of equipment to conduct farm, ranch, or forestry operations, and the provision of production inputs and production services to farmers, ranchers, foresters, and farm operations. Inclusion of those items and benefits in this manner was first introduced by section 1604 of the Food Conservation and Energy Act of 2008 (Pub. L. 110–234), which amended section 1001D of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171). This provision has been applied in other recent FSA and Commodity Credit Corporation programs that use a producer’s average adjusted gross farm income for payment eligibility or payment limitation purposes.

As provided in 7 CFR 1400.105, a payment made to a legal entity will be attributed to those members who have a direct or indirect ownership interest in the legal entity unless the payment to the legal entity has been reduced by the proportionate ownership interest of the member due to that member’s ineligibility. As in other FSA programs, attribution of payments made to legal entities will be tracked through four levels of ownership as follows:

- First level of ownership—any payment made to a legal entity that is owned in whole or in part by a person will be attributed to the person in an amount that represents the direct ownership interest in the first level or payment legal entity;<sup>19</sup>

<sup>19</sup>There will be a reduction applied for the “first level or payment legal entity,” and if the payment entity happens to be a joint venture, that reduction is applied to the first level, or highest level, for payments. The “first level or payment legal entity” is the highest level of ownership of the applicant to whom payments can be attributed or limited. If the applicant is a business type that does not have a limitation or attribution, the reduction is applied

<sup>18</sup>If a producer did not file an LFP application for 2023 or 2024 prior to the deadline, they may submit a late-filed LFP application and request relief. If relief is granted and such producer receives an LFP payment, the producer may be considered eligible for ELRP 2023 and 2024.

- Second level of ownership—any payment made to a first-level legal entity that is owned in whole or in part by another legal entity (referred to as a second-level legal entity) will be attributed to the second-level legal entity in proportion to the ownership of the second-level legal entity in the first-level legal entity; if the second-level legal entity is owned in whole or in part by a person, the amount of the payment made to the first-level legal entity will be attributed to the person in the amount that represents the indirect ownership in the first-level legal entity by the person;
- Third and fourth levels of ownership—except as provided in the second level of ownership bullet above and in the fourth level of ownership bullet below, any payments made to a legal entity at the third and fourth levels of ownership will be attributed in the same manner as specified in the second level of ownership bullet above; and
- Fourth level of ownership—if the fourth level of ownership is that of a legal entity and not that of a person, a reduction in payment will be applied to the first-level or payment legal entity in the amount that represents the indirect ownership in the first level or payment legal entity by the fourth-level legal entity.

If an individual or legal entity is not eligible to receive ELRP 2023 and 2024 payments due to the individual or legal entity failing to satisfy payment eligibility provisions, the payment made either directly or indirectly to the individual or legal entity will be reduced to zero. The amount of the reduction for the direct payment to the producer will be commensurate with the direct or indirect ownership interest of the ineligible individual or ineligible legal entity.

Like other programs administered by FSA, payments made to an Indian Tribe or Tribal organization, as defined in section 4(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), will not be subject to payment limitation.

Payments made directly or indirectly to a person who is a minor child will not be combined with the earnings of the minor's parent or legal guardian.

#### Required Forms and Deadlines

To be eligible for an ELRP 2023 and 2024 payment, a livestock producer must have an approved LFP application

to the first level, but if the business type can have the reduction applied directly to it, then the limitation applies.

on file with FSA for the applicable program year (2023, 2024, or both).<sup>20</sup>

A producer must submit the following forms for payment eligibility associated with an approved LFP application by the deadline announced by the Deputy Administrator, if not already on file with FSA for the applicable program year:

- CCC-902, Farm Operating Plan, for an individual or legal entity as provided in 7 CFR part 1400;
- CCC-901, Member Information for Legal Entities, if applicable;
- AD-1026, Highly Erodible Land Conservation (HELIC) and Wetland Conservation (WC) Certification, for the ELRP 2023 and 2024 participant and applicable affiliates; and
- FSA-510, Request for an Exception to the \$125,000 Payment Limitation for Certain Programs, accompanied by a certification from a certified public accountant or attorney as to that person or legal entity's certification, for participants and members of legal entities to be eligible for the increased payment limitation of \$250,000.

#### Notice and Comment and Effective Date

The Administrative Procedure Act (APA, 5 U.S.C. 553(a)(2)) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified actions, including matters relating to benefits or contracts. This rule governs disaster assistance payments to livestock producers and therefore falls within the benefits exemption.

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 (SBREFA) because it involves matters relating to benefits. The requirements for the regulatory flexibility analysis in 5 U.S.C. 603 and 604 are specifically tied to the requirement for a proposed rule by section 553 or any other law; in addition, the definition of rule in 5 U.S.C. 601 is tied to the publication of a proposed rule.

The Office of Management and Budget (OMB) found this rule meets the criteria in 5 U.S.C. 804(2) of the Congressional Review Act (CRA). The CRA, at 5 U.S.C. 808(2) allows an agency to make such regulations effective immediately if the agency finds there is good cause to do so. The beneficiaries of this rule have

<sup>20</sup> As provided in 7 CFR 1416.206 and publicized by FSA, the LFP application deadline for the 2023 program year was January 30, 2024, and the deadline for the 2024 program year was March 3, 2025.

been significantly impacted by disaster events, which resulted in losses due to the impact of drought and wildfire conditions during normal grazing periods in calendar years 2023 and 2024, and this assistance is necessary to support livestock producers who have incurred increased grazing and supplemental feed costs in order to avoid further livestock liquidations. To mitigate further adverse impacts on affected livestock producers for losses suffered in 2023 and 2024, USDA finds that notice and public procedure are contrary to the public interest. Therefore, USDA is not required to delay the effective date for 60 days from the date of publication to allow for Congressional review. Accordingly, this rule is effective upon publication in the **Federal Register**.

#### Executive Orders 12866, 13563, and 14192

Executive Order 12866, "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. Executive Order 14192 "Unleashing Prosperity Through Deregulation" announced the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen and to alleviate unnecessary regulatory burdens placed on the American people. In line with the Executive Order requirements, the Agency chose this regulatory approach, including leveraging existing applications and data, to maximize benefits and minimize burden on American producers. The requirements in Executive Orders 12866 and 13563 for the analysis of costs and benefits apply to rules that are determined to be significant or economically significant. This rule has been designated as economically significant.

The Office of Management and Budget (OMB) designated this rule as economically significant under Executive Order 12866 and therefore, OMB has reviewed this rule. The costs and benefits of this rule are summarized

below. The full CBA is available on [regulations.gov](https://www.regulations.gov).

### Cost Benefit Analysis Summary

Title I of the Disaster Relief Supplemental Appropriations Act, 2025 (Division B of the American Relief Act, 2025; Pub. L. 118–158) directs the Secretary to use up to \$2 billion to fund disaster assistance to livestock producers for losses incurred during calendar years 2023 and 2024 due to drought, wildfires, and floods. ELRP 2023 and 2024 will use approximately \$1 billion of the \$2 billion to provide payments to livestock producers for losses due to qualifying drought and wildfires that occurred in calendar years 2023 and 2024. Persistent and severe drought and wildfire events have significantly impacted forage availability and herd sustainability, underscoring the necessity of Federal intervention to stabilize the livestock industry and mitigate economic losses.

ELRP 2023 and 2024 compensates livestock producers for foregone profits due to drought and wildfire in 2023 and 2024. Producers may receive payments for losses in 2023, 2024, or both years. To provide a simple process that results in quick payments to producers, ELRP 2023 and 2024 payments are based on 2023 and 2024 LFP payments; hence, no additional application process is required.

Factors are applied to keep ELRP payments for eligible producers at about \$1.0 billion in total for 2023 and 2024, leaving another \$1.0 billion for other livestock producer losses provided for in the American Relief Act, 2025. Specifically, ELRP 2023 and 2024 will use a program factor of 35 percent of the LFP rate. ELRP 2023 and 2024 payouts are estimated at \$721 million associated with losses in 2023 and \$346 million associated with losses in 2024. The largest payment recipient states are those with large cattle and forage sectors in the West and Mid-West, where drought has particularly strained producers' financial viability. For 2023 losses, the top five recipient states are Texas, Oklahoma, Kansas, Missouri, and Nebraska, accounting for 66 percent of payments. For 2024 losses, the top recipient states are Oklahoma, Missouri, Texas, Montana, and Wyoming, accounting for 57 percent of payments. Over 95 percent of payments will be made in FY 2025.

### Environmental Review

The environmental impacts have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347) and the FSA

regulation for compliance with NEPA (7 CFR part 799).

The purpose of ELRP 2023 and 2024 is to provide assistance to eligible livestock producers for losses incurred during 2023 and 2024 which represent foregone profits as a result of the impact that drought and wildfire has had on forage quality and quantity losses due to a qualifying drought or wildfire in calendar years 2023 or 2024. The limited discretionary aspects of ELRP 2023 and 2024 do not have the potential to impact the human environment as they are administrative. Accordingly, these discretionary aspects are covered by the FSA Categorical Exclusions specified in § 799.31(b)(6)(iv) that apply to individual farm participation in FSA programs where no ground disturbance or change in land use occurs as a result of the proposed action or participation, and § 799.31(b)(6)(vi) that applies to safety net programs.

No Extraordinary Circumstances (§ 799.33) exist because this is an administrative payment program that does not have the potential to impact the human environment individually or collectively. As such, the implementation of ELRP 2023 and 2024 and participation in ELRP 2023 and 2024 do not constitute 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 action and this document serves as documentation of the programmatic environmental compliance decision for this federal action.

### Executive Order 13175

This rule has been reviewed in accordance 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.

USDA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that required Tribal consultation at this time. If a Tribe requests consultation,

the USDA Farm Service Agency will work with the Office of Tribal Relations to ensure meaningful consultation is provided.

### Unfunded Mandates Reform Act

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 of State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including 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 and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

### Paperwork Reduction Act Requirements

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320), requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. The information collection request has been approved by OMB under the control number of 0503–0028; Expiration Date: 10/31/2027. FSA will use LFP documentation as the basis for making ELRP 2023 and 2024 payments to producers. For the information collection changes related to the existing approval under 0503–0028, the agency is seeking to use FSA–510 with this data collection, the time per respondent is 5 minutes. This final rule is a one-time announcement of ELRP 2023 and 2024 federal financial assistance funding.

*For Further Information Contact:* Requests for additional information or copies of this information collection should be directed to Kathy Sayers, Farm Service Agency, U.S. Department of Agriculture, via email to [Kathy.Sayers@usda.gov](mailto:Kathy.Sayers@usda.gov).

*Title:* Emergency Livestock Relief Program (ELRP) 2023 and 2024.

*Form Number:* FSA–510.

*OMB Number:* 0503–0028.

*Expiration Date:* 10/31/2027.

*Type of Request:* Revision to Generic Information Collection.

*Abstract:* As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), FSA is providing producers with ELRP 2023 and 2024 payments. ELRP 2023 and 2024 will use approximately \$1 billion in funds authorized by Section 2102 of Division B of Title I of the American Relief Act, 2025 (“the Act”; Pub. L. 118–158) to eligible livestock producers for losses due to qualifying drought and qualifying wildfire occurring in calendar years 2023 and 2024. These payments will help livestock producers to offset foregone profits due to qualifying drought and qualifying wildfires.

Foregone profits represent the difference between profits actually achieved by a producer and the profits that could have been achieved by a producer in the absence of certain adverse circumstances. If funding remains available after issuing assistance to livestock producers for other eligible losses under the Act, which will be addressed in a later rule, FSA may make additional payments to ELRP 2023 and 2024 participants.

FSA will calculate payments using data already submitted to FSA by Livestock Forage Disaster Program (LFP) participants; therefore, producers are not required to file an additional application to receive ELRP 2023 and

2024 payments. A livestock producer must have an approved LFP application for either 2023, 2024, or both program years. Eligible producers may receive payment for one or both years. The eligibility criteria applicable to LFP also apply to ELRP 2023 and 2024, excluding the LFP average adjusted gross income (AGI) limitation.

*Affected Public:* Farms or businesses for profit.

*Estimated Number Respondents:* 100.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Time per Respondent:* 0.0835 hours.

*Estimated Total Annual Burden on Respondents:* 8.35 burden hours.

Respondents	Estimated annual responses	Responses per year	Hours per response	Total hours per year
100 .....	1	100	0.0835	8.35

There is no recordkeeping or third-party burden on the respondents.

**E-Government Act Compliance**

FSA is committed to complying with the E-Government Act of 2002, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

**Federal Assistance Programs**

The title and number of the Federal assistance programs, as found in the Assistance Listing, to which this document applies is 10.986—Emergency Livestock Relief Program 2023 and 2024.

**List of Subjects in 7 CFR Part 760**

Acreage allotments, dairy products, indemnity payments, pesticides and pest, reporting and recordkeeping requirements.

For the reasons discussed above, this final rule amends 7 CFR part 760 as follows:

**PART 760—INDEMNITY PAYMENT PROGRAMS**

■ 1. Revise the authority citation for part 760 to read as follows:

**Authority:** 7 U.S.C. 4501 and 1531; 16 U.S.C. 3801, note; 19 U.S.C. 2497; Title III, Pub. L. 109–234, 120 Stat. 474; Title IX, Pub. L. 110–28, 121 Stat. 211; Sec. 748, Pub. L. 111–80, 123 Stat. 2131; Title I, Pub. L. 115–123, 132 Stat. 65; Title I, Pub. L. 116–20, 133 Stat. 871; Division B, Title VII, Pub. L. 116–94, 133 Stat. 2658; Title I, Pub. L. 117–43, 135 Stat. 356; and Division N, Title I, Pub.

L. 117–328, 136 Stat. 4459; Division B, Title I, Pub. L. 118–158, 138 Stat. 1722.

■ 2. Add subpart T, consisting of §§ 760.2000 through 760.2007, to read as follows:

**Subpart T—Emergency Livestock Relief Program 2023 and 2024**

Sec.

- 760.2000 Applicability.
- 760.2001 Administration.
- 760.2002 Definitions.
- 760.2003 Eligible producers.
- 760.2004 Required forms and deadlines.
- 760.2005 Payment calculation.
- 760.2006 Payment limitation.
- 760.2007 Miscellaneous provisions.

**§ 760.2000 Applicability.**

(a) This subpart specifies the eligibility requirements and payment calculations for the Emergency Livestock Relief Program (ELRP) 2023 and 2024, which is authorized by Title I of the Disaster Relief Supplemental Appropriations Act, 2025 (Division B of the American Relief Act, 2025; Pub. L. 118–158). ELRP 2023 and 2024 provides payments to livestock producers who suffered losses incurred during 2023 and 2024 due to qualifying drought and wildfire. Payments will be made for foregone profits as a result of forage quality and quantity losses due to qualifying drought and qualifying wildfire in calendar years 2023 or 2024.

(b) To be eligible for ELRP 2023 and 2024 payments, participants must comply with all applicable provisions under this subpart.

**§ 760.2001 Administration.**

(a) ELRP 2023 and 2024 is administered under the general

supervision and direction of the Administrator, Farm Service Agency (FSA), and the Deputy Administrator for Farm Programs (Deputy Administrator).

(b) FSA representatives do not have authority to modify or waive any of the provisions of the regulations of this subpart as amended or supplemented, except as specified in paragraph (e) of this section.

(c) The State committee will take any action required by the regulations of this subpart that the county committee has not taken. The State committee will also:

(1) Correct, or require a county committee to correct, any action taken by such county committee that is not in accordance with the regulations of this subpart, or

(2) Require a county committee to withhold taking any action that is not in accordance with this subpart.

(d) No provision or delegation to a State or county committee will preclude the FSA Administrator, the Deputy Administrator, or a designee or other such person, from determining any question arising under the programs of this subpart, or from reversing or modifying any determination made by a State or county committee.

(e) The Deputy Administrator may authorize State and county committees to waive or modify non-statutory deadlines or other program requirements of this subpart in cases where lateness or failure to meet such requirements does not adversely affect operation of ELRP 2023 and 2024. Participants have no right to an exception under this provision. The Deputy Administrator’s refusal to

consider cases or circumstances or decisions not to exercise this discretionary authority under this provision will not be considered an adverse decision and is not appealable.

#### § 760.2002 Definitions.

The definitions in 7 CFR 718, 1400, and 1416 apply to this subpart, except where they conflict with the definitions in this section. The following definitions also apply.

*Average adjusted gross farm income* means the average of the person or legal entity's adjusted gross income derived from farming, ranching, and forestry operations, including losses, for the base period.

(1) If the resulting average adjusted gross farm income derived from paragraphs (1) through (13) of the definition for "income derived from farming, ranching and forestry operations" is at least 66.66 percent of the average adjusted gross income of the person or legal entity, then the average adjusted gross farm income may also take into consideration income or benefits derived from the following:

(i) The sale, trade, or other disposition of equipment to conduct farm, ranch, or forestry operations; and

(ii) The provision of production inputs and services to farmers, ranchers, foresters, and farm operations.

(2) For legal entities not required to file a Federal income tax return, or a person or legal entity that did not have taxable income in 1 or more of the tax years during the base period, the average gross farm income will be the adjusted gross farm income, including losses, averaged for the base period, as determined by FSA. For a legal entity created during the base period, the adjusted gross farm income average will include only those years of the base period for which it was in business; however, a new legal entity will not be considered "new" to the extent it takes over an existing operation and has any elements of common ownership interest and land with the preceding person or legal entity from which it took over. When there is such commonality, income of the previous person or legal entity will be averaged with that of the new legal entity for the base period. For a person filing a joint tax return, the certification of average adjusted gross farm income may be reported as if the person had filed a separate Federal tax return, and the calculation is consistent with the information supporting the filed joint return.

*Average AGI* means the average of the adjusted gross income as defined under 26 U.S.C. 62 or comparable measure of

the person or legal entity for the base period.

*Base period* means:

(1) 2019, 2020, and 2021 for 2023; and

(2) 2020, 2021, and 2022 for 2024.

*Farming operation* means a business enterprise engaged in the production of agricultural products, commodities, or livestock, operated by a person, legal entity, or joint operation. A person or legal entity may have more than one farming operation if the person or legal entity is a member of one or more legal entities or joint operations.

*Gross LFP calculated payment* means the LFP payment calculated according to 7 CFR 1416.207, prior to any payment reductions for reasons including, but not limited to, sequestration, payment limitation, and the applicant or member of an applicant that is an entity exceeding the average AGI limitation.

*Income derived from farming, ranching, and forestry operations* means income of an individual or entity derived from:

(1) Production of crops and unfinished raw forestry products;

(2) Production of livestock, aquaculture products used for food, honeybees, and products derived from livestock;

(3) Production of farm-based renewable energy;

(4) Selling (including the sale of easements and development rights) of farm, ranch, and forestry land, water or hunting rights, or environmental benefits;

(5) Rental or lease of land or equipment used for farming, ranching, or forestry operations, including water or hunting rights;

(6) Processing, packing, storing, and transportation of farm, ranch, or forestry commodities including for renewable energy;

(7) Feeding, rearing, or finishing of livestock;

(8) Payments of benefits, including benefits from risk management practices, federal crop insurance indemnities, and catastrophic risk protection plans;

(9) Sale of land that has been used for agricultural purposes;

(10) Benefits (including, but not limited to, cost-share assistance and other payments) from any Federal program made available and applicable to payment eligibility and payment limitation rules, as provided in 7 CFR part 1400;

(11) Income reported on Internal Revenue Service (IRS) Schedule F (Form 1040), *Profit or Loss from Farming*, or other schedule, approved by the Deputy Administrator, used by the person or legal entity to report income from such operations to the IRS;

(12) Wages or dividends received from a closely held corporation, an Interest Charge Domestic International Sales Corporation (also known as IC-DISC), or legal entity comprised entirely of family members when more than 50 percent of the legal entity's gross receipts for each tax year are derived from farming, ranching, and forestry activities as defined in this subpart; and

(13) Any other activity related to farming, ranching, and forestry, as determined by the Deputy Administrator.

*IRS* means the Department of the Treasury, Internal Revenue Service.

*Legal entity*: (1) Means an entity that is created under Federal or State law and that:

(i) Owns land or an agricultural commodity, or

(ii) Produces an agricultural commodity; and

(2) Includes corporations, joint stock companies, associations, limited partnerships, limited liability companies, irrevocable trusts, estates, charitable organizations, general partnerships, joint ventures, and other similar organizations created under Federal or State law including any such organization participating in a business structure as a partner in a general partnership, a participant in a joint venture, a grantor of a revocable trust, or as a participant in a similar organization. A business operating as a sole proprietorship is considered a legal entity.

*LFP* means the Livestock Forage Disaster Program under section 1501 of the Agricultural Act of 2014 (7 U.S.C. 9081) and 7 CFR part 1416, subpart C.

*Ownership interest* means to have either a legal ownership interest or a beneficial ownership interest in a legal entity. For the purposes of administering ELRP 2023 and 2024, a person or legal entity that owns a share or stock in a legal entity that is a corporation, limited liability company, limited partnership, or similar type entity where members hold a legal ownership interest and shares in the profits or losses of such entity is considered to have an ownership interest in such legal entity. A person or legal entity that is a beneficiary of a trust or heir of an estate who benefits from the profits or losses of such entity is considered to have a beneficial ownership interest in such legal entity.

*Production inputs* mean material to conduct farming operations, such as seeds, chemicals, and fencing supplies.

*Production services* mean services provided to support a farming operation, such as custom farming, custom feeding, and custom fencing.

*Qualifying drought* means drought occurring on grazing land or pastureland that is physically located in a county that is, during the normal grazing period for the specific type of grazing land or pastureland for the county, rated by the U.S. Drought Monitor as having a:

(1) D2 (severe drought) intensity in any area of the county for at least 8 consecutive weeks during the normal grazing period for the specific type of grazing land or pastureland for the county, as determined by the Secretary, or

(2) D3 (extreme drought) or higher intensity in any area of the county at any time during the normal grazing period for the specific type of grazing land or pastureland for the county, as determined by the Secretary.

*Qualifying wildfire* means fire, as provided in 7 CFR part 1416, subpart C, that resulted in an eligible grazing loss for LFP. As provided in 7 CFR 1416.205(c), the fire must have:

(1) Occurred on rangeland that was managed by a Federal agency; and

(2) Resulted in the eligible livestock producer being prohibited from grazing the normal permitted livestock on the land.

*U.S. Drought Monitor* means the system for classifying drought severity according to a range of abnormally dry to exceptional drought reported by the National Drought Mitigation Center at <http://droughtmonitor.unl.edu>. It is a collaborative effort between Federal and academic partners, produced on a weekly basis, to synthesize multiple indices, outlooks, and drought impacts on a map and in narrative form.

#### **§ 760.2003 Eligible producers.**

(a) The eligibility provisions applicable to LFP apply to ELRP 2023 and 2024, excluding the average AGI limitation. These include the provisions of: 7 CFR part 1416, subparts A and C; 7 CFR part 12; and 7 CFR 718.6.

(b) To be eligible for a payment under this subpart, a producer must have an approved LFP application on file for the 2023 or 2024 program year. Producers may receive payment for one or both years, if eligible.

(c) States, political subdivisions, and agencies thereof, are not eligible for payments under this subpart.

#### **§ 760.2004 Required forms and deadlines.**

(a) To be eligible for a payment under this subpart, a producer must have an approved LFP application on file for the applicable year (2023 or 2024) by the deadline announced by the Deputy Administrator.

(b) A producer must also submit the following forms to FSA by the deadline

announced by the Deputy Administrator if not previously filed for the applicable program year (2023 or 2024):

(1) CCC-902, Farm Operating Plan, for an individual or legal entity as provided in 7 CFR part 1400;

(2) CCC-901, Member Information for Legal Entities, if applicable;

(3) AD-1026, Highly Erodible Land Conservation (HELIC) and Wetland Conservation (WC) Certification, for the ELRP 2023 and 2024 participant and applicable affiliates; and

(4) FSA-510, Request for an Exception to the \$125,000 Payment Limitation for Certain Programs, accompanied by a certification from a certified public accountant or attorney as to that person or legal entity's certification, for participants and members of legal entities to be eligible for the payment limitation of § 760.2006(a)(2).

#### **§ 760.2005 Payment calculation.**

(a) ELRP 2023 and 2024 will use the information reported on a producer's approved CCC-853, Livestock Forage Disaster Program Application, for the applicable program year (2023 or 2024) as the basis for a payment under this subpart. Any adjustments made by FSA to the information provided on CCC-853 for the purpose of administering LFP will also apply to ELRP 2023 and 2024.

(b) An ELRP 2023 and 2024 payment will be equal to the participant's gross calculated LFP payment for the applicable program year (2023 or 2024) multiplied by the applicable ELRP 2023 and 2024 payment factor of 35 percent.

(c) If funding remains available after payments are issued for other livestock losses under the American Relief Act, 2025, FSA may issue additional payments under this subpart, based on an increased ELRP 2023 and 2024 payment factor.

#### **§ 760.2006 Payment limitation.**

(a) For each applicable year (2023 and 2024), a person or legal entity, other than a joint venture or general partnership, is eligible to receive, directly or indirectly, payments under this subpart of not more than:

(1) \$125,000 if less than 75 percent of the person or legal entity's average adjusted gross income is average adjusted gross farm income; or

(2) \$250,000 if 75 percent or more of the average adjusted gross income of the person or legal entity is average adjusted gross farm income.

(b) To be eligible for the payment limitation in paragraph (a)(2) of this section, a person or legal entity must submit FSA-510, Request for an

Exception to the \$125,000 Payment Limitation for Certain Programs, accompanied by a certification from a certified public accountant or attorney as to that person or legal entity's certification.

(c) If a producer requesting the \$250,000 payment limitation is a legal entity, all members of that entity must also complete FSA-510 and provide the required certification according to the direct attribution provisions in 7 CFR 1400.105. If a legal entity would be eligible for the \$250,000 payment limitation based on the legal entity's average adjusted gross farm income but a member of that legal entity either does not complete an FSA-510 and provide the required certification or is not eligible for the \$250,000 payment limitation, the payment to the legal entity will be reduced for the limitation applicable to the share of the ELRP 2023 or 2024 payment attributed to that member.

(d) If a producer or member of a legal entity files FSA-510 and the accompanying certification after their payment is issued but before the deadline specified in § 760.2004(b), FSA will recalculate the payment and issue the additional calculated amount.

(e) ELRP 2023 and 2024 applicants filing an FSA-510 are subject to an FSA audit of information submitted for the purpose of increasing the program's payment limitation. As a part of this audit, FSA may request income tax returns, and if requested, must be supplied by all related persons and legal entities. In addition to any other requirement under any Federal statute, relevant Federal income tax returns and documentation must be retained a minimum of 3 years after the end of the calendar year corresponding to the year for which payments or benefits are requested. Failure to provide necessary and accurate information to verify compliance, or failure to comply with these requirements will result in ineligibility for ELRP 2023 and 2024 benefits and require refund of any ELRP 2023 and 2024 payments, including interest to be calculated from the date of the disbursement to the producer.

(e) The payment limitation provisions of 7 CFR part 1400, subpart A, and 7 CFR 1400.103 through 1400.106 apply to ELRP 2023 and 2024.

(f) Payments made directly or indirectly to a person who is a minor child will not be combined with the earnings of the minor's parent or legal guardian.

(g) If an individual or legal entity is not eligible to receive ELRP 2023 and 2024 payments due to the individual or legal entity failing to satisfy payment

eligibility provisions, the payment made either directly or indirectly to the individual or legal entity will be reduced to zero. The amount of the reduction for the direct payment to the producer will be commensurate with the direct or indirect ownership interest of the ineligible individual or ineligible legal entity.

#### **§ 760.2007 Miscellaneous provisions.**

(a) In the event that any ELRP 2023 or 2024 payment resulted from erroneous information reported by the producer or if the producer's 2023 or 2024 LFP payment is recalculated after the ELRP 2023 or 2024 payment is issued, the ELRP 2023 or 2024 payment will be recalculated, and the producer must refund any excess payment to FSA, including interest to be calculated from the date of the disbursement to the producer.

(b) If FSA determines that the producer intentionally misrepresented information used to determine the producer's ELRP 2023 or 2024 payment amount, the application will be disapproved and the producer must refund the full payment to FSA with interest from the date of disbursement.

(c) Any required refunds must be resolved in accordance with debt settlement regulations in 7 CFR part 3.

(d) Participants are required to retain documentation in support of their application for 3 years after the date of approval. Participants receiving ELRP 2023 or 2024 payments or any other person who furnishes such information to USDA must permit authorized representatives of USDA or the Government Accountability Office, during regular business hours, to enter the agricultural operation and to inspect, examine, and to allow representatives to make copies of books, records, or other items for the purpose of confirming the accuracy of the information provided by the participant.

(e) Any payment under ELRP 2023 or 2024 will be made without regard to questions of title under State law and without regard to any claim or lien. The regulations governing offsets in 7 CFR part 3 apply to ELRP 2023 and 2024 payments.

(f) Participants are subject to laws against perjury and any penalties and prosecution resulting therefrom, with such laws including but not limited to 18 U.S.C. 1621. If a producer willfully makes and represents as true any verbal or written declaration, certification, statement, or verification that the producer knows or believes not to be true, in the course of either applying for or participating in ELRP 2023 and 2024, then the producer is guilty of perjury

and, except as otherwise provided by law, may be fined, imprisoned for not more than 5 years, or both, regardless of whether the producer makes such verbal or written declaration, certification, statement, or verification within or outside the United States.

(g) For the purposes of the effect of a lien on eligibility for Federal programs (28 U.S.C. 3201(e)), USDA waives the restriction on receipt of funds under ELRP 2023 and 2024 but only as to beneficiaries who, as a condition of the waiver, agree to apply the ELRP 2023 and 2024 payments to reduce the amount of the judgment lien.

(h) In addition to any other Federal laws that apply to ELRP 2023 and 2024, the following laws apply: 15 U.S.C. 714; and 18 U.S.C. 286, 287, 371, and 1001.

(i) Prompt pay interest is not applicable to payments under this subpart.

**William Beam,**

*Administrator, Farm Service Agency.*

[FR Doc. 2025-09581 Filed 5-28-25; 8:45 am]

**BILLING CODE 3411-E2-P**

## **DEPARTMENT OF AGRICULTURE**

### **Agricultural Marketing Service**

#### **7 CFR Parts 1146 and 1147**

[Doc. No. AMS-DA-25-0026]

**RIN 0581-AE45**

#### **Rescission of the Dairy Donation Program**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Direct final rule.

**SUMMARY:** This action removes from AMS' regulations the implementing regulations for the Dairy Donation Program and makes conforming amendments to the implementing regulations for the Milk Donation Reimbursement Program. The Dairy Donation Program is no longer funded by Congress; therefore, AMS has no authority to take further action under the Dairy Donation Program and its implementing regulations are obsolete. Removing the regulations will provide transparency and may reduce confusion for dairy processors and other stakeholders.

**DATES:** The rule will be effective on July 28, 2025 without further action, unless adverse comments are received on or before June 30, 2025. If adverse comments are received, AMS will publish a document in the **Federal Register** withdrawing this rule before the effective date.

**ADDRESSES:** You may submit comments on the internet at <http://www.regulations.gov> or to Lauren Becker, USDA/AMS/Dairy Programs, Order Formulation and Enforcement Division, STOP 0231—Room 2530, 1400 Independence Ave. SW, Washington, DC 20250; email: [lauren.becker@usda.gov](mailto:lauren.becker@usda.gov); telephone: 202-720-0758. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

#### **FOR FURTHER INFORMATION CONTACT:**

Lauren Becker, USDA/AMS/Dairy Programs, Order Formulation and Enforcement Division, STOP 0231—Room 2530, 1400 Independence Ave. SW, Washington, DC 20250; email: [lauren.becker@usda.gov](mailto:lauren.becker@usda.gov); telephone: 202-720-0758.

#### **SUPPLEMENTARY INFORMATION:**

This direct final rule will remove part 1147, "Dairy Donation Program," from title 7 of the CFR and make conforming amendments to part 1146, "Milk Donation Reimbursement Program." The Dairy Donation Program (DDP) was established in 2021 under the authority of section 762 of the Consolidated Appropriations Act of 2021 (Pub. L. 116-260) (86 FR 48887; Sept. 1, 2021). Under the program, eligible dairy organizations that accounted to a Federal milk marketing order and incurred a qualified expense related to certain dairy product donations could apply for and receive reimbursements for those donations. The DDP was run along with an existing Milk Donation Reimbursement Program (MDRP). The MDRP is a USDA dairy milk donation program that was established as part of the 2018 Farm Bill (Pub. L. 115-334) to facilitate the donation of fluid milk products and avoid food waste (84 FR 46653; Sept. 5, 2019).

Like the MDRP, the DDP was intended to encourage the donation of dairy products and to prevent and minimize food waste. It was also created to assist in balancing the supply chain during the COVID-19 pandemic. The DDP is no longer funded by Congress; therefore, AMS has no authority to take further action under the DDP and its implementing regulations are obsolete.

In the DDP rulemaking, AMS made conforming changes to the MDRP regulations in part 1146 to allow the two programs to operate simultaneously (86 FR 48887; Sept. 1, 2021). With this

recession of the DDP regulations, AMS is removing all references in part 1146 to “Dairy Donation and Distribution Plan” and replacing them with “Milk Donation and Distribution Plan”. AMS is also reverting the text of part 1146 to its form prior to the establishment of the DDP in September 2021 (the “2021 regulatory text”)—with three exceptions. First, rather than removing the definition of “qualified expense” (which was added to part 1146 when the DDP was established), AMS is revising the existing definition to remove the reference to dairy products, which are not eligible for reimbursement under MDRP.

Second, AMS is reverting the text of § 1146.102 to the 2021 regulatory text, except AMS is updating the words “new and continuing program participants” to “eligible partnerships,” which is the term currently used for participants, and eliminating the reference to published deadline.

Third, in § 1146.106, AMS is reverting to the 2021 regulatory text, with a few exceptions. In the paragraph (a) introductory text, AMS is reverting to the 2021 regulatory text but is removing the words “partner”, “qualified expenses,” and the term “report.” With this direct final rule, the term “report” is replaced with the term “Reimbursement Claim Form.” Removal of these words and the addition of “Reimbursement Claim Form” is in conformance with the current operation of MDRP. In the paragraph (a)(1) introductory text, AMS is retaining current regulatory text, aside from removing the reference to the DDP and replacing it with reference to the MDRP. AMS is doing so because the 2021 regulatory text required that participants submit a report for each month of the fiscal year. Under the current operation of the MDRP, eligible dairy organizations must submit the Form once; therefore, the retention of the current regulatory text will allow the current practice to continue. With respect to the subparagraphs to paragraph (a)(1), AMS is reverting to the 2021 regulatory text; however, AMS is not adding paragraph (a)(1)(v) back to the CFR. This paragraph, which required that reimbursement claims include applicable announced Federal milk marketing order prices for the month the milk was pooled, is not necessary because the information is now programmed to be automatically included. Finally, AMS is not reverting § 1146.106(a)(2) to the 2021 regulatory text. Under the current regulatory text, the documents act to “verify” the donations were made. The reporting requirements of the two versions are

identical, however the current regulatory text refers to the Reimbursement Claim Form and Eligible Distributor Certification Form by title.

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with prior notice and comment for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without first publishing a proposed rule. Removing the DDP regulations and amending the MDRP regulations will provide transparency and may reduce confusion for dairy processors and other stakeholders. Further, AMS views this action as noncontroversial and anticipates no adverse public comment. This rule will become effective, as published in this document, July 28, 2025 without further action, unless adverse comments are received on or before June 30, 2025. Adverse comments are considered to be those comments that suggest the rule should not be adopted or suggest the rule should be changed.

If AMS receives adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date. AMS will then publish a proposed rule for public comment. Following the close of that comment period, the comments will be considered, and a final rule addressing the comments will be published.

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), AMS certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. The DDP is no longer funded by Congress and is no longer in operation. The amendments made by the direct final rule will merely conform the CFR with AMS’ current operating practices. This rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by OMB. The information collection associated with the DDP, approved under the Paperwork Reduction Act (44 U.S.C. chapter 35) under the OMB Control Number 0581–0327, will be discontinued. The forms required for participation in MDRP will continue to be used and are exempt from the Paperwork Reduction Act, as explained in the final rule establishing MDRP (84 FR 46653, 46657; Sept. 5, 2019).

It is not the interest of the public or USDA to maintain regulations that are obsolete. USDA has determined that

there is no current reliance on this regulation. Further, USDA has determined the benefits of rescinding the DDP regulations and amending the MDRP regulations outweigh any cost associated with rescission.

#### List of Subjects

##### 7 CFR Part 1146

Milk, Donations, Reporting and recordkeeping requirements.

##### 7 CFR Part 1147

Dairy, Donations, Food waste, Emergency, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS amends 7 CFR chapter X as follows:

#### PART 1146—MILK DONATION REIMBURSEMENT PROGRAM

■ 1. The authority citation for part 1146 continues to read as follows:

**Authority:** Sec. 1431, Pub. L. 113–79, 128 Stat. 695, as amended.

■ 2. Amend § 1146.1 by revising the term “Qualified expense” to read as follows:

##### § 1146.1 Definitions.

\* \* \* \* \*

*Qualified expense* means the cost incurred to purchase fresh fluid milk products.

\* \* \* \* \*

■ 3. Revise § 1146.102 to read as follows:

##### § 1146.102 Milk donation and distribution plans.

Eligible partnerships must submit a completed Milk Donation and Distribution Plan to AMS in the form and manner established by AMS to be eligible for program consideration. The completed Milk Donation and Distribution Plans must:

(a) Include the physical location(s) of the eligible dairy organization’s processing plant(s) and the eligible distributor’s distribution site(s);

(b) Include an affirmation signed by both eligible partners regarding the partnership’s ability to supply, transport, store, and distribute donated milk products consistent with the commodity specifications under § 1146.3;

(c) Include an estimate of the quantity of eligible milk that the eligible dairy organization plans to donate each year, based on—

(1) Preplanned donations and  
(2) Contingency plans to address unanticipated donations; and

(d) Describe the rate at which the eligible dairy organization will be

reimbursed, not to exceed 100 percent of qualified expenses pursuant to § 1146.108.

■ 4. Revise § 1146.106 to read as follows:

**§ 1146.106 Reimbursement claims.**

(a) In order for the eligible dairy organization to receive reimbursement pursuant to § 1146.108, the participating partnership must submit a Reimbursement Claim Form and appropriate supporting documentation to AMS.

(1) Each Reimbursement Claim Form associated with an approved Milk Donation and Distribution Plan must include:

(i) The amount of eligible milk donated to the eligible distributor;

(ii) The location of the plant where the donated milk was processed;

(iii) The date the donated milk was shipped from the plant where the milk was processed; and

(iv) The date the donated milk was received by the eligible distributor.

(2) Each Reimbursement Claim Form must be accompanied by documents verifying that the donation(s) reported in the form were made. Such documentation may include, but is not limited to, copies of processing records, shipping records, bills of lading, warehouse receipts, distribution records, or other documents demonstrating the reported amount of eligible dairy products were processed, donated, and distributed in accordance with the approved Milk Donation and Distribution Plan and Eligible Distributor Certification Form and as reported on the Reimbursement Claim Form.

(b) Reimbursement requests may be submitted to AMS at any time during the fiscal year and for up to 90 days after the close of the fiscal year.

(c) AMS will review and process reimbursement requests on a quarterly basis, including those submitted by the last day of the month following the end of each quarter of the fiscal year.

(d) Incomplete reimbursement requests will be returned to the submitter for revision or completion and resubmission as necessary.

■ 5. Amend part 1146 by removing the words “Dairy Donation and Distribution Plan” wherever they appear and adding, in their place, the words “Milk Donation and Distribution Plan”.

**PART 1147—[Removed and Reserved]**

■ 6. Under the authority of sec. 762, Pub. L. 116–260, 134 Stat. 1182, remove and reserve part 1147.

**Bruce Summers,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2025–09582 Filed 5–28–25; 8:45 am]

**BILLING CODE 3410–02–P**

**DEPARTMENT OF AGRICULTURE**

**Agricultural Marketing Service**

**7 CFR Part 1240**

[Doc. No. AMS–LP–21–0028]

RIN 0581–AE07

**Rescinding Natural Grass Sod Promotion, Research, and Information Order; Referendum Procedures**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Direct final rule.

**SUMMARY:** This direct final rule rescinds the referendum procedures for the proposed Natural Grass Sod Promotion, Research, and Information Order (Sod Proposed Order), issued on December 10, 2024. The referendum failed and the Sod Proposed Order was not approved, therefore it is being withdrawn through a Notice which will also be published in the **Federal Register**. Therefore, the referendum procedures for the Sod Proposed Order are no longer necessary and AMS is rescinding the part in its entirety.

**DATES:** This direct final rule is effective July 28, 2025, without further action or notice, unless a significant adverse comment is received by June 30, 2025. If a significant adverse comment is received, AMS will publish in the **Federal Register** a withdrawal of this direct final rule prior to the effective date.

**ADDRESSES:** Interested persons are invited to submit comments concerning this document by using the electronic process available at <https://www.regulations.gov>. Written comments may also be submitted to Maribel Reyna, Director, Research and Promotion Division; Telephone: (202) 302–1139; or Email: [Maribel.Reyna@usda.gov](mailto:Maribel.Reyna@usda.gov). All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, at <https://www.regulations.gov> and will be

included in the record and made available to the public.

**FOR FURTHER INFORMATION CONTACT:** Maribel Reyna, Director, Research and Promotion Division; Telephone: (202) 302–1139; or Email: [Maribel.Reyna@usda.gov](mailto:Maribel.Reyna@usda.gov).

**SUPPLEMENTARY INFORMATION:** AMS is rescinding the referendum procedures at 7 CFR part 1240 for the Sod Proposed Order issued December 10, 2024, (89 FR 99059). The Sod Proposed Order was authorized by the Commodity Promotion, Research, and Information Act of 1996 (1996 Act or Act) (7 U.S.C. 7411–7425). AMS initiated regulatory action upon receipt and review of a proposal from Turfgrass Producers International (TPI) on June 18, 2021, requesting the establishment of a natural grass sod research and promotion program (Program). The purpose of the Program was to maintain and expand markets for natural grass sod products. The Program would have been financed by an assessment on domestic sod producers.

As part of this rulemaking process, AMS initially published two proposed rulemakings in the **Federal Register** on October 16, 2023. The first rulemaking contained the Sod Proposed Order (88 FR 71306), and the second rulemaking proposed referendum procedures for the Sod Proposed Order (88 FR 71302). In both, AMS provided additional background on the industry and the need for the Program. On December 10, 2024, AMS issued a final rule, codifying the referendum procedures at part 1240 of title 7 of the CFR (89 FR 99059). On the same day, AMS published a proposed rulemaking and referendum announcing that it would be conducting an initial referendum among eligible producers to determine whether they favored establishing the Program (89 FR 99149). The proposed rulemaking stated that the Program would be established if it was favored by a majority of industry producers voting in the referendum.

AMS conducted the initial referendum from January 13, 2025, through February 11, 2025. To be eligible to vote, current natural grass sod producers must have sold natural grass sod products in the United States during the representative period from January 1, 2024, through December 31, 2024. The Sod Proposed Order would have been implemented if approved by a simple majority of producers voting in the referendum that had been engaged in the production and sale of natural grass sod products in the United States. In the referendum, 36.49 percent of those who voted favored

implementation of the Sod Proposed Order. Therefore, the Sod Proposed Order failed the referendum vote. Accordingly, based upon the referendum results, AMS is rescinding 7 CFR part 1240, “Natural Grass Sod Promotion, Research, And Information Order; Referendum Procedures” because it is no longer needed.

#### Procedural Matters

##### Executive Orders 12866 and 13563

The proposed rule codifying 7 CFR part 1240 did not meet the criteria of a “significant regulatory action” under Executive Order (E.O.) 12866, as amended by E.O. 13563, and this direct final rule to rescind that rule does not either. Therefore, the Office of Management and Budget (OMB) has not reviewed this rulemaking under those EOs.

##### Executive Order 14192

On January 31, 2025, President Trump issued E.O. 14192, “Unleashing Prosperity Through Deregulation” (90 FR 9065). The E.O. states the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people. This action is considered an E.O. 14192 deregulatory action because it removes part 1240 from title 7 of the agency’s regulations in the CFR.

##### Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the impact of this rulemaking on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such action so that small businesses will not be disproportionately burdened. The affected industry falls under the North American Industry Classification System (NAICS) code: 111421—Nursery and Tree Production. The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural producers in this industry as those having annual receipts of no more than \$3,250,000. Using these criteria, under the Sod Proposed Order, most producers and handlers would be considered small businesses. However, pursuant to the requirements set forth in the RFA, it has been determined that this rulemaking will not have a significant economic impact on a substantial number of small entities. The Sod Proposed Order was never implemented. No additional cost or burden is expected to result from this action.

#### Good Cause Justification

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with prior notice and comment for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without first publishing a proposed rule. Removing regulations at 7 CFR part 1240 will provide transparency and may reduce confusion among sod producers and other industry stakeholders. Further, AMS views this action as noncontroversial and anticipates no adverse public comment. This rule will become effective, as published in this document, July 28, 2025 without further action, unless adverse comments are received on or before June 30, 2025. Adverse comments are considered to be those comments that suggest the rule should not be adopted or suggest the rule should be changed.

If AMS receives adverse comments, we will publish a document in the **Federal Register**, withdrawing this rule before the effective date. AMS will then publish a proposed rule for public comment. Following the close of that comment period, the comments will be considered, and a final rule addressing the comments will be published.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements being terminated were approved previously by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0348. This direct final rule is deregulatory and so would not impose any additional information collection requirements; rather, it would reduce future collection requirements by removing reporting burdens.

#### E-Government Act Compliance

The Department is committed to complying with the E-Government Act, 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

#### Executive Order 13132

This direct final rule is deregulatory and has little effect on States and local governments, so AMS anticipates that this rule will not have implications for federalism. Therefore, under E.O. 13132,

section 6(b), a federalism summary is not required. States and local governments are invited to comment if they believe a federalism summary is necessary.

#### Executive Order 12988

This direct final rulemaking has been reviewed and meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, “Civil Justice Reform.” It is not intended to have a retroactive effect. The Commodity Promotion, Research, and Information Act of 1996 (1996 Act or Act) (7 U.S.C. 7411–7425) provides that the Act shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the Act, a person subject to an order may file a petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and requesting a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall be the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of entry of USDA’s final ruling.

#### Executive Order 13175

This direct final rule has been reviewed under E.O. 13175, “Consultation and Coordination with Indian Tribal Governments,” which requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on: (1) policies that have Tribal implications, including regulations, legislative comments, or proposed legislation; and (2) 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.

AMS has assessed the impact of this direct final rule on Indian Tribes and determined that this rulemaking would

not have Tribal implications that require consultation under E.O. 13175. AMS hosts a quarterly teleconference with Tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed regulation will be shared during an upcoming quarterly call, and Tribal leaders will be informed about the proposed regulation and referendum procedures. AMS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the regulations.

#### List of Subjects in 7 CFR Part 1240

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Natural grass sod, Reporting and recordkeeping requirements.

■ Accordingly, under the authority of 7 U.S.C. 7411–7425, AMS removes 7 CFR part 1240.

#### PART 1240—[Removed]

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2025–09697 Filed 5–28–25; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA–2022–C–0098]

#### Listing of Color Additives; Myoglobin; Confirmation of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; order; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA or we) is confirming the effective date of February 19, 2025, for the final order that appeared in the **Federal Register** of January 17, 2025. The final order amends the color additive regulations to provide for the safe use of myoglobin as a color additive in ground meat and ground poultry analogue products.

**DATES:** The effective date of February 19, 2025, for the final order published in the **Federal Register** of January 17, 2025 (90 FR 5590) is confirmed.

**ADDRESSES:** For access to the docket to read background documents or

comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Mical Honigfort, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1278 or Keronica Richardson, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 17, 2025 (90 FR 5590), we amended the color additive regulations to add § 73.297 (21 CFR 73.297) “Myoglobin,” to provide for the safe use of myoglobin as a color additive in ground meat and ground poultry analogue products.

We gave interested persons until February 18, 2025, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final order. Therefore, we find that the effective date of the final order that published in the **Federal Register** of January 17, 2025, should be confirmed.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the January 17, 2025, final order. Accordingly, the amendments issued thereby became effective February 19, 2025.

Dated: May 22, 2025.

**Grace R. Graham,**

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09680 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 862

[Docket No. FDA–2025–N–1159]

#### Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Plazomicin Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the plazomicin test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the plazomicin test system’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective May 29, 2025. The classification was applicable on November 19, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, [Dina.Jerebitski@fda.hhs.gov](mailto:Dina.Jerebitski@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the plazomicin test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device

(see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person

then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

**II. De Novo Classification**

On June 25, 2018, FDA received Microgenics Corporation’s request for De Novo classification of the QMS Plazomicin Immunoassay. FDA

reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 19, 2018, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 862.3460.<sup>1</sup> We have named the generic type of device plazomicin test system, and it is identified as a device intended to measure plazomicin in human specimens. Measurements obtained by this device are used in monitoring levels of plazomicin to ensure appropriate therapy in patients with complicated urinary tract infection.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—PLAZOMICIN TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Incorrect test results .....	General Controls and Special Controls (1) (21 CFR 862.3460(b)(1)) and (2) (21 CFR 862.3460(b)(2)).
Incorrect interpretation of test results .....	General Controls and Special Controls (1) (21 CFR 862.3460(b)(1)) and (2) (21 CFR 862.3460(b)(2)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with

the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

<sup>1</sup> FDA notes that the ACTION caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate

that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

nor an environmental impact statement is required.

#### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

#### PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

**Authority:** 21 U.S.C. .351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 862.3460 to subpart D to read as follows:

##### § 862.3460 Plazomicin test system.

(a) *Identification.* A plazomicin test system is a device intended to measure plazomicin in human specimens. Measurements obtained by this device are used in monitoring levels of plazomicin to ensure appropriate therapy in patients with complicated urinary tract infection.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include the following:

(i) Precision study data that demonstrates clinically appropriate precision of the plazomicin test system. Precision studies must include a minimum of three samples containing different concentrations of plazomicin, including near medical decision points throughout the expected therapeutic range of plazomicin. Samples near the medical decision points must be clinical specimens collected from patients taking plazomicin.

(ii) Method comparison data that demonstrates clinically appropriate accuracy of the plazomicin test system, as determined by FDA. Method comparison data must be collected at a minimum of three laboratory sites.

(iii) Data from studies appropriate to demonstrate that the device is free from clinically significant interference from co-administered medications that are used in patients with complicated urinary tract infection, as determined by FDA.

(2) The device's labeling required under § 809.10 of this chapter must include a warning statement that explains: "This assay should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures."

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09638 Filed 5–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA–2025–N–1183]

#### Medical Devices; Immunology and Microbiology Devices; Classification of the Inherited Nucleotide Repeat Disorder Deoxyribonucleic Acid Test

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the inherited nucleotide repeat disorder DNA test into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the inherited nucleotide repeat disorder DNA test's classification. We are taking this action because we have determined that classifying the device into class II

(special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective May 29, 2025. The classification was applicable on February 21, 2020.

**FOR FURTHER INFORMATION CONTACT:** Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, [Dina.Jerebitski@fda.hhs.gov](mailto:Dina.Jerebitski@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the inherited nucleotide repeat disorder DNA test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section

207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

**II. De Novo Classification**

On April 18, 2019, FDA received Asuragen, Inc.’s request for De Novo classification of the AmpliDx Fragile X Dx & Carrier Screen Kit. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C.

360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 21, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.5970.<sup>1</sup> We have named the generic type of device inherited nucleotide repeat disorder DNA test, and it is identified as a prescription in vitro diagnostic device that is intended to detect and identify the number of nucleotide repeats in a gene using genomic DNA isolated from post-natal patient specimens. It is solely intended as an aid for carrier testing and as an aid for the diagnosis of inherited nucleotide repeat-associated disorders. Assay results are solely intended to be used in conjunction with other clinical and diagnostic findings. These tests do not include those indicated for use for fetal diagnostic testing or newborn screening.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—INHERITED NUCLEOTIDE REPEAT DISORDER DNA TEST RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Incorrect test results .....	Certain design verification and validation, and Certain labeling information.
Incorrect interpretation of test results .....	Certain design verification and validation, and Certain labeling information.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860,

subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR

<sup>1</sup> FDA notes that the ACTION caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate

that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

#### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 866.5970 to subpart F to read as follows:

##### § 866.5970 Inherited nucleotide repeat disorder DNA test.

(a) *Identification.* An inherited nucleotide repeat disorder DNA test is a prescription in vitro diagnostic device that is intended to detect and identify the number of nucleotide repeats in a gene using genomic DNA isolated from post-natal patient specimens. It is solely intended as an aid for carrier testing and as an aid for the diagnosis of inherited nucleotide repeat-associated disorders. Assay results are solely intended to be used in conjunction with other clinical and diagnostic findings. These tests do not include those indicated for use for fetal diagnostic testing or newborn screening.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The intended use on the device's label required under § 809.10(a)(2) of this chapter and device's labeling required under § 809.10(b)(2) of this chapter must include a statement that assay results are solely intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, and that reflex testing, clinical genetic evaluation, and genetic counseling should be offered as appropriate.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) A warning that mosaicism detected in one tissue may not reflect mosaicism in other tissues and that the significance of mosaicism should be interpreted with caution in conjunction with other laboratory and clinical information (*e.g.*, sex of patient, diagnostic testing or carrier screening, patient symptoms) and should include appropriate genetic counseling.

(ii) A prominent statement that this test is not indicated for use for fetal diagnostic testing, newborn screening or for stand-alone diagnostic purposes.

(iii) Information that addresses how to interpret different result outputs specific to the technology, such as (peaks) in the electropherograms.

(3) Design verification and validation must include the following:

(i) Appropriate design features and control elements incorporated into the testing procedure that mitigate the risk of incorrect clinical results. These include controls as determined acceptable by FDA that:

(A) Enable the user to determine when the amplification may yield incorrect results,

(B) Enable the user to determine when cross contamination may have occurred;

(C) Software risk control measures that address device system hazards;

(D) Provide software traceability that ensures all hazards are adequately controlled and that all controls have been validated in the final device design; and

(E) Ensure the instructions for use and test reports appropriately inform the user about the limitations of the assay.

(ii) Validated and acceptable, as determined by FDA, criteria for test result interpretation and reporting, including result outputs.

(iii) Acceptable, as determined by FDA, evidence demonstrating the clinical validity of the device which supports each indicated diagnostic use, including for each genotype and associated phenotype used in providing a clinical determination for the target population.

(iv) Evidence demonstrating acceptable, as determined by FDA, analytical device performance. Patient specimens must represent the full spectrum of expected clinical results and be obtained through unbiased collection. Specimens must be representative of all categories of results and across the range of repeat sizes (*e.g.*, categories and repeat sizes for Fragile X syndrome are: normal 1–44 repeats; intermediate 45–54 repeats; premutation 55–200 repeats, full mutation greater than 200 repeats), across a range of allelic combinations, be near decision points, and be from both male and female subjects. The number of specimens tested must be sufficient to obtain unbiased estimates of device performance. Analytical validation must include data demonstrating acceptable, as determined by FDA:

(A) Agreement with a comparator method(s) determined to be acceptable by FDA. This evidence must demonstrate the accuracy for detecting

the size of the nucleotide repeats and the diagnostic categorical calls in DNA in the indicated specimen type(s) from patients that are representative of the intended use population. Accuracy must be assessed for both diagnostic and carrier subsets independently.

(B) Device precision including repeatability and reproducibility, using clinical samples. The study must evaluate all possible sources of variability including, as appropriate, between-site and between operator at a minimum of three sites of which two must be external with a minimum of two operators per site, between-day on a minimum of 3 non-consecutive days, between-run, within-run, between-lot in a minimum of three lots, and between instrument on a minimum of three instruments. Precision must be demonstrated per specimen and determine for both categorical call and by the size of the repeat (*i.e.*, the percentage of replicates for which the allele fell within the target precision size range). Precision data must be calculated and presented with and without results determined to be invalid.

(C) Device performance at the limit of detection of each allele across the range of sizes and as a function of the indicated DNA input for the assay.

(D) Specificity of the reagents for their targets, absence of cross-reactivity, evaluation of sources of interference relevant to the specimen type, and a demonstration of the absence of cross contamination.

(E) Performance of the pre-analytical methods, including DNA extraction methods.

(F) Performance of the device across the range of indicated DNA input concentrations for the assay.

(G) Specimen stability throughout indicated specimen storage ranges, including under expected storage and transport conditions.

(v) Robust evidence demonstrating that the number and frequency of incorrect results due to mosaicism are clinically acceptable, as determined by FDA.

(vi) An appropriate traceability plan to minimize the risk of incorrect results over time, including a description of the molecular size standards and other reagents that may be required for result interpretation, as applicable, that demonstrate the reliable interpretation of the size of the fragments.

(vii) Acceptable, as determined by FDA, device stability protocols and acceptance criteria, that are sufficient to ensure indicated analytical and clinical performance throughout the indicated device stability period. The protocols

and acceptance criteria must be adequate to demonstrate that there is no degradation in signal intensity of full mutations when testing a specimen at the latest indicated time point within the indicated device stability that is comprised of the lowest indicated DNA input that can be used.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09641 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA-2025-N-1160]

#### Medical Devices; Immunology and Microbiology Devices; Classification of the Zika Virus Serological Reagents

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the Zika virus serological reagents into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the Zika virus serological reagents' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices in part by reducing regulatory burdens.

**DATES:** This order is effective May 29, 2025. The classification was applicable on May 23, 2019.

**FOR FURTHER INFORMATION CONTACT:** Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993-0002, 301-796-2411, [Dina.Jerebitski@fda.hhs.gov](mailto:Dina.Jerebitski@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Upon request, FDA has classified Zika virus serological reagents as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will

enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a

classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

#### II. De Novo Classification

On December 26, 2018, FDA received InBios International, Inc.'s request for De Novo classification of the ZIKV Detect 2.0 IgM Capture ELISA. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 23, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21

CFR 866.3935.<sup>1</sup> We have named the generic type of device “Zika virus serological reagents,” and it is identified as *in vitro* diagnostic devices that consist of antigens or antibodies for the detection of Zika virus or Zika antibodies in human specimens from individuals who have signs and symptoms consistent with Zika virus

infection and/or epidemiological risk factors. The detection aids in the diagnosis of current or recent Zika virus infection or serological status. Negative results obtained with this test do not preclude the possibility of Zika virus infection, past or present. Positive results should be interpreted with consideration of other clinical

information and laboratory findings and should not be used as the sole basis for treatment or other patient management decisions.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ZIKA VIRUS SEROLOGICAL REAGENTS RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Risk of false results .....	Certain device description, performance characteristics, and study details in labeling; Certain device description, validation procedures, and studies; and Certain device limitations in labeling.
Failure to correctly interpret test results .....	Certain device description, performance characteristics, and study details in labeling; and Certain device limitations in labeling.
Failure to correctly operate the device .....	Certain device description, performance characteristics, and study details in labeling; Certain device description, validation procedures, and studies; and Certain device limitations in labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E,

regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 866**

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

**PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES**

■ 1. The authority citation for part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 866.3935 to subpart D to read as follows:

**§ 866.3935 Zika virus serological reagents.**

(a) *Identification.* Zika virus serological reagents are *in vitro* diagnostic devices that consist of antigens or antibodies for the detection of Zika virus or Zika antibodies in

human specimens from individuals who have signs and symptoms consistent with Zika virus infection and/or epidemiological risk factors. The detection aids in the diagnosis of current or recent Zika virus infection or serological status. Negative results obtained with this test do not preclude the possibility of Zika virus infection, past or present. Positive results should be interpreted with consideration of other clinical information and laboratory findings and should not be used as the sole basis for treatment or other patient management decisions.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The labeling required under § 809.10(b) of this chapter must include:

(i) An intended use with a detailed description of what the device detects (Zika IgM antibodies, other Zika antibodies, or Zika antigens), the type of results provided to the user, the specimen type for which testing is indicated (*e.g.*, serum, whole blood), the clinical indications appropriate for test use, and the specific population(s) for which the test is intended.

(ii) Performance characteristics from analytical and clinical studies required under paragraphs (b)(2)(ii) and (iii) of this section.

(iii) A detailed explanation of the interpretation of results and criteria for validity of results (*e.g.*, criteria that internal or external quality controls must meet in order for a test/test run to be valid, minimum signal strength that

<sup>1</sup> FDA notes the ACTION caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the

document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register’s (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

the sample has to yield to be interpretable as a valid result).

(iv) Limiting statements indicating that:

(A) Results are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. The test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.

(B) Device results are intended to be followed up according to the latest professional guidelines (*e.g.*, recommendations from the Centers for Disease Control and Prevention) for the diagnosis of Zika virus infection.

(C) Negative test results do not preclude the possibility of Zika virus infection, past or present.

(D) Specimens can result in false negative results on the device if collected outside of the appropriate response window for specific Zika virus antigens or antibodies, as determined by scientific evidence (*e.g.*, for IgM <7 days post symptom onset (ps0) or risk of exposure and if collected past 84 days ps0).

(v) Detailed instructions for use that minimize the risk of generating a false positive or false negative result (*e.g.*, co-testing of other matrices).

(2) Design verification and validation must include:

(i) A detailed device description, including all device parts (*e.g.*, Zika antigen target, other flavivirus antigen target, capture antibodies), instrument requirements, ancillary reagents required but not provided, and the technological characteristics, including all pre-analytical methods for specimen processing.

(ii) Detailed documentation and results from analytical performance studies including: characterization of the cut-off(s), analytical sensitivity to a standardized reference material that FDA has determined is appropriate (*e.g.*, World Health Organization reference standard or the Centers for Disease Control and Prevention reference standard), class specificity for human antibodies (*e.g.*, IgM or IgG), analytical specificity (cross reactivity including cross reactivity to other flaviviruses), interference, carryover/cross contamination, specimen stability, hook effect (if applicable), matrix equivalency (if applicable), freeze-thaw studies (if applicable), and reproducibility.

(iii) Detailed documentation and results from clinical studies, including the clinical study protocol (with a description of the testing algorithm and results interpretation table), detailed clinical study report, including line data

of the clinical study results, and other appropriate statistical analysis. The samples used in the clinical study must be collected from subjects representative of the full spectrum of the intended use population (*e.g.*, endemic and non-endemic regions if both are indicated).

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09639 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 876

[Docket No. FDA-2025-N-1163]

#### Medical Devices; Gastroenterology-Urology Devices; Classification of the Temporarily-Placed Urethral Opening System for Symptoms of Benign Prostatic Hyperplasia

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective May 29, 2025. The classification was applicable on February 25, 2020.

**FOR FURTHER INFORMATION CONTACT:** Mark Kreitz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2630, Silver Spring, MD 20993-0002, 301-796-7019, [Mark.Kreitz@fda.hhs.gov](mailto:Mark.Kreitz@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA has classified the temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 & (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section

513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act).

As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD & C Act, defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

**II. De Novo Classification**

On April 2, 2019, FDA received Mediate Ltd.'s request for De Novo classification of the iTind System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the

establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 25, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 876.5510.<sup>1</sup> We have named the generic type of device temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia, and it is identified as a prescription use device that is inserted transurethrally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

**TABLE 1—TEMPORARILY-PLACED URETHRAL OPENING SYSTEM FOR SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA RISKS AND MITIGATION MEASURES**

Identified risks to health	Mitigation measures
Adverse tissue reaction .....	Clinical performance testing, Biocompatibility evaluation, and Labeling.
Infection .....	Clinical performance testing, Sterilization validation, Shelf life testing, and Labeling.
Untreated symptoms due to device deployment failure .....	Clinical performance testing, Non-clinical performance testing, Shelf life testing, and Labeling.
Bleeding, perforation, trauma, obstruction, incontinence, dysuria, urgency due to device failure or difficult removal.	Clinical performance testing, Non-clinical performance testing, Shelf life testing, Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, temporarily-placed urethral opening systems for symptoms of benign prostatic hyperplasia are for

prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

**III. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Paperwork Reduction Act of 1995**

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control

<sup>1</sup> FDA notes that the ACTION caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate

that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

#### PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5510 to subpart F to read as follows:

##### § 876.5510 Temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia.

(a) *Identification.* A temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia (BPH) is a prescription use device that is inserted transurethally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate improvement in urinary outflow symptoms and document the adverse event profile.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following

performance characteristics must be tested:

- (i) Deployment and removal; and
- (ii) Mechanical strength.

(6) Labeling must include:

(i) Instructions for use, including the recommended training for safe use of the device;

(ii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events; and

(iii) A shelf life.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09640 Filed 5–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 100

[Docket No. USCG–2025–0441]

##### Special Local Regulations; Marine Events Within the Fifth Coast Guard District; Washington, DC Dragon Boat Festival

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a special local regulation for a recurring marine event in the Fifth Coast Guard District. This regulation applies to the Washington, DC Dragon Boat Festival. This action is intended to restrict vessel traffic in a portion of the Upper Potomac River near Washington, DC, in order to provide for the safety of life on navigable waters during the event.

**DATES:** On May 31, 2025, from 7:30 a.m. until 6:30 p.m., the regulations in 33 CFR 100.501 will be enforced for the location identified in table 2 to 33 CFR 100.501(i)(2) for the event denominated as “Washington, DC Dragon Boat Festival.”

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email [MDNCRMarineEvents@uscg.mil](mailto:MDNCRMarineEvents@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce special local regulations in 33 CFR 100.501 for the Washington, DC Dragon Boat Festival

regulated area from 7:30 a.m. to 6:30 p.m. on May 31, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. As stated in footnote one to table 2 to paragraph (i)(2), the enforcement dates and times for each of the listed events in the table are subject to change. Due to inclement weather, the Washington, DC Dragon Boat Festival has been rescheduled (for this year only) from the third weekend in May to May 31, 2025, for a one-day event. Our regulation for marine events within the Fifth Coast Guard District, § 100.501, specifies the location of the regulated area for the Washington, DC Dragon Boat Festival, which encompasses portions of the navigable waters of the Upper Potomac River. During the enforcement periods, as reflected in § 100.100(c), the operator of a vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcast.

Dated: May 21, 2025.

**Patrick C. Burkett,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.*

[FR Doc. 2025–09644 Filed 5–28–25; 8:45 am]

**BILLING CODE 9110–04–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2025–0385]

RIN 1625–AA00

##### Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain navigable waters of Lake Erie offshore Edgewater Beach in Cleveland, Ohio. This action is necessary to provide for the safety of life on these navigable waters during the US Rowing Beach Sprints Mini Camp. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port,

Sector Eastern Great Lakes, or a designated representative.

**DATES:** This rule is effective from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0385 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 about this rule, call or email Cody Mayerer at Marine Safety Unit Cleveland’s Waterways Management Division, U.S. Coast Guard; telephone 216–937–0111, email [D09-SMB-MSUCLEVELAND-WWM@uscg.mil](mailto:D09-SMB-MSUCLEVELAND-WWM@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 the 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 because it is impracticable. The sponsor did not notify the Coast Guard of this marine event with adequate time to provide a reasonable comment period and consider those comments before issuing the rule and establishing the safety zone by May 31, 2025.

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 immediate action is needed to ensure the safety of participants during the duration of the US Rowing Beach Sprints Mini Camp.

##### 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, Eastern Great Lakes (COTP) has determined that a safety zone is required to ensure the safety of participants and the navigable waters before, during, and after the scheduled marine event.

##### IV. Discussion of the Rule

This rule establishes a safety zone from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025. The safety zone will cover all navigable waters and tributaries within 250 meters (820 ft) offshore Edgewater Park Beach. There will be 2 parallel lines of 3 buoy’s perpendicular to shore extending 250 meters from water’s edge. The boundaries of the safety zone form a rectangle with the four corners of the polygon located in the following positions: (1) 41°29’22” N, 081°44’20” W; (2) 41°29’29” N, 081°44’25” W; (3) 41°29’25” N, 081°44’34” W; (4) 41°29’18” N, 081°44’29” W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the US Rowing Mini Camp is in session. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

##### 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.

###### 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. 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 rule. This safety zone would restrict navigation for a relatively small area near Edgewater Beach for the course area for 13 hours on one day, and 2 hours on the second day.

###### 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 will 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 that will restrict navigation through the course area for 13.0 hours one day, and 2.5 hours on the second day. 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. 1. 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.

#### **List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and record keeping 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.T09–0385 to read as follows:

#### **§ 165.T09–0385 Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH**

(a) *Location.* The safety zone covers all navigable waters and tributaries of Lake Erie within Edgewater Park Beach. The boundaries of the safety zone form a rectangle with the corners of the polygon located at the following coordinates: (1) 41°29′22″ N, 081°44′20″ W; (2) 41°29′29″ N, 081°44′25″ W; (3) 41°29′25″ N, 081°44′34″ W; (4) 41°29′18″ N, 081°44′29″ W then return to position (1) above (NAD 83).

(b) *Enforcement Period.* This section will be enforced from 6:30 a.m. to 7:30 p.m. on May 31, 2025, and from 1:30 p.m. to 3:30 p.m. on June 1, 2025.

(c) *Definitions.* *Official Patrol Vessel* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Eastern Great Lakes in the enforcement of the regulations in this section. Participant means all persons and vessels attending the event.

(d) *Regulations.* (1) The Coast Guard may patrol the event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM.”

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators.

(3) Spectator vessels desiring to transit the safety zone may do so only with prior approval of the Patrol Commander and when so directed by that officer and will be operated at a no wake speed in a manner which will not endanger participants in the event or any other craft.

(4) No spectator shall anchor, block, loiter, or impede the through transit of official patrol vessels in the safety zone during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) The Patrol Commander may forbid and control the movement of all vessels in the safety zone. When hailed or signaled by an official patrol vessel, a

vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(6) Any spectator vessel may anchor outside the regulated areas specified in this chapter, but may not anchor in, block, or loiter in a navigable channel.

(7) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary.

(8) The Patrol Commander will terminate enforcement of the safety zone at the conclusion of the event.

Dated: May 13, 2025.

**Sean M. Murray**

*Commander, U.S. Coast Guard, Alternate Captain of the Port Sector Eastern Great Lakes.*

[FR Doc. 2025–09590 Filed 5–28–25; 8:45 am]

**BILLING CODE 9110–04–P**

### **DEPARTMENT OF HOMELAND SECURITY**

#### **Coast Guard**

#### **33 CFR Part 165**

[Docket Number USCG–2025–0364]

**RIN 1625–AA00**

#### **Safety Zone; Delaware River, Camden, NJ, Battleship New Jersey**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for waters of the Delaware River, in Camden, NJ, for a clay shoot aboard the Battleship New Jersey on June 26, 2025, or on a rain date before July 4, 2025. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the clay shoot. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Delaware Bay (COTP).

**DATES:** This rule is effective from June 26, 2025, through July 4, 2025. It will only be subject to enforcement, however, on the one day during that time period when the event takes place. Absent postponement, that date will be June 26, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2025–0364 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 Petty Officer Dylan Caikowski, Sector Delaware Bay, Waterways Management Division, U.S. Coast Guard; telephone (206) 815-6688, option 3, email [SecDelBayWWM@uscg.mil](mailto:SecDelBayWWM@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
 COTP Captain of the Port Sector Delaware Bay  
 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

On April 1, 2025, an organization notified the Coast Guard that it will be conducting a clay shoot from the decommissioned, historic Battleship New Jersey, in Camden, NJ, from 1 p.m. to 6 p.m. on June 26, 2025. The participants will fire bird shot at clay targets from the port side of the Battleship New Jersey into the Delaware River.

The Coast Guard is issuing this temporary rule under the 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 because it is impracticable to do so. There is insufficient time to publish an NPRM, allow for a reasonable comment period, and publish a final rule, given that the rule must be in force by June 26, 2025 to serve its purpose.

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**. It is impracticable to delay the effective date of this rule because it must be in place by June 26 to serve its intended purpose.

##### 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 Delaware Bay (COTP) has determined that clay shoot from the Battleship New Jersey could pose a risk to waterway users if normal

vessel traffic were allowed to transit within 800 feet of the Battleship New Jersey. Possible hazards include risks of injury or death from dangerous projectiles hitting vessels traversing through the regulated area.

##### IV. Discussion of the Rule

This rule establishes a safety zone from 1 p.m. through 6 p.m. on June 26, 2025, or on a rain date no later than July 4, 2025. The specific date and time of any rain date will be published via Local Notice to Mariners and Broadcast Notice to Mariners. The safety zone will cover all navigable waters within 800 feet of the Battleship New Jersey, on the Delaware River, in Camden, NJ. The coordinates of the safety zone are provided in the proposed language of the rule, below. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled clay shoot. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

##### 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.

###### 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. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size and duration of the regulated area, which would impact a small, designated area of the Delaware River. Vessels will be able to safely transit around the regulated area during the enforcement period. The Coast Guard will provide advance notification of the special local regulation to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

###### B. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, do not apply this rule. They do not apply because this rule fits a 5

U.S.C. 553(b)(B) good-cause exception for notice-and-comment rulemaking, and rules not subject to notice and comment are not required to do regulatory flexibility analyses.

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 safety zone lasting only 5 hours that will prohibit entry within 800 feet of the Battleship New Jersey, on the Delaware River, in Camden, NJ. 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. 1. 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.

### 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.T05–0364 to read as follows:

#### § 165.T05–0364 Safety Zone; Delaware River, Camden, NJ, Battleship New Jersey.

(a) *Location.* All navigable waters within 800 feet of the Battleship New

Jersey, on the Delaware River, in Camden, NJ, located at approximate position latitude 39°56.36' N, longitude 075°07.99' W.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port (COTP), Sector Delaware Bay in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter or remain in the zone, contact the COTP or the COTP's representative via VHF–FM channel 16 or 215–271–4807. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) No vessel may take on bunkers or conduct lightering operations within the safety zone during its enforcement period.

(4) This section applies to all vessels except those engaged in law enforcement, aids to navigation servicing, and emergency response operations.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This zone will be enforced from 1 p.m. through 6 p.m. on June 26, 2025, or a rain date no later than July 4, 2025. The specific date and time of any rain date will be published via Local Notice to Mariners and Broadcast Notice to Mariners.

Dated: May 14, 2025.

**Kate F. Higgins-Bloom,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Delaware Bay.*

[FR Doc. 2025–09589 Filed 5–28–25; 8:45 am]

**BILLING CODE 9110–04–P**

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2025–0432]

#### Safety Zone; Lakeshore State Park, Milwaukee, WI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Safety Zone, Lakeshore State Park, Milwaukee, WI on a portion of Lake Michigan in Milwaukee, WI. This action is intended to protect personnel, vessels, and the marine environment from potential hazards created by a land-based fireworks display. During the enforcement period listed below, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated representative.

**DATES:** The regulations in 33 CFR 165.929 will be enforced for the Lakeshore State Park safety zone event listed in item 2 in Table 4 to § 165.929, from 10:00 p.m. to 11:30 p.m., on May 31, 2025.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email Lieutenant Commander Jessica Anderson, Waterways Management Division, Sector Lake Michigan, U.S. Coast Guard; telephone: (414) 747–7182, email: *D09-SMB-SECLAKEMICHIGAN-WWM@uscg.mil*.

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce a safety zone regulation in 33 CFR 165.929 for the Lakeshore State Park fireworks event in item 2 in Table 4 to § 165.929 from 10:00 p.m. to 11:30 p.m. on May 31, 2025. The regulation for recurring marine events within the State of Wisconsin in item 2 in Table 4 to § 165.929, specifies the location of the regulated area for this event. All vessels must obtain permission from the Captain of the Port (COTP) Lake Michigan, or designated on-scene representative to enter, move within, or exit this safety zone during the enforcement time listed in this notice of enforcement. Vessels and persons granted permission to enter the safety zone must obey all lawful orders or directions of the COTP Lake Michigan or designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel must proceed as directed.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with notification of this enforcement period via Broadcast Notice to Mariners. The COTP Lake Michigan may be reached by contacting the Coast Guard Sector Lake Michigan Command Center at (414) 747–7182. An

on-scene designated representative may be reached via VHF-FM Channel 16.

Dated: May 22, 2025.

**J.B. Parker,**

*Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.*

[FR Doc. 2025-09643 Filed 5-28-25; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2025-0376]

RIN 1625-AA00

#### Safety Zone; USS Lexington, Corpus Christi, TX

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for navigable waters off the port side of the USS Lexington in Corpus Christi Bay, while the United States Army conducts jump training. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by this exercise. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi.

**DATES:** This rule is effective on June 7, 2025, from 7 a.m. through 11 a.m.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2025-0376 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 about this rule, call or email Lieutenant Timothy Cardenas, Waterways Management Division, U.S. Coast Guard; (361) 244-4784, email [Timothy.J.Cardenas@uscg.mil](mailto:Timothy.J.Cardenas@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 the 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 because it is impracticable. On April 28, 2025, the United States (U.S.) Army notified the Coast Guard that it would be conducting training on June 7, 2025, involving Army personnel jumping from the deck of the museum vessel USS Lexington into Corpus Christi Bay. This safety zone must be established prior to the exercise to protect United States Army personnel, the public, vessels, and the marine environment from potential hazards created during this training exercise. The Coast Guard therefore lacks sufficient time to provide a reasonable comment period and then a period to 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 prompt action is needed to respond to potential safety hazards associated with this U.S. Army training exercise.

##### 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 Corpus Christi (COTP) has determined that potential hazards associated with a jump training exercise on June 7, 2025, will be a safety concern for participating U.S. Army personnel and for anyone within the safety zone off the port side of the USS Lexington. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the exercise occurs.

##### IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. through 11 a.m. on June 7, 2025. The safety zone will cover all navigable waters within the area encompassed by a line connecting the following points: beginning at Point 1: 27°48'57.76" N, 97°23'19.17" W; thence to Point 2: 27°48'50.75" N, 97°23'16.62"

W; thence to Point 3: 27°48'54.34" N, 97°23'5.73" W; thence to Point 4: 27°49'0.15" N, 97°23'11.33" W; thence returning to Point 1. No vessel or person will be permitted to enter the temporary safety zone during the period in which the rule is subject to enforcement without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 (156.8 MHz) or by telephone at (361) 939-0450. The Coast Guard will issue Broadcast Notices to Mariners and Safety Marine Information Broadcasts to inform the public of these restrictions.

##### 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.

###### 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. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the safety zone. The safety zone covers 1 quarter of a square mile area of the Corpus Christi Bay outside of the navigational channel, and vessels will be able to transit around this area unimpeded. The temporary safety zone will be subject to enforcement for a period of only four hours on June 7, 2025. Vessels may also be allowed to enter the zone during the enforcement period with prior approval of the COTP.

###### 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 will 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 establishing a temporary safety zone for navigable waters in Corpus Christi Bay lasting approximately four hours on one day. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created during a U.S. Army jump training exercise. 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. 1. 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.

#### 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.T08–0376 to read as follows:

#### § 165.T08–0376 Safety Zones; Corpus Christi Bay, Corpus Christi, TX.

(a) *Location.* The following area is a safety zone: All waters of Corpus Christi Bay, from surface to bottom, encompassed by a line connecting the following points: Point 1 at 27°48'57.76" N, 97°23'19.17" W; thence to Point 2 at 27°48'50.75" N, 97°23'16.62" W; thence to Point 3 at 27°48'54.34" N, 97°23'5.73" W; thence to Point 4 at 27°49'0.15" N, 97°23'11.33" W; thence returning to Point 1. These coordinates are based on World Geodetic System (WGS) 84.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Corpus Christi (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by on Channel 16 VHF–FM (156.8 MHz) or by telephone at (361) 939–0450. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 7 a.m. through 11 a.m. on June 7, 2025.

Dated: May 19, 2025.

**Torrey H. Bertheau,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.*

[FR Doc. 2025–09677 Filed 5–28–25; 8:45 am]

**BILLING CODE 9110–04–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2020–0449; FRL–12713–01–OCSPP]

#### Florylpicoxamid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of florylpicoxamid in or on multiple commodities which are identified and discussed later in this document. Corteva Agriscience, LLC requested

these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective on May 29, 2025. Objections and requests for hearings must be received on or before July 28, 2025, 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-2020-0449, is available at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, 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: [RDNRNotices@epa.gov](mailto:RDNRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*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).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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 . . ."

*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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the docket ID number EPA-HQ-OPP-2020-0449 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 July 28, 2025.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_upload.nsf](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

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 at <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. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of October 27, 2020 (85 FR 68030 (FRL-10015-86-OCSP)), 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 0F8836) by Dow AgroSciences LLC (currently Corteva Agriscience, LLC), 9330 Zionsville Road, Indianapolis, IN. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide florylpicoxamid, (1S)-2,2-bis(4-fluorophenyl)-1-methylethyl N-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate in or on barley, bran at 0.2 parts per million (ppm); barley, grain at 0.05 ppm; barley, hay at 2.0 ppm; barley, straw at 0.9 ppm; beans, dried shelled (except soybean), straw at 0.9 ppm; beet, sugar, dried pulp at 0.4 ppm; beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 0.3 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.02 ppm; pea, dried shelled, hay at 8.0 ppm; pea, dried shelled, vines at 3.0 ppm; rapeseed subgroup 20A, fodder/straw at 2.0 ppm; rapeseed subgroup 20A, seed at 0.04 ppm; wheat, aspirated grain fractions at 0.1 ppm; wheat, bran at 0.05 ppm; wheat, forage at 2.0 ppm; wheat, grain at 0.02 ppm; wheat, hay at 4.0 ppm; wheat, straw at 0.3 ppm; and in or on the raw agricultural commodity cattle, fat at 0.02 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; egg at 0.02 ppm; goat, fat at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproduct at 0.02 ppm; horse, fat at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproduct at 0.02 ppm; milk at 0.02 ppm; poultry, fat at 0.02 ppm;

poultry, liver at 0.02 ppm; poultry, muscle at 0.02 ppm; sheep, fat at 0.02 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts at 0.02 ppm. The Agency's notice of filing document referenced a summary of the petition prepared by Corteva Agriscience, LLC, the registrant, which is available in the docket. Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified several tolerance expressions, the tolerances, and commodity definitions. The reasons for these changes are explained in this document.

### III. Aggregate Risk Assessment and Determination of Safety

#### A. EPA's Safety Determination

Consistent with FFDC section 408(b)(2)(D), and the factors specified in FFDC section 408(b)(2)(D), 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 florylpicoxamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with florylpicoxamid follows.

#### B. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. Florylpicoxamid is a picolinamide fungicide that inhibits the quinone oxidase enzyme of Complex III in the mitochondrial electron transport chain, leading to disruption of cellular respiration. A mammalian mode of action is not known. The studies available in the toxicity database indicate that toxicity is low for florylpicoxamid and are protective of toxicity from mammalian metabolites of florylpicoxamid. The only adverse effects were observed in a 90-day oral study in dogs, a developmental study in rabbits, and a combined chronic/carcinogenicity study in rats. In the other studies, effects were not observed at the highest doses tested, ranging from 123 mg/kg/day to the limit dose of 1000 mg/kg/day. The systemic effect of decreased body weight, an effect

common to the picolinamide chemical class, was the most consistent seen throughout the database.

Adaptive liver effects including increased liver weights and very slight to slight hepatocellular hypertrophy were among the most common observations in the florylpicoxamid database. In the absence of corroborating toxic effects such as clinical chemistry (e.g., liver enzymes) or other histopathological changes (e.g., hepatocellular necrosis and inflammation), these effects are considered an adaptive response of the liver as it activates to metabolize the xenobiotic, rather than being adverse.

No increased fetal or offspring susceptibility was observed in developmental toxicity studies in rats and rabbits or in reproductive and fertility effects studies in rats. The only effect of note in those studies was late abortions seen in two maternal rabbits.

No evidence of neurotoxicity or immunotoxicity was seen throughout the toxicity database for florylpicoxamid, and a non-guideline 90-day oral study in rats that evaluated these systems did not reveal treatment-related effects up to the highest dose tested (185 mg/kg/day). No toxicity was seen up to the limit dose in a 28-day dermal study. Florylpicoxamid has low acute oral, inhalation, and dermal toxicity, and is not a skin or eye irritant (Toxicity Category IV, except for oral and dermal Toxicity Categories of III), or a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by florylpicoxamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the document "Florylpicoxamid: Human Health Risk Assessment for the New Active Ingredient" at pages 20–23 in docket ID number EPA-HQ-OPP-2020-0449.

#### C. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the NOAEL and the LOAEL. Uncertainty/safety factors are used in conjunction

with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

For more detailed information on the toxicological endpoints for florylpicoxamid used for human risk assessment can be found in the document "Florylpicoxamid Human Health Risk Assessment for the New Active Ingredient" in docket ID number EPA-HQ-OPP-2020-0449.

#### D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to florylpicoxamid, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from florylpicoxamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for florylpicoxamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (USDA 2005–2010 NHANES/WWEIA). As to residue levels in food, EPA conducted a partially refined chronic aggregate dietary (food and drinking water) exposure and risk assessment and incorporated 100% crop treated (PCT) for all commodities. The chronic dietary exposure analysis incorporated recommended tolerances for livestock commodities, as the residues of concern for both tolerance enforcement and risk assessment are the same in livestock. While the residue of concern for tolerance enforcement in plants is parent florylpicoxamid only, the residues of concern for risk assessment are florylpicoxamid and

metabolite X12485649. Therefore, to account for the residues of concern for risk assessment, the chronic dietary exposure analysis incorporated average field trial residues of florylpicoxamid and metabolite X12485649 for all plant commodities (raw and processed) in this action.

The analysis incorporated default processing factors. Additionally, the submitted wheat and barley residue data demonstrate that residues of X12485649 concentrate in wheat bran and barley bran. Therefore, anticipated residues of 0.054 ppm and 0.051 ppm based on the residues of concern for risk assessment were used for barley bran and wheat bran, respectively.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that florylpicoxamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is not required.

iv. *Anticipated residue and PCT information.* EPA did not use PCT information in the dietary assessment for florylpicoxamid. Tolerance level residues were assumed for all livestock commodities. 100 PCT was assumed for all crop commodities.

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.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for florylpicoxamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of florylpicoxamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>.

Based on the Pesticide in Water Calculator model (PWC Version 2.001),

which utilizes the Pesticide Root Zone Model (PRZM5) and the Variable Volume Water Model (VWWM), the estimated drinking water concentrations (EDWCs) of florylpicoxamid residues of concern for acute exposures are estimated to be 37.5 parts per billion (ppb) for surface water and 318 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 32 ppb for surface water and 212 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 212 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Florylpicoxamid is not currently registered for any specific use patterns that would result in residential handler exposure, but there are residential post-application exposures expected from contact with previously treated turf on golf courses. There is the potential for dermal post-application exposure for youth (11 to <16 years old) and adults exposed as a result of golfing on treated turf. Residential post-application exposure is expected to be short-term in duration. Intermediate-term exposures are not likely. Dermal exposures only are anticipated while golfing on treated turf; however, there is no dermal endpoint selected for children. Therefore, only dermal exposures for adults and youths (11 to <16 years old) have been quantitatively assessed and there are no additional routes to combine.

*Cumulative effects from substances with a common mechanism of toxicity.* 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 florylpicoxamid and any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that florylpicoxamid does not have a common mechanism of toxicity

with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>.

#### *E. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No increased prenatal or postnatal susceptibility was detected in developmental or reproductive studies in rats and rabbits, as no fetal or offspring effects were observed in either study. The late abortions observed in rabbit are considered a maternal effect only.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for florylpicoxamid is complete.

ii. There is no indication that florylpicoxamid is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional Uncertainty Factors to account for neurotoxicity.

iii. There is no evidence that florylpicoxamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The partially refined chronic dietary assessment utilized tolerance-level residues for livestock commodities, field trial residue data for all plant commodities (raw and processed) to account for residues of concern for risk assessment, 100 PCT, and default processing factors. EPA made conservative (protective) assumptions in

the ground and surface water modeling used to assess exposure to florylpicoxamid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by florylpicoxamid.

#### F. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, florylpicoxamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to florylpicoxamid from food and water will utilize 4.3% of the cPAD for females 13–49 years old the population group with the highest risk estimate. The population subgroup with the highest dietary exposure is all infants (<1 year old), with an exposure of 0.016275 mg/kg/day at 3.5% of the cPAD. As there are no anticipated long-term residential exposures based on the explanation in Unit III.C.3., the chronic aggregate assessment is equivalent to the chronic dietary assessment.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Florylpicoxamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to florylpicoxamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the

combined short-term food, water, and residential exposures result in aggregate MOEs of 2,200 for adults and 2,900 for youth (11 to <16 years). Dermal exposures only are anticipated while golfing on treated turf. Because EPA's level of concern for florylpicoxamid is a MOE of 100 or below, these MOEs are not of concern.

#### 4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential exposure scenarios which are expected to be intermediate-term, florylpicoxamid is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, florylpicoxamid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to florylpicoxamid residues.

### IV. Other Considerations

#### A. Analytical Enforcement Methodology

The petitioner has proposed a multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; JRF Method No. AU298R0) for the determination of florylpicoxamid in plant and livestock commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### 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 Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to

which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for florylpicoxamid.

#### C. Response to Comments

Two comments were received in response to the October 27, 2020, notice of filing. One comment was from Sheryl Kunickis, Ph.D., Director at the United States Department of Agriculture in support of the petition, discussing reported efficacy of florylpicoxamid, describing it as having “excellent foliar uptake and redistribution properties on dicot and monocot plants, as well as excellent curative reachback activity” and being “highly active against a broad spectrum of diseases”. Dr. Kunickis discussed the benefits of florylpicoxamid as a novel mode of action with no cross resistance and states “[b]ased on its reported efficacy and novel mode of action, USDA believes that florylpicoximide [*sic*] demonstrates potential to serve as a beneficial new tool for U.S. growers.” The Agency appreciates the supportive comments from Dr. Kunickis, and one additional Anonymous commenter, and is moving forward with issuing the tolerance.

#### D. Revisions to Petitioned-For Tolerances

Based on EPA's review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested under its authority in FFDCA section 408(d)(4)(A)(i). Some commodity terms are altered to be consistent with Agency nomenclature and to reflect the crop group definition updates from 2022. EPA is not establishing tolerances on barley, bran; beet, sugar, dried pulp; wheat, aspirated grain fractions; and wheat, bran. The Agency determined that the residue of concern is parent only and parent did not concentrate in these processed commodities. Therefore, separate tolerances are not required as they are covered by the tolerances on the associated raw agricultural commodities.

EPA is removing the plant metabolite X12485649 as a residue of concern for tolerance enforcement for plants. Both parent and metabolite X12485649 were the major residues in plant metabolism studies, and both were found in quantifiable amounts in magnitude of the residue for crops. Residues of parent florylpicoxamid would be sufficient to detect misuse and serve as the residue

of concern for tolerance enforcement for plants. Therefore, the tolerance expression for plant commodities is parent only.

To support the updated 2022 crop group definitions, EPA updated the crop commodity definitions by changing pea and bean, dried shelled, except soybean, subgroup 6C to vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E and vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F; and pea, dried shelled, vines and pea, dried shelled, hay to vegetable, legume, forage and hay, except soybean, subgroup 7–22A. EPA also corrected the commodity definitions by changing poultry, muscle to poultry, meat, and beet, sugar, tops to beet, sugar, leaves. To align with the labeled uses, the Agency is not establishing tolerances on the full rapeseed subgroup 20A and is instead establishing a tolerance only on canola.

EPA is establishing tolerance levels lower than what the petitioner requested for barley, grain corrected to 0.03 ppm, barley, hay to 1.5 ppm, barley, straw to 0.5 ppm, beet, sugar, leaves to 0.1 ppm, beet, sugar, roots to 0.01 ppm, vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E to 0.01 ppm, vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F to 0.01 ppm, vegetable, legume, forage and hay, except soybean, subgroup 7–22A to 6 ppm, rapeseed subgroup 20A to 0.015 ppm, wheat, forage to 1.5 ppm, wheat, grain to 0.01 ppm, wheat, hay to 3 ppm, and wheat, straw to 0.05 ppm. This corrects for the plant residue of concern for tolerance expression being the florylpicoxamid parent compound only.

## V. Conclusion

Therefore, tolerances are established for residues of florylpicoxamid, (1S)-2,2-bis(4-fluorophenyl)-1-methylethyl N-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate, in or on barley, grain at 0.03; barley, hay at 1.5; barley, straw at 0.5; beet, sugar, leaves at 0.1; beet, sugar, roots at 0.01; vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E at 0.01; vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F at 0.01; vegetable, legume, forage and hay, except soybean, subgroup 7–22A at 6; canola at 0.015; wheat, forage at 1.5; wheat, grain at 0.01; wheat, hay at 3; wheat, straw at 0.05 ppm. Tolerances are established for residues of florylpicoxamid, (1S)-2,2-bis(4-fluorophenyl)-1-methylethyl N-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate, and its metabolite, (2S)-1,1-bis(4-

fluorophenyl)propan-2-yl N-[[3-hydroxy-4-methoxy-pyridin-2-yl]carbonyl]-L-alaninate, in or on cattle, fat at 0.02; cattle, meat at 0.02; cattle, meat byproducts at 0.02; egg at 0.02; goat, fat at 0.02; goat, meat at 0.02; goat, meat byproducts at 0.02; hog, fat at 0.02; hog, meat at 0.02; hog, meat byproducts at 0.02; horse, fat at 0.02; horse, meat at 0.02; horse, meat byproducts at 0.02; milk at 0.02; poultry, fat at 0.02; poultry, liver at 0.02; poultry, meat at 0.02; sheep, fat at 0.02; sheep, meat at 0.02; sheep, meat byproducts at 0.02 ppm.

## VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/regulations/and-executive-orders>.

### A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

### B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

### C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

### D. Regulatory Flexibility Act (RFA)

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

### E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small

governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

### F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects 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.

### G. 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.

### H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866.

### I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

### J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

### K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: May 22, 2025.

Edward Messina,

Office Director, Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA is amending 40 CFR chapter I 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. Add § 180.727 to subpart C to read as follows:

**§ 180.727 Florylpicoxamid; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of

florylpicoxamid, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in table 1 is to be determined by measuring only florylpicoxamid ((1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate) in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Barley, grain .....	0.03
Barley, hay .....	1.5
Barley, straw .....	0.5
Beet, sugar, leaves .....	0.1
Beet, sugar, roots .....	0.01
Canola .....	0.015
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E .....	0.01
Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F .....	0.01
Vegetable, legume, forage and hay, except soybean, subgroup 7–22A .....	6
Wheat, forage .....	1.5
Wheat, grain .....	0.01
Wheat, hay .....	3
Wheat, straw .....	0.05

(2) Tolerances are established for residues of florylpicoxamid, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in table 2 is to

be determined by measuring only the sum of florylpicoxamid ((1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate) and its metabolite (2*S*)-1,1-bis(4-

fluorophenyl)propan-2-yl *N*-[[3-hydroxy-4-methoxypyridin-2-yl]carbonyl]-L-alaninate, calculated as the stoichiometric equivalent of florylpicoxamid, in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat .....	0.02
Cattle, meat .....	0.02
Cattle, meat byproducts .....	0.02
Egg .....	0.02
Goat, fat .....	0.02
Goat, meat .....	0.02
Goat, meat byproducts .....	0.02
Hog, fat .....	0.02
Hog, meat .....	0.02
Hog, meat byproducts .....	0.02
Horse, fat .....	0.02
Horse, meat .....	0.02
Horse, meat byproducts .....	0.02
Milk .....	0.02
Poultry, fat .....	0.02
Poultry, liver .....	0.02
Poultry, meat .....	0.02
Sheep, fat .....	0.02
Sheep, meat .....	0.02
Sheep, meat byproducts .....	0.02

(b)–(d) [Reserved]

[FR Doc. 2025–09679 Filed 5–28–25; 8:45 am]

BILLING CODE 6560–50–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Parts 417, 422, 423, and 460**

[CMS–4208–CN]

RIN 0938–AV40

**Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors in the final rule that appeared in the April 15, 2025 **Federal Register**, titled “Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.”

**DATES:** *Effective date:* This correcting document is effective May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Lucia Patrone, (410) 786–8621—General Questions.

**SUPPLEMENTARY INFORMATION:****I. Background**

In FR Doc. 2025–06008 of April 15, 2025 (90 FR 15792), there were a few technical and typographical errors that are identified and corrected in this correcting document. The corrections in this correcting document are applicable to the effective date beginning June 3, 2025, as if they had been included in the document that appeared in the April 15, 2025, **Federal Register**.

**II. Summary of Errors**

On page 15899, we made an error in the CMS identification number of a collection of information request.

On page 15903, we made errors in Table 11 which provides the summary of the transfers and costs for the final rule. For the entry regarding costs, we

made errors in the first year and year range of the costs.

**III. Waiver of Proposed Rulemaking and Delay in Effective Date**

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment on a proposed rule. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment for rulemaking to carry out the administration of the Medicare program under title XVIII of the Act. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements. In cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in the effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this correcting document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements of the APA or section 1871 of the Act. This correcting document corrects typographical and technical errors in the preamble of the final rule but does not make substantive changes to the policies that were adopted in the

final rule. As a result, this correcting document is intended to ensure that the information in the final rule accurately reflects the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the regulatory text correction in this document into the final rule or delaying the effective date would be unnecessary, as we are not altering our policies or regulatory changes, but rather, we are simply implementing the policies and regulatory changes that we previously proposed, requested comment on, and subsequently finalized.

This final rule correcting document is intended solely to ensure that the final rule accurately reflects policies and regulatory changes that have been adopted through rulemaking. Furthermore, such notice and comment procedures would be contrary to the public interest because it is in the public's interest to ensure that the final rule accurately reflects our policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

**IV. Correction of Errors**

In FR Doc. 2025–06008 of April 15, 2025 (90 FR 15792), make the following corrections:

1. On page 15899, second column, third full paragraph, lines 4 and 5, the parenthetical reference “(CMS–10662)” is corrected to read “(CMS–10062)”.

2. On page 15903, top half of the page, in the table titled “Table 11—Summary of the Transfers and Costs of the Final Rule by Provision and Year”, the fourth row (COSTS),

a. Second column, the year “2026” is corrected to read “2025”.

b. Last column, the years “2026–2035” are corrected to read “2025–2034”.

**Cortney L. McCormick,**

*Executive Secretary to the Department, Department of Health and Human Services.*

[FR Doc. 2025–09695 Filed 5–28–25; 8:45 am]

BILLING CODE 4120–01–P

**DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service****50 CFR Part 17**

[Docket No. FWS-R6-ES-2022-0093;  
FXES1113090000-256-FF09E22000]

RIN 1018-BG56

**Endangered and Threatened Wildlife and Plants; Removal of Colorado Hookless Cactus From the List of Endangered and Threatened Plants**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), are removing Colorado hookless cactus (*Sclerocactus glaucus*) from the Federal List of Endangered and Threatened Plants. Recent taxonomic studies have indicated that the currently listed entity is actually two species: *Sclerocactus glaucus* and *Sclerocactus dawsoniae* (previously identified as *S. dawsonii* in the proposed rule). When we use the common name “Colorado hookless cactus” or refer to “the species” in this final rule, we are referring to information or conclusions regarding both species (*S. glaucus* and *S. dawsoniae*) as the currently listed entity. When we are referring to information or analysis pertaining to one species, we will use the new scientific names of *S. glaucus* or *S. dawsoniae*. After a review of the best available scientific and commercial information, we find that delisting Colorado hookless cactus is warranted. Our review indicates that the threats to the Colorado hookless cactus have been eliminated or reduced to the point that the species no longer meets the definition of an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). Accordingly, the prohibitions and conservation measures provided by the Act, particularly through sections 4 and 7, will no longer apply to the Colorado hookless cactus.

**DATES:** This rule is effective June 30, 2025.

**ADDRESSES:** This final rule is available on the internet at <https://www.regulations.gov>. Comments and materials we received are available for public inspection at <https://www.regulations.gov> at Docket No. FWS-R6-ES-2022-0093

*Availability of supporting materials:* This rule and supporting documents, including references cited, the 5-year review, the recovery outline, the species

status assessment (SSA) report, the proposed delisting rule, and the post-delisting monitoring (PDM) plan, are available at <https://www.regulations.gov> at Docket No. FWS-R6-ES-2022-0093.

**FOR FURTHER INFORMATION CONTACT:**

Nathan Darnall, Western Colorado Supervisor, U.S. Fish and Wildlife Service, Colorado Ecological Services Field Office, 445 West Gunnison Avenue, Grand Junction, CO 81501; telephone 970-628-7181. 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:**

**Executive Summary**

*Why we need to publish a rule.* Under the Act, a species warrants delisting if it no longer 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). The Colorado hookless cactus is listed as a threatened species, and we are delisting it. Delisting a species 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 are delisting the Colorado hookless cactus because the species has recovered to the point at which it no longer meets the definition of an endangered or threatened species.

*The basis for our action.* Under the Act, we may determine that a species is an endangered species or a 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. The determination to delist a species must be based on an analysis of the same factors.

Under the Act, we must review the status of all listed species at least once every 5 years. We must delist a species if we determine, on the basis of the best available scientific and commercial

data, that the species is neither a threatened species nor an endangered species. Our regulations at 50 CFR 424.11(e) identify four reasons why we might determine a species shall be delisted: (1) The species is extinct, (2) the species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species, (3) new information that has become available since the original listing decision shows the listed entity does not meet the definition of an endangered species or a threatened species, or (4) new information that has become available since the original listing decision shows the listed entity does not meet the definition of a species. Here, we have determined that the Colorado hookless cactus has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species; therefore, we are delisting it.

**Previous Federal Actions**

Please refer to the proposed rule to delist the Colorado hookless cactus published on April 11, 2023 (88 FR 21582), for a detailed description of previous Federal actions concerning this species.

**Peer Review**

A species status assessment (SSA) team prepared the SSA report for Colorado hookless cactus to inform the 2021 5-year review and updated it in 2024. 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 of listing and recovery actions under the Act (<https://www.fws.gov/sites/default/files/documents/peer-review-policy-directors-memo-2016-08-22.pdf>), we solicited independent scientific review of the information contained in the Colorado hookless cactus SSA report. As discussed in the proposed rule, we sent the SSA report to five independent peer reviewers and received three responses. The peer reviews can be found at <https://www.regulations.gov>. In preparing the proposed rule, we incorporated the results of these reviews, as appropriate, into the SSA report, which was the foundation for the proposed rule and

this final rule. A summary of the peer review comments and our responses can be found in the proposed rule (88 FR 21582, April 11, 2023).

### Summary of Changes From the Proposed Rule and Draft Post-Delisting Monitoring Plan

We considered all comments and information we received during the comment period on our proposed rule to delist Colorado hookless cactus (88 FR 21582, April 11, 2023). This consideration resulted in the following changes from the proposed rule and draft post-delisting monitoring (PDM) plan to this final rule and the updated PDM plan.

In this final rule, we changed the scientific name *Sclerocactus dawsonii* to *S. dawsoniae* based on taxonomic nomenclature standards and a recently published article establishing it as a new species (McGlaughlin and Naibauer 2024, entire).

In the proposed rule and SSA version 1.1, we reported a minimum population estimate of 103,086 plants for *Sclerocactus glaucus* with a 90 percent lower confidence level estimate of 68,120 plants (88 FR 21582 at 21592, April 11, 2023; Service 2022, p. 14). We now consider the 90 percent lower confidence value of 68,120 plants to be a better reflection of the minimum population estimate for the *S. glaucus* total population size than the mean estimate of 103,086 plants provided by the Bureau of Land Management (BLM) (Krening et al. 2021a, p. 8), as this allows us to be more conservative given the less comprehensive sampling in the study that produced these estimates (as compared to the sampling effort from the *S. dawsoniae* study (see *Current Condition*; Service 2025, pp. 20–21)).

Similarly, in the proposed rule and SSA version 1.1, we reported a minimum population estimate of 31,867 and the 90 percent lower confidence level estimate of 21,058 plants for *Sclerocactus dawsoniae* (88 FR 21582 at 21592, April 11, 2023; Service 2022, p. 14). This minimum population estimate was derived using *S. glaucus* macroplot estimates as a surrogate for *S. dawsoniae* (Krening et al. 2021a, p. 8). We have updated in this rule the minimum population estimate for *S. dawsoniae* to 17,362 plants based on a BLM technical report that used *S. dawsoniae* data to derive the estimate (Krening and Holsinger 2024, entire). We consider the updated minimum population estimate to better reflect *S. dawsoniae*'s total population size. We also provide additional explanation of the BLM methodology to derive population estimates for both species. We note that

the updated minimum population estimates do not necessarily reflect a change in the species' numbers per se, but rather an improvement in the accuracy of information about their population sizes.

In this final rule we have also provided additional information about protections afforded to BLM sensitive species, and livestock grazing effects to Colorado hookless cactus, in our pessimistic future scenario.

In this final rule, we no longer consider or rely on the protections identified in the 2012 livestock grazing programmatic biological opinion for Colorado hookless cactus (Service 2012, entire). Once this final rule goes into effect, the grazing terms and conditions identified in the biological opinion will not apply to *S. glaucus* or *S. dawsoniae*. Therefore, in this rule we do not mention the protections afforded to Colorado hookless cactus under the programmatic biological opinion, as these protections have no bearing on our determination of the status of the listed entity under the Act.

We have also revised the PDM plan by updating the baseline densities for both species with 2022 and 2023 trend monitoring data (Service 2024, entire). We and our partners will use the baseline densities to track the trend of the species over the PDM timeframe.

### Summary of Comments and Recommendations

In the proposed rule published on April 11, 2023 (88 FR 21582), we requested that all interested parties submit written comments on the proposal by June 12, 2023. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. On April 10, 2023, we published a press release on our website inviting the public to comment. Newspaper notices inviting the general public to comment were published in the Grand Junction Daily Sentinel. We did not receive any requests for a public hearing. We received 13 public comments addressing the proposed rule, representing 10 individuals and 3 organizations. All substantive information received during the comment period has either been incorporated directly into this final determination or is addressed below.

*Comment (1):* Several commenters stated that invasive species can negatively affect survival and recruitment of Colorado hookless cactus and increase the risk of fire in the species' habitat, and that invasive species were underrepresented in the

current and future condition analyses of Colorado hookless cactus. One commenter stated that we relied on optimistic measures to support delisting even though invasive species could have greater effects in the future.

*Response (1):* The commenters did not provide information to support their comment or suggestions for how to better represent the negative effects of invasive species in our analysis. The BLM Colorado hookless cactus technical assessment and habitat condition analysis provide the best scientific and commercial data available to examine current invasive species levels within Colorado hookless cactus analysis units (AUs) and potential effects to the species (Krening and Dawson 2020, p. 35; Holsinger and Krening 2021, entire). According to this information, current invasive species levels do not negatively affect the species or habitat quality at the AU level. Only individual plants experience detrimental effects of invasive weeds in localized areas (Service 2025, pp. 16–21; Krening and Dawson 2020, p. 35). We also evaluated future increases in effects from invasive species in combination with other stressors (livestock grazing, off-highway-vehicle (OHV) use, oil and gas development, utility corridor development and climate change) in our pessimistic future scenario (see *Future Scenarios and Future Condition*).

While fire extent and severity may increase as invasive species cover increases, wildfires within the range of Colorado hookless cactus have resulted in only very localized impacts to both species. One example of a recent fire is the Logan Fire in the Roan Creek AU in 2023 that killed 11 plants (Freitag 2023, pers. comm.; Service 2025, pp. 37–38); this number represents far less than 1 percent of *S. dawsoniae* plants in an AU that has a minimum population estimate of 14,901. The Logan Fire was small in extent despite the high levels of invasive plant cover in the area (Service 2025, appendix 1). We expect both species will continue to experience localized effects from fire in the future. The majority of their habitat is sparsely vegetated; both species are widely dispersed across the landscape; and their ranges contain many barriers such as canyons, roads, and rivers that serve as firebreaks despite potential future increases in invasive species cover.

*Comment (2):* Several commenters stated that the BLM minimum population size estimates for Colorado hookless cactus are not reliable because the monitoring plot (macroplot) locations were subjectively selected by the researchers. One commenter recommended that we carefully evaluate

the validity of the study before delisting the species, and another commenter considered our reliance on the BLM population size estimates to delist Colorado hookless cactus to be arbitrary and capricious.

*Response (2):* We disagree with the commenters that the Colorado hookless cactus minimum population size estimates are arbitrary and capricious and not reliable. We used the *S. glaucus* minimum population size estimates reported in a published peer-reviewed journal article (Krening et al. 2021a, entire). The sampling methods and analysis in this study—rather than reliance on census counts—are commonly used for plants with large populations sizes (Elzinga et al. 1999, pp. 37–38, 61–88). In this final rule, we relied on the *S. dawsoniae* minimum population size estimates reported in a BLM Technical Note with *S. dawsoniae* data (Krening and Holsinger 2024, entire) that used the same methodology as the published study (Krening et al. 2021a, entire) and received internal peer review.

We consider the BLM methods and population estimates of Krening et al. 2021a (entire) and Krening and Holsinger 2024 (entire) to be better and more reliable than earlier methods and population estimates. The BLM methods have been peer reviewed, were systematically implemented rangewide, and provide minimum population estimates that are smaller than the actual population size. Earlier methods were not peer reviewed and were applied inconsistently across the species' range with data collected opportunistically from different sources. While macroplots were placed subjectively for both species, transect locations within macroplots were randomly selected and represent a variety of habitat conditions for Colorado hookless cactus according to the BLM's habitat condition index. We relied on the minimum population estimates that were conservatively based on the transect data (see *Current Condition*). We consider the *S. glaucus* and *S. dawsoniae* minimum population estimates to be reliable and the best scientific information available, and we are not aware of better estimates of population size for the two species. Therefore, we continue to rely on the Colorado hookless cactus minimum population size estimates provided by the studies mentioned herein (Krening et al. 2021a, entire; Krening and Holsinger 2024, entire; Holsinger and Krening 2024, entire; Service 2025, pp. 13–14, 24–27). Furthermore, the PDM plan relies on the sampling protocols in Krening et al. (2021a, entire).

*Comment (3):* Several commenters stated that the SSA report and proposed rule downplayed the effects and future risk of oil and gas development on *S. dawsoniae* and failed to analyze the cumulative impacts of this and other stressors. The commenters considered widespread habitat degradation and a downward trend to be likely for *S. dawsoniae* because the entire population is subject to oil and gas leasing, there are producing wells throughout its range, and over half of its range is unprotected from development.

*Response (3):* We review the best scientific and commercial information available when conducting a threats analysis. The identification of factors that could impact a species negatively is not sufficient to compel a finding that listing (or maintaining a currently listed species) on the Federal Lists of Endangered and Threatened Wildlife and Plants is appropriate. In determining whether a species meets the definition of a threatened or endangered species, 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, as well as the cumulative effect of the threats (see *Regulatory Framework*).

The commenters did not provide additional information to support their comment. As we discuss below, leased areas do not equate to areas of surface disturbance; only small subsets of these areas are actively being explored or developed (see *Stressors*). We evaluated current and future scenarios with the SSA framework, which analyzes the cumulative impact of stressors on the species (see *Cumulative Impacts*). We evaluated the potential for increases in oil and gas development, along with other stressors, in the pessimistic future scenario, and found that the loss of resiliency for *S. dawsoniae* AUs will be modest and no major changes in redundancy or representation are expected (see *Future Scenarios and Future Condition*).

*Comment (4):* Two commenters questioned the protections afforded to Colorado hookless cactus by its designation as a BLM sensitive species. The first commenter cited an oil and gas project that resulted in the loss of 53 plants of another BLM sensitive species, Harrington's beardtongue (*Penstemon harringtonii*), as evidence of the limited protections that designation provides. The first commenter was concerned that we are considering only the species-level viability when evaluating the status of Colorado hookless cactus. The

second commenter stated that we do not acknowledge the risk of losing the BLM 200-meter (m) 656 feet (ft) avoidance buffer for oil and gas development if Colorado hookless cactus is delisted.

*Response (4):* We disagree with the first commenter that we can expect the loss of Colorado hookless cactus populations despite its designation as a BLM sensitive species. The example provided by the commenter identifies localized, not population-level, loss of Harrington's beardtongue. We assess the viability of Colorado hookless cactus at the population and species levels as described in the *Analytical Framework* section, below. We acknowledge that the avoidance buffer for Colorado hookless cactus on BLM lands will decrease from the 200 m (656 ft) applied to federally listed plant species to 100 m (328 ft) afforded to BLM sensitive species for oil and gas development and other surface-disturbing activities (see *Conservation Efforts and Regulatory Mechanisms*). In addition, BLM has discretion to relocate proposed energy development projects up to and beyond 200 m (656 ft) for BLM sensitive species in areas with a controlled surface use stipulation (see *Conservation Efforts and Regulatory Mechanisms*, below).

*Comment (5):* Several commenters provided a published journal article about dust effects to a federally listed plant in Utah outside of Colorado hookless cactus' range that estimated 2.5 tons of dust are deposited along a road corridor every year (Lewis et al. 2017, p. 431). Commenters stated that there is no substantive discussion or evaluation of dust effects to *S. dawsoniae* in the SSA report and proposed rule.

*Response (5):* We considered dust effects to both species in the SSA report as a stressor that is generated from multiple threats, including oil and gas development, OHV recreational use, and utility corridors. The best available information indicates that dust is not negatively impacting *S. glaucus* or *S. dawsoniae* at the population or species levels (Service 2025, pp. 17–18). The Lewis et al. (2017) paper specifically mentions the estimated dust deposition reported by the commenters is a generalization and was not measured. We note that the commenters provided information on dust effects for other species and locations but did not provide new information on dust within the ranges of *S. glaucus* or *S. dawsoniae* or dust effects specific to the two species.

*Comment (6):* Several commenters stated that our analysis in the SSA report and proposed rule underestimated the effects of livestock grazing on Colorado hookless cactus and

ignored the best available science regarding this stressor. Commenters were concerned that livestock grazing may pose a demographic threat at the population level for Colorado hookless cactus because cattle can uproot and crush larger plants crucial to reproduction and cactus occurrences have been extirpated by concentrated sheep use. Additionally, several commenters stated that many grazing allotments within the Colorado hookless cactus' range do not meet BLM land health assessment standards.

*Response (6):* We considered the effects of livestock grazing to both species in the SSA report. Despite some grazing allotments within the two species' ranges not meeting BLM land health assessment standards, the best available information indicates that livestock grazing is not negatively impacting *S. glaucus* or *S. dawsoniae* at the population or species level (see *Stressors*, below; Service 2025, pp. 16–19). The BLM rangeland health assessment standards are not tailored to Colorado hookless cactus; rather, they describe specific conditions needed for public land health, such as the presence of streambank vegetation and adequate canopy or ground cover (43 CFR part 4100, subpart 4180). In the pessimistic scenario in the SSA report, we considered the potential for increased impacts from livestock grazing into the future. Even in this scenario, we project high or moderate resiliency in all but one of the *S. glaucus* AUs and in both *S. dawsoniae* AUs. We note that the commenters provided information on livestock grazing effects for other species and locations but did not provide new information on livestock grazing within the ranges of *S. glaucus* or *S. dawsoniae* or evidence of livestock grazing effects specific to the two species.

*Comment (7):* One commenter stated that BLM would not provide any restrictions on their lands for livestock grazing if the two *Sclerocactus* species were delisted.

*Response (7):* We disagree with the commenter that BLM would not provide any restrictions on their lands for livestock grazing if the two species were delisted. BLM administers special land management designations called Areas of Critical Environmental Concern (ACECs). Across the range of *S. glaucus* and *S. dawsoniae*, BLM has 11 ACECs, including 5 totaling 18,093 acres (ac) (7,321 hectares (ha)) where livestock use is managed or prohibited to benefit listed and BLM sensitive species in all or part of the management area (the River Rims, Escalante Canyon, Adobe Badlands, Pyramid Rock, and Atwell

Gulch ACECs; see *Stressors*). In addition, on lands without special designations, BLM includes standard permit terms and conditions for their livestock grazing permits such as seasonal utilization levels, reductions due to drought or fire, and other restrictions on open grazing (see *Conservation Efforts and Regulatory Mechanisms*). These measures are not dependent on the listed status of Colorado hookless cactus.

*Comment (8):* Two commenters stated that we did not consider any levels of increased livestock grazing in our pessimistic future scenario or the cumulative impacts from climate change, invasive species, oil and gas development, and OHV recreation.

*Response (8):* We included a plausible range of livestock grazing levels on BLM lands in our future scenarios, including an increase in effects from livestock grazing on Colorado hookless cactus habitat and individuals in the pessimistic future scenario. Even in this pessimistic scenario, *S. glaucus* is projected to maintain high or moderate resiliency for all but one AU, and *S. dawsoniae* is projected to maintain high or moderate resiliency in both AUs, along with continued redundancy and representation for both species. Regarding our evaluation of cumulative effects, see our response to *Comment (3)*, above.

*Comment (9):* One commenter stated that we failed to consider the well-known impacts of livestock grazing on biological soil crusts (BSCs) that influence water availability, nutrient cycling, and soil erosion in semi-arid high-elevation deserts; nor did we consider the severity of future drought conditions caused by climate change. However, the commenter acknowledged that BSCs are difficult to detect and their reductions by livestock grazing may not be readily apparent. The commenter provided supporting published literature on this topic (Duniway et al. 2018, entire; Belnap and Eldridge 2001, entire).

*Response (9):* We recognize the function of BSCs to promote soil stability and nutrient cycling, and we considered the published literature provided by the commenter. We agree with the commenter that BSCs may be difficult to detect; the best available information within Colorado hookless cactus' range identifies the amount of bare ground and native and invasive plant cover and no information on BSCs. The commenter does not provide additional information on BSCs' impact to Colorado hookless cactus, and we have no information to indicate that BSCs, or the lack thereof, are having

lasting population-level effects for the two species. We evaluated the effects of stressors that impact BSCs, such as livestock grazing or invasive species, as part of the habitat condition index metric in our SSA report. We evaluated water availability during the growing season with a water deficit metric. These two metrics provide two of the four scores in the current and future resiliency evaluation.

*Comment (10):* One commenter considered our cumulative effects evaluation to be inadequate because we determined that predation, herbicides, pesticides, and collection and commercial trade were not AU- or species-level threats, and thus were not addressed in the current or future resiliency analysis.

*Response (10):* While some of these threats to the species were identified in the initial 1979 listing rule or may be threats at a localized level, all of them are known to impact only individual plants and are less of a concern than originally suggested. Only threats that had the potential now or in the future to have AU- or species-level effects to either species were included in the resiliency analysis. The threats mentioned by the commenter are limited in magnitude such that they will not cause a measurable impact to either cactus species currently or in the future. More information on these stressors and how we considered them can be found in section 4.1 of the SSA report (Service 2025, pp. 16–19).

*Comment (11):* One commenter stated that we did not mention that Colorado OHV registrations have increased dramatically since 2000, which would lead to an increase in OHV use in the species' habitat. The commenter also stated that we did not evaluate the many possible indirect impacts of OHV use to Colorado hookless cactus. Further, the commenter stated that the exclusion of non-motorized recreation (mountain bikes, hiking, camping, etc.) as a stressor is backed with no direct evidence and may be criticized because the likelihood for these activities would coincide with OHV recreation.

*Response (11):* The purpose of the SSA is to gather and compile information on the status of these species to assess their current condition and project the species' future condition. The commenter did not provide information on how OHV use has changed in the species' range. Moreover, the commenter did not specify or provide information regarding any other possible indirect impacts of OHV use to the species that we did not evaluate. We evaluated the effects of OHV use that include plant loss or

damage; soil compaction; and increased erosion, sedimentation, and dust in the SSA report (Service 2025, pp. 17–18). As we stated in our response to a peer reviewer (*Comment 2*) in the proposed rule (88 FR 21582 at 21584, April 11, 2023), we did not include non-motorized recreation (mountain bikes, hiking, camping, etc.) in our resiliency evaluation due to the relatively small footprint and localized impacts of these activities, BLM's general avoidance of Colorado hookless cactus when designing non-motorized trail routes, and the lack of species- or AU-level effects.

*Comment (12)*: One commenter stated that our assertion in the proposed rule that collection is not causing population- or species-level effects to Colorado hookless cactus is counter to the species' final listing rule and justification for not designating critical habitat. The commenter claims that we are being arbitrary and capricious with respect to the threat of collection when we know the species is "highly desirable."

*Response (12)*: We disagree with the commenter's claim that we were arbitrary and capricious in regard to our evaluation of the threat of collection for Colorado hookless cactus. As we stated in our response to a peer reviewer (*Comment 8*) in the proposed rule (88 FR 21582 at 21585, April 11, 2023), the best available information indicates that collection has not occurred at the level anticipated at the time of listing and is not having population- or species-level effects on either species (Krening and Dawson 2020, p. 36). Furthermore, given the taxonomic splits since listing between the two Utah *Sclerocactus* species and Colorado's *S. glaucus* and *S. dawsoniae*, the species mentioned in the final listing rule (44 FR 58868, October 11, 1979) as prized by cactus collectors for its beautiful purplish-red flowers is now known to be Uinta Basin hookless cactus (*Sclerocactus wetlandicus*), not *S. glaucus* or *S. dawsoniae*. Finally, the Convention on International Trade in Endangered Species (CITES) is a regulatory mechanism that helps to prevent and enforce against the illegal collection and trade of protected species, including Colorado hookless cactus. CITES protections apply to all members of the cactus family (*Cactaceae*), and as such, *S. glaucus* or *S. dawsoniae* will receive protections after delisting under the Act (see *Conservation Efforts and Regulatory Mechanisms*).

*Comment (13)*: One commenter stated that we did not demonstrate how conservation measures to protect Colorado hookless cactus would

continue to be enforced and be effective post-delisting in the BLM National Conservation Areas (NCAs), Areas of Critical Environmental Concern (ACECs), and Wilderness Study Areas (WSAs).

*Response (13)*: Protections for Colorado hookless cactus will remain in NCAs, ACECs, and WSAs regardless of its Federal listing status. These areas represent approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs (see *Conservation Efforts and Regulatory Mechanisms*). Species-specific protections are afforded to Colorado hookless cactus in BLM's current Dominguez-Escalante NCA resource management plan (RMP), and 8 of 11 ACECs across the range of the species specifically reference the protection of Colorado hookless cactus as a foundational goal. Likewise, NCAs, ACECs, Wilderness Areas, and WSAs are designed to protect multiple resources, not only the Colorado hookless cactus. The 1964 Wilderness Act (Pub. L. 88–577) and the Federal Land Policy and Management Act (FLPMA; 43 U.S.C. 1782) afford protections to wilderness areas and WSAs and do not allow for permanent disturbances. BLM manages these areas and will also manage for Colorado hookless cactus as a BLM sensitive species, affording both species protections.

*Comment (14)*: Several commenters stated that the draft PDM plan's reliance on 17 macroplots provides insufficient monitoring of the two species and new or increasing site-specific stressors within their ranges. The commenters recommended that the PDM plan include rangewide monitoring of site-specific stressors across the two species' range, and that monitoring should begin prior to delisting.

*Response (14)*: The PDM plan relies on the sampling protocols used in Krening et al. (2021a, entire), which are sufficient to detect rangewide trends for both species (see *Comment (2)*). We also consider the PDM sufficient to detect new or increasing stressors within the two species' ranges because BLM will provide information on newly approved, permitted, or implemented projects and impacts to Colorado hookless cactus on an annual basis (Service 2024, pp. 13–15). While the final PDM plan does not identify a specific mechanism to intervene following stressor impacts, it identifies actions that may be taken should monitoring indicate a substantial decline in the Colorado hookless cactus' density or distribution. These actions include meeting with conservation

partners, extending the monitoring period, modifying monitoring practices, initiating a rangewide status assessment, or relisting Colorado hookless cactus, if warranted. During the PDM monitoring period, we will continue to work with our conservation partners to develop and implement an effective PDM plan for Colorado hookless cactus that includes an appropriate duration to detect trends, identifies potential and increasing stressors, and evaluates the impact of stressors. The monitoring identified in the PDM plan began before work began on this rulemaking action, starting in 2011 by BLM and in 2007 by the Denver Botanic Gardens (Krening et al. 2021b, p. 4; DePrenger-Levin and Hufft 2021, pp. 3–5; Service 2024, entire).

*Comment (15)*: Two commenters were concerned that we relied on an unpublished genetic study (McGlaughlin and Naibauer 2021, entire) to inform the proposed delisting rule and noted that the genetic results have not been recognized by NatureServe.

*Response (15)*: Since the publication of the proposed listing rule, the authors of the genetic study published their results in a peer-reviewed journal in December 2023 (McGlaughlin and Naibauer 2023, entire) and published the official species description for *S. dawsoniae* in 2024 (McGlaughlin and Naibauer 2024, entire). Because of the recency of this taxonomic split, there may be a delay in recognizing the Colorado hookless cactus (*S. glaucus*) and Dawson's hookless cactus (*S. dawsoniae*), on websites such as NatureServe (<https://explorer.natureserve.org>) and the Integrated Taxonomic Information System (<https://www.usgs.gov/tools/integrated-taxonomic-information-system-itis>). However, the information we relied upon in drafting this rulemaking action still constitutes the best available scientific information on these species' taxonomy.

*Comment (16)*: One commenter stated that we should not have confidence in BLM's ability to prevent livestock grazing from harming the Colorado hookless cactus because BLM has a long history of ignoring illegal grazing as identified in a 2016 U.S. Government Accountability Office (GAO) report.

*Response (16)*: We have no information that illegal grazing is occurring in the Colorado hookless cactus' range (Lincoln 2025, pers. comm). The 2016 GAO report identifies 38 incidences of non-compliances in the State of Colorado, but the report does not identify the locations where unauthorized grazing is occurring.

Therefore, we did not include this information in our SSA report. BLM's management plans allow it to include obligatory stipulations in its grazing permit renewals that require reductions in the number of livestock and adjustments to the timing, duration, and season of livestock use for the benefit of natural resources (see *Livestock Grazing*, below). BLM will address impacts to Colorado hookless cactus from a variety of stressors, including livestock grazing, with additional monitoring and management interventions, as identified in the PDM plan (Service 2024, entire).

### Background

A thorough review of the taxonomy, life history, and ecology of the Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*) is presented in the SSA Report Version 1.2 (Service 2025, entire). Colorado hookless cactus has undergone a series of taxonomic revisions since its original 1979 listing. When listed, the range of *Sclerocactus glaucus* was considered to include western Colorado and northeastern Utah (Uinta Basin hookless cactus complex). A reevaluation of morphological characteristics, phylogenetic studies, and common garden experiments led to the determination that the Uinta Basin hookless cactus complex was in fact three distinct species: *Sclerocactus glaucus* (Colorado hookless cactus), *Sclerocactus brevispinus* (Pariette cactus), and *Sclerocactus wetlandicus* (Uinta Basin hookless cactus) (Heil and Porter 2004, pp. 197–207; Hochstätter 1993, pp. 82–92). *Sclerocactus glaucus* was determined to be restricted to the Colorado and Gunnison River basins in western Colorado, while *Sclerocactus brevispinus* and *Sclerocactus wetlandicus* are limited to the Uinta Basin in eastern Utah. In 2009, the Service published a final rule recognizing and accepting this revised taxonomy of the three species and determined that all three species would continue to be listed as threatened (74 FR 47112, September 15, 2009). Most recently, in 2017, genetic studies identified three distinct regional groups of Colorado hookless cactus in Colorado: the northern, Grand Valley, and Gunnison River groups (Schwabe et al. 2015, p. 447; McLaughlin and Ramp-Neale 2017, p. 5). The most recent genetic analyses, using Random Site-Associated DNA sequencing, determined that the northern group should be recognized as a distinct species, hereinafter *Sclerocactus dawsoniae*, or *S. dawsoniae* (McLaughlin and Naibauer 2023, p. 5). The Grand Valley and Gunnison River groups share connectivity and form a

genetically cohesive group, which represents a second distinct species, hereinafter collectively referred to as *Sclerocactus glaucus*, or *S. glaucus* (McLaughlin and Naibauer 2023, p. 5). Because of the recency of this taxonomic split, the currently listed entity is still considered to be the Colorado hookless cactus, which encompasses both *S. glaucus* and *S. dawsoniae*; thus, both *Sclerocactus glaucus* and *Sclerocactus dawsoniae* are the subjects of our SSA report and this final delisting rule.

Given the recent nature of this new taxonomic information, most literature on the species draws conclusions regarding both *S. glaucus* and *S. dawsoniae* without distinguishing between the two. Thus, when we use the common name “Colorado hookless cactus” in this final rule, we are referring to information or conclusions regarding both species (*S. glaucus* and *S. dawsoniae*). When we are referring to information or analysis pertaining to one species, we will use the new scientific names of *S. glaucus* or *S. dawsoniae*.

*S. glaucus* and *S. dawsoniae* are endemic cactus species found in the Colorado and Gunnison River basins and their tributary canyons in Garfield, Mesa, Montrose, and Delta Counties in western Colorado. The species occur on alluvial benches and colluvial slopes from 1,372 to 2,195 m (4,500 to 7,200 ft) in semi-arid high-elevation desert (Holsinger 2021, pers. comm.; Service 2025, p. 9). The species display a patchy, generalist distribution and have been found to grow primarily in small, discrete colonies of individuals in various upland desert habitats and communities (Krening and Dawson 2020, p. 18; Service 2025, p. 9).

For the purposes of analysis in our SSA report, we divided the ranges of *S. glaucus* and *S. dawsoniae* into analysis units (AUs). *S. glaucus* occurs in eight AUs in a range that extends approximately 2,802 square kilometers (km<sup>2</sup>) (1,082 square miles (mi<sup>2</sup>)) from the Grand Valley, through the high desert at the foot of the Grand Mesa, and along the alluvial terraces of the Gunnison River and the Dominguez and Escalante Creek drainages to near Montrose. *S. dawsoniae* occurs over an area of approximately 505 km<sup>2</sup> (195 mi<sup>2</sup>) in two AUs along the Colorado River from DeBeque downstream toward the Grand Valley and along the Roan and Plateau Creek drainages. BLM owns and manages approximately 72 percent and 68 percent, respectively, of the land that comprises the *S. glaucus* and *S. dawsoniae* AUs (Service 2025, pp. 19–22).

*S. glaucus* and *S. dawsoniae* are morphologically indistinguishable from each other and can be identified from one another only by genetic analysis or location. They are both leafless, flowering, stem-succulent plants with short, cylindrical bodies usually 3 to 12 centimeters (cm) (1.2 to 4.8 inches (in)) but up to 30 cm (12 in) tall and 4 to 9 cm (1.6 to 3.6 in) in diameter (Service 2025, pp. 7–8). The brown coloring of the spines on mature plants is unique to *S. glaucus*, *S. dawsoniae*, and *S. parviflorus*, as compared to other cactus species in the area (Service 2025, p. 7).

Colorado hookless cactus has three life stages: seeds, seedlings, and mature reproductive adults. Colorado hookless cactus plants are considered hardy, long-lived perennial species (*i.e.*, high survival probabilities and low levels of recruitment) (BLM 2018, p. 15). Based on high observed seedling survival, once a seedling is established, there is a high probability of an individual persisting to reproductive stage (BLM 2018, p. 14; Service 2025, p. 13). Pollinator-assisted outcrossing (xenogamy) is the primary mode of genetic exchange for the Colorado hookless cactus (Janeba 2009, p. 67; Tepedino et al. 2010, p. 382; Service 2025, p. 8). Plants usually flower in late April and early May. Plants do not flower until they reach a diameter of more than 4 cm (1.6 in) (BLM 2018, p. 14); plants are likely at least 4 to 6 years old before they become reproductive and continue to flower throughout their relatively long life (DePrenger-Levin 2021, pers. comm.; Service 2025, p. 13). Colorado hookless cactus can live for many years, but their exact longevity is unknown.

### Recovery Criteria

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of section 4 of the Act, that the species be removed from the Lists of Endangered and Threatened Wildlife and Plants.

Recovery plans provide a roadmap for us and our partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to evaluate progress towards recovery and assess the species' likely future condition. However, they are not

regulatory documents and do not substitute for the determinations and promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species or to delist a species is ultimately based on an analysis of the best scientific and commercial data available to determine whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and that the species is robust enough that it no longer meets the definition of an endangered species or a threatened species. In other cases, we may discover new recovery opportunities after having finalized the recovery plan. Parties seeking to conserve the species may use these opportunities instead of methods identified in the recovery plan. Likewise, we may learn new information about the species after we finalize the recovery plan. The new information may change the extent to which existing criteria are appropriate for identifying recovery of the species. The recovery of a species is a dynamic process requiring adaptive management that may, or may not, follow all of the guidance provided in a recovery plan.

A recovery plan for Colorado hookless cactus was not prepared due to lack of staff capacity; therefore, specific delisting criteria were not developed for the species. However, we developed a recovery outline for Colorado hookless cactus in 2010 (Service 2010, entire). A recovery outline is a succinct document that presents a preliminary recovery strategy and actions to direct recovery efforts for a newly listed species until a recovery plan is completed. Additionally, we reviewed the status of the species in the 2008 and 2021 5-year status reviews (Service 2008, entire; Service 2021, entire). In the 2008 review, we identified remaining threats to the species and actions that could be taken to make progress in addressing those threats and ensuring long-term management. One such recommendation was to conduct rangewide inventories and improve population monitoring (Service 2008, p. 4). Denver Botanic Gardens and BLM have closely monitored Colorado hookless cactus at multiple sites

throughout its range since 2007 (DePrenger-Levin and Hufft 2021, entire; Krening et al. 2021b, entire). Based on over a decade of this rich monitoring data, BLM developed a method of estimating population size and trends in 2021 for *S. glaucus* (Krening et al. 2021a, entire) and in 2023 for *S. dawsoniae* (Krening and Holsinger 2024, entire), representing the best available scientific and commercial information for the species regarding total population size (Krening et al. 2021a, entire; Krening and Holsinger 2024, entire).

The 2010 recovery outline also included an initial action plan for the species' recovery that included actions such as (1) expanding comprehensive surveying to improve our understanding of trends; (2) establishing formal land management designations to provide for long-term protection of important populations and habitat; (3) directing development projects to avoid cactus occurrences and incorporate standard conservation measures; (4) encouraging investigations into *Sclerocactus* species' vulnerability to climate change; and (5) resolving open taxonomic questions for the species. The Service and its partners have since accomplished all five of these actions.

Since 2010, BLM and the Denver Botanic Gardens have expanded their annual monitoring program to assess demographic trends and improve estimation of the species' population sizes; these estimates indicate there are substantially more Colorado hookless cactus plants on the landscape than were known at the time of listing and have changed our understanding of the degree to which the species are resilient to the threats apparent at the time of listing. As stated previously, BLM has also established multiple ACECs and an NCA that provide long-term protection to BLM sensitive plants and habitats. In the past 11 years, multiple assessments of the species' vulnerability to climate change have concluded that Colorado hookless cactus has low vulnerability to future climatic changes (Price 2018, appendix 3 of Krening and Dawson 2020, p. 60; Still et al. 2015, p. 116; Treher et al 2012, pp. 8, 52). Finally, as discussed at length above in this document, recent genetic research has determined that Colorado hookless cactus is in fact two separate species: *S. glaucus* and *S. dawsoniae*, thus resolving an open taxonomic question for the species, as identified by the recovery outline.

## 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, the Service 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 23919). That final rule is now in effect and is incorporated into the current regulations. Our analysis for this decision applied our current regulations. Given that we proposed delisting this species under our prior regulations (revised in 2019), we have also undertaken an analysis of whether the decision would be different if we had continued to apply the 2019 regulations and we concluded that the decision would be the same. The analyses under both the regulations currently in effect and the 2019 regulations are available on <https://www.regulations.gov>.

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. The determination to delist a species must be based on an analysis of the same five factors.

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 delisted. 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 Colorado hookless cactus’ 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 species’ ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species’ viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated individual species’ life-history needs. The next stage involved an assessment of the historical and current condition of the species’ demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage

of the SSA involved making predictions about the species’ 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 a species 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 FWS–R6–ES–2022–0093 on <https://www.regulations.gov>.

#### **Summary of Biological Status and Threats**

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species’ current and future condition, in order to assess the species’ overall viability and the risks to that viability. In addition, the SSA report (Service 2025, entire) documents our comprehensive biological status review for the species, including an assessment of the potential threats to the species.

The following is a summary of this status review and the best available information gathered since that time that has informed this decision.

#### *Species Needs*

Individuals of both species of Colorado hookless cactus need certain habitat factors, including shallow exposed sandy or shale soils of sedimentary parent material or gravelly deposits of river alluvium; a semi-arid, high-elevation desert climate (elevations from 1,200–2,000 m (3,937–6,561 ft) with 20–30 cm (8–12 in) of rain per year; and a period of deep cold during winter months to facilitate germination the following spring (Service 2025, pp. 8, 11–12). To be sufficiently resilient, populations, referred to as analytical units (AUs) of both species require survivorship and recruitment at rates that are able to sustain AUs, in addition to pollinator connectivity between individuals and clusters of plants within the AU. Adequately resilient AUs also contain enough individuals across each life stage (seed, seedling, and mature reproductive adult) to bounce back after experiencing environmental stressors such as intermediate disturbance, occasional drought, or intensive grazing.

The number of AUs across the landscape influence redundancy of Colorado hookless cactus. AUs, synonymous with populations, include many cactus individuals and were delineated by natural geological and ecological features and management

boundaries within each species' range (Service 2025, pp. 6–8). More AUs across the range of each species increase each species' ability to withstand catastrophic events. Individuals and AUs inhabiting diverse ecological settings and exhibiting genetic or phenological variation add to the level of representation across the species' ranges. The greater diversity observed in genetics, habitats, and morphology, the more likely Colorado hookless cactus is to be able to adapt to change over time. Thus, both species need (1) a sufficient number and distribution of sufficiently resilient AUs to withstand catastrophic events (redundancy) and (2) a range of genetic, morphologic, and habitat variation that allows the species to adapt to changing environmental conditions (representation) (Service 2025, pp. 15–16). The SSA report provides additional detail on the species' individual-, population-, and species-level needs (Service 2025, pp. 10–16).

#### Stressors

In our SSA, we evaluated stressors and other actions that can positively or negatively affect Colorado hookless cactus at the individual, AU (population), or species levels, either currently or into the future (Service 2025, pp. 16–19). A wide variety of stressors may influence the resiliency of Colorado hookless cactus, either by directly affecting individuals or by reducing the quality and quantity of habitats.

Stressors that have the potential to present AU-level effects for both species include livestock use, invasive species, oil and gas development, OHV recreational use, development and maintenance of utility corridors, and the effects of global climate change (Krening and Dawson 2020, p. 30; Service 2025, pp. 16–19). We determined that oil shale deposit development and gold mining, predation, herbicide and pesticide application, or collection and commercial trade are not threats to the existence of the species (even though they were identified as such in the 1979 listing rule), so we do not discuss them in detail in this rule (Service 2025, pp. 16–19).

Additionally, approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs have special BLM land management designations in the form of NCAs, ACECs, a WSA, and a Wilderness Area. These designations limit or exclude the authorization of certain land uses, and some designations were specifically created for the conservation of natural resources. The protections

provided by these management designations are not contingent upon the species' federally listed status, and these designations help to facilitate the maintenance and recovery of cactus occurrences because they are areas where Colorado hookless cactus is not likely to be disturbed or adversely altered by land-use actions (Krening and Dawson 2020, p. 26). Eight of 11 ACECs specifically reference the protection of Colorado hookless cactus as a foundational goal. We discuss the specific protections each of these areas provides, and the ways in which they reduce specific stressors, under the relevant stressors below; we also discuss these conservation measures further under Conservation Efforts and Regulatory Mechanisms. While the majority of the remaining habitat is on private lands, approximately 28 percent for *S. glaucus* and 32 percent for *S. dawsoniae*, we do not have reliable information for Colorado hookless cactus on private lands. Since the private lands are interspersed with BLM lands, we assume that the stressors are the same on BLM and private lands (Service 2025, pp. 20–22).

#### Livestock Use

BLM owns and manages approximately 72 percent and 68 percent, respectively, of the land that comprises *S. glaucus* and *S. dawsoniae* AUs (Service 2025, pp. 19–22). While approximately 5 percent of this habitat excludes or manages for livestock use for the purposes of minimizing impacts to Colorado hookless cactus, nearly all habitat that occurs on BLM lands allows for livestock use. Moderate to heavy domestic livestock grazing has been observed to cause physical damage to *Sclerocactus* plants through trampling; however, on rare occasions do cattle directly trample or dislodge cactus plants (Service 1990, p. 11). We have no information to indicate that cattle browse on individual *Sclerocactus* plants since their spines generally make them undesirable livestock forage (Dawson 2025, entire; Hornbeck 2025, entire). A study on another federally listed cactus, *S. wrightiae*, found that cacti density increased more rapidly in a fenced plot excluded from cattle grazing than in an unfenced plot with a reduced cattle stocking rate (Clark and Clark 2007, p. 21). Overgrazing (the continued heavy grazing beyond the recovery capacity of forage plants) by domestic livestock can have a negative impact on North American xeric (very dry and low humidity) ecosystems (Jones 2000, p. 158). For example, overgrazing can facilitate the establishment of invasive species like

*Bromus tectorum*, known as cheatgrass (Masters and Sheley 2001, p. 503; DiTomaso et al. 2016, p. 435), which are difficult to eradicate and tend to outcompete native vegetation, including cacti.

Currently, BLM manages livestock activities to protect sensitive plants in the Adobe Badlands, River Rims, and Escalante Canyon ACECs (BLM 2017, p. 240, p. 258; Krening and Dawson 2020, p. 28; Service 2025, pp. 19–22). In the Atwell Gulch ACEC, BLM excludes livestock grazing entirely on 2,600 ac (1,052 ha), and in the Pyramid Rock ACEC, no livestock grazing is allowed (Krening and Dawson 2020, p. 29; Service 2025, pp. 20–22). BLM monitoring indicates that livestock are not present in these protected areas (Krening and DePrenger-Levin 2023, entire). BLM's management plans allow it to include obligatory stipulations in its grazing permit renewals that require reductions in the number of livestock and adjustments to the timing, duration, and season of livestock use for the benefit of natural resources; such changes in grazing permits would primarily affect future grazing intensity in the Cactus Park (*S. glaucus*), Devil's Thumb (*S. glaucus*), Gunnison River East (*S. glaucus*), Roan Creek (*S. dawsoniae*), and Plateau Creek AUs (*S. dawsoniae*).

Currently, livestock use is affecting individual plants in localized areas and is not resulting in population-level effects based on stable or increasing population-level trends (Service 2025, pp. 18–19; Krening and DePrenger-Levin 2023, entire); however, these effects could increase in the future if no corrective action is taken to address future problem areas. Thus, we included an analysis in the SSA to examine the species' potential response to future changes and increases to this stressor (Service 2025, pp. 28–36).

#### Invasive Species

Invasive weeds, including *Bromus tectorum* (cheatgrass) and *Halogeton glomeratus* (halogeton), are prevalent on BLM and private lands within the range of Colorado hookless cactus (Krening and Dawson 2020, p. 35). Invasive weeds alter the ecological characteristics of cactus habitat, making it less suitable for the species (Service 1990, p. 11). In addition, invasive annual weeds are often able to outcompete perennial native species for the essential nutrient nitrogen under drought conditions (Everard et al. 2010, pp. 85, 93–94). However, despite their prevalence throughout the range of Colorado hookless cactus species, individual plants experience extreme

detrimental effects of invasive weeds only in localized areas (Service 2025, pp. 16–22; Krening and Dawson BLM 2020, p. 35).

Currently, invasive vegetation affects only individual Colorado hookless cactus plants; invasive species are not causing any broad-scale reductions in recruitment or survival in entire AUs. However, the effects of invasive vegetation could increase in the future if infestations expand or if treatments become less effective. Thus, we included an analysis in the SSA to examine the species' potential response to future changes and increases to this stressor (Service 2025, pp. 16–22, 28–36).

#### Oil and Gas Development

Oil and gas development can also affect Colorado hookless cactus plants and habitat. Increased surface disturbance from wells, roads, and pipelines for oil and gas projects can fragment or destroy habitat; disturb individuals; increase erosion, soil compaction, and sedimentation; destroy pollinator habitat; increase airborne dust and subsequent dust accumulation on cacti, which can increase tissue temperature and reduce photosynthesis, thus decreasing plant growth, vigor, and water use efficiency; indirectly increase recreational access to habitat through increased road construction; and increase invasive vegetation because of the associated surface disturbances (Service 2010, pp. 6–7).

For *S. glaucus*, only 5 percent of the AUs (19,365 ac (7,837 ha) of 379,348 total ac (153,517 ha) of habitat) are within BLM lands leased for oil and gas (BLM 2021, unpaginated). This proportion is higher for *S. dawsoniae*; 58 percent of the area within AUs are leased for oil and gas development on BLM lands (65,384 ac (26,419 ha) of 112,723 total ac (45,617 ha) of habitat) (BLM 2021, unpaginated). However, leased areas do not equate to areas of surface disturbance; even if these areas are leased for oil and gas development, only small subsets of these areas are actually being actively explored or extracted (Colorado Oil and Gas Conservation Commission (COGCC) 2022a, unpaginated). Moreover, oil and gas development does not occur throughout all of the species' ranges; for *S. glaucus*, active wells are only in the Devil's Thumb AU (one active well site), North Fruita Desert AU (10 active well sites), Whitewater AU (26 active well sites), and a very small portion of the Palisade AU (one active well site) (COGCC 2022b, unpaginated). For *S. dawsoniae*, while oil and gas development occurs in both AUs (Roan

Creek (60 active well sites) and Plateau Creek (51 active well sites)), 42 percent of these AUs are not leased for oil and gas development (COGCC 2022b, unpaginated; BLM 2021, unpaginated). Additionally, there are no new or pending permits to drill new oil and gas wells within either species' range; however, as we describe in more detail below, development could increase within portions of *S. dawsoniae*'s range in the future (COGCC 2022c, unpaginated; COGCC 2022d, unpaginated).

Additionally, BLM's resource planning documents include conservation measures to minimize adverse impacts of natural resource extraction to listed and sensitive species, including the Colorado hookless cactus; these measures include limiting oil and gas development within a 100-m (328-ft) buffer around any currently occupied or historically occupied Colorado hookless cactus habitat, when possible and with some exceptions (Krening and Dawson 2020, p. 34; BLM 2015a, p. B–13; BLM 2015b, p. B–22; BLM 2020, p. B–9). While these limitations and buffers are not obligatory, BLM applies them, with certain exceptions, to BLM sensitive species, which *S. glaucus* and *S. dawsoniae* will become once Colorado hookless cactus is removed from the List of Endangered and Threatened Plants (see *Conservation Efforts and Regulatory Mechanisms*). Even without the protections given to BLM sensitive species, based on our analysis of Colorado Oil and Gas Conservation Commission (COGCC) data, current oil and gas extraction is relatively limited throughout the range of both species compared to the amount of occupied habitat (COGCC 2022a, unpaginated; COGCC 2022b, unpaginated; COGCC 2022c, unpaginated; COGCC 2022d, unpaginated). Moreover, due to their biology and life history characteristics, both species are relatively resilient to nearby disturbance (as we discuss further in our analysis of Current Condition below).

Furthermore, approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs have special BLM land management designations in the form of NCAs, ACECs, a WSA, and a Wilderness Area, which further protect the species from the impacts of oil and gas development (Service 2025, pp. 16–22). The protections provided by these management designations are not contingent upon the species' federally listed status, and these designations help to facilitate the maintenance and recovery of cactus occurrences because

they are areas where neither the Colorado hookless cactus is likely to be disturbed nor will its habitat be adversely altered by land-use actions (Krening and Dawson 2020, p. 26). All 30 percent of the areas within *S. glaucus* AUs that have special land management designations include stipulations that either withdraw lands from oil, gas, and mineral development, implement “no-surface-occupancy” stipulations, or prohibit surface-disturbing activities (Service 2025, pp. 19–22). Therefore, no new oil and gas activity is permitted in almost 30 percent of *S. glaucus*'s range (with the exception of portions of the Devil's Thumb AU); these areas where no new oil and gas activity is permitted coincide with over half (over 56 percent) of the estimated *S. glaucus* occurrences (Service 2025, pp. 14, 21–22). Similarly, all 41 percent of the areas within *S. dawsoniae* AUs that have special land management designations include no-surface-occupancy stipulations that limit oil and gas development in these portions of the species' range.

Thus, currently, oil and gas development is affecting only a small proportion of individual Colorado hookless cactus plants, due to limited leasing and development and BLM's protective measures; however, the effects of oil and gas development could increase in the future. Nevertheless, given the variable oil and gas potential (none, low, medium, and high potential) of the area, and the protections outlined above, the only AUs where oil and gas development could plausibly increase in the future are the Roan Creek and Plateau Creek AUs (*S. dawsoniae*) with high oil and gas potential (BLM 2024, entire; Service 2025, p. 30). Thus, we included an analysis in the SSA to examine the species' potential response to future changes in this stressor (Service 2025, pp. 28–36).

#### Off-Highway Vehicle Recreational Use

Off-highway vehicle (OHV) use can cause soil compaction and erosion, which can physically damage habitat, the surrounding plant community, and the hydrology of the area. OHVs can also carry invasive and introduced plants to new sites and present a risk of spilled contaminants, such as oil spills, gasoline, and grease. OHV use can also injure or kill above-ground plants or cause direct harm to plants through accumulation of dust. OHV use can create especially negative impacts when users travel off designated routes (Service 2025, pp. 16–19).

The relatively barren nature and other topographical features of Colorado hookless cactus habitat make it

desirable to OHV users (Krening and Dawson 2020, p. 38). Even though OHV recreation is popular and widespread within Colorado hookless cactus habitat, there is little evidence of direct negative impacts to plants (Service 2010, p. 8; Krening and Dawson 2020, p. 38).

BLM's resource planning documents include conservation measures to minimize adverse impacts of land use to listed and sensitive species, including the Colorado hookless cactus (BLM 2015a, pp. 49, 102–105; BLM 2015b, pp. 26, 101–103, 123, 145, 147, 150; BLM 2015c, p. M–25; BLM 2020, pp. II–87, I–4–I–10). In their Travel Management Plans for the Grand Junction and Uncompahgre Field Offices, BLM identified multiple routes for closure to protect sensitive areas (BLM 2015c, p. M–24; BLM 2020, p. I–7). These two travel management plans cover the entirety of *S. glaucus*'s range and the majority of *S. dawsoniae*'s range. While the resource management plan for the Colorado River Valley Field Office, which covers the remainder of *S. dawsoniae*'s range, does not contain a travel management plan specifically, it includes strategies for “Comprehensive Trails and Travel Management,” including limiting recreational use to designated routes (BLM 2015b, pp. 102–104). Additionally, as stated previously in this document, approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs have special BLM land management designations in the form of NCAs, ACECs, a WSA, and a Wilderness Area, which further protect the species from the impacts of OHV use by limiting routes within 200 m (656 ft) of sensitive plants or prohibiting all motorized travel (Krening and Dawson 2020, pp. 27–29; Service 2025, pp. 19–22). For example, when the Dominguez-Escalante NCA was created in 2009, which covers 210,172 ac (85,053 ha) within the Dominguez-Escalante, Gunnison River East, and Cactus Park AUs, 268 miles of routes were closed to mechanized and motorized travel, which includes the use of OHVs (BLM 2017, p. 282; Krening and Dawson 2020, p. 27).

As human populations continue to grow in the areas surrounding Colorado hookless cactus, demand for OHV recreation is likely to continue to increase. However, BLM would be able to add routes only in areas outside of the aforementioned ACECs, WSA, and Wilderness Area. Any increases in designated OHV routes would occur as a result of land use planning processes that would comply with the stipulations of the FLPMA and the National Environmental Policy Act (Krening and

Dawson 2020, p. 38). Given the protections detailed above, and the accessibility of certain areas to OHV users, the only AUs where OHV use could plausibly increase in the future are the North Fruita Desert, Devil's Thumb, Gunnison Gorge, and Whitewater AUs (*S. glaucus*) (Service 2025, p. 30). The area represented in these four AUs constitutes approximately half of *S. glaucus*' AU range, but it is unlikely that OHV use would occur across the entire area of these AUs. Through similar processes, BLM may also choose to close areas to recreation or access if necessary to protect sensitive resources (Krening and Dawson 2020, p. 38). It is plausible that implementation of travel management plans could lead to route closures in *S. glaucus* AUs (Devil's Thumb, Gunnison Gorge, Whitewater, Palisade, Dominguez-Escalante, North Fruita Desert) and *S. dawsoniae* AUs (Plateau Creek, and Roan Creek AUs).

Thus, currently, OHV use is affecting only a small proportion of individual Colorado hookless cactus plants; however, the effects of OHV use could increase in the future if recreational opportunities expand. Therefore, we included an analysis in the SSA to examine the species' potential response to future changes in this stressor (Service 2025, pp. 28–36).

#### Development and Maintenance of Utility Corridors

The installation and maintenance of utility corridors can result in damage, loss, or relocation of plants; fragmentation of habitat; and increases in invasive species (Krening and Dawson 2020, p. 34; Service 2025, pp. 17–19). Multiple transmission lines occur within Colorado hookless cactus habitat and “approximately 1,200 plants have been transplanted in association with these projects” (Bio-Logic 2008 as cited in Krening and Dawson 2020, p. 34). While every AU has a utility corridor within it, most corridors intersect only a small portion of the AU. Additionally, some of these utility lines are along already-disturbed corridors (e.g., major highways).

In addition to the limited scope of utility corridor development and maintenance within Colorado hookless cactus habitat, federally protected areas further limit the impacts that utility corridor development can have on the species. Six of the seven ACECs within *S. glaucus*' range and all four of the ACECs within *S. dawsoniae*'s range include right-of-way exclusion or avoidance areas (Service 2025, pp. 19–22).

Based on practical locations for utility corridors, and on these protections, it is plausible that development could increase in the energy corridor that intersects the Whitewater, Devil's Thumb, and Cactus Park AUs and along the I–70 corridor in the Palisade AU (Service 2025, p. 30). It is also plausible that developers could replace an existing powerline with a larger structure in the Devil's Thumb and Whitewater AUs to increase capacity, which could cause significant ground disturbance (Service 2025, p. 30). Finally, developers could build additional pipelines in the Roan Creek and Plateau Creek AUs (Service 2025, p. 30).

Thus, currently, development and maintenance of utility corridors are affecting only individual Colorado hookless cactus plants, partly due to BLM's avoidance and mitigation measures; however, the effects of this stressor could increase in the future if development expands. Therefore, we included an analysis in the SSA to examine the species' potential response to future changes in this stressor.

#### Climate Change

Climate change may affect long-term survival of native species, including *Sclerocactus*, especially if longer or more frequent droughts occur. Within the range of Colorado hookless cactus, under lower emission scenarios, summer maximum temperature is expected to increase 4 °F (2.2 °C) and under higher emission scenarios summer maximum temperature is expected to increase 10 °F (5.6 °C) by mid-century, compared to the historical average between 1971 and 2000 (North Central Climate Adaptation Science Center and CIRES 2021, unpaginated). Extreme droughts, like those that occurred in 2002 and 2018, could also become more frequent by mid-century. Historically, droughts of this scale did not occur with this frequency within the range of the species (North Central Climate Adaptation Science Center and CIRES 2021, unpaginated). By mid-century, under lower emissions scenarios, these extreme droughts could occur two to three times per decade or, under higher emissions scenarios, eight to nine times per decade (North Central Climate Adaptation Science Center and CIRES 2021, unpaginated).

In addition, invasive annual weeds are often able to outcompete perennial native species for the essential nutrient nitrogen under drought conditions (Everard et al. 2010, pp. 85, 93–94). Drought conditions could further hinder BLM's efforts to control invasive weeds and restore native vegetation, which is

already difficult due to the extreme environment of the Colorado and Gunnison River basins (Service 1990, p. 11).

Climate change vulnerability analyses concluded that Colorado hookless cactus likely has low vulnerability to climate change (Krening and Dawson 2020, pp. 43–44); however, these analyses predated the taxonomic split of Colorado hookless cactus and thus analyzed the range that contains both *S. glaucus* and *S. dawsoniae*. First, NatureServe's Climate Change Vulnerability Index (CCVI), which evaluates species' vulnerability to climate change based on multiple factors, indicated that Colorado hookless cactus was "not vulnerable" or "presumed stable" rangewide, meaning the number of plants or range extent is not likely to increase or decrease considerably by mid-century (Treher et al. 2012, pp. 8, 52). Second, a combination of CCVI and species distribution modeling (SDM) methods indicated that Colorado hookless cactus "will not be vulnerable to climate change" within the next 30 years (Still et al. 2015, p. 116). This analysis predicted that the Colorado hookless cactus' range could shift or increase under projected changes in climate given the Colorado hookless cactus has no dispersal constraints and vast areas of suitable habitat beyond known occurrences (Still et al. 2015, p. 116). Finally, an additional SDM effort, which aimed to predict changes to the species' range under five different future climate scenarios, concluded that climate change does not present a threat, because all but one model indicates that either no range contraction will occur or that range extent will expand by midcentury (Price 2018, appendix 3 of Krening and Dawson 2020, p. 60).

Although multiple different models predict the Colorado hookless cactus has low vulnerability to climate change, Colorado Natural Heritage Program's (CNHP) CCVI suggested that Colorado hookless cactus is extremely vulnerable to climate change given "(1) natural and anthropogenic barriers to movement; (2) likelihood of short seed dispersal distances; (3) lack of variation in annual precipitation in occupied habitat over last 50 years; (4) potential increase in climate influenced disturbances within its habitat, (5) potential for wind and solar energy development within its range, and (6) pollinator specificity" (CNHP 2015, p. 533). Although the weight of research indicates both species likely have low vulnerability to climate change, given the uncertainty that this CNHP study introduced, we included an analysis in the SSA to

examine the species' potential response to future changes in this stressor.

#### *Conservation Efforts and Regulatory Mechanisms*

Positive actions, in the form of conservation efforts such as land protections and regulations, have reduced sources of habitat degradation, and multiple agencies, volunteers, and community members are committed to the conservation and preservation of Colorado hookless cactus. BLM owns and manages approximately 72 percent and 68 percent, respectively, of the land that comprises *S. glaucus* and *S. dawsoniae* AUs (Service 2025, pp. 19–22). The majority of the remaining habitat is privately owned; less than 1 percent is owned by State or local governments (Service 2025, p. 19).

Within the range of the Colorado hookless cactus, BLM has included conservation measures in its resource planning documents to minimize adverse impacts of land use to listed and BLM sensitive species, including the Colorado hookless cactus (Krening and Dawson 2020, p. 26). For example, BLM RMPs for the Colorado River Valley, Grand Junction, and Uncompahgre field offices (the three BLM field offices within the range of the species) include restrictions on surface-disturbing activities for BLM sensitive species, such as controlled surface use stipulations 100 m (328 ft) away from occupied habitat, and the ability to move a project more than 200 m (656 ft) away from occupied habitat (BLM 2015a, B–39; BLM 2015b, B–30; BLM 2020, B–21). In addition, the RMPs have motorized recreation restrictions, energy development restrictions, and grazing management; provisions for research to aid in better understanding the effects of stressors on the species and guide conservation efforts; and provisions for habitat improvements and vegetation management (e.g., reducing encroachment of woody species, fuels management, closing of livestock allotments, or maintaining rangeland health standards) (Service 2025, pp. 19–22, 28–36; BLM 2015a, pp. 41, 68; BLM 2020, p. II–24).

Even without the protections of the Act, both species would remain BLM sensitive species for at least 10 years (BLM 2008, entire; Dawson 2023, pers. comm.). Beyond this timeframe, they may remain BLM sensitive species as long as they meet either of the following criteria: (1) either species has recently undergone, is undergoing, or is predicted to undergo a downward trend such that the viability of the species or a distinct population segment of the species is at risk across all or a

significant portion of the species' range; or (2) either species depends on ecological refugia or specialized or unique habitats on BLM-administered lands, and there is evidence that such areas are threatened with alteration such that the continued viability of the species in the area would be at risk (BLM 2008, entire; Dawson 2023, pers. comm.).

Once delisted, or if *S. glaucus* or *S. dawsoniae* are removed from BLM's sensitive species list, the measures specific to listed and sensitive species in these RMPs would no longer apply (e.g., buffers around oil and gas development). However, the majority of measures in these RMPs are not unique to Colorado hookless cactus, but rather provide protections for resources in NCAs and ACECs and for other BLM sensitive species where the species occur. While these conservation measures are not obligatory, BLM implements them to meet the goals and objectives identified in RMPs, unless there are waivers, exceptions, or modifications for a specific project, for effective land management and rangeland health as required under FLPMA (43 U.S.C. 1701 *et seq.*). Continued responsible management of the landscapes in which the Colorado hookless cactus occurs, even if not directed specifically towards the species, will still provide benefit.

Further, approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs have special BLM land management designations in the form of NCAs, ACECs, a WSA, and a Wilderness Area (Service 2025, pp. 19–22). These designations limit or exclude the authorization of certain land uses, and some designations were specifically created for the conservation of natural resources; of 11 ACECs across the species' range, 8 specifically reference the protection of Colorado hookless cactus as a foundational goal. The protections provided by these management designations are not contingent upon the species' federally listed status, and these designations help to facilitate the maintenance and recovery of cactus occurrences, because they are areas where Colorado hookless cactus is not likely to be disturbed or adversely altered by land-use actions (Krening and Dawson 2020, p. 26). We discuss the specific protections each of these areas provides under the relevant stressors above.

The BLM RMP for the Dominguez-Escalante NCA identifies Colorado hookless cactus as a priority species and includes species-specific protections that will continue into the future under

the existing RMP. The species-specific protections include controlling noxious weeds, minimizing livestock use in Escalante Canyon, reducing route density within 200 m (656 ft) of Colorado hookless cactus occurrences, and limiting trail development and permitted activities in known habitat. BLM will continue monitoring and have a conservation goal that at least 80 percent of populations show evidence of recruitment. Species-specific restrictions will also be applied within 100 m (328 ft) of any known occurrences for Colorado hookless cactus as long as it is a BLM sensitive species, in addition to the protections described above (BLM 2017, pp. II., 34–35). The NCA contains the Dominguez Canyon WSA and the Dominguez Canyon Wilderness.

BLM designates ACECs under FLPMA (43 U.S.C. 1702(a), 1712(c)(3)). ACECs do not have an expiration date, and removing an ACEC designation is not simple. A withdrawal of an ACEC can be made only by the Office of the Secretary (43 U.S.C. 1714); additionally, the ACECs that include *S. glaucus* and *S. dawsoniae* habitat were designated to protect multiple species and resources in addition to the Colorado hookless cactus (Service 2025, table 6, pp. 19–22). Likewise, NCAs, WSAs, and Wilderness Areas are designated to protect multiple resources, not only the Colorado hookless cactus (1964 Wilderness Act (Pub. L. 88–577)). Therefore, it is unlikely that these special management designations will change in the coming decades.

We describe each of these BLM areas with special management designations, and the specific protections they provide, in table 6 of the SSA report (Service 2025, pp. 19–22) and in table 2 of the 5-year status review (Service 2021, pp. 10–11). The current condition of the species provides insight into the effectiveness of these protected areas; all but one of the *S. glaucus* AUs and both *S. dawsoniae* AUs have high resiliency, including moderate to high habitat condition (see *Current Condition*, below; Service 2025, pp. 26–27). This conclusion demonstrates that both due to the species' natural hardiness and to these land protections and other conservation efforts, stressors are not currently meaningfully affecting the species' survival and growth.

No regulatory mechanisms or conservation efforts protect Colorado hookless cactus on private, State, or local lands.

International trade in all *Sclerocactus* species is regulated by the Convention on International Trade in Endangered Species of Wild Flora and Fauna

(CITES), an international agreement ratified by most countries worldwide since 1975. The purpose of CITES is to regulate the international wildlife trade to safeguard certain species from over-exploitation. *S. glaucus* is currently listed as an Appendix I species under CITES and will remain an Appendix I species after delisting under the Act. Trade in Appendix I species is permitted only in exceptional circumstances. Under CITES, exporters must obtain a permit for international shipment of specimens. Because Appendix I applies to the cactus family (*Cactaceae*), *S. dawsoniae* is also considered an Appendix I species (CITES 2024, entire; Leuteritz 2024, entire). More information on CITES can be found at: <https://cites.org/eng/disc/how.php>.

#### 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 species. To assess the current and future condition of the species, we evaluate the effects of all the relevant factors that may be influencing the species, 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 listed entity, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

For example, to assess current resiliency, we used a condition category table (see *Current Condition* below) to analyze how livestock use, invasive species, oil and gas development, OHV recreational use, development and maintenance of utility corridors, and the effects of global climate change, taken together, may influence habitat condition, survivorship, population size, and water availability. Similarly, we analyzed how changes in these stressors, when considered together, may influence habitat condition, survivorship, population size, and water availability in the future. We also considered how these same stressors may affect the species' current and future redundancy and representation.

#### Current Condition

In our SSA report, we evaluate current condition by examining current levels of resiliency in the eight *S. glaucus* AUs and two *S. dawsoniae* AUs, and implications for redundancy and representation. Here, we summarize

our evaluation of current condition for resiliency, redundancy, and representation. Additional detail regarding our analysis is provided in the SSA report (Service 2025, pp. 22–28).

#### Resiliency

We describe the resiliency for each of the 10 AUs in terms of the habitat and demographic factors needed by the Colorado hookless cactus (Service 2025, pp. 10–16, 22–28). We developed a categorical model to calibrate resiliency based on the range of habitat and demographic conditions in each AU. In a categorical model, we first identify resource or demographic factors that contribute to the species' resiliency; typically, these factors align with the individual resource needs and population-level needs we identified in the SSA analysis. We then define threshold values for each identified resource or demographic factor that represent high, moderate, or low levels of that factor. Finally, we evaluate whether the current levels of each resource or demographic factor in an AU fall within the predetermined thresholds for a high, moderate, or low score for the category; we then average these scores for each category to develop an overall current resiliency score for each AU.

For Colorado hookless cactus, our categorical model assessed the resiliency of each AU by evaluating (1) the condition of habitat in each AU based on an index that evaluates a number of habitat factors including invasive species cover, bare ground, native perennial cover, the relative size of the AU, and the probability of occurrence based on a BLM habitat suitability model (Holsinger and Krening 2021, p. 5); (2) the summer water deficit, a proxy for drought and soil moisture that approximates the availability of water; (3) survival rates for each species, calculated from long-term monitoring data collected by BLM and the Denver Botanic Gardens; and (4) a minimum population size estimate for each AU provided by BLM (Service 2025, pp. 22–24). We selected these habitat and demographic factors based on their importance to the species' resiliency and because we could evaluate them relatively consistently across all 10 AUs. We then used this categorical model as a key to evaluate resiliency for each AU by systematically evaluating the current condition of each habitat and demographic factor. The AUs with higher overall resiliency are at less risk from potential stochastic events, such as climatic variation, than AUs with lower overall resiliency. Our SSA report provides additional detail

regarding the methodology we used to evaluate resiliency for each of the 10 AUs (Service 2025, pp. 22–28).

When measured against the metrics outlined in our categorical model (Service 2025, pp. 22–24), all but one of the *S. glaucus* AUs have high resiliency. This finding is due to the large estimated number of individuals in each AU, high levels of survivorship, adequate habitat resources, and a current summer water deficit (averaged over the past decade) that is similar to the historical average. The only AU that does not have high resiliency is the Palisade AU, which has moderate resiliency overall due to its extremely small population size and moderate score for the habitat condition index. This AU is considerably smaller in area than the other AUs. A major highway (U.S. Interstate 70) and the Colorado River also cut through this AU, fragmenting the habitat. Additionally, a high proportion of this AU is on private and State lands, which contain existing forms of development (e.g., truck stop, shooting range, power plant) that present additional stressors to the species and its habitat (Lincoln 2021, pers. comm.).

Both *S. dawsoniae* AUs have high resiliency (see table 1 below). This score is due to the high estimated number of individuals in each AU, high levels of survivorship, high and moderate availability of habitat features that support the species, and a current summer water deficit that is similar to the historical average. The stressors operating in the Plateau Creek AU and the Roan Creek AU are comparable, but the Plateau Creek AU is geographically smaller, which partly influences its

lower rating for the population size category (Lincoln 2021, pers. comm.).

Rangewide monitoring efforts have demonstrated a stable trend over recent years and have also provided a detailed understanding of demographic features and population dynamics. Across their limited ranges, both species of Colorado hookless cactus are relatively abundant, which contributes to the high levels of resiliency in all but one AU. At the time of listing in 1979 (prior to current taxonomic revisions—See Background for discussion of taxonomy), it was thought that the combined total for what are now considered to be four separate species (*S. glaucus*, *S. dawsoniae*, *S. brevispinus*, and *S. wetlandicus*) consisted of approximately 15,000 individual plants in both Colorado and Utah (44 FR 58868, October 11, 1979). After the taxonomic split in 2009, estimates from CNHP suggested there were approximately between 19,000 and 22,000 plants for the total rangewide number of individuals in both species (*S. glaucus* and *S. dawsoniae*), based on observations within element occurrence records, which do not represent a total count of plants for the entire range of the species (Service 2025, pp. 13–14). However, as we discuss below, we now know that there are many more plants than previously reported.

BLM conducted a novel sampling-based procedure to estimate the minimum population size of *S. glaucus* from 16 sampled macroplots across the species' range that encompass a variety of different habitat conditions informed by a species-specific habitat index (Krening et al. 2021a, entire). They estimated the total minimum population size for the taxon by applying the

average minimum plant density estimate of the sampled macroplots to *S. glaucus*' total rangewide occupied habitat acreage. To provide a conservative rangewide estimate across all landownerships (BLM, private, State, and local lands), BLM applied the 90 percent lower confidence level value as the minimum population size for each AU. Despite their conservative approach, this method produced a population size estimate for the species that is much higher than previous estimates (Krening et al. 2021a, entire).

BLM conducted a similar procedure to estimate the minimum population size for *S. dawsoniae* (Krening and Holsinger 2024, entire; Service 2025, pp. 20–21). BLM estimated minimum plant densities in 30 sampled macroplots using the same methods as the *S. glaucus* study described above. BLM did not apply the 90 percent lower confidence level value as the minimum population size for each *S. dawsoniae* AU because of the increased sample size and spatially balanced design (Krening and Holsinger 2024, entire).

Using this sampling-based procedure to determine the minimum number of plants in each AU, *S. glaucus* has a minimum population estimate of at least 68,120 plants (90 percent lower confidence level estimate), and *S. dawsoniae* has a minimum population estimate of 17,362 plants (Service 2025, p. 14; Krening et al. 2021a, p. 8; Krening and Holsinger 2024, entire). Based on the most recent (2023) BLM monitoring report for the species, both species demonstrate an increasing trend compared to the baseline density (Krening and DePrenger-Levin 2023, pp. 6–7).

TABLE 1—RESILIENCY OF *S. GLAUCUS* AND *S. DAWSONIAE*

[Based on current demographic, distribution, and habitat conditions in the species' AUs (Service 2025, pp. 26–28).]

Species	Analysis unit	Habitat condition index	Survivorship	Minimum population size	Summer water deficit *	Overall AU resiliency score
<i>S. glaucus</i> .....	Whitewater .....	High .....	High .....	High .....	High .....	High.
	Palisade .....	Moderate ....		Low .....	High .....	Moderate.
	Dominguez-Escalante .....	High .....		High .....	High .....	High.
	North Fruita Desert .....	Moderate ....		Moderate .....	High .....	High.
	Devil's Thumb .....	High .....		Moderate .....	High .....	High.
	Cactus Park .....	High .....		High .....	High .....	High.
<i>S. dawsoniae</i> ...	Gunnison Gorge .....	Moderate ....	High .....	Moderate .....	High .....	High.
	Gunnison River East .....	High .....		High .....	High .....	High.
	Plateau Creek .....	Moderate ....		Moderate .....	High .....	High.
	Roan Creek .....	High .....		High .....	High .....	High.

\* Note: "High" in summer water deficit refers to a high resiliency rating, rather than a high water deficit.

Redundancy

Redundancy describes the number and distribution of AUs, such that the greater the number and the wider the distribution of the AUs, the better the Colorado hookless cactus can withstand

catastrophic events. The plausibility of catastrophic events also influences species' redundancy; if catastrophic events are unlikely within the range of the species, catastrophic risk is inherently lower. We are unaware of

any plausible activity or naturally occurring event that would constitute a catastrophic event for Colorado hookless cactus. For example, fire is not a common occurrence in *S. glaucus* or *S. dawsoniae* habitat as this habitat lacks

the fuels to sustain a burn, though increased invasive species presence could elevate this risk (Service 2025, p. 28). Additionally, the range of *S. glaucus* and *S. dawsoniae* contains natural and humanmade barriers (*i.e.*, rivers, canyons, highways) that would constrain the spread of any catastrophic fire throughout the entire range of Colorado hookless cactus. Redundancy for narrow endemic species is intrinsically limited; however, *S. glaucus* plants are distributed broadly across the range of the species in eight AUs, providing redundancy throughout its relatively small geographic range. With only two AUs, *S. dawsoniae* redundancy is limited; however, as a narrowly endemic plant, it has likely always had a small range and limited redundancy, and there has not been a known decrease in redundancy compared with its historical range. Additionally, given the lack of plausible catastrophic events across the range of *S. glaucus* and *S. dawsoniae*, even the narrow range of *S. dawsoniae* does not introduce appreciable catastrophic risk.

#### Representation

*S. glaucus* and *S. dawsoniae* exhibit some ecological and morphological variability, coupled with low to moderate genetic diversity among AUs (McGlaughlin and Naibauer 2021, p. 22). Inbreeding is not an immediate concern for either species (McGlaughlin and Naibauer 2021, p. 22). Additionally, *S. glaucus* demonstrates sufficient connectivity, which results in ongoing and recent genetic exchange (McGlaughlin and Naibauer 2021, p. 2). *S. dawsoniae* is genetically isolated and diverged from *S. glaucus*; all genetic analyses support that *S. dawsoniae* is a distinct entity (McGlaughlin and Naibauer 2024, entire).

#### Future Scenarios and Future Condition

In our SSA report, we forecasted the resiliency of *S. glaucus* and *S. dawsoniae* AUs and their redundancy and representation to mid-century (the mean of projections for 2040 to 2069) using a range of plausible future scenarios. After mid-century, the changes in climate conditions that different climate models and emissions scenarios project begin to diverge widely (Rangwala et al. 2021, p. 4); in other words, the spread of potential projected temperature increases broadens substantially after mid-century. Therefore, we focused our analysis of future condition on mid-century to avoid the large uncertainty in climate change at the end of the twenty-first century (Rangwala et al. 2021, p. 4). We also selected this timeframe because

we can make reliable predictions regarding changes in other stressors to *S. glaucus* and *S. dawsoniae*, such as land management. This timeframe encompasses at least one revision to BLM resource management plans and is biologically meaningful to *S. glaucus* and *S. dawsoniae* for us to begin to understand the response of ecosystems to those changes.

We used future climate models downscaled to the ranges of *S. glaucus* and *S. dawsoniae*, in combination with forecasted changes in the location and intensity of stressors, to develop three future scenarios and evaluate the condition of *S. glaucus* and *S. dawsoniae* under each of those scenarios. By capturing a range of plausible future scenarios, we can assume that actual future conditions will likely fall somewhere between these projected scenarios. Detailed descriptions of each scenario are available in the SSA report (Service 2025, pp. 28–36).

As many of the stressors that affect *S. glaucus* and *S. dawsoniae* occur on BLM lands, future scenarios were developed with input from BLM about plausible changes in the location and intensity of stressors on BLM land. Given some level of uncertainty about the conditions that will occur by mid-century, these scenarios represent three future conditions—optimistic, continuation, and pessimistic—to capture the plausible range of future conditions the species may experience. Therefore, our evaluation of future conditions presents a plausible range of expected species responses. While the metrics used to assess the current resiliency of *S. glaucus* and *S. dawsoniae* AUs are quantitative, we do not have a reliable way to quantitatively forecast these metrics into the future. Instead, future conditions are expressed qualitatively, using the results of our current condition analysis as the baseline. Species experts used professional judgment to predict how the species and their habitats would respond to each future scenario (Krening 2021, pers. comm.).

**Optimistic.** In the optimistic scenario, the overall resiliency of each AU for both species remains the same as the current condition. Although the overall resiliency of each AU does not change, the resiliency of the Plateau Creek (*S. dawsoniae*) and Devil's Thumb (*S. glaucus*) AUs increases slightly due to higher ratings for habitat conditions and population size, respectively. Under this scenario, decreases in activities such as grazing and OHV use (consistent with current stipulations in BLM grazing permits and travel management plans)

that degrade *S. glaucus* and *S. dawsoniae* habitat allow for passive restoration, which leads to improved habitat conditions in the Plateau Creek AU and an increase in population size in the Devil's Thumb AU. Summer water deficit is expected to slightly decrease, meaning more water is available for germination, growth, and reproduction. Redundancy and representation for *S. dawsoniae* increase under this scenario, as compared to the current condition, due to an increase in resiliency in the Plateau Creek AU. Redundancy and representation of *S. glaucus* also increase slightly under this scenario due to an increase in resiliency in the Devil's Thumb AU.

**Continuation.** In the continuation scenario, we expect resiliency, redundancy, and representation to remain relatively unchanged from the current condition. Resiliency of the Palisade AU (*S. dawsoniae*) is moderate; resiliency of all other AUs is high. Despite the increase in water deficit as compared to historical conditions under this scenario (meaning that less water would be available to the plants), this slight decrease in water availability would have minimal impact because it is well within the range of variability that *S. glaucus* and *S. dawsoniae* have historically experienced.

**Pessimistic.** In the pessimistic scenario, hot and dry conditions may negatively affect survivorship and recruitment of the species. Water deficit is more than one standard deviation higher than the historical mean, meaning that, on average, less water is available to support germination, growth, and reproduction. Under the pessimistic scenario, although BLM land management direction and special land management designations do not change, continued ground disturbance and habitat degradation may occur. This projection could be driven by several factors: Livestock grazing without corrective action for impacts to the range may lead to increased impacts to habitat and plant communities; and increasing OHV use (due to increased demand from population growth), increasing demand for oil and gas development and utility corridor development, and an increase in invasive plant species may negatively affect the amount and quality of habitat available and reduce survival rates and overall population sizes, leading to a decrease in resiliency in the Whitewater, Palisade, North Fruita Desert, Devil's Thumb, Cactus Park, Gunnison Gorge, and Gunnison River East AUs (*S. glaucus*) and in the Plateau Creek AU (*S. dawsoniae*). Overall, one *S. glaucus* AU is in high condition, six

*S. glaucus* AUs are in moderate condition, and one is in low condition. *S. dawsoniae* has one AU in high condition and one AU in moderate condition.

Redundancy and representation of *S. glaucus* decreases slightly in this scenario due to the decrease in resiliency in all but one AU; although no AUs are expected to be extirpated, each AU contains multiple clusters of plants, and some diversity within AUs could be lost. However, even in the most pessimistic plausible scenario, all but 1 of the 8 AUs are expected to have at least 500 to 10,000 plants, thereby preserving much of the species' redundancy and representation. Despite high and moderate resiliency of the two *S. dawsoniae* AUs, representation and redundancy are lower than under the optimistic and continuation scenarios and under current condition due to the Plateau Creek AU's moderate resiliency; this AU had high resiliency under all other scenarios. With only two known *S. dawsoniae* AUs, the loss of one of these AUs due to catastrophic, natural, or human-caused events would cause a severe loss of redundancy and representation of the species; however, loss of either AU is not expected, even under the pessimistic scenario. As with *S. glaucus*, some variation within AUs could be reduced under this scenario; however, ecological, morphological, and genetic variation will continue to be represented by the multiple AUs across *S. dawsoniae*'s range.

#### Determination of Colorado Hookless Cactus (*S. glaucus* and *S. dawsoniae*) 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.

When we listed the Colorado hookless cactus as threatened on October 11, 1979, we identified the potential development of oil shale deposits and gold mining (Factor A), off-road vehicle use (Factor A), collecting pressure (Factor B), livestock grazing (Factor C), and an inadequacy of existing regulatory mechanisms (Factor D) as threats to the existence of the species (44 FR 58868, October 11, 1979). In our SSA, we evaluated these stressors and additional stressors that were identified after the time of listing. Much more is presently known about the species' stressors than at the time of listing.

Several of the stressors identified in the original listing decision are no longer relevant. Given the taxonomic changes, and thus range extent changes, that the species has undergone in the past 40 years, oil shale and tar sands development and hybridization are no longer relevant stressors (Service 2025, p. 16). Additionally, collection from the wild has not occurred at the level anticipated at the time of listing; collection is not having population- or species-level effects on either species (Krening and Dawson 2020, p. 36). Thus, stressors that could influence both species of the Colorado hookless cactus at the AU or species scale include livestock use (Factor A), invasive species (Factor A), oil and gas development (Factor A), OHV recreational use (Factor A), development and maintenance of utility corridors (Factor A), and the effects of global climate change (Factor A). Although livestock grazing was categorized as a stressor under Factor C at the time of listing, we believe that the effects of livestock grazing are better characterized by Factor A. The spines on cactus plants generally make them undesirable forage to livestock; however, livestock can degrade habitat conditions by trailing through and trampling habitat. Only on rare occasions do cattle directly trample or dislodge cactus plants.

We also evaluated a variety of conservation efforts and mechanisms across the 10 AUs of both species that either reduce or ameliorate stressors or improve the condition of habitats or demographics. These conservation efforts and mechanisms include five BLM RMPs that, taken together, cover the range of the species. They include motorized recreation restrictions, energy development restrictions, and grazing management; research to aid in better understanding the effects of stressors on the species and guide conservation efforts; and habitat improvements and

vegetation management (Service 2025, pp. 19–22, 28–36). With 72 percent of *S. glaucus* and 68 percent of *S. dawsoniae* AU acres occurring on BLM land, BLM's implementation of the regulatory mechanisms in their resource planning documents on all of their lands within the range of the species (Factor D) has helped to address the stressors we identified under Factors A and B. While we cannot attribute the currently high resiliency of both species (*S. glaucus* and *S. dawsoniae*) to one specific conservation measure, this high resiliency demonstrates the amelioration of relevant stressors and the adequacy of the existing regulatory mechanisms, both due to the combination of conservation measures in place and the hardiness of the plants (having a demonstrated ability to tolerate nearby disturbance).

In addition to the implementation of measures that minimize impacts to the Colorado hookless cactus on all BLM lands, approximately 30 percent of the land in *S. glaucus* AUs and 41 percent of the land in *S. dawsoniae* AUs have special BLM land management designations (Factor D), which further limit or exclude the authorization of certain land uses and further help to facilitate the maintenance and recovery of cactus occurrences, because they are areas where Colorado hookless cactus occurrences are not likely to be disturbed or adversely altered by land-use actions (Krening and Dawson 2020, p. 26). The protections provided by these management designations are not contingent upon the species' federally listed status.

#### Status Throughout All of Its Range: *Sclerocactus glaucus*

Currently, seven of the eight *S. glaucus* AUs have high resiliency, and one AU has moderate resiliency (Service 2025, pp. 26–28). The highly resilient AUs have high estimated numbers of individuals, high levels of survivorship, adequate habitat resources, and a current water deficit that is similar to the historical average. One AU has moderate resiliency due to its extremely small population size and moderate score for the habitat index; this AU covers a considerably smaller area than the other AUs. Rangewide monitoring has shown a stable trend for Colorado hookless cactus, with no indication of widespread decline. This monitoring has also informed our understanding that *S. glaucus* is currently much more abundant than originally estimated at the time of listing in 1979. At the time of listing, and prior to the taxonomic splits between the 2 Utah *Sclerocactus* species and Colorado's *S. glaucus* and *S.*

*dawsoniae*, it was thought that the combined total for the now 4 species consisted of approximately 15,000 individual plants in both Colorado and Utah; now, the minimum population estimate for *S. glaucus* alone is 68,120 plants (90 percent lower confidence level).

We are unaware of any plausible activity or naturally occurring event that would constitute a catastrophic event for this species. Thus, while the species is a narrow endemic with a small range compared to wide-ranging species, *S. glaucus*'s relatively large range for a narrow endemic, with eight AUs, and the lack of plausible catastrophic events reduce catastrophic risk for this species, thereby enhancing redundancy. The individuals within and among the AUs also exhibit genetic, ecological, and morphological diversity, contributing to the species' representation.

Moreover, our understanding of the species' stressors has changed since the time Colorado hookless cactus was listed. Multiple identified stressors are no longer relevant to the species, given past taxonomic changes and subsequent changes in the geographic range of the species (*i.e.*, oil shale and tar sands development) or because they are not occurring at a scale anticipated at the time of listing (*i.e.*, collection). We also have found that, while OHV use and invasive species have the potential to detrimentally impact Colorado hookless cactus, they have caused only minor, localized impacts (Krening and Dawson 2020, pp. 35, 38). Oil and gas development occurs in only a small portion of three of the eight *S. glaucus* AUs.

Since Colorado hookless cactus was listed, the BLM land in the species' range now includes NCAs, ACECs, a WSA, and a Wilderness Area (Service 2025, pp. 19–22). These designations limit or exclude the authorization of certain land uses, and most of these designations specifically reference the protection of Colorado hookless cactus as a foundational goal. The protections provided by these management designations are not contingent upon the species' federally listed status, and these designations have helped to facilitate the maintenance and recovery of cactus occurrences, because they are areas where Colorado hookless cactus is not likely to be disturbed or its habitat adversely altered by land-use actions (Krening and Dawson 2020, p. 26). While we cannot attribute the currently high resiliency of all but one AU to one specific conservation measure, this high resiliency demonstrates the amelioration of relevant stressors, both due to the combination of conservation

measures in place and the hardiness of the plant (which has shown an ability to tolerate nearby disturbance).

Given the currently high level of resiliency in seven of the eight *S. glaucus* AUs and moderate resiliency of one AU, the additional plants we now know to occur throughout the species' range, the lack of significant imminent stressors, and the low likelihood of catastrophic events, we find that *S. glaucus* currently has sufficient ability to withstand stochastic and catastrophic events, and to adapt to environmental changes.

For the purposes of our analysis of the species' future condition, we defined the foreseeable future for both *S. glaucus* and *S. dawsoniae* to mid-century (the mean of 2040 to 2069). After mid-century, the changes in climate conditions that different climate models and emissions scenarios project begin to diverge widely (Rangwala et al. 2021, p. 4); in other words, after mid-century, there is a wide variability in temperature projections among different climate models. This variability makes future conditions beyond the mid-century difficult to reliably assess. Therefore, we focused our analysis of future condition on mid-century to avoid the large degree of uncertainty in how climate change is projected to manifest at the end of the twenty-first century (Rangwala et al. 2021, p. 4). We also selected this timeframe because it allows us to reliably predict changes in species' stressors and land management and is biologically meaningful to both species for us to begin to understand the response of ecosystems to those changes.

By mid-century, we anticipate a range of plausible future conditions for *S. glaucus*. Under the optimistic scenario, the condition of the species is likely to improve over the current condition, with resiliency projected to increase slightly in one *S. glaucus* AU. BLM's closure of certain OHV routes and effective implementation of changes in grazing permit stipulations would lead to decreased grazing and OHV pressures, causing improved habitat conditions and an increase in the number of individuals in the AU (Service 2025, pp. 31–32). In the continuation scenario, we expect resiliency, redundancy, and representation to remain relatively unchanged from the current condition, because stressors and conservation efforts would remain very similar to what the species is currently experiencing.

In the pessimistic scenario, although BLM management planning documents and special land management

designations do not change, grazing without corrective action for impacts to the range, an increase in OHV use, increased demand for utility corridor development, an increase in invasive plant species, and a considerable decrease in water availability due to climate change may negatively affect the amount and quality of habitat available, and reduce survival rates and overall population sizes. This is the only scenario in which the condition of *S. glaucus* is projected to decline: One AU's resiliency remains high, six AUs decrease from high to moderate resiliency, and one AU decreases to low resiliency. Even under this pessimistic scenario, the species maintains moderate levels of survival and high or moderate habitat condition in the majority of AUs, despite increasing stressors. In all three scenarios, all eight AUs will remain extant, thereby continuing to contribute to the redundancy and representation of the species.

Given these future projections of resiliency, redundancy, and representation to mid-century, *S. glaucus* could experience a slight decrease in viability under one of the three future scenarios (the pessimistic scenario); however, even in this most pessimistic scenario, all AUs will remain extant and seven of the eight AUs will have moderate to high resiliency.

Two factors support this consistently moderate to high future resiliency: BLM conservation actions and the species' biological characteristics. First, the high to moderate resiliency of *S. glaucus* AUs is, in part, due to land protections and regulations implemented by BLM (Factor D) that will continue to be implemented into the future, even in the absence of protections afforded by the Act, as described under Conservation Efforts and Regulatory Mechanisms above. These protections will continue to limit the potential effects of stressors on *S. glaucus* in the future.

Second, independent of future BLM management, the species' biological characteristics moderate its response to increasing stressors. *S. glaucus* is a habitat generalist, which means the species is not constrained to a specific habitat niche; the species' flexible resource requirements increase its resiliency to potential future increases in stressors and its ability to adapt to future change (representation). This determination is evidenced by *S. glaucus*' past ability to maintain high survivorship and resiliency, even in the face of ongoing stressors that the Service originally determined could lead to decline (*e.g.*, OHV use, invasive

species). Additionally, multiple modeling efforts have concluded that Colorado hookless cactus likely has low vulnerability to climate change, given its dispersal capabilities and opportunities for expansion into vast areas of suitable habitat (Krening and Dawson 2020, pp. 43–44). Although conditions could become considerably drier under the pessimistic climate scenario, *S. glaucus* is hardy and already adapted to arid environments. Individuals of this species live many decades and have maintained healthy recruitment and survival, even through droughts and other climatic variation in the past (BLM 2018, pp. 14–15; Hegewisch and Abatzoglou 2020, entire). These characteristics allow the species to maintain moderate survivorship and resiliency, even under the pessimistic scenario.

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, the species currently has sufficient levels of resiliency, redundancy, and representation, and is anticipated to maintain sufficient levels under each of the future scenarios, such that *S. glaucus* will be able to withstand stochastic events, catastrophic events, and environmental change now and into the foreseeable future. Thus, after assessing the best available information, we conclude that *S. glaucus* is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

#### *Status Throughout All of Its Range: Sclerocactus dawsoniae*

Currently, both *S. dawsoniae* AUs have high resiliency (Service 2025, pp. 26–28). The highly resilient AUs have moderate to high estimated numbers of individuals (*i.e.*, a minimum population estimate of 17,362 plants total), high levels of survivorship, high and moderate condition of habitat features, and a current water deficit that is similar to the historical average. These high current levels of resiliency reduce the current extinction risk for *S. dawsoniae* because they lower the risk to the species from stochastic variation. Rangewide monitoring has shown a stable trend for *S. dawsoniae*, with no indication of widespread decline and greater abundance than originally estimated. When Colorado hookless cactus was listed in 1979 and prior to the taxonomic splits between the 2 Utah *Sclerocactus* species and Colorado's *S. glaucus* and *S. dawsoniae*, it was thought that the combined total for the now 4 species consisted of approximately 15,000 individual plants in both Colorado and Utah; now, the

minimum population estimate for *S. dawsoniae* plants alone is 17,362.

Additionally, the two AUs and the individuals within the AUs exhibit ecological and morphological variability (McGlaughlin and Naibauer 2021, p. 22), contributing to the representation of the species. In terms of redundancy, we are unaware of any plausible activity or naturally occurring event that would constitute a catastrophic event for this species. Given the lack of plausible catastrophic events across the range of *S. dawsoniae*, even its narrow range (two AUs) does not introduce appreciable catastrophic risk.

Moreover, our understanding of stressors to the Colorado hookless cactus has changed since the time of the original listing rule (44 FR 58868; October 11, 1979). Multiple identified stressors are no longer relevant to the species, given past taxonomic changes and subsequent changes in the geographic range of the species (*e.g.*, oil shale and tar sands development) or because they are not occurring at a scale anticipated at the time of listing (*i.e.*, collection). We also have found that, while OHV use and invasive species had the potential to detrimentally impact the species, they have caused only minor, localized impacts (Krening and Dawson 2020, pp. 35, 38).

Since Colorado hookless cactus was listed, NCAs, ACECs, a WSA, and a Wilderness Area have been designated on BLM land where the species occurs (Service 2025, pp. 19–22). These designations limit or exclude the authorization of certain land uses, and most of these designations specifically reference the protection of Colorado hookless cactus as a foundational goal. The protections provided by these management designations are not contingent upon the species' federally listed status, and these designations have helped to facilitate the maintenance and recovery of cactus occurrences, because they are areas where Colorado hookless cactus is not likely to be disturbed or adversely altered by land-use actions (Krening and Dawson 2020, p. 26). While we cannot attribute the currently high resiliency of both AUs to one specific conservation measure, this high resiliency demonstrates the amelioration of relevant stressors, both due to the combination of conservation measures in place and the hardiness of the plant (which has shown an ability to tolerate nearby disturbance).

By mid-century (the foreseeable future), we anticipate a range of plausible future conditions for *S. dawsoniae*. Under the optimistic scenario, the condition of the species

improves, with resiliency expected to increase slightly in one *S. dawsoniae* AU due to decreased grazing and OHV pressures, causing improved habitat conditions. In the continuation scenario, we expect resiliency, redundancy, and representation to remain relatively unchanged from the current condition, as stressors and conservation efforts remain very similar to what the species is currently experiencing. In the pessimistic scenario, although BLM management planning documents and special land management designations do not change, continued livestock grazing without corrective action for impacts to the range, increasing demand for oil and gas development and utility corridor development, and an increase in invasive plant species will cause ground disturbance and habitat degradation that is projected to negatively affect the species, which would cause a decrease in resiliency in one of the two *S. dawsoniae* AUs. Additionally, only under this pessimistic scenario does water availability drop considerably below the historical average (*i.e.*, more than one standard deviation). This is the only scenario in which we foresee resiliency decreasing for either of the species' two AUs; one AU's resiliency remains high, and one AU decreases to moderate resiliency. Even in the pessimistic scenario, survivorship in both AUs remains high. In all three scenarios, both AUs will remain extant, thereby continuing to contribute to the redundancy and representation of the species.

Given these future projections of resiliency, redundancy, and representation to mid-century, *S. dawsoniae* could experience a slight increase in extinction risk under one of the three future scenarios; however, even in the pessimistic scenario, both AUs will remain extant with moderate to high resiliency. Two factors support this moderate to high future resiliency: BLM conservation actions and the species' biological characteristics. First, this high to moderate resiliency of *S. dawsoniae* AUs is, in part, due to land protections and regulations implemented by BLM (Factor D) that will continue to be implemented into the future even in the absence of protections afforded by the Act, as described under Conservation Efforts and Regulatory Mechanisms above. These protections will continue to limit the potential effects of stressors on *S. dawsoniae* in the future.

Second, independent of future BLM management, the species' biological characteristics moderate its response to increasing stressors. Like *S. glaucus*, *S.*

*dawsoniae* is a habitat generalist, which means the species is not constrained to a specific habitat niche; the species' flexible resource requirements increase its resiliency to potential future increases in stressors and its ability to adapt to future change (representation). This finding is evidenced by *S. dawsoniae*'s past ability to maintain high survivorship and resiliency, even in the face of ongoing stressors that the Service originally determined could lead to decline (*e.g.*, OHV use, invasive species). Additionally, multiple modeling efforts have indicated that Colorado hookless cactus likely has low vulnerability to climate change, given its dispersal capabilities and opportunities for expansion into vast areas of suitable habitat (Krening and Dawson 2020, pp. 43–44). Although conditions could become considerably drier under the pessimistic climate scenario, *S. dawsoniae* is hardy and already adapted to arid environments. Individuals of this species live many decades and have maintained healthy recruitment and survival, even through droughts and other climatic variation in the past (BLM 2018, pp. 14–15; Hegewisch and Abatzoglou 2020, *entire*). These characteristics would allow *S. dawsoniae* to maintain high survivorship and moderate to high resiliency, even under the pessimistic scenario.

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, the species currently has sufficient levels of resiliency, redundancy, and representation, and is anticipated to maintain sufficient levels in each of the plausible future scenarios, such that *S. dawsoniae* will be able to withstand stochastic events, catastrophic events, and environmental change now and within the foreseeable future. Therefore, after assessing the best available information, we conclude that *S. dawsoniae* is not in danger of extinction now or likely to become so in the foreseeable future 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. Having determined that *S. glaucus* and *S. dawsoniae* are not in danger of extinction or likely to become so in the foreseeable future throughout all of their range, we now consider whether either may be in danger of extinction (*i.e.*,

endangered) or likely to become so in the foreseeable future (*i.e.*, threatened) in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction or likely to become so in the foreseeable future in that portion. Depending on the case, it might be more efficient for us to address the “significance” question or the “status” question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

In undertaking this analysis for *S. glaucus* and *S. dawsoniae*, we choose to address the status question first. We began by identifying portions of the range where the biological status of the species may be different from their biological status elsewhere in their range. For this purpose, we considered information pertaining to the geographic distribution of (a) individuals of the species, (b) the threats that the species face, and (c) the resiliency condition of populations.

For *S. glaucus*, we evaluated the range of the species to determine if the species is in danger of extinction now or likely to become so in the foreseeable future in any portion of its range. The range of a species can theoretically be divided into portions in an infinite number of ways. We focused our analysis on portions of the species' range that may meet the definition of an endangered species or a threatened species. For *S. glaucus*, we considered whether the threats or their effects on the species are greater in any biologically meaningful portion of the species' range than in other portions such that the species is in danger of extinction now or likely to become so in the foreseeable future in that portion. We examined the following threats: livestock use, invasive species, oil and gas development, OHV use, development and maintenance of utility corridors, and climate change, including cumulative effects.

Livestock use, invasive species, OHV use, development and maintenance of utility corridors, and climate change occur uniformly across the species' range; there are no portions of the species' range where these stressors occur more intensely. Oil and gas development is occurring in only three AUs (North Fruita Desert, Whitewater, and Palisade AUs), so this threat may be elevated in this area. However, despite this development activity, the North Fruita Desert and Whitewater AUs currently have high resiliency and are

expected to maintain this high resiliency under two of three future scenarios. Under the pessimistic scenario, North Fruita Desert and Whitewater AUs have moderate resiliency. Oil and gas development is occurring in only a small portion of the Palisade AU (there is only one active well site across more than 9,269 ac (3,751 ha)), and, while this AU has moderate resiliency currently and could drop to low resiliency under the pessimistic scenario, this possible change is due to the AU's small size and thus inherently low number of plants, not due to oil and gas development. Thus, even though oil and gas development may be concentrated in these AUs, it is not producing a species' response that would indicate the plants therein are in danger of extinction now or in the foreseeable future.

Moreover, although the Palisade AU has a low population size and is the only AU to rank low in resiliency in any future scenario, the AU occupies the smallest area of any *S. glaucus* AU and contributes the least to the species' redundancy and representation. Therefore, this AU is not considered to be a biologically meaningful portion of the species' range where threats are impacting individuals differently from how they are affecting the species elsewhere in its range such that the status of the species in that portion differs from its status in any other portion of the species' range.

Overall, we found no biologically meaningful portions of *S. glaucus*' range where threats are impacting individuals differently from how they are affecting the species elsewhere in its range such that the status of the species in that portion differs from its status in any other portion of the species' range.

Therefore, we find that the species is not in danger of extinction or likely to become so within the foreseeable future in any significant portion of its range. This does not conflict with the courts' holdings in *Desert Survivors v. Department of the Interior*, 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018) and *Center for Biological Diversity v. Jewell*, 248 F. Supp. 3d. 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy on Interpretation of the Phrase “Significant Portion of Its Range” in the Endangered Species Act's Definitions of “Endangered Species” and “Threatened Species” (79 FR 37578, July 1, 2014), including the definition of “significant” that those court decisions held to be invalid.

For *S. dawsoniae*, we evaluated the range of the species to determine if the

species is in danger of extinction now or likely to become so in the foreseeable future in any portion of its range. The range of a species can theoretically be divided into portions in an infinite number of ways. We focused our analysis on portions of the species' range that may meet the definition of an endangered species or a threatened species. For *S. dawsoniae*, we considered whether the threats or their effects on the species are greater in any biologically meaningful portion of the species' range than in other portions such that the species is in danger of extinction or likely to become so within the foreseeable future in that portion. We examined the following threats: livestock use, invasive species, oil and gas development, OHV use, development and maintenance of utility corridors, and climate change, including cumulative effects.

Overall, the threats to this species are uniformly distributed throughout its range, and we did not identify a significant concentration of threats or the species' response to those threats that would increase extinction risk in any portion. Oil and gas development occurs in both AUs, as does livestock use, OHV use, invasive species infestation, and development and maintenance of utility corridors. The small range of the species will not experience substantially different temperature or precipitation changes as a result of climate change.

We found no biologically meaningful portions of *S. dawsoniae*'s range where threats are impacting individuals differently from how they are affecting the species elsewhere in its range such that the status of the species in that portion differs from its status in any other portion of the species' range.

Therefore, we find that the species is not in danger of extinction or likely to become so within the foreseeable future in any significant portion of its range. This finding does not conflict with the courts' holdings in *Desert Survivors v. Department of the Interior*, 321 F. Supp. 3d 1011, 1070–74 (N.D. Cal. 2018) and *Center for Biological Diversity v. Jewell*, 248 F. Supp. 3d 946, 959 (D. Ariz. 2017) because, in reaching this conclusion, we did not apply the aspects of the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37578, July 1, 2014), including the definition of "significant" that those court decisions held to be invalid.

#### Determination of Status

Based on the best scientific and commercial data available, we determine that *S. glaucus* and *S. dawsoniae* do not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. In accordance with our regulations at 50 CFR 424.11(e)(2) currently in effect, *S. glaucus* and *S. dawsoniae* have recovered to the point at which they no longer meet the definition of an endangered species or a threatened species. Therefore, we are removing Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*) from the Federal List of Endangered and Threatened Plants.

#### Effects of This Rule

This rule revises 50 CFR 17.12(h) by removing Colorado hookless from the Federal List of Endangered and Threatened Plants. On the effective date of this rule (see **DATES**, above), the prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, will no longer apply to this species. Federal agencies will no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*).

There is no critical habitat designated for this species, so there will be no effect to 50 CFR 17.96.

#### Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been recovered. Post-delisting monitoring (PDM) refers to activities undertaken to verify that a species delisted due to recovery remains secure from the risk of extinction after the protections of the Act no longer apply. The primary goal of PDM is to monitor the species to ensure that its status does not deteriorate, and if a decline is detected, to take measures to halt the decline so that proposing it as endangered or threatened is not again needed. If at any time during the monitoring period data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing.

We have prepared a PDM plan for Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*). We published a notice of availability of a draft PDM plan with the proposed delisting rule (88 FR 21582, April 11, 2023), and we

addressed all comments to the plan under Summary of Comments and Recommendations and revised the draft PDM plan according to the information we received. Therefore, we consider the plan final. As discussed in the proposed rule, the PDM plan: (1) Summarizes the status of Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*) at the time of proposed delisting; (2) describes frequency and duration of monitoring; (3) discusses monitoring methods and potential sampling regimes; (4) defines what potential triggers will be evaluated to address the need for additional monitoring; (5) outlines reporting requirements and procedures; (6) proposes a schedule for implementing the PDM plan; and (7) defines responsibilities. It is our intent to work with our partners toward maintaining the recovered status of Colorado hookless cactus (*S. glaucus* and *S. dawsoniae*).

#### Required Determinations

##### *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), Executive Order 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 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 notified the Ute Mountain, Jicarilla Apache Nation, Southern Ute, Ute Mountain Ute, and Navajo Nation Tribes of our recommendation to delist the Colorado hookless cactus in our 5-year status review in 2021, and of the proposed delisting rule (88 FR 21582, April 11, 2023). We did not receive comments from Tribes, and we are not aware of

any Tribal interests or concerns associated with this final determination.

#### 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 Colorado Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

#### Authors

The primary authors of this rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Colorado Ecological Services Field Office.

#### List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation.

#### Signing Authority

Paul Souza, Regional Director, Region 8, Exercising the Delegated Authority of the Director of the U.S. Fish and Wildlife Service, approved this action on April 24, 2025, for publication. On May 21, 2025, Paul Souza 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.

#### Regulation Promulgation

Accordingly, we 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.

#### § 17.12 [Amended]

■ 2. In § 17.12, amend paragraph (h) by removing the entry for “*Sclerocactus glaucus*” under Flowering Plants from the List of Endangered and Threatened Plants.

#### 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. 2025–09692 Filed 5–28–25; 8:45 am]

**BILLING CODE 4333–15–P**

# Proposed Rules

Federal Register

Vol. 90, No. 102

Thursday, May 29, 2025

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 AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 1240

[Doc. No. AMS-LP-21-0028]

RIN 0581-AE07

#### Natural Grass Sod Promotion, Research, and Information Order: Withdrawal of Proposed Rule

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice of withdrawal of proposed rulemaking and termination of rulemaking proceeding.

**SUMMARY:** The Agricultural Marketing Service (AMS) is withdrawing the proposed rule published in the **Federal Register** on December 10, 2024, that proposed a new grass sod research and promotion program under the Commodity Promotion, Research, and Information Act of 1996. The proposed Order was submitted to the U.S. Department of Agriculture (USDA) by Turfgrass Producers International (TPI), a group of natural grass sod producers. AMS conducted a referendum among eligible producers to determine whether they favor establishing a national promotion, research, and information program (Program). After reviewing the results of the producer referendum, a simple majority of industry producers who voted in the referendum are not in favor of establishing a Program, and therefore, the proposed rule is being withdrawn.

**DATES:** As of May 29, 2025, the proposed rule published December 10, 2024 (89 FR 99149) is withdrawn.

**ADDRESSES:** Maribel Reyna, Research and Promotion Division; Livestock and Poultry Program, AMS, USDA; Room 2092-S, STOP 0249; 1400 Independence Avenue SW, Washington, DC 20250-0249; telephone: (202) 302-1139; email: [Maribel.Reyna@usda.gov](mailto:Maribel.Reyna@usda.gov).

**FOR FURTHER INFORMATION CONTACT:** Maribel Reyna; Director; Research and

Promotion Division; Livestock and Poultry Program, AMS, USDA; telephone: (202) 302-1139; or email: [Maribel.Reyna@usda.gov](mailto:Maribel.Reyna@usda.gov).

**SUPPLEMENTARY INFORMATION:** This withdrawal is issued pursuant to the Commodity Promotion, Research, and Information Act of 1996 (1996 Act or Act) (7 U.S.C. 7411-7425).

This action withdraws a proposed rule published in the **Federal Register** on December 10, 2024, for the establishment of an industry-funded promotion, research, and information program for natural grass sod products (89 FR 99149).

In accordance with the procedures established in the final rule, "Natural Grass Sod Promotion, Research, and Information Order; Referendum Procedures" (89 FR 99059; December 10, 2024), codified at 7 CFR part 1240, AMS conducted an initial referendum to determine whether issuance of the proposed Order was favored by natural grass sod producers. The voting period was January 13, 2025, through February 11, 2025. To be eligible to vote, current natural grass sod producers had to have sold natural grass sod products in the United States during the representative period from January 1, 2024, through December 31, 2024. Eligible producers provided evidence of natural grass sod sales during the representative period. Ballots were mailed to all known eligible natural grass sod producers on or before January 10, 2025. Ballots were received by the Referendum Agents no later than the close of business 5 p.m. (Eastern Standard Time) on February 11, 2025.

After reviewing and tabulating the ballots April 7, 2025, through April 10, 2025, AMS determined that the results of the votes showed that a simple majority of producers were not in favor of issuance of an Order. AMS received a total of 411 ballots, 348 of which were valid. Two hundred and twenty-one (221) producers voted against, and one hundred and twenty-seven (127) producers voted in favor of the proposed Order.

#### REFERENDUM VOTING RESULTS AS REQUIRED BY THE ORDER

	Number	Percent
Yes .....	127	36.49
No .....	221	63.51

#### REFERENDUM VOTING RESULTS AS REQUIRED BY THE ORDER—Continued

	Number	Percent
Total Valid Ballots .....	348	100

Accordingly, the proposed rule to implement a new grass sod research and promotion program under the 1996 Act published in the **Federal Register** on December 10, 2024 (89 FR 99149) is hereby withdrawn.

#### List of Subjects in 7 CFR Part 1240

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Natural grass sod, Reporting and recordkeeping requirements.

**Authority:** 7 U.S.C. 7411-7425.

**Erin Morris,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2025-09696 Filed 5-28-25; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF ENERGY

### 10 CFR Part 429

[EERE-2022-BT-TP-0028]

RIN 1904-AF49

#### Energy Conservation Program: Test Procedure for Central Air Conditioners and Heat Pumps

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Notice of proposed rulemaking and request for comment.

**SUMMARY:** The U.S. Department of Energy (DOE) proposes to delay the applicability of certain product-specific enforcement provisions related to the controls verification procedure established in a recently published final rule amending the test procedures for central air conditioners and heat pumps. DOE is seeking comment from interested parties on the proposal.

**DATES:** DOE will accept comments, data, and information regarding this proposal no later than June 30, 2025. See section IV of this document, "Submission of Comments," for details.

**ADDRESSES:** Interested persons are encouraged to submit comments using

the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) under docket number EERE-2022-BT-TP-0028. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2022-BT-TP-0028, by any of the following methods:

(1) *Email*: [CACandHeatPump2022TP0028@ee.doe.gov](mailto:CACandHeatPump2022TP0028@ee.doe.gov). Include the docket number EERE-2022-BT-TP-0028 in the subject line of the message.

(2) *Postal Mail*: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-1445. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier*: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

*Docket*: The docket for this activity, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at [www.regulations.gov](http://www.regulations.gov). All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at [www.regulations.gov/docket/EERE-2022-BT-TP-0028](http://www.regulations.gov/docket/EERE-2022-BT-TP-0028). The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section IV

of this document for information on how to submit comments through [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:**

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (240) 255-0630. Email: [ApplianceStandardsQuestions@ee.doe.gov](mailto:ApplianceStandardsQuestions@ee.doe.gov).

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-4798. Email: [peter.cochran@hq.doe.gov](mailto:peter.cochran@hq.doe.gov).

**SUPPLEMENTARY INFORMATION:**

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- I. Authority and Background
- II. Discussion
  - A. Summary of Comments Received
  - B. Conclusion and Proposal
- III. Procedural Issues and Regulatory Review
- IV. Submission of Comments
- V. Approval of the Office of the Secretary

**I. Authority and Background**

The Energy Policy and Conservation Act, Public Law 94-163, as amended (EPCA),<sup>1</sup> authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291-6317, as codified) Title III, Part B of EPCA<sup>2</sup> established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. Central air conditioners (CACs) and central air conditioning heat pumps (HPs) (collectively, CAC/HPs) are included in the list of “covered products” for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292 (a)(3)) DOE’s currently applicable test procedure for CAC/HPs is prescribed at 10 CFR part 430, subpart B, appendix M1 (appendix M1).

On January 7, 2025, DOE published a final rule amending the Federal test

procedure for CAC/HPs (January 2025 Final Rule). 90 FR 1224. The January 2025 Final Rule amended the currently applicable test procedure at appendix M1 and also established a new test procedure at 10 CFR part 430, subpart B, appendix M2 (“appendix M2”), the use of which would be required beginning on the compliance date of any future amended standards for CAC/HPs based on the new efficiency metrics established in appendix M2. *Id.* at 1284. Additionally, the January 2025 Final Rule established enforcement provisions related to the use of a controls verification procedure (CVP), to be conducted per industry standards AHRI 210/240-2024 and AHRI 1600-2024, for the purposes of assessment and enforcement testing of CAC/HPs. *Id.* at 1255-1265.

On January 20, 2025, President Trump issued the “Regulatory Freeze Pending Review” memorandum, which was published in the **Federal Register** on January 25, 2025. 90 FR 8249. This presidential action ordered all executive departments and agencies to consider postponing for 60 days from the date of the Presidential Memorandum the effective date of certain rules published in the **Federal Register** for the purpose of reviewing any questions of fact, law, and policy that the rules may raise. Additionally, executive departments and agencies were to consider opening a comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by the rules postponed under the memorandum.

Consistent with the “Regulatory Freeze Pending Review” Presidential Memorandum of January 20, 2025, DOE delayed the effective date of the January 2025 Final Rule to March 21, 2025 (February 2025 delay of effective date). 90 FR 9001 (Feb. 5, 2025). DOE also requested comments on the impacts of a further delay of the test procedures as well as legal, factual, or policy issues raised by the rule.

DOE received comments in response to the February 2025 delay of effective date from the interested parties listed in Table I.1.

**TABLE I.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE FEBRUARY 2025 DELAY OF EFFECTIVE DATE NOTICE**

Commenter(s)	Reference in this NOPR	Comment No. in the docket	Commenter type
Air-Conditioning, Heating, and Refrigeration Institute .....	AHRI .....	48	Trade Association.

<sup>1</sup> All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116-260 (Dec. 27, 2020), which

reflect the last statutory amendments that impact Parts A and A-1 of EPCA.

<sup>2</sup> For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

TABLE I.1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE FEBRUARY 2025 DELAY OF EFFECTIVE DATE NOTICE—Continued

Commenter(s)	Reference in this NOPR	Comment No. in the docket	Commenter type
Bosch Home Comfort .....	Bosch .....	51	Manufacturer.
Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison; collectively, the California Investor-Owned Utilities.	CA IOUs .....	56	Utilities.
Carrier Global Corporation .....	Carrier .....	45	Manufacturer.
Daikin Comfort Technologies North America Inc .....	Daikin .....	57	Manufacturer.
Fujitsu General America, Inc .....	FGAI .....	59	Manufacturer.
GE Appliances .....	GE Appliances .....	50	Manufacturer.
Johnson Controls .....	JCI .....	52	Manufacturer.
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, and National Consumer Law Center.	Joint Advocates .....	55	Advocacy Organiza-tions.
Lennox International Inc .....	Lennox .....	46	Manufacturer.
LG Electronics U.S.A., Inc .....	LG .....	54	Manufacturer.
Mitsubishi Electric US, Inc .....	Mitsubishi .....	47	Manufacturer.
Northwest Energy Efficiency Alliance .....	NEEA .....	49	Advocacy Organization.
Rheem Manufacturing Company .....	Rheem .....	53	Manufacturer.
Trane Technologies .....	Trane .....	58	Manufacturer.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.<sup>3</sup>

In light of the comments received in response to the February 2025 delay of effective date, consistent with the Presidential memorandum of January 20, 2025, DOE further delayed the effective date of the January 2025 Final Rule by 60 days to May 20, 2025. 90 FR 13052 (Mar. 20, 2025).

The following section discusses DOE's further consideration of the comments received in response to the February 2025 delay of effective date regarding the effective date of the CVP provisions established by the January 2025 Final Rule.

## II. Discussion

### A. Summary of Comments Received

To the extent that commenters advocated for a further delay in the effective date of the January 2025 Final Rule, such concerns were largely limited to the CVP provisions established by the January 2025 Final Rule.

AHRI recommended that DOE further delay the compliance date of the CVP enforcement provisions to no sooner than July 2026 to provide additional time for laboratories to demonstrate testing performance within the CVP tolerances established in the January 2025 Final Rule. (AHRI, No. 48 at p.2)

<sup>3</sup> The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for insert product. (Docket No. EERE-2022-BT-TP-0028, which is maintained at: [www.regulations.gov](http://www.regulations.gov)). The references are arranged as follows: (commenter name, comment docket ID number at page of that document).

AHRI stated that it has begun to analyze round robin CVP test data being collected by third-party test laboratories and that it would work to collect additional test data during the 2025 certification program year. (*Id.*) AHRI commented that it would share relevant findings with DOE by Spring 2026. (*Id.*)

Comments from Bosch, Daikin, FGAI, JCI, and Rheem similarly recommended a delay of the CVP enforcement provisions until no sooner than July 2026. (Bosch, No. 51 at p. 2; Daikin, No. 57 at p. 2; FGAI, No. 59 at p. 2; JCI, No. 52 at pp. 1–2; Rheem, No. 53 at p. 2) Bosch asserted that, without sufficient time to demonstrate tolerances can be met, variable-speed systems would face inconsistent compliance requirements putting the products at a market disadvantage. (Bosch, No. 51 at p. 2) Daikin asserted that, without further delay of the CVP provisions, consumers would experience negative consequences in the form of either reduced product choice or products with reduced consumer utility. (Daikin, No. 57 at p. 2) Daikin cited concerns regarding procedure repeatability, demonstrability of tolerances, and a potential need for product redesign to comply with the CVP. (*Id.* at pp. 2–4) FGAI expressed concerns regarding the procedure's repeatability and lack of clarity dealing with defrost. (FGAI, No. 59 at p. 2) JCI expressed concerns regarding the CVP's technical complexity, repeatability, and specified parameters and tolerances. (JCI, No. 52 at p. 2) JCI also commented that it is still assessing its ability to perform CVP testing in all of its global laboratories, which may require controls algorithm updates and, in some case, conditioning equipment upgrades that take

substantial capital investment and time to complete. (*Id.*)

GE Appliances requested that DOE either issue a policy stating that the CVP would not be used in enforcement testing until validated, and that the CVP would not apply to products using R-410A refrigerant; or use the notice and comment process to remove the CVP provisions from the CFR until they may be updated and replaced. (GE Appliances, No. 50 at p. 3) GE Appliances expressed concerns regarding the procedure's completeness, repeatability/reproducibility, lack of clarity dealing with defrost, and applicability to R-410A products. (*Id.* at pp. 1–2) GE Appliances asserted that, without further delay of these provisions, CVP enforcement would lead to reduced consumer choice and increased costs for CAC/HPs. (*Id.* at p. 2)

LG requested that DOE delay the effective date of the CVP enforcement provisions until either the compliance date of appendix M2, which would coincide with any future amended standards for CAC/HPs based on the new metrics established in appendix M2; or until no sooner than July 2028. (LG, No. 54 at p. 1) LG reiterated the importance of CVP tolerances to account for differences between regulatory testing and CVP test conditions, for example in indoor chamber temperature and humidity as well as airflow control settings. (*Id.*)

Mitsubishi urged DOE to indefinitely postpone the CVP enforcement provisions. (Mitsubishi, No. 47 at p. 1) Mitsubishi expressed concerns regarding procedure repeatability, variable-speed product mischaracterization, reflections of real-

world building heat transfer scenarios, discrepancies with regulatory test conditions, transition period tolerances, and lack of clarity dealing with defrost and oil return cycles. (*Id.* at p. 2)

Carrier, Lennox, and Trane supported DOE proceeding with the January 2025 Final Rule, as finalized, without further delays to its effective date. (Carrier, No. 45 at p. 1; Lennox, No. 46 at p. 1; Trane, No. 58 at p. 2) Carrier stated that it has evaluated the CVP extensively and concluded the procedure appropriately represents the operation of variable-speed equipment, to ensure systems perform as certified. (Carrier, No. 45 at p. 2)

The CA IOUs and the Joint Advocates recommended that DOE keep the effective date of July 2025 for the January 2025 Final Rule, as published. (CA IOUs, No. 56 at pp. 1–2; Joint Advocates, No. 55 at p. 1) The Joint Advocates commented that the CVP would help ensure the tested performance of variable-speed equipment reasonably reflects field performance. (*Id.*)

NEEA supported the January 2025 Final Rule, including the CVP, which it asserted is critical to protect the marketplace from products with inaccurate performance claims. (NEEA, No. 49 at p. 1) NEEA commented in detail on the CVP, recommending several improvements that DOE could consider in the future to address concerns expressed by manufacturers. (*Id.* at pp. 2–6) NEEA provided specific recommendations regarding thermostat calibration, the thermal capacitance values used in the virtual building load equations, oil return cycles, multi-zone systems, and temperature ramping during transition periods. (*Id.* at pp. 4–6)

### B. Conclusion and Proposal

In summary, multiple commenters have provided reasonable justification for further delaying implementation of the CVP enforcement provisions of the January 2025 Final Rule, with most commenters suggesting a one-year delay. In consideration of these comments, DOE has tentatively determined that delaying implementation of the CVP enforcement provisions is warranted. DOE proposes to delay implementation of the CVP provisions at 10 CFR 429.134(k)(4) established in the January 2025 Final Rule by one year until July 7, 2026. DOE requests comment on this proposal.

### III. Procedural Issues and Regulatory Review

DOE concludes that the determinations made pursuant to the

various procedural requirements applicable to the January 2025 Final Rule remain unchanged for this NOPR. These determinations are set forth in the January 2025 Final Rule and are adopted here. 90 FR 1224, 1268–1272.

#### IV. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

*Submitting comments via www.regulations.gov.* The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (“CBI”). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of

comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

*Submitting comments via email, hand delivery/courier, or postal mail.*

Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (“faxes”) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

*Campaign form letters.* Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters’ names compiled into one or more PDFs. This reduces comment processing and posting time.

*Confidential Business Information.* Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked “confidential” including all the information believed to be confidential, and one copy of the document marked “non-confidential” with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

## V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

### List of Subjects in 10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

### Signing Authority

This document of the Department of Energy was signed on May 15, 2025, by Louis Hrkman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 22, 2025.

#### Jennifer Hartzell,

Alternate Federal Register Liaison Officer,  
U.S. Department of Energy.

For the reasons stated in the preamble, DOE is proposing to amend part 429 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

### PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

**Authority:** 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Amend § 429.134 by revising the introductory text to paragraph (k) to read as follows:

### § 429.134 Product-specific enforcement provisions.

\* \* \* \* \*

(k) *Central air conditioners and heat pumps.* Before July 7, 2025, the provisions in this section of this title as it appeared in the 10 CFR parts 200–499 edition revised as of January 1, 2023, are applicable. On and after July 7, 2025, provisions in paragraph (k)(1), (k)(2) and (k)(3) shall apply. On and after July 7, 2026, provisions in paragraph (k)(4) shall also apply.

\* \* \* \* \*

[FR Doc. 2025–09591 Filed 5–28–25; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 106 and 117

[Docket No. FDA–2024–D–2604]

#### Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event: Draft Guidance for Industry; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notification of availability; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is reopening the comment period for a draft guidance entitled “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event: Guidance for Industry,” which was announced in the **Federal Register** of January 7, 2025. We are taking this action in response to requests to allow interested persons additional time to submit comments before FDA begins work on the final guidance.

**DATES:** FDA is reopening the comment period on our draft guidance published January 7, 2025 (90 FR 1052). Submit either electronic or written comments by July 28, 2025, to ensure that we consider your comment on this draft guidance before we begin work on the final guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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–D–2604 for “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” Received comments 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.” We will review this copy, including the claimed confidential information, in our 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

**FOR FURTHER INFORMATION CONTACT:** Benjamin Warren, Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-645-7004, [Benjamin.Warren@fda.hhs.gov](mailto:Benjamin.Warren@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 7, 2025 (90 FR 1052), we published a document announcing the availability of a draft guidance entitled “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” The notice of availability opened a docket with a 120-day comment period, that closed on May 7, 2025.

We have received requests to extend the comment period for the draft guidance. The requests conveyed concern that a 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance. We have considered the requests and have concluded that an extension of the

comment period by 60 days is appropriate. The extension will allow adequate time for interested persons to submit comments without significantly delaying the final guidance.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09653 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2025-0355]

RIN 1625-AA00

#### Safety Zone; Ohio River MM 469.5–470.5 and Licking River MM 0.0 to 0.3, Cincinnati, OH

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary safety zone from Mile Marker 469.5–Mile Marker 470.5 of the Ohio River and from Mile Marker 0.0–Mile Marker 0.3 of the Licking River. This action is necessary to provide for the safety of life on these navigable waters near Cincinnati, OH, during the Red Bull Flugtag sporting event occurring on August 9, 2025. This safety zone prohibits persons and vessels from transiting through the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 30, 2025.

**ADDRESSES:** You may submit comments identified by docket number USCG-2025-0355 using the Federal Decision-Making Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rule, call or email MST2 William Quinby, Marine Safety Detachment Cincinnati, U.S. Coast Guard; telephone

(513) 921-9033, email [William.E.Quinby@uscg.mil](mailto:William.E.Quinby@uscg.mil).

### SUPPLEMENTARY INFORMATION:

#### I. Table of Abbreviations

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

#### II. Background, Purpose, and Legal Basis

The Red Bull Flugtag event will be held in Cincinnati, Ohio, at Sawyer Point Park and Yeatman’s Cove, near the Ohio River and Licking River, on August 9, 2025. During this event, teams launch homemade, human-powered flying machines from a ramp into the water. The purpose of this rulemaking is to ensure the safety of vessels, participants, and the navigable waters in the vicinity of this event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

#### III. Discussion of Proposed Rule

This proposed rule would establish a safety zone from 7 a.m. through 6 p.m. on August 9, 2025. The safety zone will cover all navigable waters from Mile Marker 469.5–Mile Marker 470.5 of the Ohio River and Mile Marker 0.0–Mile Marker 0.3 of the Licking River. The duration of the zone is intended to protect waterway users, vessels, event participants, and the marine environment in these navigable waters while the sporting event is occurring. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

#### IV. Regulatory Analyses

We developed this proposed 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.

##### 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 proposed rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, this proposed rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the duration of the safety zone. The duration of the safety zone is eleven hours, and vessels will be able to contact the COTP for directions on how to transit around or seek permission to enter.

#### *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 proposed rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rulemaking would economically affect it.

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 proposed rule. If the proposed rule will 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

#### *C. Collection of Information*

This proposed 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 rulemaking 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 proposed 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 proposed 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. If you believe this proposed rule has implications for federalism or Indian Tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

#### *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 proposed rule will not result in such an expenditure, we do discuss the effects of this rulemaking elsewhere in this preamble.

#### *F. Environment*

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule involves a safety zone lasting 11 hours that would prohibit any vessel or person from entering the safety zone without obtaining permission from the Captain of the Port (COTP) of Sector Ohio Valley or a designated representative. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### **V. Public Participation and Request for Comments**

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

*Submitting comments.* We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2025–0355 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

*Viewing material in docket.* To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

*Personal information.* We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

#### **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 is proposing to amend 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 § 100.T08–0355 to read as follows:

**§ 165.T08–0355 Safety Zone; Ohio River MM 469.5–470.5 and Licking River MM 0.0 to 0.3, Cincinnati, OH.**

(a) *Regulated area.* This section applies to the following area: Ohio River Mile Marker 469.5–Miler Marker 470.5,

extending the entire river and the Licking River from Mile Marker 0.0–Mile Marker 0.3, extending the entire river.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Ohio Valley (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) This section establishes a safety zone from 7 a.m. through 6 p.m. on August 9, 2025. The safety zone will cover all navigable waters designated in paragraph (a) of this section. No vessel or person will be permitted to enter the safety zone

without obtaining permission from the COTP or a designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by contacting the Patrol Commander via VHF–FM radio channel 16 or phone at 1–800–253–7465. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 7 a.m. through 6 p.m. on August 9, 2025.

Dated: May 19, 2025.

**H.R. Mattern,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.*

[FR Doc. 2025–09663 Filed 5–28–25; 8:45 am]

**BILLING CODE 9110–04–P**

# Notices

Federal Register

Vol. 90, No. 102

Thursday, May 29, 2025

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

### 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 June 30, 2025 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](http://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.

### Animal and Plant Health Inspection Service

*Title:* Highly Pathogenic Avian Influenza (HPAI); Additional Testing, and Reporting of HPAI in Livestock and Milk.

*OMB Control Number:* 0579–0496.

*Summary of Collection:* The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if required to prevent the spread of any livestock or poultry pest or disease. Part of the mission of APHIS' Veterinary Services (VS) business unit is preventing foreign animal disease outbreaks in the United States, and monitoring, controlling, and eliminating a disease outbreak should one occur.

Highly pathogenic avian influenza (HPAI) is a contagious viral disease of domestic poultry and wild birds, and is deadly to domestic poultry, wiping out entire flocks within a matter of days. HPAI is a threat to the poultry industry, animal health, human health, trade, and the economy worldwide. In the United States, HPAI H5N1 was detected in dairy cattle in March of 2024.

On April 24, 2024, APHIS announced a Federal Order to assist with developing a baseline of critical information and limiting the spread of H5N1 in dairy cattle. The Federal Order requires testing lactating dairy cattle prior to interstate movement and mandatory reporting from laboratories of positive Influenza A cases in livestock as well as epidemiological reporting.

On December 6, 2024, APHIS issued a second Federal Order to help limit the spread of H5N1. This order specifically addresses the spread of the virus through raw milk and adds testing of raw (unpasteurized) milk to detect and provide data for the control and eradication of HPAI. As of April 11, 2025, USDA has confirmed 1,020 HPAI H5N1 clade 2.3.4.4b virus detections in 17 States. APHIS has also confirmed 123 detections in poultry premises across 14 States with the same HPAI H5N1 virus B3.13 genotype detected in dairy cattle.

*Need and Use of the Information:* The second Federal Order specifically

addresses the spread of the virus through raw milk and adds testing of raw (unpasteurized) milk to detect and provide data for the control and eradication of HPAI. Samples will be collected at facilities that ship, receive, or transfer milk interstate. Laboratories and State veterinarians must report positive Influenza A nucleic acid detection results (e.g., polymerase chain reaction (PCR) or genetic sequencing) in diagnostic samples obtained from livestock, including raw (unpasteurized) milk, to APHIS. While movement controls implemented under the earlier Federal Order have had a positive effect on reducing transmission across State lines, HPAI infections linger in States that have not been able to institute a widespread bulk milk testing program.

*Description of Respondents:*

Businesses; State, Local, and Tribal.

*Number of Respondents:* 2,650.

*Frequency of Responses:* Reporting; On occasion; Quarterly.

*Total Burden Hours:* 82,655.

**Rachelle Ragland-Greene,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2025–09608 Filed 5–28–25; 8:45 am]

BILLING CODE 3410–34–P

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0024]

#### Notice of Decision To Authorize the Importation of Fresh Pineapple (*Ananas comosus*) Fruit From Indonesia Into the United States

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our decision to authorize the importation of fresh pineapple fruit (*Ananas comosus*) for consumption from Indonesia into the United States. Based on findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of

fresh pineapple fruit (*Ananas comosus*) for consumption from Indonesia into the United States.

**DATES:** Imports may be authorized beginning May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Ms. Gina Stiltner, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPO, APHIS, 1400 Independence SW, Washington, DC 20250; (518) 760-2468; [Gina.L.Stiltner@USDA.gov](mailto:Gina.L.Stiltner@USDA.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

Under the regulations in “Subpart L—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the U.S. Department of Agriculture’s (USDA’s) Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. Under that process, APHIS proposes to authorize the importation of a fruit or vegetable into the United States if, based on findings of a pest risk analysis, we determine that the measures can mitigate the plant pest risk associated with the importation of that fruit or vegetable. APHIS then publishes a notice in the **Federal Register** announcing the availability of the pest risk analysis that evaluates the risks associated with the importation of a particular fruit or vegetable. Following the close of the 60-day comment period, APHIS will issue a subsequent **Federal Register** notice announcing whether or not we will authorize the importation of the fruit or vegetable subject to the phytosanitary measures specified in the notice.

In accordance with that process, we published a notice<sup>1</sup> in the **Federal Register** on December 30, 2024 (89 FR 106416–106417, Docket No. APHIS–2020–0024), in which we announced the availability, for review and comment, of a pest risk analysis that evaluated the risks associated with the importation of fresh pineapple fruit

(*Ananas comosus*)<sup>2</sup> for consumption from Indonesia into the United States. The pest risk analysis consisted of a pest risk assessment identifying pests of quarantine significance that could follow the pathway of the importation of fresh pineapple fruit (*Ananas comosus*) for consumption from Indonesia into the United States and a risk management document (RMD) identifying phytosanitary measures to be applied to that commodity to mitigate the pest risk.

We solicited comments on the notice for 60 days, ending on February 28, 2025. We received four comments by that date. They were from the national plant protection organization (NPPO) of Indonesia, two representatives of plant health agencies in Indonesia, and an industry organization in Indonesia.

Three of the commenters requested that the variety limitation for market access be removed. One commenter stated that if the pineapples are harvested while at least 70 percent mature, varietal restrictions are unwarranted. This commenter cited export protocols for pineapples from Indonesia to China and New Zealand that do not have varietal restrictions. Two commenters asked that the restrictions be removed to allow importation of a Queen variety of pineapple, which is grown in Indonesia and currently exported to five countries. These commenters stated that the fruit fly pests have not been reported to them by the receiving countries. One commenter requested that the restrictions be relieved for MD2, a pineapple that the commenter stated shares morphological characteristics with the Smooth Cayenne variety that made it similarly inhospitable as a host for *Bactrocera* spp. This latter commenter provided an unpublished study in support of their request.<sup>3</sup>

Under APHIS’ regulations in 7 CFR part 319.5, if a change to our import requirements for plants and plant products is requested, the NPPO of the country from which the commodities would be exported must submit information to APHIS regarding the requested change. This information must include, among other things, the scientific name, synonyms, and taxonomic classification of the commodity.

In accordance with these regulations, the NPPO of Indonesia submitted a request to authorize the importation into the United States of fresh pineapple

from Indonesia. Our pest risk assessment therefore evaluated the plant pest risk associated with the importation into the United States of fresh pineapple from Indonesia, broadly construed.

However, our RMD proposed different conditions for importation of Smooth Cayenne varieties and hybrids than for other varieties. This was, as the RMD noted, based on long-standing scientific literature documenting that the Smooth Cayenne variety does not support eggs or larvae of the oriental fruit fly, *Bactrocera dorsalis*, even when the variety is grown in areas of high oriental fruit fly populations.

There is a possibility that harvesting pineapples before full ripeness may be a sufficient mitigation for fruit fly risk, thus obviating the need for varietal restrictions. However, we were unable to locate peer-reviewed data supporting the assertion that harvesting pineapples up to 70 percent ripeness obviates the need for any other risk management measure targeting fruit flies.

The absence of pest detections on Queen variety pineapples exported from Indonesia to other countries does not, in and of itself, indicate that Smooth Cayenne variety and Queen variety pineapples from Indonesia are of equivalent plant pest risk. That said, we did endeavor to find evidence that the Queen variety that the commenters mentioned is also at least 50 percent Smooth Cayenne, but no such evidence was available.

Accordingly, based on the absence of peer-reviewed evidence in support of the above requests, we are not able to grant them at this time and within the context of this notice. We do, however, welcome such data and, if provided, may take appropriate action to revise market access for fresh pineapples from Indonesia.

With regard to the MD2 variety, APHIS has evaluated the relevant data and determined that the MD2 variety satisfies the requirement that pineapples be at least 50 percent Smooth Cayenne by lineage. This notice will therefore allow the importation without treatment of MD2 variety pineapple fruit in addition to any variety of pineapple that is shown to have at least 50 percent Smooth Cayenne parentage. We have issued an updated RMD (dated April 29, 2025) with the justification section updated to reflect this determination. To obtain a copy of the updated RMD, you can contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Commenters also requested APHIS revise its “Medium” risk classification in the pest list for *Bactrocera dorsalis*, based on Indonesia’s trade records,

<sup>1</sup> To view the notice, the supporting documents, and comments received, go to [www.regulations.gov](http://www.regulations.gov). Enter APHIS–2020–0024 in the Search field.

<sup>2</sup> In our pest risk analysis, APHIS considered the importation pathway to include whole pineapple fruit with or without crown.

<sup>3</sup> To view the study, attached to the comment, go to [www.regulations.gov](http://www.regulations.gov). Enter APHIS–2020–0024 in the Search field.

which they stated have indicated no complaints for that pest. The commenters attributed the trouble-free pineapple export record to pest management practices in Indonesia.

We did not consider standard agricultural practices, such as field mitigations that would control *B. dorsalis*, or, in fact, the application of any other mitigations, in developing the pest risk assessment, unless we could conclusively associate them with commercial production of pineapples in Indonesia. We did identify culling and washing as standard commercial practices used within Indonesia for commercially produced pineapple.

We acknowledge that the likelihood of *B. dorsalis* entering with the commodity may be Low as it mainly infests damaged or overripe fruit. APHIS rated the pest risk potential as Medium in the pest risk assessment, however, due to the High likelihood of establishment in the United States and the unacceptable risk posed by an introduction of *B. dorsalis* on U.S. agriculture. Additionally, and as mentioned in the RMD, *B. dorsalis* is far less likely to attack and develop in pineapples of the Smooth Cayenne variety, or those with Smooth Cayenne parentage. Further, commercial practices, such as culling of damaged fruit, will further reduce the likelihood that *B. dorsalis* will enter the United States on fresh pineapple fruit from Indonesia. Thus, APHIS determined that a revision to the risk classification for *B. dorsalis* was not warranted.

Some commenters indicated that commercial irradiation and vapor heat treatment facilities for quarantine treatment of plants are not present in Indonesia, so the commodities would need to be treated in the United States. One commenter requested that APHIS consider recognizing and certifying irradiation facilities in Indonesia.

As stated in the RMD, APHIS notes that irradiation, carried out in accordance with the provisions of 7 CFR part 305, which contains our regulations governing phytosanitary treatments, is approved as a treatment for any imported regulated article. In this regard, 305.9 stipulates the required certifications, agreements, workplans, preclearance notifications, and payment for inspection and monitoring of irradiation facilities located in foreign countries. Likewise, vapor heat treatment may be conducted in facilities in foreign countries, if the facility has been approved by APHIS in accordance with 305.8 and treatment is conducted in accordance with that section. APHIS can assess whether these provisions have been met when Indonesia's NPPO

considers Indonesia to have facilities that would meet the requirements of the regulations.

Therefore, in accordance with § 319.56–4(c)(3)(iii), we are announcing our decision to authorize the importation into the United States of fresh pineapple fruit (*Ananas comosus*) with or without the crown for consumption from Indonesia subject to the phytosanitary measures identified in the updated RMD that accompanied the initial notice.

These conditions will be listed in the USDA, APHIS ACIR database (<https://acir.aphis.usda.gov/s/>). In addition to these specific measures, each shipment must be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the recordkeeping and burden requirements associated with this action are included under the Office of Management and Budget control number 0579–0049.

#### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this notice, please contact [APHIS.PRA@usda.gov](mailto:APHIS.PRA@usda.gov).

(Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.)

Done in Washington, DC, this 22nd day of May 2025.

**Michael Watson,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2025–09657 Filed 5–28–25; 8:45 am]

BILLING CODE 3410–34–P

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS–2025–0003]

#### Notice of Request To Renew an Approved Information Collection: Certificates of Medical Examination

**AGENCY:** Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (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, FSIS is announcing its intention to renew an approved information collection regarding certificates of medical examination. The approval for this information collection will expire on November 30, 2025. FSIS is making no changes to the existing information collection.

**DATES:** Submit comments on or before July 28, 2025.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2025–0003. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call 202–720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

**FOR FURTHER INFORMATION CONTACT:** Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

#### SUPPLEMENTARY INFORMATION:

*Title:* Certificates of Medical Examination.

*OMB Number:* 0583–0167.

*Type of Request:* Renewal of an approved information collection.

*Abstract:* FSIS has been delegated the authority to exercise the functions of the

Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled.

FSIS is requesting renewal of an approved information collection regarding certificates of medical examination. The approval for this information collection will expire on November 30, 2025. FSIS is making no changes to the existing information collection.

The current information collection approval includes two FSIS forms that are completed by healthcare providers for medication certification. First, FSIS uses Form 4339-1, "Certificate of Medical Examination (with Medical History)" to determine whether an applicant for a Food Inspector, Consumer Safety Inspector, or Veterinary Medical Officer in-plant position meets the medical qualification standards for the position approved by the Office of Personnel Management (OPM). The certificates of medical examination ensure accurate collection of the required data. The OPM-approved medical qualification standards apply only to positions in FSIS, not positions in other Federal agencies. When requesting that applicants for the positions listed above undergo the medical examination, a representative of FSIS notifies the applicants in writing of the reasons for the examination, the process, and the consequences of the failure to report for an examination or provide medical documentation. Any physical condition that would hinder an individual's full, efficient, and safe performance of his or her duties is considered disqualifying for employment, except when the individual presents convincing evidence that he or she can perform the essential functions of the job efficiently and without hazard.

Second, FSIS uses Form 4306-5, "Medical Documentation for Employee's Reasonable Accommodation Request," to help determine whether the Agency will provide reasonable accommodation to qualified individuals. In accordance with the Rehabilitation Act of 1973 and the Americans with Disabilities Act Amendments Act of 2008, FSIS makes reasonable accommodations for the known physical or mental limitations of qualified individuals with disabilities, unless the accommodation would

impose an undue hardship on the operation of FSIS. FSIS requires medical information from a health care provider to determine whether the person's condition rises to the level of disability under the law and to determine whether the limitations can be effectively accommodated.

FSIS has made the following estimates based upon an information collection assessment:

*Respondents:* Health Care Providers.

*Estimated Total Number of Annual*

*Respondents:* 1,250 respondents.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on*

*Respondents:* 1,542 hours.

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. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250-3700; 202-720-5046.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations,

**Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service that provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. The available information ranges from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### USDA 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, 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 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 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,

DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: [program.intake@usda.gov](mailto:program.intake@usda.gov).

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**Denise Eblen,**

*Administrator.*

[FR Doc. 2025–09611 Filed 5–28–25; 8:45 am]

BILLING CODE 3410–DM–P

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS–2025–0002]

#### Notice of Request To Renew an Approved Information Collection: Industry Responses to Noncompliance Records

**AGENCY:** Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (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, FSIS is announcing its intention to renew an approved information collection regarding industry responses to noncompliance records. The approval for this information collection will expire on November 30, 2025. FSIS is making no changes to the existing information collection.

**DATES:** Submit comments on or before July 28, 2025.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2025–0002. Comments received in response to this docket will be made

available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call 202–720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

**FOR FURTHER INFORMATION CONTACT:** Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

#### SUPPLEMENTARY INFORMATION:

*Title:* Industry Responses to Noncompliance Records.

*OMB Number:* 0583–0146.

*Type of Request:* Renewal of an approved information collection.

*Abstract:* FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled.

FSIS is requesting renewal of an approved information collection regarding industry responses to noncompliance records. The approval for this information collection will expire on November 30, 2025. FSIS is making no changes to the existing information collection.

The noncompliance record, FSIS Form 5400–4, serves as FSIS’ official record of noncompliance with one or more regulatory requirements. Inspection program personnel use the form to document their findings and provide written notification of the official establishment’s failure to comply with regulatory requirements. The establishment management receives a copy of the form and has an opportunity to respond in writing using the noncompliance record form. The establishment management can also choose to respond to FSIS electronically by using the Industry Module in PHIS.

FSIS has made the following estimates based upon an information collection assessment:

*Respondents:* Official establishments.

*Estimated total number of respondents:* 7,057.

*Estimated annual number of responses per respondent:* 17.

*Estimated total annual burden on respondents:* 119,969 hours.

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. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS’ functions, including whether the information will have practical utility; (b) the accuracy of FSIS’ estimate of the burden of the proposed collection of information, including the validity of the method 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service that provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. The available information ranges from recalls to export information,

regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### USDA 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, 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 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 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, DC 20250-9410; (2) fax: (202) 690-7442; or (3) email: [program.intake@usda.gov](mailto:program.intake@usda.gov).

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**Denise Eblen,**

*Administrator.*

[FR Doc. 2025-09609 Filed 5-28-25; 8:45 am]

**BILLING CODE 3410-DM-P**

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### Agency Information Collection Activities: Disaster Supplemental Nutrition Assistance Program (D-SNAP)

**AGENCY:** Food and Nutrition Service (FNS), USDA.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is an extension, with change, of a currently approved collection. This information collection is associated with waiver request and reporting by State agencies to operate a Disaster Supplemental Nutrition Assistance Program (D-SNAP) to temporarily provide food assistance to households following a disaster.

**DATES:** Written comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments may be sent to: Sasha Gersten-Paal, Director, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via fax to the attention of Sasha Gersten-Paal at 703-305-2507 or via email to [sasha.gersten-paal@usda.gov](mailto:sasha.gersten-paal@usda.gov). Comments will also be accepted through the Federal eRulemaking Portal. Go to <https://www.regulations.gov>, and follow the online instructions for submitting comments electronically. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this information collection should be directed to Sasha Gersten-Paal at 703-305-2507.

**SUPPLEMENTARY INFORMATION:** 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 shall have 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 that were 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, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Title:* Disaster Supplemental Nutrition Assistance Program (D-SNAP).

*Form Number:* N/A.

*OMB Control Number:* 0584-0336.

*Expiration Date:* November 30, 2025.

*Type of Request:* Extension, with change, of a previously approved collection.

*Abstract:* Pursuant to section 412 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5179) and section 5(h)(1) of the Food and Nutrition Act of 2008 (7 U.S.C. 2014(h)), the Secretary of Agriculture has the authority to establish a Disaster Supplemental Nutrition Assistance Program (D-SNAP), which is a temporary program that State agencies may operate to provide food assistance to households affected by a disaster. D-SNAP is separate and distinct from the Supplemental Nutrition Assistance Program (SNAP) because it has different standards of eligibility, is operated for a limited duration, and only provides one month of benefits to eligible households.

State agencies submit formal waiver requests to operate D-SNAP to the Food and Nutrition Service (FNS) for approval and may only request to operate D-SNAP in areas that have received a Presidential major disaster declaration with authorization for Individual Assistance, also known as an IA declaration. For a major disaster declaration, the Federal Emergency Management Agency (FEMA) Regional Office deploys staff to conduct joint Preliminary Damage Assessments (PDAs) in conjunction with State, local, Tribal Nation, and/or territory representatives. The Governor or Tribal Executive then submits a declaration request. FEMA submits a recommendation to the President regarding the declaration request and the final determinations are at the sole discretion of the President.

In their D-SNAP waiver requests, State agencies outline the impact of the disaster on households and/or businesses, the proposed procedures for conducting D-SNAP, designate the areas where they wish to operate, and provide estimates of benefit issuance. Using clearly defined criteria, FNS created a waiver template for State agencies to submit their D-SNAP requests electronically through the FNS

### Waiver Information Management System (WIMS).

Once an initial waiver request to operate D–SNAP is approved by FNS, State agencies will submit any subsequent request to modify or extend operations to eligible areas to FNS for approval. These modification or extension requests are typically used when a disaster impacts different areas of a State in different ways or at different times. Subsequent modification and extension requests require substantially less time to prepare than the initial D–SNAP waiver request. These requests are submitted electronically through WIMS.

Along with the waiver request to operate D–SNAP in areas that have received an IA declaration, FNS asks that the State agency submit a sample of their D–SNAP application for households applying for assistance. Per FNS D–SNAP guidance, this application should include information about the head of household, the impact of the disaster on the household, household members, household income and resources, a penalty warning, and USDA's nondiscrimination statement. FNS provides State agencies with a sample application in the D–SNAP Toolkit. State agencies submit their sample application electronically through WIMS.

Additionally, before a State agency operates a D–SNAP, FNS asks the State agency to provide a draft of their press release for FNS to review. State agencies are expected to issue a press release to publicize the application period to households impacted by the disaster that may need assistance. FNS asks State agencies to issue their press release at least several days before the application period for D–SNAP opens to the public. Per D–SNAP Guidance, the press release should include information about the operation such as the counties or ZIP Codes approved for assistance, application dates, application sites and hours of operation, and other information that potential applicants may need. FNS provides State agencies with an example press release in the D–SNAP Toolkit. The draft press release is submitted by State agencies electronically through WIMS.

During the application period for a D–SNAP, State agencies submit daily data reports to FNS. Daily reports ensure that FNS can monitor State agency capacity and benefit issuance to maintain a high level of customer service and integrity in D–SNAP operations. The reporting template includes data such as the number of new applications taken, the number of applications approved and denied, the amount of benefits issued,

the number of pending applications, the number of supplements approved, and the amount of supplements issued. For operations containing a virtual component, the daily report also captures telephonic operation and card issuance data. FNS provides State agencies with a daily report template to provide this data to the agency. State agencies submit daily data reports electronically through WIMS.

Six months after the closing date of the D–SNAP application period, State agencies will submit a post disaster report to FNS. The post disaster report ensures that FNS understands all aspects of the D–SNAP operation and can identify opportunities for improvement. The report template asks that State agencies summarize the impact of the disaster, detail the D–SNAP operation and procedures utilized, provide case review results, and reflect on changes that could be considered in the future. FNS provides State agencies with a post disaster report template to provide this information to the agency. State agencies submit post-disaster review reports electronically through WIMS.

This information collection request contains only burden estimates associated with the State agency's waiver request and some reporting for D–SNAP operations. All burden imposed on State agencies and households associated with the certification of D–SNAP households performed by State agencies is approved under OMB Control Number 0584–0064 (SNAP Forms: Applications, Periodic Reporting, Notices; expiration date: 05/31/2026).

Burden for the remainder of State reporting of D–SNAP data on the FNS–292B (Report of Disaster Supplemental Nutrition Assistance Benefit Issuance) is approved under two separate OMB Control Numbers. The recordkeeping burden for FNS–292B is approved under OMB Control Number 0584–0037 (expiration date: 9/30/2026), and the reporting burden for FNS–292B is approved under OMB Control Number 0584–0594 (Food Programs Reporting System; expiration date: 3/31/2025). None of the burden activities for the other approved OMB control numbers cited in this notice have been outlined in this submission.

Because it is impossible to predict the number of natural disasters and extreme weather events that result in an IA declaration in a given year, and because some State agencies may find that operation of a D–SNAP is not warranted even upon receipt of an IA declaration, FNS is revising the burden estimate for submitting a waiver request to operate

D–SNAP based on the annual average number of formal D–SNAP waiver requests submitted and approved since this collection was last approved. From Federal Fiscal Year 2022 to 2024, an average of 9 State agencies requested to operate D–SNAP each year and an average of 4 State agencies requested to modify and/or extend. The number of hours per response has not changed for submitting a waiver request, but the estimated total burden hours has increased due to the higher number of State agency requests.

FNS is adding several reporting activities by State agencies to this information collection that have not been captured by previous submissions. State agency administration of D–SNAP has evolved over time and FNS is seeking to ensure that we are accounting for the full amount of burden hours. Including the additional burden hours by State agencies via the submission of the sample application, draft press release, daily reports, and the post disaster report accurately captures the information collection burden of administering D–SNAP.

### Summary of Burden Hours

#### Reporting

*Affected Public:* State, local, Tribal Nation, territory agency or government.

*Estimated Number of Respondents:* 49. An average of 9 State agencies submit D–SNAP waiver requests each year, and out of those original 9 State agencies, an average of 4 State agencies will submit subsequent waiver requests to modify or extend those already approved D–SNAPs. Each new D–SNAP waiver request includes submitting a sample application and draft press release. Additionally, daily reports are submitted each day that the D–SNAP application period is open, and the post disaster report is submitted several months later. This is an increase from the previously approved information collection as there has been a steady increase in the number of disasters occurring throughout the country since the previous information collection was approved and additional activities have been added to more accurately capture the burden of administering D–SNAP.

*Estimated Number of Responses per Respondent:* 30. State agencies submit an average of 2 D–SNAP waiver requests per year and an average of 2 subsequent modification or extension requests per year. This represents an increase from the previous information collection due to the addition of the sample application, draft press release, daily reports, and post disaster report.

*Estimated Total Annual Responses:* 260. This represents an increase from the previous information collection due to the increasing number of State agencies experiencing disasters and subsequently requesting to operate D-SNAP and the addition of the sample application, draft press release, daily reports, and post disaster report.

*Estimated Time per Response:* 27. Approximately 10 hours for State agency D-SNAP waiver requests, 3 hours for each subsequent modification or extension request, 1 hour for a sample application, 2 hours for a draft press release, 1 hour for a daily report, and 10 hours for a post disaster report. This is an increase from the previous information collection due to the

addition of the sample application, draft press release, daily reports, and post disaster report.

*Estimated Total Annual Burden on Respondents:* 618. This is an increase from the previous information collection due to the addition of the sample application, draft press release, daily reports, and post disaster report.

Respondent	Estimated number of respondents	Responses annual per respondent	Total annual responses	Estimated avg. number of hours per response	Estimated total hours
State agency—Submission of D-SNAP Waiver Request ...	9	2	18	10	180
State agency—Submission of D-SNAP modification or extension request .....	4	2	8	3	24
State agency—Submission of sample application .....	9	2	18	1	18
State agency—Submission of draft press release .....	9	2	18	2	36
State agency—Submission of daily reports .....	9	20	180	1	180
State agency—Submission of post disaster Report .....	9	2	18	10	180
<b>Total Reporting Burden .....</b>	<b>49</b>	<b>30</b>	<b>260</b>	<b>27</b>	<b>618</b>

**James C. Miller,**  
*Administrator, Food and Nutrition Service.*  
 [FR Doc. 2025-09645 Filed 5-28-25; 8:45 am]  
**BILLING CODE 3410-30-P**

**DEPARTMENT OF AGRICULTURE**

**Food and Nutrition Service**

**Agency Information Collection Activities: Proposed Collection; Comment Request—Generic Clearance To Conduct Formative Research or Development of Nutrition Education and Promotion Materials and Related Tools and Grants for FNS Population Groups**

**AGENCY:** Food and Nutrition Service (FNS), USDA.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other interested parties to comment on a proposed information collection. This collection is an extension of a currently approved collection. This information collection will conduct research in support of FNS’ goal of delivering science-based nutrition education to targeted audiences. This information collection will also conduct research that will assist FNS in identifying effective design and implementation approaches to use to develop and assess grants. From development through testing of materials and tools with the target audience, FNS plans to conduct data collections that involve formative research including focus groups,

interviews (dyad, triad, telephone, etc.), surveys and Web-based collection tools.

**DATES:** Written comments must be received on or before July 28, 2025.

**ADDRESSES:** *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 has 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, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to the Planning and Regulatory Affairs Office, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th floor, Alexandria, VA 22314. Comments may also be sent via *fns-prao@usda.gov*. Comments will also be accepted through the Federal eRulemaking Portal. Go to *https://www.regulations.gov*, and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will be a matter of public record.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or

copies of this information collection should be directed to Planning and Regulatory Affairs Office at (703) 305-2403 or via email at *fns-prao@usda.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Generic Clearance to Conduct Formative Research or Development of Nutrition Education, Promotion Materials and Related Tools, and Grants for FNS Population Groups.

*OMB Number:* 0584-0524.

*Expiration Date:* February 28, 2026.

*Type of Request:* Extension of a currently approved information collection.

*Abstract:* This information collection is based on section 19 of the Child Nutrition Act of 1966 (42 U.S.C. 1787), section 5 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1754) and section 11(f) of the Food and Nutrition Act of 2008 (7 U.S.C. 2020). This request for approval of information collection is necessary to obtain input into the development of nutrition education interventions for population groups served by the U.S. Department of Agriculture, Food and Nutrition Service (USDA-FNS). FNS also uses this collection to obtain input that can be used to develop and assess grants. Interventions need to be designed so that they can be delivered through different types of media and in a variety of formats for diverse audiences.

FNS develops a variety of resources to support nutrition education and promotion activities. These resources are designed to convey science-based, behavior-focused nutrition messages about healthy eating and physical activity to children and adults eligible to participate in FNS nutrition

assistance programs and to motivate them to consume more healthful foods as defined by the Dietary Guidelines for Americans (DGA). This includes education materials, messages, promotion tools and interventions for the diverse population served by the Federal nutrition programs as well as WIC, Team Nutrition, Food Distribution and other programs.

Obtaining formative input and feedback is fundamental to FNS' success in delivering science-based nutrition messages and reaching diverse segments of the population in ways that are meaningful and relevant. This includes conferring with the target audience, individuals who serve the target audience, and key stakeholders on the communication strategies and interventions that will be developed and on the delivery approaches that will be used to reach consumers. The formative research and testing activities described will help in the development of effective education and promotion tools and communication strategies. Collection of this information will increase FNS' ability to formulate nutrition education interventions that resonate with the intended target population, particularly low-income families.

FNS also uses formative input and feedback to determine how best to

develop and assess grants so that grant recipients can successfully meet their goals under these grants. To do this, FNS confers with grant recipients to obtain input regarding their experiences, expectations, challenges, and lessons learned while implementing the grant.

Formative research methods and information collection will include focus groups, interviews (dyad, triad, telephone, etc.), surveys and Web-based data collection. The data obtained will provide input regarding the potential use of materials and products during both the developmental and testing stages, in addition to the development of grants. Key informant interviews will be conducted in order to determine future nutrition education and grant needs, tools and dissemination strategies. This task involves collecting a diverse array of information from a variety of groups including: people familiar with the target audiences; individuals delivering nutrition education intervention materials and projects; program providers at State and local levels; program participants; grant recipients, and other relevant informants associated with FNS programs.

Findings from all data collection will be included in summary reports submitted to USDA-FNS. The reports

will describe the data collection methods, findings, conclusions, implications, and recommendations for the development and effective dissemination of nutrition education materials and related tools for FNS population groups. There will be no specific quantitative analysis of data. No attempt will be made to generalize the findings to be nationally representative or statistically valid. There are no recordkeeping or third party disclosure burden requirements.

**Reporting Burden**

FNS estimates the total annual burden hours are a total of 46,823 burden hours for 3 years. Additionally, the total annual responses are a total of 120,710 total responses for 3-year approval. See the 3-year approval estimates below.

*Affected Public:* State, Local and Tribal Government; Individuals and Households; and Business or Other for Profit.

*Estimated Number of Respondents:* 120,710 respondents.

*Estimated Number of Responses per Respondent:* 1 response.

*Estimated Total Annual Responses:* 120,710.

*Estimate of Time per Respondent:* .39 hours.

*Estimated Total Annual Reporting Burden Hours:* 46,823 hours.

Collection instruments	Estimated number respondents	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Focus Group Screeners .....	11,250	1	11,250	0.25	2,813
Interview Screeners/Surveys .....	22,500	1	22,500	0.25	5,625
Focus Groups .....	6,750	1	6,750	2	13,500
Intercept Interviews .....	2,000	1	2,000	0.5	1,000
Dyad/Triad Interviews .....	3,000	1	3,000	1.00	3,000
Telephone Interviews .....	13,500	1	13,500	0.5	6,750
Surveys .....	7,000	1	7,000	0.5	3,500
Web-based Collections .....	4,500	1	4,500	0.5	2,250
Confidentiality Agreements .....	30,000	1	30,000	0.167	5,010
Forms (web-based consumer feedback, response, pre/post-test forms, etc.) .....	20,210	1	20,210	0.167	3,375
<b>3-Year Total Reporting Burden .....</b>	<b>120,710</b>	<b>1</b>	<b>120,710</b>	<b>.39</b>	<b>46,823</b>

**James C. Miller,**  
 Administrator, Food and Nutrition Service.

[FR Doc. 2025-09642 Filed 5-28-25; 8:45 am]

**BILLING CODE 3410-30-P**

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A-351-864]

**Hard Empty Capsules From Brazil: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that hard empty capsules (capsules) from Brazil are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Gemma Larsen, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-8125.

**SUPPLEMENTARY INFORMATION:****Background**

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 20, 2024.<sup>1</sup> On March 5, 2025, Commerce postponed the preliminary determination of this investigation until May 22, 2025.<sup>2</sup> For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix II 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 Investigation**

The merchandise covered by this investigation is capsules from Brazil. For a complete description of the scope of this investigation, see Appendix I.

**Scope Comments**

In accordance with the *Preamble* to Commerce's regulations,<sup>4</sup> in the *Initiation Notice*, Commerce set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).<sup>5</sup> Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*. For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, see the Preliminary Scope Decision Memorandum.<sup>6</sup> Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice*. See the scope in Appendix I to this notice. In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case and rebuttal briefs.<sup>7</sup>

**Methodology**

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, see the Preliminary Decision Memorandum.

**All-Others Rate**

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the

preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for ACG do Brasil S.A. (ACG Brazil), the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis*, or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for ACG Brazil is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

On December 10, 2024, Commerce received a timely no-shipment certification from Genix Industria Farmaceutica LTDA (Qualicaps Brazil) stating that "Qualicaps Brazil had no exports, shipments, or sales of subject merchandise to the United States during period of investigation."<sup>8</sup> On December 16, 2024, Commerce subsequently suspended the deadlines established in the initial antidumping duty (AD) questionnaire for Qualicaps Brazil.<sup>9</sup> On March 31, 2025, Commerce released the results of a U.S. Customs and Border Protection (CBP) data query showing no entries of capsules from Qualicaps Brazil during the POI and gave interested parties an opportunity to comment.<sup>10</sup> Commerce did not receive comments on the CBP data from any interested party. As such, Commerce preliminarily finds that Qualicaps Brazil is subject to the all-others rate.

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

<sup>1</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

<sup>2</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in Less-Than-Fair-Value Investigations*, 90 FR 11257 (March 5, 2025).

<sup>3</sup> See Memorandum, "Decision Memorandum for the Preliminary Determination in the Less-Than-

Fair-Value Investigation of Hard Empty Capsules from Brazil," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

<sup>5</sup> See *Initiation Notice*, 89 FR at 91685.

<sup>6</sup> See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam:

Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Decision Memorandum).

<sup>7</sup> *Id.* at 10.

<sup>8</sup> See Qualicaps Brazil's Letter, "Notification of No Shipments," dated December 10, 2024.

<sup>9</sup> See Commerce's Letter, "Suspension of Deadlines for Qualicaps Brazil," dated December 16, 2024.

<sup>10</sup> See Commerce's Letter, "Results of Inquiry to U.S. Customs and Border Protection," dated March 31, 2025.

Exporter/producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
ACG do Brasil S.A .....	77.29	Not Applicable.
All Others .....	77.29	Not Applicable.

### Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct CBP to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) the cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the "Preliminary Determination" section above. These suspension of liquidation instructions will remain in effect until further notice.

### Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if

appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

### Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

### Public Comment

Case briefs or other written comments, excluding scope comments, may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.<sup>11</sup> A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. 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.<sup>12</sup> Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>13</sup>

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 briefs that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised

in their briefs.<sup>14</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>15</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

### Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by exporters for postponement of the final

<sup>11</sup> See 19 CFR 351.309(c)(1)(i); see also 19 CFR 351.303 (for general filing requirements).

<sup>12</sup> 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*).

<sup>13</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>14</sup> We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

<sup>15</sup> See *APO and Service Final Rule*.

determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 30, 2025, pursuant to 19 CFR 351.210(e), ACG Brazil requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.<sup>16</sup> On May 9, 2025, Lonza Greenwood LLC (the petitioner) also submitted a postponement request.<sup>17</sup> In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

### U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: May 22, 2025.

**Christopher Abbott,**

*Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Investigation

The merchandise subject to the scope of the investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one

closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia–National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of the investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of the investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of the investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of the investigation are those that disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the investigation is dispositive.

### Appendix II

#### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Affiliation
- V. Discussion of the Methodology
- VI. Currency Conversion
- VII. Adjustments to the Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
- VIII. Recommendation

[FR Doc. 2025–09698 Filed 5–28–25; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A–552–843]

### Certain Corrosion-Resistant Steel Products From the Socialist Republic of Vietnam: Amended Preliminary Affirmative Determination of Sales at Less Than Fair Value

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) is amending its preliminarily affirmative determination in the less-than-fair-value (LTFV) investigation of certain corrosion-resistant steel products (CORE) from the Socialist Republic of Vietnam (Vietnam) to correct for significant ministerial errors. The period of investigation (POI) is January 1, 2024, through June 30, 2024.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Jacob Waddell, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1369.

#### SUPPLEMENTARY INFORMATION:

#### Background

On April 10, 2024, Commerce published in the **Federal Register** its preliminary affirmative determination in the LTFV investigation of CORE from Vietnam.<sup>1</sup> On April 14, 2025, the petitioners<sup>2</sup> timely alleged that Commerce made significant ministerial errors in the *Preliminary Determination*.<sup>3</sup> Also on April 14, 2025, Hoa Sen Group (HSG), Ton Dong A Corporation (TDA), the Government of Vietnam, and Maruichi Sun Steel Trading Company (Maruichi) timely alleged that Commerce made ministerial

<sup>1</sup> See *Certain Corrosion-Resistant Steel Products from the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 90 FR 15343 (April 10, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

<sup>2</sup> The petitioners are Steel Dynamics, Inc., Nucor Corporation, United States Steel Corporation, Wheeling-Nippon Steel, Inc., and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC.

<sup>3</sup> See Petitioners' Letter, "Petitioners' Comments on Significant Ministerial Errors in the Preliminary Determination," dated April 14, 2025 (Petitioners' Allegation).

<sup>16</sup> See ACG Brazil's Letter, "Request to Postpone the Final Determination," dated April 30, 2025.

<sup>17</sup> See Petitioner's Letter, "Lonza's Request for Postponement of the Department's Antidumping Duty Final Determinations," dated May 9, 2025.

errors in the *Preliminary Determination*.<sup>4</sup>

**Scope of the Investigation**

The product covered by this investigation is CORE from Vietnam. For a complete description of the scope of this investigation, see Appendix I.

**Legal Framework**

A ministerial error is defined as including “errors in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which {Commerce} considers ministerial.”<sup>5</sup> A ministerial error is considered to be “significant” if its correction, either singly or in combination with other errors, would result in: (1) a change of at least five

absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin calculated in the preliminary determination; or (2) a difference between a weighted-average dumping margin of zero (or *de minimis*) and a weighted-average dumping margin of greater than *de minimis* or vice versa.<sup>6</sup> Pursuant to 19 CFR 351.224(e), Commerce “will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination.”

**Analysis of Significant Ministerial Errors**

In the *Preliminary Determination*, we find that Commerce made significant ministerial errors within the meaning of section 735(e) of the Act and 19 CFR

351.224(f) and (g)(1) in calculating the estimated weighted-average dumping margins for HSG and TDA. Accordingly, pursuant to 19 CFR 351.224(e), Commerce is amending its *Preliminary Determination* to correct for these significant ministerial errors by revising the weighted-average dumping margins for HSG, TDA, the non-individually examined separate rate companies, and the Vietnam-Wide Entity. For a detailed discussion of the alleged ministerial errors, as well as Commerce’s analysis, see the Ministerial Error Memorandum.<sup>7</sup>

**Amended Preliminary Determination**

As a result of correcting the significant ministerial errors, Commerce determines that the following amended preliminary estimated weighted-average dumping margins exist:

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent) <sup>8</sup>
Hoa Sen Group/Hoa Sen Nghe An One Member Limited Liabilities Company/Hoa Sen Nhon Hoi—Binh Dinh One Member Limited Liabilities Company. <sup>9</sup>	Hoa Sen Group/Hoa Sen Nghe An One Member Limited Liabilities Company/Hoa Sen Nhon Hoi—Binh Dinh One Member Limited Liabilities Company.	132.10	N/A
Ton Dong A Corporation	Ton Dong A Corporation	51.64	N/A
China Steel and Nippon Steel Viet Nam Joint Stock Company.	China Steel and Nippon Steel Viet Nam Joint Stock Company.	91.87	N/A
Hoa Phat Steel Sheet Limited Liability Company	Hoa Phat Steel Sheet Limited Liability Company	91.87	N/A
Maruichi Sun Steel Joint Stock Company	Maruichi Sun Steel Joint Stock Company	91.87	N/A
Nam Kim Steel Joint Stock Company	Nam Kim Steel Joint Stock Company	91.87	N/A
Pomina Flat Steel Joint Stock Company	Pomina Flat Steel Joint Stock Company	91.87	N/A
Sam Hwan Vina Co., Ltd	Sam Hwan Vina Co., Ltd	91.87	N/A
Southern Steel Sheet Co., Ltd	Southern Steel Sheet Co., Ltd	91.87	N/A
Tay Nam Steel Manufacturing & Trading Co., Ltd	Tay Nam Steel Manufacturing & Trading Co., Ltd	91.87	N/A
TVP Steel Trading Joint Stock Company	TVP Steel Trading Joint Stock Company	91.87	N/A
Viet Phap Steel Corrugated Joint Stock Company.	Viet Phap Steel Corrugated Joint Stock Company.	91.87	N/A
Vietnam-Wide Entity		* 178.89	136.57

\* Rate based on facts available with adverse inferences.

**Disclosure**

We intend to disclose the calculations performed for this amended preliminary determination to parties within five days after public announcement or, if there is no public announcement, within five days of the date of

publication of this notice, in accordance with 19 CFR 351.224(b).

**Amended Cash Deposits and Suspension of Liquidation**

The collection of cash deposits and suspension of liquidation will be revised according to the rates calculated in this amended preliminary

determination, in accordance with section 733(d) of the Act. Because this amended preliminary determination results in an increased cash deposit rate, this rate will be effective on the date of publication of this notice in the **Federal Register**. These suspension of

<sup>4</sup> See HSG’s Letter, “Preliminary Determination Ministerial Error Comments,” dated April 14, 2025 (HSG’s Allegation); see also TDA’s Letter, “TDA’s Ministerial Error Comments,” dated April 14, 2025 (TDA’s Allegation); see also Maruichi’s Letter, “Maruichi Ministerial Error Comment,” dated April 14, 2025 (Maruichi’s Allegation); see also Government of Vietnam’s Letter, “GOV’s Comments on the Preliminary Determination,” dated April 14, 2025 (GOV’s Allegation).

<sup>5</sup> See section 735(e) of the Tariff Act of 1930, as amended (the Act); see also 19 CFR 351.224(f).

<sup>6</sup> See 19 CFR 351.224(g).

<sup>7</sup> See Memorandum, “Ministerial Error Allegation Regarding the Preliminary Determination,” dated concurrently with this notice (Ministerial Error Memorandum).

<sup>8</sup> We are not applying an export subsidy offset to the mandatory respondents because Commerce found no export subsidies were provided to HSG and TDA. See *Certain Corrosion-Resistant Steel Products from the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Antidumping Duty Determination*, 90 FR 9235 (February 10, 2025), and accompanying Preliminary Decision Memorandum.

Similarly, no offset applies to the separate rate companies because their rate is based on the rates determined for HSG and TDA. For the Vietnam-wide entity, we have determined the amount of the offset based on the *CVD Preliminary Determination* for the non-responsive companies subject to total AFA. See also Memorandum, “Calculation of CVD Subsidy Offset for the Vietnam-Wide Entity,” dated concurrently with this **Federal Register** Notice.

<sup>9</sup> Commerce preliminarily determines that HSG, Hoa Sen Nghe An One Member Limited Liabilities Company, and Hoa Sen Nhon Hoi—Binh Dinh One Member Limited Liabilities Company are a single entity. See Preliminary Decision Memorandum.

liquidation instructions will remain in effect until further notice.

### U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of our amended preliminary determination.

### Notification to Interested Parties

This amended preliminary determination is issued and published in accordance with sections 733(d) and 777(i)(1) of the Act and 19 CFR 351.224 (e).

Dated: May 22, 2025.

**Abdelali Elouaradia,**

*Deputy Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Investigation

The products covered by this investigation are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.*, in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.*, in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.*, products which have been “worked after rolling” (*e.g.*, products which have been beveled or rounded at the edges).

For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.*, the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of these investigations are products in which: (1) iron predominates, by weight, over each of the other contained elements; and (2) the carbon content is 2 percent or less, by weight.

Subject merchandise also includes corrosion-resistant steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching and/or slitting or any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the in-scope corrosion resistant steel.

All products that meet the written physical description are within the scope of these investigations unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this investigation:

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (“terne plate”) or both chromium and chromium oxides (“tin free steel”), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;

- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness;

- Certain clad stainless flat-rolled products, which are three-layered corrosion-resistant carbon steel flat-rolled products less than 4.75 mm in composite thickness that consist of a carbon steel flat-rolled product clad on both sides with stainless steel in a 20%-60%-20% ratio; and

Also excluded from the scope of the antidumping duty investigation on corrosion resistant steel from Taiwan are any products covered by the existing antidumping duty order on corrosion-resistant steel from Taiwan. *See Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81FR 48390 (July 25, 2016); *Corrosion-Resistant Steel Products from Taiwan: Notice of Third Amended Final Determination of Sales at Less Than Fair Value Pursuant to Court Decision and Partial Exclusion from Antidumping Duty Order*, 88 FR 58245 (August 25, 2023).

Also excluded from the scope of the antidumping duty investigation on corrosion-resistant steel from the United Arab Emirates and the antidumping duty and countervailing duty investigations on corrosion-resistant steel from the Socialist Republic of Vietnam are any products covered by the existing antidumping and countervailing duty orders on corrosion-resistant steel from the People's Republic of China and the Republic of Korea and the antidumping duty order on corrosion-resistant steel from Taiwan. *See Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390 (July 25, 2016); *see also Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea and the People's Republic of China: Countervailing Duty Order*, 81 FR 48387 (July 25, 2016). This exclusion does

not apply to imports of corrosion-resistant steel that are entered, or withdrawn from warehouse, for consumption in the United States for which the relevant importer and exporter certifications have been completed and maintained and all other applicable certification requirements have been met such that the entry is entered into the United States as not subject to the antidumping and countervailing duty orders on corrosion-resistant steel from the People's Republic of China, the antidumping and countervailing duty orders on corrosion-resistant steel from the Republic of Korea, or the antidumping duty order on corrosion-resistant steel from Taiwan.

The products subject to the investigation are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0040, 7210.49.0045, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7212.60.0000, 7225.91.0000, 7225.92.0000, 7226.99.0110, and 7226.99.0130.

The products subject to the investigation may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.99.0090, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigation is dispositive.

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**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) received scope ruling applications, requesting that scope inquiries be conducted to determine whether identified products are covered by the scope of antidumping duty (AD) and/or countervailing duty (CVD) orders and that Commerce issue scope rulings pursuant to those inquiries. In accordance with Commerce's regulations, we are notifying the public of the filing of the scope ruling applications listed below in the month of April 2025.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:**

Yasmin Bordas, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482-3813.

**SUPPLEMENTARY INFORMATION:****Notice of Scope Ruling Applications**

In accordance with 19 CFR 351.225(d)(3), we are notifying the public of the following scope ruling applications related to AD and CVD orders and findings filed in or around the month of April 2025. This notification includes, for each scope application: (1) identification of the AD and/or CVD orders at issue (19 CFR 351.225(c)(1)); (2) concise public descriptions of the products at issue, including the physical characteristics (including chemical, dimensional and technical characteristics) of the products (19 CFR 351.225(c)(2)(ii)); (3) the countries where the products are produced and the countries from where the products are exported (19 CFR 351.225(c)(2)(i)(B)); (4) the full names of the applicants; and (5) the dates that the scope applications were filed with Commerce and the name of the ACCESS scope segment where the scope applications can be found.<sup>1</sup> This notice does not include applications which have been rejected and not properly resubmitted. The scope ruling applications listed below are available on Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), at <https://access.trade.gov>.

*Scope Ruling Applications*

**Narrow Woven Ribbons with Woven Selvage from the People's Republic of China (China) (A-570-952/C-570-953); Ribbon Shoelaces;**<sup>2</sup> produced in

and exported from China; submitted by Vango LLC (Vango); April 28, 2025; ACCESS scope segment "Vango LLC ribbon shoelaces Scope"

*Notification to Interested Parties*

This list of scope ruling applications is not an identification of scope inquiries that have been initiated. In accordance with 19 CFR 351.225(d)(1), if Commerce has not rejected a scope ruling application nor initiated the scope inquiry within 30 days after the filing of the application, the application will be deemed accepted and a scope inquiry will be deemed initiated the following day—day 31.<sup>3</sup> Commerce's practice generally dictates that where a deadline falls on a weekend, Federal holiday, or other non-business day, the appropriate deadline is the next business day.<sup>4</sup> Accordingly, if the 30th day after the filing of the application falls on a non-business day, the next business day will be considered the "updated" 30th day, and if the application is not rejected or a scope inquiry initiated by or on that particular business day, the application will be deemed accepted and a scope inquiry will be deemed initiated on the next business day which follows the "updated" 30th day.<sup>5</sup>

In accordance with 19 CFR 351.225(m)(2), if there are companion AD and CVD orders covering the same merchandise from the same country of origin, the scope inquiry will be conducted on the record of the AD proceeding. Further, please note that pursuant to 19 CFR 351.225(m)(1), Commerce may either apply a scope ruling to all products from the same country with the same relevant physical characteristics, (including chemical, dimensional, and technical characteristics) as the product at issue, on a country-wide basis, regardless of the producer, exporter, or importer of those products, or on a company-specific basis.

and a width ranging from 3/8" to 2", materials including cotton and/or polyester.

<sup>3</sup> In accordance with 19 CFR 351.225(d)(2), within 30 days after the filing of a scope ruling application, if Commerce determines that it intends to address the scope issue raised in the application in another segment of the proceeding (such as a circumvention inquiry under 19 CFR 351.226 or a covered merchandise inquiry under 19 CFR 351.227), it will notify the applicant that it will not initiate a scope inquiry, but will instead determine if the product is covered by the scope at issue in that alternative segment.

<sup>4</sup> See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

<sup>5</sup> This structure maintains the intent of the applicable regulation, 19 CFR 351.225(d)(1), to allow day 30 and day 31 to be separate business days.

For further information on procedures for filing information with Commerce through ACCESS and participating in scope inquiries, please refer to the Filing Instructions section of the Scope Ruling Application Guide, at [https://access.trade.gov/help/Scope\\_Ruling\\_Guidance.pdf](https://access.trade.gov/help/Scope_Ruling_Guidance.pdf). Interested parties, apart from the scope ruling applicant, who wish to participate in a scope inquiry and be added to the public service list for that segment of the proceeding must file an entry of appearance in accordance with 19 CFR 351.103(d)(1) and 19 CFR 351.225(n)(4). Interested parties are advised to refer to the case segment in ACCESS as well as 19 CFR 351.225(f) for further information on the scope inquiry procedures, including the timelines for the submission of comments.

Please note that this notice of scope ruling applications filed in AD and CVD proceedings may be published before any potential initiation, or after the initiation, of a given scope inquiry based on a scope ruling application identified in this notice. Therefore, please refer to the case segment on ACCESS to determine whether a scope ruling application has been accepted or rejected and whether a scope inquiry has been initiated.

Interested parties who wish to be served scope ruling applications for a particular AD or CVD order may file a request to be included on the annual inquiry service list during the anniversary month of the publication of the AD or CVD order in accordance with 19 CFR 351.225(n) and Commerce's procedures.<sup>6</sup>

Interested parties are invited to comment on the completeness of this monthly list of scope ruling applications received by Commerce. Any comments should be submitted to Scot Fullerton, Acting Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to [CommerceCLU@trade.gov](mailto:CommerceCLU@trade.gov).

This notice of scope ruling applications filed in AD and CVD proceedings is published in accordance with 19 CFR 351.225(d)(3).

Dated: May 22, 2025.

**Scot Fullerton,**

*Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

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**BILLING CODE 3510-DS-P**

<sup>6</sup> See *Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*, 86 FR 53205 (September 27, 2021).

<sup>1</sup> See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300, 52316 (September 20, 2021) (*Final Rule*) ("It is our expectation that the **Federal Register** list will include, where appropriate, for each scope application the following data: (1) identification of the AD and/or CVD orders at issue; (2) a concise public summary of the product's description, including the physical characteristics (including chemical, dimensional and technical characteristics) of the product; (3) the country(ies) where the product is produced and the country from where the product is exported; (4) the full name of the applicant; and (5) the date that the scope application was filed with Commerce.")

<sup>2</sup> The product is a functional shoelace made of a ribbon material modified with fitted with aglets and modified with heat cutting (to split the plastic into the two shoelace tips). The shoelace material is made of ribbon with and without a selvage edge (*i.e.*, flocking, knit, cut edge, or other) with a length ranging from 25" to 65" (depending on shoe size)

**DEPARTMENT OF COMMERCE**

**International Trade Administration**

[A-555-005]

**Paper File Folders From Cambodia: Preliminary Negative Determination of Sales at Less Than Fair Value and Postponement of Final Determination**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that paper file folders from Cambodia are not being, or are not likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Kelsie Hohenberger, 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) 482-2517.

**SUPPLEMENTARY INFORMATION:**

**Background**

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 19, 2024.<sup>1</sup> On February 24, 2025, Commerce postponed the preliminary determination of this investigation until May 21, 2025.<sup>2</sup>

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix II 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 Investigation**

The products covered by this investigation are paper file folders from

Cambodia. For a complete description of the scope of this investigation, see Appendix I.

**Scope Comments**

In accordance with the *Preamble* to Commerce's regulations,<sup>4</sup> we set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).<sup>5</sup> No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*. Commerce is not modifying the scope language as it appeared in the *Initiation Notice*.

**Methodology**

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, see the Preliminary Decision Memorandum.

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists:

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Three-Color Stone Stationery (Cambodia) Co., Ltd./Three-Color Stone Manufacture Limited <sup>6</sup> .....	0.00	Not Applicable.

For this preliminary determination, Commerce calculated an estimated weighted-average dumping margin of zero for the only individually examined respondent, TCS. Consistent with section 733(b)(3) of the Act, Commerce disregards zero rates and preliminarily determines that the single entity with a zero rate has not made sales of subject merchandise at LTFV.

Consistent with section 733(d) of the Act, Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters because it has not made an

affirmative preliminary determination of sales at LTFV.

**Critical Circumstances Allegation**

On May 7, 2025, the petitioner alleged that critical circumstances exist with respect to imports of paper file folders from Cambodia.<sup>7</sup> Commerce issued a questionnaire to TCS, requesting information regarding exports of paper file folders from Cambodia to the United States.<sup>8</sup> Section 733(e)(1) of the Act provides that Commerce, upon receipt of a timely-filed allegation of critical circumstances, will determine whether there is a reasonable basis to believe or

suspect that: (A)(i) there is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise; or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at LTFV and that there was likely to be material injury by reason of such sales; and (B) there have been massive imports of the subject merchandise over a relatively short period. However, as stated above, because Commerce preliminarily calculated a zero rate for the sole

<sup>1</sup> See *Paper File Folders from Cambodia and Sri Lanka: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91322 (November 19, 2024) (*Initiation Notice*).

<sup>2</sup> See *Paper File Folders from Cambodia and Sri Lanka: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations*, 90 FR 10473 (February 24, 2025).

<sup>3</sup> See Memorandum, "Decision Memorandum for the Preliminary Negative Determination in the Less-

Than-Fair-Value Investigation of Paper File Folders from Cambodia," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

<sup>5</sup> See *Initiation Notice*.

<sup>6</sup> Three-Color Stone Stationery (Cambodia) Co., Ltd. submitted a response on behalf of itself and its

affiliated reseller, Three-Color Stone Manufacture Limited. Commerce preliminarily determines that it is appropriate to treat these companies as a single entity. See Preliminary Decision Memorandum. We refer to the companies collectively as TCS.

<sup>7</sup> See Petitioner's Letter, "Petitioner's Allegation of Critical Circumstances," dated May 7, 2025.

<sup>8</sup> See Commerce's Letter, "Supplemental Questionnaire," dated May 16, 2025.

mandatory respondent, TCS, the entity has not made sales of subject merchandise at LTFV. Therefore, pursuant to 19 CFR 351.204(e), the respondent will not be subject to provisional measures under sections 703(d) or section 733(d) of the Act. Consequently, Commerce has not conducted a critical circumstances analysis for this preliminary determination.

### Suspension of Liquidation

Because Commerce has made a negative preliminary determination of sales at LTFV with regard to subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation or to require a cash deposit of estimated antidumping duties for entries of paper file folders from Cambodia.

### Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

### Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

### Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.<sup>9</sup> Rebuttal briefs, limited to issues raised in the case briefs, may be

filed no later than five days after the date for filing case briefs. Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>10</sup>

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 briefs that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.<sup>11</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>12</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number, (2) the number of participants, and whether any participant is a foreign national, and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

### Postponement of Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such

postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On May 16, 2025, pursuant to 19 CFR 351.210(e), the petitioner and TCS requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.<sup>13</sup> In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is negative; (2) the petitioner has requested the postponement of the final determination; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination. Because we have preliminarily determined that sales of subject merchandise are not being sold at LTFV, provisional measures are not being applied to imports of subject merchandise pursuant to section 733(d) of the Act. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

### U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine 75 days after the final determination whether imports of paper file folders from Cambodia are materially injuring, or threaten material injury to, the U.S. industry.

### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

<sup>9</sup> 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*).

<sup>10</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>11</sup> We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

<sup>12</sup> See *APO and Service Final Rule*.

<sup>13</sup> See Petitioner's Letter, "Petitioner's Request for Postponement of the Final Determinations," dated May 16, 2025; and TCS's Letter, "TCS's Request to Postpone Final Determination," dated May 16, 2025.

Dated: May 21, 2025.

**Abdelali Elouaradia,**

*Deputy Assistant Secretary for Enforcement and Compliance.*

## Appendix I

### Scope of the Investigation

The products within the scope of this investigation are file folders consisting primarily of paper, paperboard, pressboard, or other cellulose material, whether coated or uncoated, that has been folded (or creased in preparation to be folded), glued, taped, bound, or otherwise assembled to be suitable for holding documents. The scope includes all such folders, regardless of color, whether or not expanding, whether or not laminated, and with or without tabs, fasteners, closures, hooks, rods, hangers, pockets, gussets, or internal dividers. The term “primarily” as used in the first sentence of this scope means 50 percent or more of the total product weight, exclusive of the weight of fasteners, closures, hooks, rods, hangers, removable tabs, and similar accessories, and exclusive of the weight of the packaging.

Subject folders have the following dimensions in their folded and closed position: lengths and widths of at least 8 inches and no greater than 17 inches, regardless of depth.

The scope covers all varieties of folders, including but not limited to manila folders, hanging folders, fastener folders, classification folders, expanding folders, pockets, jackets, and wallets.

Excluded from the scope are:

- mailing envelopes with a flap bearing one or more adhesive strips that can be used permanently to seal the entire length of a side such that, when sealed, the folder is closed on all four sides;
- binders, with two or more rings to hold documents in place, made of paperboard or pressboard encased entirely in plastic;
- binders consisting of a front cover, back cover, and spine, with or without a flap; to be excluded, a mechanism with two or more metal rings that must be included on or adjacent to the interior spine;
- non-expanding folders with a depth exceeding 2.5 inches and that are closed or closeable on the top, bottom, and all four sides (e.g., boxes or cartons);
- expanding folders that have: (1) 13 or more pockets; (2) a flap covering the top; (3) a latching mechanism made of plastic and/or metal to close the flap; and (4) an affixed plastic or metal carry handle;
- folders that have an outer surface (other than the gusset, handles, and/or closing mechanisms, if any) that is covered entirely with fabric, leather, and/or faux leather;
- fashion folders, which are defined as folders with all of the following characteristics: (1) plastic lamination covering the entire exterior of the folder; (2) printing, foil stamping, embossing (i.e., raised relief patterns that are recessed on the opposite side), and/or debossing (i.e., recessed relief patterns that are raised on the opposite side), covering the entire exterior surface area of the folder; (3) at least two visible and printed or foil stamped colors (other than the color of the base paper), each

of which separately covers no less than 10 percent of the entire exterior surface area; and (4) patterns, pictures, designs, or artwork covering no less than thirty percent of the exterior surface area of the folder;

- portfolios, which are folders having: (1) a width of at least 16 inches when open flat; (2) no tabs or dividers; and (3) one or more pockets that are suitable for holding letter size documents and that cover at least 15 percent of the surface area of the relevant interior side or sides; and

- report covers, which are folders having: (1) no tabs, dividers, or pockets; and (2) one or more fasteners or clips, each of which is permanently affixed to the center fold, to hold papers securely in place.

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) category 4820.30.0040. Subject imports may also enter under other HTSUS classifications. While the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

## Appendix II

### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Affiliation and Single Entity Treatment
- V. Discussion of the Methodology
- VI. Recommendation

[FR Doc. 2025–09659 Filed 5–28–25; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A–542–806]

#### Paper File Folders From Sri Lanka: Preliminary Affirmative Determination of Sales at Less Than Fair Value

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that paper file folders from Sri Lanka are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Rachel Jennings, 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) 482–1110.

**SUPPLEMENTARY INFORMATION:**

## Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 19, 2024.<sup>1</sup> On February 24, 2025, Commerce postponed the preliminary determination of this investigation until May 21, 2025.<sup>2</sup>

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix II 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 Investigation

The products covered by this investigation are paper file folders from Sri Lanka. For a complete description of the scope of this investigation, see Appendix I.

## Scope Comments

In accordance with the *Preamble* to Commerce’s regulations,<sup>4</sup> we set aside a period of time for parties to raise issues regarding product coverage (i.e., scope).<sup>5</sup> No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*. Commerce is not modifying the scope language as it appeared in the *Initiation Notice*.

## Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to section 776(a) and (b) of the Act, Commerce has

<sup>1</sup> See *Paper File Folders from Cambodia and Sri Lanka: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91322 (November 19, 2024) (*Initiation Notice*).

<sup>2</sup> See *Paper File Folders from Cambodia and Sri Lanka: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations*, 90 FR 10473 (February 24, 2025).

<sup>3</sup> See Memorandum, “Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Paper File Folders from Sri Lanka” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

<sup>5</sup> See *Initiation Notice*.

preliminarily relied upon facts otherwise available, with adverse inferences (AFA), to Lanka Educational Products Pvt Ltd (Lanka Educational Products), because Lanka Educational Products did not respond to Commerce's requests for information. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

#### All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Pursuant to section 735(c)(5)(B) of the Act, if the estimated weighted-average dumping margins established for all exporters and producers individually examined are zero, *de minimis*, or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated weighted-average dumping margin for all other producers or exporters.

Commerce has preliminarily determined the estimated weighted-average dumping margin for the individually examined respondent under section 776 of the Act. Consequently, consistent with section 735(c)(5)(B) of the Act, Commerce's normal practice under these circumstances has been to calculate the all-others rate as a simple average of the alleged dumping margins from the petition.<sup>6</sup> For a full description of the methodology underlying Commerce's

analysis, *see* the Preliminary Decision Memorandum.

#### Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)
Lanka Educational Products Pvt Ltd .....	*91.28
All Others .....	57.43

\* Rate based on facts available with adverse inferences.

#### Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

#### Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the individually examined company (*i.e.*, Lanka Educational Products) in this investigation in accordance with section

776 of the Act, and the applied AFA rate is based solely on the petition, there are no calculations to disclose.

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

#### Verification

Because the examined respondent in this investigation did not provide information requested by Commerce, and Commerce preliminarily determines that the examined respondent has been uncooperative, we will not conduct verification as provided under section 782(i)(1) of the Act.

#### Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary determination, unless the Secretary alters the time limit. 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.<sup>7</sup> Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>8</sup>

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 briefs that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.<sup>9</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We

<sup>7</sup> 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*).

<sup>8</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>9</sup> We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

<sup>6</sup> *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany*, 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany*, 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2; *see also* *Notice of Final Determination of Sales at Less Than Fair Value: Raw Flexible Magnets from Taiwan*, 73 FR 39673, 39674 (July 10, 2008); *Steel Threaded Rod from Thailand: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Preliminary Determination of Critical Circumstances*, 78 FR 79670, 79671 (December 31, 2013), unchanged in *Steel Threaded Rod from Thailand: Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances*, 79 FR 14476, 14477 (March 14, 2014).

intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>10</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number, (2) the number of participants, and whether any participant is a foreign national, and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

### Final Determination

Section 735(a)(1) of the Act and 19 CFR 351.210(b)(1) provide that Commerce will issue the final determination within 75 days after the date of its preliminary determination. Accordingly, Commerce will make its final determination no later than 75 days after the signature date of this preliminary determination.

### U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 21, 2025.

**Abdelali Elouaradia,**

*Deputy Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Investigation

The products within the scope of this investigation are file folders consisting primarily of paper, paperboard, pressboard, or other cellulose material, whether coated or uncoated, that has been folded (or creased in preparation to be folded), glued, taped, bound, or otherwise assembled to be suitable for holding documents. The scope includes all such folders, regardless of color, whether or not expanding, whether or not laminated, and with or without tabs, fasteners, closures, hooks, rods, hangers, pockets, gussets, or internal dividers. The term "primarily" as used in the first sentence of this scope means 50 percent or more of the total product weight, exclusive of the weight of fasteners, closures, hooks, rods, hangers, removable tabs, and similar accessories, and exclusive of the weight of the packaging.

Subject folders have the following dimensions in their folded and closed position: lengths and widths of at least 8 inches and no greater than 17 inches, regardless of depth.

The scope covers all varieties of folders, including but not limited to manila folders, hanging folders, fastener holders, classification folders, expanding folders, pockets, jackets, and wallets.

Excluded from the scope are:

- mailing envelopes with a flap bearing one or more adhesive strips that can be used permanently to seal the entire length of a side such that, when sealed, the folder is closed on all four sides;
- binders, with two or more rings to hold documents in place, made of paperboard or pressboard encased entirely in plastic;
- binders consisting of a front cover, back cover, and spine, with or without a flap; to be excluded, a mechanism with two or more metal rings must be included on or adjacent to the interior spine;
- non-expanding folders with a depth exceeding 2.5 inches and that are closed or closeable on the top, bottom, and all four sides (*e.g.*, boxes or cartons);
- expanding folders that have: (1) 13 or more pockets; (2) a flap covering the top; (3) a latching mechanism made of plastic and/or metal to close the flap; and (4) an affixed plastic or metal carry handle;
- folders that have an outer surface (other than the gusset, handles, and/or closing mechanisms, if any) that is covered entirely with fabric, leather, and/or faux leather;
- fashion folders, which are defined as folders with all of the following characteristics: (1) plastic lamination covering the entire exterior of the folder; (2) printing, foil stamping, embossing (*i.e.*, raised relief patterns that are recessed on the opposite side), and/or debossing (*i.e.*, recessed relief patterns that are raised on the opposite side), covering the entire exterior surface area of the folder; (3) at least two visible and printed or foil stamped colors (other than the color of the base paper), each

of which separately covers no less than 10 percent of the entire exterior surface area; and (4) patterns, pictures, designs, or artwork covering no less than thirty percent of the exterior surface area of the folder;

- portfolios, which are folders having: (1) a width of at least 16 inches when open flat; (2) no tabs or dividers; and (3) one or more pockets that are suitable for holding letter size documents and that cover at least 15 percent of the surface area of the relevant interior side or sides; and

- report covers, which are folders having: (1) no tabs, dividers, or pockets; and (2) one or more fasteners or clips, each of which is permanently affixed to the center fold, to hold papers securely in place.

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) category 4820.30.0040. Subject imports may also enter under other HTSUS classifications. While the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

### Appendix II

#### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Application of Facts Available and Use of Adverse Inference
- V. Recommendation

[FR Doc. 2025-09660 Filed 5-28-25; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

[C-570-191]

#### Sol Gel Alumina-Based Ceramic Abrasive Grains From the People's Republic of China: Alignment of Final Countervailing Duty Determination With Final Less-Than-Fair-Value Determination

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Suresh Maniam, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1603.

#### SUPPLEMENTARY INFORMATION:

#### Background

On January 6, 2025, the U.S. Department of Commerce (Commerce) initiated the countervailing duty (CVD) investigation of sol gel alumina-based ceramic abrasive grains (ceramic

<sup>10</sup> See APO and Service Final Rule.

abrasive grains) from the People's Republic of China (China).<sup>1</sup> Simultaneously, Commerce initiated the less-than-fair-value (LTFV) investigation of ceramic abrasive grains from China.<sup>2</sup> The CVD investigation and the LTFV investigation cover the same class or kind of merchandise.

### Alignment With Final LTFV Determinations

On May 19, 2025, in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), Saint-Gobain Ceramics & Plastics Inc. (the petitioner) timely requested an alignment of the final CVD determination with the final LTFV determination of ceramic abrasive grains from China.<sup>3</sup> Therefore, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4)(i), Commerce is aligning the final CVD determination with the final LTFV determination. Consequently, the final CVD determination will be issued on the same date as the final LTFV determination, which is currently scheduled to be issued no later than August 11, 2025, unless postponed.

This notice is issued and published pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(4)(I).

Dated: May 22, 2025.

#### Christopher Abbott,

*Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2025-09665 Filed 5-28-25; 8:45 am]

**BILLING CODE 3510-DS-P**

<sup>1</sup> See *Sol Gel Alumina-Based Ceramic Abrasive Grains from the People's Republic of China: Initiation of Countervailing Duty Investigation*, 90 FR 3175 (January 14, 2025) (*Initiation Notice*); see also *Sol Gel Alumina-Based Ceramic Abrasive Grains from the People's Republic of China: Initiation of Countervailing Duty Investigation; Correction*, 90 FR 7659 (January 22, 2025) (*Correction Initiation Notice*). Commerce corrected a typographical error in the scope language in the *Correction Initiation Notice*.

<sup>2</sup> See *Sol Gel Alumina-Based Ceramic Abrasive Grains from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation*, 90 FR 3179 (January 14, 2025); see also *Sol Gel Alumina-Based Ceramic Abrasive Grains from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation; Correction*, 90 FR 7657 (January 22, 2025) (*AD Correction Initiation Notice*). Commerce corrected a typographical error in the scope language in the *Correction Initiation Notice*.

<sup>3</sup> See Petitioner's Letter, "Request to Align Final Countervailing Duty Determination with the Companion Antidumping Duty Final Determination," dated May 19, 2025.

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-533-934]

#### Hard Empty Capsules From India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that hard empty capsules (capsules) from India are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2023, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Luke Caruso or Joseph Molokwu, 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) 482-2081 or (202) 482-8043, respectively.

#### SUPPLEMENTARY INFORMATION:

##### Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 20, 2024.<sup>1</sup> On March 5, 2025, Commerce postponed the preliminary determination of this investigation until May 22, 2025.<sup>2</sup> For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public

<sup>1</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

<sup>2</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair Value Investigations*, 90 FR 11257 (March 5, 2025).

<sup>3</sup> See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from India" dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

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 Investigation

The merchandise covered by this investigation is capsules from India. For a complete description of the scope of this investigation, see Appendix I.

#### Scope Comments

In accordance with the *Preamble* to Commerce's regulations,<sup>4</sup> in the *Initiation Notice*, Commerce set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).<sup>5</sup> Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*. For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, see the Preliminary Scope Decision Memorandum.<sup>6</sup> Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice*. See the scope in Appendix I to this notice. In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case and rebuttal briefs.<sup>7</sup>

#### Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, see the Preliminary Decision Memorandum.

#### All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

<sup>5</sup> See *Initiation Notice*.

<sup>6</sup> See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Decision Memorandum).

<sup>7</sup> *Id.* at 10.

preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any

zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated estimated weighted-average dumping margins for ACG Associated Capsules Private Limited (ACG India)<sup>8</sup> and HealthCaps India Limited (HIL) that are not zero, *de minimis*, or based entirely on facts otherwise available. Commerce

calculated the all-others rate using an average of the estimated weighted-average dumping margins calculated for the examined respondents.<sup>9</sup>

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter or producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for export subsidy offsets) (percent) <sup>10</sup>
ACG Associated Capsules Private Limited; ACG Universal Capsules Private Limited; and Custom Capsules Private Limited <sup>11</sup> .....	24.78	14.91
HealthCaps India Limited .....	3.60	0.00
All Others .....	14.19	4.32

**Suspension of Liquidation**

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit as follows: (1) The cash deposit rate for the subject merchandise exported by a company listed above will be equal to the company-specific estimated weighted-average dumping margins, as adjusted for the export subsidy offset, determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin, as adjusted for the export subsidy offset, established for that producer of the subject merchandise and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping

margin, as adjusted for the export subsidy offset.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the “Preliminary Determination” section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

**Disclosure**

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination under administrative protective order within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

**Verification**

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

<sup>8</sup> On April 21, 2025, Commerce determined that ACG India, Customs Capsules Private Limited and ACG Universal Capsules Private Limited are affiliated companies (collectively, ACG) pursuant to section 771(33)(E) of the Act. See Memorandum, “Preliminary Affiliation and Collapsing Analysis Memorandum,” dated April 21, 2025 (Collapsing Memorandum), and accompanying Preliminary Decision Memorandum.

<sup>9</sup> With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each

company’s publicly-ranged U.S. sales values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, e.g., *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53662 (September 1, 2010), and accompanying Issues and Decision Memorandum at Comment 1. Publicly-ranged U.S. sales values are not available for all the companies in this investigation. Accordingly, we cannot calculate a weighted-average margin to consider applying to the non-selected respondents in this proceeding. Instead, we have determined to apply the simple average of the margins we calculated for the selected companies to the

companies not selected for individual examination in this proceeding. For a complete analysis of the data, see Memorandum, “Subsidy Offset Calculation for Mandatory Respondents and All Others Rate,” dated concurrently with this notice.

<sup>10</sup> Adjusted for export subsidies of 9.87 percent for all companies. See *Hard Empty Capsules from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination*, 90 FR 14356 (April 1, 2025), and accompanying Preliminary Decision Memorandum.

<sup>11</sup> Commerce preliminarily determines that ACG Associated Capsules Private Limited, ACG Universal Capsules Private Limited and Custom Capsules Private Limited are a single entity. See Preliminary Decision Memorandum.

## Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. 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.<sup>12</sup> Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>13</sup>

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 investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.<sup>14</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>15</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce

intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

## Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On May 2, 2025, pursuant to 19 CFR 351.210(e)(2), ACG requested Commerce postpone the final determination, by 60 days after the publication of the preliminary determination and provisional measures be extended to a period not to exceed six months.<sup>16</sup> On May 9, 2025, pursuant to 19 CFR 351.210(b)(2)(i) and 19 CFR 351.210(e)(i), Lonza Greenwood LLC (the petitioner) requested that, if the preliminary determination was negative, that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.<sup>17</sup> In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(e)(2), because: (1) the preliminary determination is affirmative; (2) the requesting exporters accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

## U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

## Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 22, 2025.

## Christopher Abbott,

*Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix I

### Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigations regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that

<sup>12</sup> 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*).

<sup>13</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>14</sup> We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

<sup>15</sup> See *APO and Service Final Rule*.

<sup>16</sup> See ACG's Letter, "Request to Postpone the Final Determination," dated May 2, 2025.

<sup>17</sup> See Petitioner's Letter, "Request for Postponement of the Department's Antidumping Duty Final Determination," dated May 9, 2025.

disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigations is dispositive.

## Appendix II

### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Affiliation and Single Entity Treatment
- V. Discussion of the Methodology
- VI. Currency Conversion
- VII. Adjustments to Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
- VIII. Recommendation

[FR Doc. 2025–09700 Filed 5–28–25; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

[A–570–992]

#### Monosodium Glutamate From the People’s Republic of China: Final Affirmative Determination of Circumvention

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) determines that imports of monosodium glutamate (MSG) completed in Malaysia using glutamic acid produced in the People’s Republic of China (China) are circumventing the antidumping duty (AD) order on MSG from China.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Thomas Cloyd, 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) 482–1246.

#### SUPPLEMENTARY INFORMATION:

## Background

On February 21, 2025, Commerce published in the **Federal Register** its *Preliminary Determination* that imports of MSG completed in Malaysia using glutamic acid produced in China are circumventing the *Order*.<sup>1</sup> Pursuant to section 781(e) of the Tariff Act of 1930, as amended (the Act), on March 20, 2025, Commerce notified the U.S. International Trade Commission (ITC) of its preliminary affirmative determination of circumvention.<sup>2</sup> The ITC did not request consultations with Commerce.

On April 28, 2025, CPF Legacy, LLC dba C. Pacific and JEFI Enterprise (USA) Inc. (collectively, the U.S. Importers) and Ajinomoto Health & Nutrition North America, Inc. (Ajinomoto NA) submitted case briefs.<sup>3</sup> On May 5, 2025, the U.S. Importers and Ajinomoto NA submitted a letter in lieu of a rebuttal brief and a rebuttal brief, respectively.<sup>4</sup> On March 18, 2025, Commerce extended the deadline for issuing the final determination in this circumvention inquiry until May 22, 2025.<sup>5</sup>

For a summary of events that occurred since the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for consideration in the final determination, see the Issues and Decision Memorandum.<sup>6</sup>

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

<sup>1</sup> See *Monosodium Glutamate from the People’s Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Order*, 80 FR 487 (January 6, 2015) (*Order*); see also *Monosodium Glutamate from the People’s Republic of China: Preliminary Affirmative Determination of Circumvention*, 90 FR 10068 (February 21, 2025) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

<sup>2</sup> See Commerce’s Letter, “Notification of Affirmative Preliminary Determination of Circumvention,” dated March 20, 2025.

<sup>3</sup> See U.S. Importers’ Letter, “Importers’ Administrative Case Brief,” dated April 28, 2025; see also Ajinomoto NA’s Letter, “Comments on Preliminary Determination,” dated April 28, 2025.

<sup>4</sup> See U.S. Importers’ Letter, “CPF & JEFI’s Letter in Lieu of Rebuttal Brief,” dated May 5, 2025; see also Ajinomoto NA’s Letter, “Rebuttal Comments,” dated May 5, 2025.

<sup>5</sup> See Memorandum, “Extension of Deadline for the Final Determination in Circumvention Inquiry,” dated March 18, 2025.

<sup>6</sup> See Memorandum, “Issues and Decision Memorandum for the Circumvention Inquiry of the Antidumping Duty Order on Monosodium Glutamate from the People’s Republic of China,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

complete version of the Issues and Decision Memorandum can be accessed at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

## Scope of the Order

The product covered by the scope of the *Order* is MSG from China. For a full description of the scope of the *Order*, see Appendix I of this notice.

## Merchandise Subject to the Circumvention Inquiry

This circumvention inquiry covers MSG finished in Malaysia using glutamic acid produced in China and subsequently exported from Malaysia to the United States (inquiry merchandise).

## Analysis of Comments Received

All issues raised in this inquiry are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix II. Based on our analysis of the comments received, we made changes to the *Preliminary Determination*, as described below, and at Comments 1 and 2 of the Issues and Decision Memorandum.

## Methodology and Final Circumvention Determination

Commerce conducted this circumvention inquiry in accordance with section 781(b) of the Act and 19 CFR 351.226. For this final determination, Commerce relied on facts available under section 776(a) of the Act, including facts available with adverse inferences (AFA) under section 776(b) of the Act with respect to Ajinoriki, due to Ajinoriki’s failure to participate in Commerce’s required on-site verification of the information contained in Ajinoriki’s questionnaire responses. For further explanation of Commerce’s decision to rely on AFA with respect to Ajinoriki, see the Issues and Decision Memorandum. As a result, in accordance with section 781(b) of the Act, Commerce determines that the inquiry merchandise exported from Malaysia by Ajinoriki is circumventing the *Order*. Furthermore, Commerce is applying this affirmative determination of circumvention of the *Order* on a country-wide basis. Also, because Commerce was unable to verify the information which may support Ajinoriki’s eligibility to certify, as AFA, Ajinoriki is no longer eligible to certify that its shipments to the United States of MSG, produced or exported by Ajinoriki do not contain Chinese-origin glutamic acid. Finally, no other producer or exporter of MSG has cooperated in this inquiry; as a result, Commerce is applying this final affirmative determination of

circumvention on a country-wide basis. Thus, as a result of Commerce's country-wide affirmative determination of circumvention, Commerce is removing the certification process established in the *Preliminary Determination*.<sup>7</sup> In a future administrative review, companies may be able to revisit the issue of eligibility for certifications of their entries of inquiry merchandise.

We have continued to apply the methodology relied upon for the *Preliminary Determination*, including our use of AFA with respect to the non-responsive companies: (1) Ajinoriki MSG Sdn Bhd; (2) Aruni Enterprise M Sdn Bhd; (3) Habita Foods Industries Sdn Bhd; (4) Delisauce World Foods Sdn Bhd; (5) Suntraco Food Industries Sdn Bhd; (6) Yeo Hiap Seng (Malaysia) Berhad; (7) Bidor Kwong Heng Sdn Bhd; and (8) Scigate Industries 002998063-A, pursuant to sections 776(a) and (b) of the Act, for our final determination. As AFA, we continue to determine that MSG exported to the United States by these non-responsive companies are circumventing the *Order*. For a detailed explanation of our determination, see the *Preliminary Determination* PDM.

See the "Suspension of Liquidation and Cash Deposit Requirements" section, below, for details regarding suspension of liquidation and cash deposit requirements.

### Suspension of Liquidation and Cash Deposit Requirements

Based on the affirmative country-wide determinations of circumvention, in accordance with 19 CFR 351.226(l)(3)(iii)(A) and (B) and 19 CFR 351.227(l)(3)(iii), we will direct CBP to suspend liquidation and require a cash deposit of estimated duties on all unliquidated entries of MSG completed or assembled in Malaysia using Chinese-origin glutamic acid, that were entered, or withdrawn from warehouse, for consumption prior to 5/15/2024 (the date of initiation of the circumvention inquiry), back to, and including, November 4, 2021,<sup>8</sup> and (ii) that were entered, or withdrawn from warehouse, for consumption on or after May 15, 2024.

For all suspended U.S. entries of inquiry merchandise, the AD cash deposit rate will be the cash deposit rate for the China-wide entity (*i.e.*, 56.54

percent).<sup>9</sup> Commerce has established the following third-country case number in the Automated Commercial Environment (ACE) for such entries: Malaysia A-557-992-000.

Cash deposits for entries of MSG from Malaysia already subject to the *Order* should continue to be collected in accordance with existing CBP instructions and Chinese ACE numbers for such entries: A-570-992.

These suspension of liquidation instructions and cash deposit requirements will remain in effect until further notice.

### Opportunity To Request an Administrative Review

Each year during the anniversary month of the publication of an AD or CVD order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Act, may request, in accordance with 19 CFR 351.213, that Commerce conduct an administrative review of that AD or CVD order, finding, or suspended investigation. Interested parties who wish to request that Commerce conduct an administrative review should wait until Commerce announces via the **Federal Register** the next window during the anniversary month (*e.g.* November 2025) of the *Order* to submit such requests.

### Administrative Protective Order (APO)

This notice will serve as the only reminder to all parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). 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 the terms of an APO is a sanctionable violation.

### Notification to Interested Parties

Commerce is issuing and publishing this notice in accordance with sections 781(b) and 777(i) of the Act, and 19 CFR 351.226(g)(2).

Dated: May 22, 2025.

#### Christopher Abbott,

*Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Order

The scope of this *Order* covers MSG, whether or not blended or in solution with other products. Specifically, MSG that has

been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in this order regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging.

MSG in monohydrate form has a molecular formula of C<sub>5</sub>H<sub>8</sub>NO<sub>4</sub>Na·H<sub>2</sub>O, a Chemical Abstract Service (CAS) registry number of 6106-04-3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of C<sub>5</sub>H<sub>8</sub>NO<sub>4</sub>Na, a CAS registry number of 142-47-2, and a UNII number of C3C196L9FG.

Merchandise covered by the scope of this *Order* is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2922.42.10.00. Merchandise subject to the *Order* may also enter under HTSUS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.

### Appendix II

#### List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Use of Facts Otherwise Available and Application of Adverse Inferences
- V. Discussion of the Issues
  - Comment 1: Whether to Apply AFA to Ajinoriki
  - Comment 2: Whether Ajinoriki Should Be Ineligible for the Certification Program
  - Comment 3: Whether Commerce Should Apply Antidumping Cash Deposits Prior to the Date of the Initiation of the Circumvention Inquiry
  - Comment 4: Whether the U.S. Importers Should Have Been Allowed to Submit New Factual Information
  - Comment 5: Whether Commerce Should Reverse Its Circumvention Finding
- VI. Recommendation

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<sup>7</sup> See *Preliminary Determination*, 90 FR at Appendix II.

<sup>8</sup> November 4, 2021, was the date Commerce's circumvention regulations became effective. See *Regulations To Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300 (September, 20, 2021).

<sup>9</sup> See *Order*.

**DEPARTMENT OF COMMERCE****International Trade Administration**

[C–570–210]

**Fiberglass Door Panels From the People’s Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Sam Brummitt at (202) 482–7851, AD/CVD Operations, III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:****Background**

On April 9, 2025, the U.S. Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of fiberglass door panels from the People’s Republic of China.<sup>1</sup> Currently, the preliminary determination is due no later than June 13, 2025.

**Postponement of Preliminary Determination**

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner<sup>2</sup> makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless

<sup>1</sup> See *Fiberglass Door Panels from the People’s Republic of China: Initiation of Countervailing Duty Investigation*, 90 FR 15692 (April 15, 2025) (*Initiation Notice*).

<sup>2</sup> The petitioner is the American Fiberglass Door Coalition.

it finds compelling reasons to deny the request.

On May 19, 2025, the petitioner submitted a timely request that Commerce postpone the preliminary CVD determination.<sup>3</sup> The petitioner stated that it requests postponement “to ensure that Commerce is able to sufficiently review all questionnaire responses and request clarification and additional information as necessary” before reaching a preliminary determination.<sup>4</sup> In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigations was initiated, *i.e.*, August 18, 2025.<sup>5</sup> Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: May 22, 2025.

**Christopher Abbott,**

*Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2025–09690 Filed 5–28–25; 8:45 am]

**BILLING CODE 3510–DS–P**

<sup>3</sup> See Petitioner’s Letter, “Request to Postpone the Preliminary Determination,” dated May 19, 2025.

<sup>4</sup> *Id.*

<sup>5</sup> Postponing the preliminary determination to 130 days after initiation would place the deadline on Sunday, August 17, 2025. Commerce’s practice dictates that where a deadline falls on a weekend or Federal holiday, the appropriate deadline is the next business day. See *Notice of Clarification: Application of “Next Business Day” Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended*, 70 FR 24533 (May 10, 2005).

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A–570–184]

**Hard Empty Capsules From the People’s Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that hard empty capsules (capsules) from the People’s Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2024, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Janz or Jerry Xiao, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2972 or (202) 482–2273, respectively.

**SUPPLEMENTARY INFORMATION:****Background**

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 20, 2024.<sup>1</sup> On March 5, 2025, Commerce postponed the preliminary determination of this investigation until May 22, 2025.<sup>2</sup> For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix

<sup>1</sup> See *Hard Empty Capsules from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

<sup>2</sup> See *Hard Empty Capsules from Brazil, the People’s Republic of China, India, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations*, 90 FR 11257 (March 5, 2025).

<sup>3</sup> See Memorandum, “Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from the People’s Republic of China,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

II 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 Investigation**

The merchandise covered by this investigation is capsules from China. For a complete description of the scope of this investigation, see Appendix I.

**Scope Comments**

In accordance with the *Preamble* to Commerce's regulations,<sup>4</sup> in the *Initiation Notice*, Commerce set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).<sup>5</sup> Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*. For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, see the Preliminary Scope Decision Memorandum.<sup>6</sup> Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice*. See the scope in Appendix I to this notice. In the Preliminary Scope Decision Memorandum, Commerce established

the deadline for parties to submit scope case and rebuttal briefs.<sup>7</sup>

**Methodology**

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated constructed export prices in accordance with section 772(b) of the Act. Because China is a non-market economy (NME), within the meaning of section 771(18) of the Act, Commerce has calculated normal value in accordance with section 773(c) of the Act. Furthermore, pursuant to sections 776(a) and (b) of the Act, Commerce has preliminarily relied upon partial facts otherwise available, with adverse inferences, in determining the estimated weighted-average dumping margin for Shandong Healsee Capsule Ltd. (Shandong Healsee). For a full description of the methodology underlying Commerce's preliminary determination, see the Preliminary Decision Memorandum.

**Combination Rates**

In the *Initiation Notice*,<sup>8</sup> Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.<sup>9</sup>

**Separate Rate Companies and the China-Wide Entity**

We preliminarily granted a separate rate to certain respondents that we did not select for individual examination.<sup>10</sup> In calculating the rate for non-individually examined separate rate respondents in an NME LTFV

investigation, Commerce normally looks to section 735(c)(5)(A) of the Act, which pertains to the calculation of the all-others rate in a market economy LTFV investigation, for guidance. Pursuant to section 735(c)(5)(A) of the Act, normally this rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for those companies individually examined, excluding zero and *de minimis* estimated weighted-average dumping margins and any estimated weighted-average dumping margins based entirely under section 776 of the Act.

In this investigation, Commerce preliminarily calculated individual estimated weighted-average dumping margins for Shandong Healsee and Shanxi JC Biological Technology Co., Ltd. (Shanxi JC) that are not zero, *de minimis*, or based entirely on facts otherwise available. Thus, the estimated weighted-average dumping margins calculated for Shandong Healsee and Shanxi JC are the basis on which we preliminarily determined the estimated weighted-average dumping margin for the non-examined, separate rate companies in this investigation.<sup>11</sup>

Furthermore, because we preliminarily do not find that the China-wide entity failed to cooperate in this investigation, we also preliminarily assigned this same rate as the estimate weighted-average dumping margin for the China-wide entity.<sup>12</sup>

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Producer	Exporter	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Shandong Healsee Capsule Ltd .....	Shandong Healsee Capsule Ltd .....	172.24	Not Applicable.
Shanxi JC Biological Technology Co., Ltd .....	Shanxi JC Biological Technology Co., Ltd .....	5.40	Not Applicable.
Guizhou Guang De Li Pharmaceuticals Co., Ltd ..	Guizhou Guang De Li Pharmaceuticals Co., Ltd ..	88.82	Not Applicable.
Hebei Kangxin Plant Capsule Co., Ltd .....	Hebei Kangxin Plant Capsule Co., Ltd .....	88.82	Not Applicable.
Hubei Kornnac Pharmaceutical Co., Ltd. <sup>13</sup> .....	Hubei Kornnac Pharmaceutical Co., Ltd .....	88.82	Not Applicable.
Jiangsu Lefan Capsule Co., Ltd .....	Jiangsu Lefan Capsule Co., Ltd .....	88.82	Not Applicable.
Jiujiang Angtai Capsule Co., Ltd .....	Jiujiang Angtai Capsule Co., Ltd .....	88.82	Not Applicable.
Qingdao Yiqing Biotechnology Co., Ltd .....	Qingdao Yiqing Biotechnology Co., Ltd .....	88.82	Not Applicable.
Shaanxi Genex Bio-Tech Co., Ltd .....	Shaanxi Genex Bio-Tech Co., Ltd .....	88.82	Not Applicable.

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

<sup>5</sup> See *Initiation Notice*, 89 FR at 91685.

<sup>6</sup> See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Decision Memorandum).

<sup>7</sup> *Id.* at 10.

<sup>8</sup> See *Initiation Notice*, 89 FR at 91689.

<sup>9</sup> See Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, "Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non-Market Economy Countries," (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at <https://enforcement.trade.gov/policy/bull05-1.pdf>.

<sup>10</sup> See the Preliminary Decision Memorandum for further discussion.

<sup>11</sup> See Memorandum, "Preliminary Calculation of the Dumping Margin for Respondents Not Selected for Individual Examination," dated concurrently with this notice.

<sup>12</sup> See Preliminary Decision Memorandum for further discussion.

<sup>13</sup> Hubei Kornnac Pharmaceutical Co., Ltd. (Hubei Kornnac) initially filed a separate rate application under the name "Hubei Humanwell Pharmaceutical Excipients Co., Ltd." and subsequently notified Commerce that the company's name changed to Hubei Kornnac. We preliminarily determine it is appropriate to allow the name change. See Preliminary Decision Memorandum for further discussion.

Producer	Exporter	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Shanghai Guang De Li Capsule Co., Ltd .....	Shanghai Guang De Li Capsule Co., Ltd .....	88.82	Not Applicable.
Shanxi Guangsheng Medicinal Capsule Co., Ltd. A.K.A. Shanxi Guangsheng Capsule Co., Ltd.	Shanxi Guangsheng Medicinal Capsule Co., Ltd. A.K.A. Shanxi Guangsheng Capsule Co., Ltd.	88.82	Not Applicable.
Shaoxing Kangke Capsule Co., Ltd .....	Shaoxing Kangke Capsule Co., Ltd .....	88.82	Not Applicable.
Shaoxing Renhe Capsule Co., Ltd .....	Shaoxing Renhe Capsule Co., Ltd .....	88.82	Not Applicable.
Xinchang County Hexin Capsule Co., Ltd .....	Xinchang County Hexin Capsule Co., Ltd .....	88.82	Not Applicable.
Xinchang County No.6 Capsule Factory .....	Xinchang Paulo Import And Export Co., Ltd .....	88.82	Not Applicable.
Shaoxing Kangke Capsule Co., Ltd .....	Xinchang Paulo Import And Export Co., Ltd .....	88.82	Not Applicable.
Zhejiang Huaguang Capsule Co., Ltd .....	Xinchang Paulo Import And Export Co., Ltd .....	88.82	Not Applicable.
Shanxi Guangsheng Capsule Co., Ltd .....	Xinchang Paulo Import And Export Co., Ltd .....	88.82	Not Applicable.
Zhejiang Pujiang Enerkang Capsule Co., Ltd .....	Xinchang Paulo Import And Export Co., Ltd .....	88.82	Not Applicable.
Yantai Oriental Pharmacap Co., Ltd .....	Yantai Oriental Pharmacap Co., Ltd .....	88.82	Not Applicable.
Ningbo Capsulcn Capsule Co., Ltd .....	Zhejiang Capsulcn Machinery Co., Ltd .....	88.82	Not Applicable.
Shaoxing Zhongya Capsules Industry Co., Ltd ....	Zhejiang Capsulcn Machinery Co., Ltd .....	88.82	Not Applicable.
Shandong Healsee Capsule Ltd .....	Zhejiang Capsulcn Machinery Co., Ltd .....	88.82	Not Applicable.
Zhejiang Guangju yuan Biotechnology Co., Ltd ....	Zhejiang Capsulcn Machinery Co., Ltd .....	88.82	Not Applicable.
Zhejiang Huaguang Capsule Co., Ltd .....	Zhejiang Capsulcn Machinery Co., Ltd .....	88.82	Not Applicable.
Zhejiang Huaguang Capsule Co., Ltd .....	Zhejiang Huaguang Capsule Co., Ltd .....	88.82	Not Applicable.
Zhejiang Huili Capsules Co., Ltd .....	Zhejiang Huili Capsules Co., Ltd .....	88.82	Not Applicable.
Zhejiang Lujian Capsule Co., Ltd .....	Zhejiang Lujian Capsule Co., Ltd .....	88.82	Not Applicable.
China-Wide Entity .....		88.82	Not Applicable.

**Suspension of Liquidation**

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above, as follows:

(1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of China producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-country exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the China producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic

subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. However, Commerce has not made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies; thus, Commerce has not offset the calculated estimated weighted-average dumping margins in this preliminary determination.

These suspension of liquidation instructions will remain in effect until further notice.

**Disclosure**

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

**Verification**

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

**Public Comment**

Case briefs or other written comments, excluding scope comments, may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation. A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. 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.<sup>14</sup> Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>15</sup>

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 investigation, we instead request that interested parties provide at the beginning of their briefs a public,

<sup>14</sup> 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*).

<sup>15</sup> See 19 CFR 351.309(c)(2) and (d)(2)

executive summary for each issue raised in their briefs.<sup>16</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>17</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

### Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On May 5 and 6, 2025, pursuant to 19 CFR 351.210(e), Shandong Healsee and

Shanxi JC, respectively, requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.<sup>18</sup> On May 9, 2025, Lonza Greenwood LLC (the petitioner) also submitted a postponement request.<sup>19</sup> In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

### U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: May 22, 2025.

### Christopher Abbott,

*Deputy Assistant Secretary, for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

### Appendix I

#### Scope of the Investigation

The merchandise subject to the scope of this investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body).

The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of this investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of this investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of this investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of this investigation are those that disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this investigation is dispositive.

### Appendix II

#### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Discussion of the Methodology
- V. Adjustment Under Section 777(A)(f) of the Act
- VI. Adjustments to the Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
- VII. Currency Conversion
- VIII. Recommendation

[FR Doc. 2025–09699 Filed 5–28–25; 8:45 am]

**BILLING CODE 3510-DS-P**

<sup>16</sup> We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

<sup>17</sup> See *APO and Service Final Rule*.

<sup>18</sup> See Shandong Healsee's Letter, “Request to Postpone Final Determination,” dated May 5, 2025; see also Shanxi JC's Letter, “Shanxi JC's Request to Postpone Final Determination,” dated May 6, 2025.

<sup>19</sup> See Petitioner's Letter, “Lonza's Request for Postponement of {Commerce's} Antidumping Duty Final Determinations,” dated May 9, 2025.

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A–552–847]

**Hard Empty Capsules From the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The U.S. Department of Commerce (Commerce) preliminarily determines that hard empty capsules (capsules) from the Socialist Republic of Vietnam (Vietnam) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is April 1, 2024, through September 30, 2024. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable May 29, 2025.

**FOR FURTHER INFORMATION CONTACT:** Jinny Ahn or Harrison Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0339 or (202) 482–7421, respectively.

**SUPPLEMENTARY INFORMATION:****Background**

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 20, 2024.<sup>1</sup> On March 5, 2025, Commerce postponed the preliminary determination of this investigation until May 22, 2025.<sup>2</sup> For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.<sup>3</sup> A list of topics included in the Preliminary Decision Memorandum is included as Appendix

II 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 Investigation**

The merchandise covered by this investigation is capsules from Vietnam. For a complete description of the scope of this investigation, see Appendix I.

**Scope Comments**

In accordance with the *Preamble* to Commerce's regulations,<sup>4</sup> in the *Initiation Notice*, Commerce set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).<sup>5</sup> Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*. For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, see the Preliminary Scope Decision Memorandum.<sup>6</sup> Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice*. See the scope in Appendix I to this notice. In the Preliminary Scope Decision Memorandum, Commerce established the deadline for parties to submit scope case and rebuttal briefs.<sup>7</sup>

**Methodology**

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated constructed export prices in accordance with section 772(b) of the Act. Because Vietnam is a non-market economy (NME), within the meaning of section 771(18) of the Act, Commerce has calculated normal value in accordance with section 773(c) of the Act. For a full description of the methodology underlying Commerce's

preliminary determination, see the Preliminary Decision Memorandum.

**Combination Rates**

In the *Initiation Notice*, Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation.<sup>8</sup> Policy Bulletin 05.1 describes this practice.<sup>9</sup>

**Separate Rate Companies and the Vietnam-Wide Entity**

In this investigation, Commerce received one separate rate application, from Suheung Vietnam Co., Ltd. (SHVN), and we are preliminarily granting a separate rate to SHVN. In calculating the rate for non-individually examined separate rate respondents in an NME LTFV investigation, Commerce normally looks to section 735(c)(5)(A) of the Act, which pertains to the calculation of the all-others rate in a market economy LTFV investigation, for guidance. Pursuant to section 735(c)(5)(A) of the Act, normally this rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for those companies individually examined, excluding zero and *de minimis* estimated weighted-average dumping margins and any estimated weighted-average dumping margins based entirely under section 776 of the Act.

SHVN is the only respondent that Commerce individually examined in this investigation and Commerce preliminarily calculated an estimated weighted-average dumping margin for SHVN that is not zero, *de minimis*, or based entirely on facts available. Accordingly, while there are no separate rate respondents in this investigation, because we preliminarily do not find that the Vietnam-wide entity failed to cooperate in this investigation, we preliminarily assigned the estimated weighted-average dumping margin calculated for SHVN to the Vietnam-wide entity.<sup>10</sup>

<sup>1</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684 (November 20, 2024) (*Initiation Notice*).

<sup>2</sup> See *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Less-Than-Fair Value Investigations*, 90 FR 11257 (March 5, 2025).

<sup>3</sup> See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Hard Empty Capsules from the Socialist Republic of Vietnam," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

<sup>4</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

<sup>5</sup> See *Initiation Notice*, 89 FR at 91685.

<sup>6</sup> See Memorandum, "Less-Than-Fair-Value and Countervailing Duty Investigations of Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Scope Comments Decision Memorandum for the Preliminary Determination," dated March 24, 2025 (Preliminary Scope Decision Memorandum).

<sup>7</sup> *Id.* at 10.

<sup>8</sup> See *Initiation Notice*, 89 FR at 80202.

<sup>9</sup> See Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, "Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations Involving Non-Market Economy Countries," (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at <https://enforcement.trade.gov/policy/bull05-1.pdf>.

<sup>10</sup> See Preliminary Decision Memorandum at the section, "Separate Rate Determinations," for further discussion.

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent) <sup>11</sup>
Suheung Vietnam Co., Ltd .....	Suheung Vietnam Co., Ltd .....	9.99	8.35
Vietnam-Wide Entity .....		9.99	8.35

**Suspension of Liquidation**

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) for the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Vietnam producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the Vietnam-wide entity; and (3) for all third-country exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Vietnam producer/exporter combination (or the Vietnam-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce

has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the “Preliminary Determination” chart of estimated weighted-average dumping margins above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

**Disclosure**

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the

preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

**Verification**

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

**Public Comment**

Case briefs or other written comments, excluding scope comments, may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.<sup>12</sup> A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. 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.<sup>13</sup> Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.<sup>14</sup>

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 investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.<sup>15</sup> Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We

<sup>11</sup> We are applying an export subsidy offset to the mandatory respondent. See *Hard Empty Capsules from the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination*, 90 FR 14240 (March 31, 2025) (CVD Preliminary Determination), and accompanying Preliminary Decision

Memorandum. For the Vietnam-wide entity, we have determined the amount of the offset based on the CVD Preliminary Determination.

<sup>12</sup> See 19 CFR 351.309(c)(1)(i); see also 19 CFR 351.303 (for general filing requirements).

<sup>13</sup> 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*).

<sup>14</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>15</sup> We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the 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).<sup>16</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

#### Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

In May 2025, pursuant to 19 CFR 351.210(e)(2), the petitioner<sup>17</sup> and SHVN requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.<sup>18</sup>

Additionally, pursuant to 19 CFR 351.210(b)(2)(i) and (e)(1), the petitioner and SHVN requested that Commerce postpone the final determination and that provisional measures be extended up to 135 days contingent upon negative preliminary determinations in these investigations.<sup>19</sup> In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

#### U.S. International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, Commerce will notify the ITC of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

#### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: May 22, 2025.

#### Christopher Abbott,

*Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

#### Appendix I

##### Scope of the Investigation

The merchandise subject to the scope of the investigation is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80

percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in hard empty capsules are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of the investigation regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of the investigation regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of the investigation regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of the investigation are those that disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the investigation is dispositive.

#### Appendix II

##### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Selection of Respondents
- V. Discussion of the Methodology
- VI. Currency Conversion
- VII. Adjustment Under Section 777A(f) of the Act
- VIII. Adjustments to the Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
- IX. Recommendation

[FR Doc. 2025–09702 Filed 5–28–25; 8:45 am]

**BILLING CODE 3510-DS-P**

<sup>16</sup> See *APO and Service Final Rule*.

<sup>17</sup> The petitioner in this proceeding is Lonza Greenwood LLC.

<sup>18</sup> See Petitioner's Letter, "Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Lonza's Request for Postponement of the Department's

Antidumping Duty Final Determinations" dated May 9, 2025; see also SHVN's Letter, "Hard Empty Capsules from Vietnam," dated May 13, 2025.

<sup>19</sup> *Id.*

**DEPARTMENT OF DEFENSE****Office of the Secretary**

[Docket ID: DoD–2024–OS–0142]

**Submission for OMB Review;  
Comment Request**

**AGENCY:** Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

**ACTION:** 30-Day information collection notice.

**SUMMARY:** The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by June 30, 2025.

**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](http://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:** Reginald Lucas, (571) 372–7574, [whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil](mailto:whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil).

**SUPPLEMENTARY INFORMATION:**

*Title; Associated Form; and OMB Number:* Police Records Check; DD Form 369; OMB Control Number 0704–0007.

*Type of Request:* Revision.  
*Number of Respondents:* 199,521.  
*Responses per Respondent:* 1.  
*Annual Responses:* 199,521.  
*Average Burden per Response:* 27 minutes.

*Annual Burden Hours:* 89,784.  
*Needs and Uses:* Title 10, United States Code, sections 504, 505, and 12102 establish minimal standards for enlistment into the Armed Forces. Among other items, these sections specifically prohibit the enlistment of those convicted of a felony. The Services have therefore developed standards which address the acceptability for Service persons with police records, adverse juvenile adjudications, or court convictions. The standards are designed to screen out categories of persons who have probability of either having serious disciplinary problems or may not be able to adjust to the disciplinary demands of the Armed Forces. This information collection is needed to

identify persons who may be undesirable for military service. The existence of a police record is one of the factors considered in establishing eligibility for enlistment or entry into highly sensitive career fields. Therefore, verification data from the individual and law enforcement agencies must be obtained before enlistment can occur. The form associated with this information collection is DD Form 369, “Police Record Check.” It is used by recruiters to inquire on applicants’ backgrounds prior to acceptance to the Armed Forces, when, in the judgment of the recruiter, an applicant may be withholding information of prior offense history.

*Affected Public:* Individuals or households.

*Frequency:* On occasion.

*Respondent’s Obligation:* Voluntary.

*DoD Clearance Officer:* Mr. Reginald Lucas.

Dated: May 22, 2025.

**Stephanie J. Bost,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2025–09686 Filed 5–28–25; 8:45 am]

**BILLING CODE 6001–FR–P**

**DEPARTMENT OF ENERGY****Critical Material List; Addition of Metallurgical Coal Used for Steelmaking**

**AGENCY:** Office of Fossil Energy and Carbon Management, Department of Energy.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Energy (DOE) is issuing this notice to advise the public that DOE has added metallurgical coal used for steelmaking to the DOE Critical Material List. This notice also provides the link to the assessment that forms the justification for including metallurgical coal used in steelmaking on the Critical Material List. Meeting the policy goal of U.S. steel dominance will require dramatic increases in domestic metallurgical coal production and use and thereby supports the determination that metallurgical coal used for steelmaking is a DOE critical material.

**FOR FURTHER INFORMATION CONTACT:** Questions may be addressed to David Alleman or Burt Thomas, U.S. Department of Energy (FE–32), Office of Research and Development, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington,

DC 20585; (202) 586–0147 or (240) 243–3991; [david.alleman@hq.doe.gov](mailto:david.alleman@hq.doe.gov) or [burt.thomas@hq.doe.gov](mailto:burt.thomas@hq.doe.gov).

**SUPPLEMENTARY INFORMATION:** Section 7002(a)(2) of the Energy Act of 2020 defines “critical materials” to be: (A) any non-fuel mineral, element, substance, or material that the Secretary of Energy determines (i) has high risk for supply chain disruption; and (ii) serves an essential function in one or more energy technologies, including technologies that produce, transmit, store, and conserve energy [referred to here as a critical material for energy]; or (B) a critical mineral [as designated by the Secretary of the Interior].<sup>1</sup>

On August 4, 2023, DOE published its “Notice of Final Determination on 2023 DOE Critical Materials List” (hereinafter Critical Materials List).<sup>2</sup> The Critical Materials List includes the following:

- *Critical materials for energy:* aluminum, cobalt, copper\*, dysprosium, electrical steel\* (grain-oriented electrical steel, non-grain-oriented electrical steel, and amorphous steel), fluorine, gallium, iridium, lithium, magnesium, natural graphite, neodymium, nickel, platinum, praseodymium, terbium, silicon\*, and silicon carbide\*.

- *Critical minerals:* The Secretary of the Interior, acting through the Director of the U.S. Geological Survey (USGS), published a 2022 final list of critical minerals that includes the following 50 minerals: “Aluminum, antimony, arsenic, barite, beryllium, bismuth, cerium, cesium, chromium, cobalt, dysprosium, erbium, europium, fluorspar, gadolinium, gallium, germanium, graphite, hafnium, holmium, indium, iridium, lanthanum, lithium, lutetium, magnesium, manganese, neodymium, nickel, niobium, palladium, platinum, praseodymium, rhodium, rubidium, ruthenium, samarium, scandium, tantalum, tellurium, terbium, thulium, tin, titanium, tungsten, vanadium, ytterbium, yttrium, zinc, and zirconium.”<sup>3</sup>

The critical materials for energy included on the Critical Material List are based on the criticality assessed in the short- and medium-term. A detailed description of DOE’s methodology can

<sup>1</sup> Section 7002(a)(2) of the Energy Act of 2020 is codified at 30 U.S.C. 1606(a)(2).

<sup>2</sup> U.S. Dep’t of Energy, *Notice of Final Determination on 2023 DOE Critical Materials List*, 88 FR 51792 (August 4, 2023), <https://www.federalregister.gov/documents/2023/08/04/2023-16611/notice-of-final-determination-on-2023-doe-critical-materials-list>.

<sup>3</sup> The asterisks (\*) indicates materials not designated as critical minerals by the Secretary of Interior.

be found in its *Critical Minerals Assessment* published on its website in July 2023.<sup>4</sup>

By this Notice, the Secretary of Energy advises the public of the addition of metallurgical coal to DOE's Critical Material List. The assessment<sup>5</sup> that forms the justification for including metallurgical coal used in the production of steel on the Critical Material List can be found on DOE's website: <https://www.energy.gov/cmm/what-are-critical-materials-and-critical-minerals>. The assessment concludes that the current U.S. steel market and its reliance on metallurgical coal puts the industry on track for significant import reliance. Meeting the policy goal of U.S. steel dominance will require dramatic increases in domestic metallurgical coal production and use, and thereby supports the determination that coal used for steelmaking is a DOE critical material. Furthermore, this action directly supports the President's policy goals of reinvigorating the U.S. coal industry and achieving American energy dominance as explained in Executive Order 14261, "Reinvigorating America's Beautiful Clean Coal Industry and Amending Executive Order 14241".<sup>6</sup>

#### Signing Authority

This document of the Department of Energy was signed on May 22, 2025, by Tala Goudarzi, Principal Deputy Assistant Secretary, Office of Fossil Energy and Carbon Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

<sup>4</sup> U.S. Dept't of Energy, *Critical Materials Assessment* (July 2023), [https://www.energy.gov/sites/default/files/2023-07/doe-critical-material-assessment\\_07312023.pdf](https://www.energy.gov/sites/default/files/2023-07/doe-critical-material-assessment_07312023.pdf).

<sup>5</sup> U.S. Dep't of Energy, *The Intrinsic Role of Coal in Achieving Steel Dominance* (May 2025), [<https://www.energy.gov/cmm/what-are-critical-materials-and-critical-minerals>].

<sup>6</sup> E.O. 14261 of April 8, 2025, *Reinvigorating America's Beautiful Clean Coal Industry and Amending Executive Order 14241*, 90 FR 15517 (April 14, 2025), <https://www.govinfo.gov/content/pkg/FR-2025-04-14/pdf/2025-06380.pdf>.

Signed in Washington, DC, on May 22, 2025.

**Treana V. Garrett,**

*Federal Register Liaison Officer, U.S. Department of Energy.*

[FR Doc. 2025-09607 Filed 5-28-25; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Combined Notice of Filings

Take notice that the commission received the following accounting Request filings:

#### Filings Instituting Proceedings

*Docket Numbers:* AC25-101-000.  
*Applicants:* MDE Midstream, LLC.  
*Description:* MDE Midstream, LLC submits request for approval of proposed journal entries re acquisition of Medallion Midstream Services, LLC, et al. by Plains Oryx Permian Basin Pipeline LLC on 02/02/2025.  
*Filed Date:* 5/21/25.  
*Accession Number:* 20250521-5174.  
*Comment Date:* 5 p.m. ET 6/11/25.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

*Docket Numbers:* RP25-903-000.  
*Applicants:* Rover Pipeline LLC.  
*Description:* 4(d) Rate Filing: Houskeeping Filing on 5-22-25 to be effective 6/22/2025.  
*Filed Date:* 5/22/25.  
*Accession Number:* 20250522-5039.  
*Comment Date:* 5 p.m. ET 6/3/25.

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.

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, community organization, 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](mailto:OPP@ferc.gov).

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2025-09666 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 10806-015]

#### City of Holyoke Gas & Electric Department; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Extension of License Term.
- b. *Project No.:* P-10806-015.
- c. *Date Filed:* May 14, 2025.
- d. *Applicant:* City of Holyoke Gas & Electric Department.
- e. *Name of Project:* Station No. 5 Hydroelectric Project (P-10806).
- f. *Location:* The project is located on the Connecticut River in the City of Holyoke, Hampden County, Massachusetts.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.
- h. *Applicant Contact:* Sarah LaRose, Senior Project Engineer, City of Holyoke Gas & Electric Department, 99 Suffolk Street, Holyoke, MA 01040, (413) 9409, [slrose@hged.com](mailto:slrose@hged.com).
- i. *FERC Contact:* Rebecca Martin, (202) 502-6012, [rebecca.martin@ferc.gov](mailto:rebecca.martin@ferc.gov).
- j. *Deadline for filing comments, motions to intervene, and protests:* June 20, 2025.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <https://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the

eComment system at <https://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@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: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P-10806-015. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

*k. Description of Request:* The City of Holyoke Gas & Electric Department, licensee for the Station No. 5 Hydroelectric Project No. 10806 filed a request with the Commission for a 9-year, 3-month extension of the 40-year license for the project, currently expiring on May 3, 2030. The new expiration date for the project would be August 31, 2039. The licensee requests the extension to align the project license expiration date with the Holyoke Project No. 2004 and the Holyoke Number 4 Project No. 7758. The licensee states that aligning the expiration dates for the projects would allow a more synchronized approach to the relicensing process because the projects are all interdependent.

*l. Locations of the Application:* This filing may be viewed on the Commission's website at <https://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. You may also register online at <https://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects.

For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

*m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.*

*n. Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

*o. Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

*p. 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, 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](mailto:OPP@ferc.gov).*

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09604 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2611-093]

#### Hydro Kennebec, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380, Commission staff reviewed Hydro Kennebec, LLC's request for a temporary variance of the license for the Hydro-Kennebec Hydroelectric Project No. 2611 and has prepared an Environmental Assessment (EA) for the project.<sup>1</sup> The licensee proposes to install 3-foot-high flashboards at the project instead of the normal 6-foot-high flashboards to lower the reservoir elevation by 3 feet (elevation of 78 feet U.S. Geological Survey Datum) to allow for repairs to a spillway gate. The temporary variance would begin immediately and last until the gate is repaired, but no later than December 31, 2025. The Hydro-Kennebec Project is located on the Kennebec River in Kennebec and Somerset counties, Maine and does not occupy federal land.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed temporary variance, alternatives to the proposed action, and concludes that the temporary variance, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at <https://www.ferc.gov> using the "eLibrary" link. Enter the docket number (P-2611) in the docket number field to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

You may also register online at <https://www.ferc.gov/docs-filing/esubscription.asp> 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

<sup>1</sup> The unique identification number for documents relating to this environmental review is EAXX-019-20-000-1746012887.

Commission proceedings. OPP can help members of the public, including landowners, 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*.

For further information, contact Steven Sachs at 202-502-8666 or *steven.sachs@ferc.gov*.

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09672 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2071-090]

#### PacifiCorp; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380, Commission staff reviewed PacifiCorp's application for a license amendment of the Yale Hydroelectric Project No. 2071 and has prepared an Environmental Assessment (EA) for the project.<sup>1</sup> The licensee proposes to install a rock filter and drain berm on the downstream side of the Yale saddle dam. A new toe ditch would collect seepage intercepted by the filter and drain berm and route it into a drainage swale below the dam. The licensee also proposes to place additional riprap on the upstream side of the Yale saddle dam, requiring a 2-week-long reservoir drawdown. The Yale Hydroelectric Project is located on the Lewis River in Clark and Cowlitz counties, Washington and occupies federal land administered by the U.S. Bureau of Land Management.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed modifications to the Yale saddle dam, alternatives to the proposed action, and concludes that the proposed amendment, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

<sup>1</sup> The unique identification number for documents relating to this environmental review is EAXX-019-20-000-1727194731.

The EA may be viewed on the Commission's website at <https://www.ferc.gov> using the "elibrary" link. Enter the docket number (P-2071) in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

You may also register online at <https://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by June 23, 2025.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support. 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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket numbers P-2071-090.

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, 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*.

For further information, contact Steven Sachs at 202-502-8666 or *steven.sachs@ferc.gov*.

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09671 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 15366-000]

#### Town of Stowe Electric Department; Notice of Intent To Prepare an Environmental Assessment

On July 2, 2024, the Town of Stowe Electric Department filed an application for an exemption from licensing for the 150-kilowatt Smith's Falls Hydroelectric Project No. 15366. The project would be located on the Little River in Lamoille County, Vermont.

In accordance with the Commission's regulations, on March 13, 2025, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that exempting the project from licensing would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an environmental assessment (EA) on the application to exempt the project from licensing.<sup>1</sup>

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final decision on the exemption application.

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, community organizations, 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*.

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	September 15, 2025.

Any questions regarding this notice may be directed to Joshua Dub by

<sup>1</sup> For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1744215115.

telephone at (202) 502-8138 or by email at [Joshua.Dub@ferc.gov](mailto:Joshua.Dub@ferc.gov).

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09674 Filed 5-28-25; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 14867-003]

#### Scott's Mill Hydro, LLC; Notice of Application Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* 14867-003.

c. *Date filed:* March 21, 2022.

d. *Applicant:* Scott's Mill Hydro, LLC (Scott's Mill).

e. *Name of Project:* Scott's Mill Hydroelectric Project (Scott's Mill Project or project).

f. *Location:* On the James River in the City of Lynchburg and Bedford and Amherst Counties, Virginia.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Mr. Mark Fendig, Luminaire Technologies, Inc., 9932 Wilson Highway, Mouth-of-Wilson, VA 24363; phone: (540) 320-6762.

i. *FERC Contact:* Jody Callihan at (202) 502-8278, or [jody.callihan@ferc.gov](mailto:jody.callihan@ferc.gov).

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* on or before 5:00 p.m. Eastern Time on July 21, 2025; reply comments are due on or before 5:00 p.m. Eastern Time on September 4, 2025.

The Commission strongly encourages electronic filing. Please file comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at <https://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@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, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, 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: Scott's Mill Hydroelectric Project (P-14867-003).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

1. The Scott's Mill Hydroelectric Project would consist of: (1) an existing masonry dam containing two spillways separated by a 25-foot-wide stone pier, with one 735-foot-long, 15-foot-high overflow spillway and the other a 140-foot-long, 16-foot-high arch-section spillway; (2) an impoundment with a surface area of 305 acres at the normal pool elevation of 516.4 feet North American Vertical Datum of 1988 (NAVD 88); (3) a new modular powerhouse containing nine generating units with a total installed capacity of 4.5 megawatts that would be installed immediately downstream of the existing arch-section spillway of the dam; (4) a new 1,200-foot-long overhead transmission line; and (5) appurtenant facilities.

To increase flow through the modular powerhouse, Scott's Mill proposes to remove the top 6.8 feet of the existing arch-section spillway of the dam and add 2-foot-high flashboards to the existing overflow spillway. On August 9, 2022, Scott's Mill filed a Settlement Agreement for the project's licensing proceeding, on behalf of itself, the U.S. Fish and Wildlife Service (FWS), and Virginia Department of Wildlife Resources (Virginia DWR). As part of the Settlement Agreement, Scott's Mill proposes to: (1) operate the project in a run-of-river mode, with a 1-inch veil flow [~40 cubic feet per second (cfs)] over the main spillway at all times; (2) implement an impoundment refill

protocol whereby 90% of the project inflow is released downstream when refilling the impoundment following a drawdown; (3) install and operate, from March 1 through November 30 of each year, two permanent fishways (one on each bank of the James River) to facilitate the upstream passage of American eel and sea lamprey; (4) install upstream passage for American shad and riverine (resident) fish species when requested by Interior; (5) provide a downstream fish passage flow of 225 cfs (parallel to the trash racks, with a 2-inch clear spacing) to guide fish towards a downstream fish passage structure; (6) install trash racks with a 0.75-inch clear spacing if the downstream fish passage effectiveness studies, planned for post-licensing, indicate the target downstream passage survival rate of 95% cannot be achieved with the proposed methods (*i.e.*, a 225-cfs downstream fish passage flow and trash racks with a 2-inch clear spacing); (7) develop a fishway operation and maintenance plan, streamflow and water level monitoring plan, and recreation management plan; (8) implement the Invasive Species Management Plan, Northern Long-Eared Bat Management Plan, and Bald Eagle Management Plan filed with the Settlement Agreement; and (9) conduct the following post-licensing studies in cooperation with FWS and Virginia DWR: (a) upstream and downstream fish passage effectiveness, (b) water quality, and (c) wetted perimeter and flow demonstration. While not part of the Settlement Agreement, Scott's Mill also proposes, in its license application, to: (1) direct half of the powerhouse outflow to the main channel (*i.e.*, to the east of Anthony Island); and (2) develop an erosion and sediment control plan and wetlands mitigation plan. The estimated annual energy production of the project is 20,700 megawatt-hours.

m. A copy of the application can 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 (*i.e.*, P-14867). For assistance, contact FERC Online Support (see item j above).

All filings must (1) bear in all capital letters the title "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name of the person submitting the filing; and (4) otherwise comply with

the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

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, community organizations, 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](mailto:OPP@ferc.gov).

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 (see item j above).

o. The applicant must file no later than 60 days following the date of issuance of this notice: (1) a copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

*p. Procedural Schedule:*

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Deadline for filing comments, recommendations, terms and conditions, and prescriptions.	July 21, 2025.
Deadline for filing reply comments.	September 4, 2025.

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**  
*Secretary.*

[FR Doc. 2025–09667 Filed 5–28–25; 8:45 am]

**BILLING CODE 6717–01–P**

**DEPARTMENT OF ENERGY**

**Federal Energy Regulatory Commission**

[Project No. 2574–092]

**Merimil Limited Partnership; Notice Of Reasonable Period of Time for Water Quality Certification Application**

On May 13, 2025, Merimil Limited Partnership submitted to the Federal Energy Regulatory Commission (Commission) documentation from the Maine Department of Environmental Protection (Maine DEP) that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Merimil Limited Partnership, in conjunction with the above captioned project on May 8, 2025. Pursuant to the Commission’s regulations,<sup>1</sup> we hereby notify Maine DEP of the following.

*Date of Receipt of the Certification Request:* May 8, 2025.

*Reasonable Period of Time to Act on the Certification Request:* One year, May 8, 2026.

If Maine DEP fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**  
*Secretary.*

[FR Doc. 2025–09600 Filed 5–28–25; 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:* EC25–89–000.  
*Applicants:* Entergy Louisiana, LLC, Entergy Mississippi, LLC, System Energy Resources, Inc.

*Description:* Joint Application for Authorization Under Section 203 of the Federal Power Act of Entergy Louisiana, LLC, et al.

*Filed Date:* 5/19/25.

*Accession Number:* 20250519–5242.

*Comment Date:* 5 p.m. ET 6/9/25

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG25–339–000.

<sup>1</sup> 18 CFR 4.201(e).

*Applicants:* Hecate Energy Outpost Solar LLC.

*Description:* Hecate Energy Outpost Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5026.

*Comment Date:* 5 p.m. ET 6/12/25.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER25–1806–001.

*Applicants:* Tucson Electric Power Company.

*Description:* Compliance filing: Supplement to Order 904 Compliance Filing to be effective 6/26/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5071.

*Comment Date:* 5 pm ET 6/12/25.

*Docket Numbers:* ER25–1980–000.

*Applicants:* Clinton Solar, LLC.

*Description:* Supplement to April 17, 2025, Clinton Solar LLC tariff filing.

*Filed Date:* 5/15/25.

*Accession Number:* 20250515–5196.

*Comment Date:* 5 p.m. ET 6/5/25.

*Docket Numbers:* ER25–2278–001.

*Applicants:* NSTAR Electric Company.

*Description:* Tariff Amendment: Fe Taft LLC—Related Facilities Agreement v2 to be effective 5/22/2025.

*Filed Date:* 5/21/25.

*Accession Number:* 20250521–5151.

*Comment Date:* 5 p.m. ET 6/11/25.

*Docket Numbers:* ER25–2281–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* 205(d) Rate Filing: Amendment to ISA, SA No. 6771; Queue No. AE2–019 to be effective 7/21/2025.

*Filed Date:* 5/21/25.

*Accession Number:* 20250521–5143.

*Comment Date:* 5 p.m. ET 6/11/25.

*Docket Numbers:* ER25–2282–000.

*Applicants:* Public Service Company of New Mexico.

*Description:* 205(d) Rate Filing: Transmission Construction and Interconnection Agreement to be effective 5/7/2025.

*Filed Date:* 5/21/25.

*Accession Number:* 20250521–5166.

*Comment Date:* 5 p.m. ET 6/11/25.

*Docket Numbers:* ER25–2283–000.

*Applicants:* Choctaw Fields Solar Project, LLC.

*Description:* Initial Rate Filing: Market-Based Rate Application to be effective 7/21/2025.

*Filed Date:* 5/21/25.

*Accession Number:* 20250521–5168.

*Comment Date:* 5 p.m. ET 6/11/25.

*Docket Numbers:* ER25–2284–000.

*Applicants:* American Electric Power Service Corporation, Ohio Power Company.

*Description:* 205(d) Rate Filing: Ohio Power Company submits tariff filing per 35.13(a)(2)(iii): AEP submits revised ILDSA—SA No. 1420 ATT 1 to be effective 8/1/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5013.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2285–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* 205(d) Rate Filing: 1875R8 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 5/1/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5015.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2286–000.

*Applicants:* New York State Electric & Gas Corporation, New York Independent System Operator, Inc.

*Description:* 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): NYISO–NYSEG Joint 205: Amended LGIA High Bridge Wind (SA2657) (CEII) to be effective 5/8/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5034.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2287–000.

*Applicants:* Northern States Power Company, a Wisconsin corporation.

*Description:* 205(d) Rate Filing: 2025–05–22 NSP–RFMU—Project Badger—FSA—0.0.0 to be effective 5/23/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5045.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2288–000.

*Applicants:* Commonwealth Edison Company.

*Description:* 205(d) Rate Filing: ComEd submits Amended IA SA No. 4212 to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5075.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2289–000.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* 205(d) Rate Filing: 2025–05–22\_SA 4322 MidAmerican–MidAmerican 1st Rev GIA (J1530) to be effective 5/20/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5088.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2290–000.

*Applicants:* Alabama Power Company, Georgia Power Company, Mississippi Power Company.

*Description:* 205(d) Rate Filing: Alabama Power Company submits tariff

filing per 35.13(a)(2)(iii): PowerSouth NITSA Amendment (Add Rifle Range Delivery Point) to be effective 4/23/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5093.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2291–000.

*Applicants:* Cherrywood Solar I, LLC. *Description:* 205(d) Rate Filing: Application for Market-Based Rate Authorization to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5099.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2292–000.

*Applicants:* Excelsior Energy Center, LLC.

*Description:* 205(d) Rate Filing: Application for Market-Based Rate Authorization—Excelsior Energy Ctr. to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5101.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2293–000.

*Applicants:* Sebree Solar II, LLC.

*Description:* 205(d) Rate Filing: Application for Market-Based Rate Authorization—Sebree Solar II to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5104.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2294–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* 205(d) Rate Filing: 4193R2 City of Paris NITSA NOA to be effective 8/1/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5109.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2295–000.

*Applicants:* Tri-State Generation and Transmission Association, Inc.

*Description:* 205(d) Rate Filing: Amendment to Tri-State WAPA–RMR Balancing Authority Service Agreement to be effective 4/23/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5110.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2296–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* 205(d) Rate Filing: Submission of Revisions to Implement the Expedited Resource Adequacy Study to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5121.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2297–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* 205(d) Rate Filing: SPP–MISO JOA Revisions to Include SPP

ERAS in JTIQ Process to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5137.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* ER25–2298–000.

*Applicants:* Midcontinent Independent System Operator, Inc. *Description:* 205(d) Rate Filing: 2025–05–22\_MISO–SPP JOA re: SPP ERAS to be effective 7/22/2025.

*Filed Date:* 5/22/25.

*Accession Number:* 20250522–5142.

*Comment Date:* 5 p.m. ET 6/12/25.

*Docket Numbers:* TX25–5–000.

*Applicants:* Seattle City Light.

*Description:* Application for Order Directing Transmission Service and Interconnection of Facilities of Seattle City Light under TX25–5.

*Filed Date:* 5/20/25.

*Accession Number:* 20250520–5190.

*Comment Date:* 5 p.m. ET 6/10/25.

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.

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, community organizations, 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](mailto:OPP@ferc.gov).

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**

Secretary.

[FR Doc. 2025–09673 Filed 5–28–25; 8:45 am]

**BILLING CODE 6717–01–P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Project No. 8377–030]

**Isabella Partners; Notice of Availability of Environmental Assessment**

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380, Commission staff reviewed Isabella Partners' application for a capacity amendment of the Isabella Hydroelectric Project No. 8377 and have prepared an Environmental Assessment (EA) for the project.<sup>1</sup> The licensee proposes to construct and operate a new 5-megawatt (MW) generating unit which would be located in a new 40-foot-by-45-foot concrete structure adjacent to the existing powerhouse, resulting in an increase of the project's total installed capacity from 12.8 MW to 17.8 MW. The Isabella Hydroelectric Project located on the Kern River in Kern County, California at the U.S. Army Corps of Engineers (Corps)' Isabella Dam on lands administered by the Corps.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed new generating unit, alternatives to the proposed action, and concludes that the proposed capacity amendment, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at <https://www.ferc.gov> using the "elibrary" link. Enter the docket number (P–8377–030) in the docket number field to access the document. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by June 20, 2025.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://www.ferc.gov/docs-filing/>

[ecomment.asp](https://www.ferc.gov/docs-filing/ecomment.asp). Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support. 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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket numbers P–8377–030.

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, 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](mailto:OPP@ferc.gov).

For further information, contact Zeena Aljibury at 202–502–6065 or [zeena.aljibury@ferc.gov](mailto:zeena.aljibury@ferc.gov).

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2025–09603 Filed 5–28–25; 8:45 am]

**BILLING CODE 6717–01–P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Project No. 3409–032]

**Boyne USA, Inc.; Notice of Meeting**

a. *Project Name and Number:* Boyne River Hydroelectric Project No. 3409–032.

b. *Applicant:* Boyne USA, Inc.

c. *Date and Time of Meeting:* Thursday, June 5, 2025 from 10:00 a.m. to 11:00 a.m. Eastern Time.

d. *FERC Contact:* Michael Davis at (202) 502–8339 or [michael.davis@ferc.gov](mailto:michael.davis@ferc.gov).

e. *Purpose of Meeting:* Commission staff will hold a meeting with representatives from the Little Traverse Bay Bands of Odawa Indians to discuss fisheries, erosion, and water quality in

regards to the Boyne River Hydroelectric Project relicensing. The meeting will be held virtually via Microsoft Teams.

f. Intervenor in the referenced proceeding may attend the meeting as observers; however, participation will be limited to representatives from the Little Traverse Bay Bands of Odawa Indians and Commission staff. If meeting attendees decide to disclose information about a specific location which could create a risk or harm to an archaeological site or Native American cultural resource, attendees other than Little Traverse Bay Bands of Odawa Indians and Commission staff will be excused for that portion of the meeting.

g. A summary of the meeting will be placed in the public record of this proceeding. As appropriate, the meeting summary will include both a public, redacted version that excludes any information about the specific location of the archeological site or Native American cultural resource and an unredacted privileged version. Intervenor planning to attend the meeting should notify Michael Davis at (202) 502–8339 or [michael.davis@ferc.gov](mailto:michael.davis@ferc.gov) by Tuesday, June 3, 2025 to RSVP and to receive specific instructions for logging in to the meeting.

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2025–09602 Filed 5–28–25; 8:45 am]

**BILLING CODE 6717–01–P**

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Project No. 2611–091]

**Hydro Kennebec, LLC; Notice of Reasonable Period of Time for Water Quality Certification Application**

On May 13, 2025, Hydro Kennebec, LLC submitted to the Federal Energy Regulatory Commission (Commission) documentation from the Maine Department of Environmental Protection (Maine DEP) that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Hydro Kennebec, LLC, in conjunction with the above captioned project on May 8, 2025. Pursuant to the Commission's regulations,<sup>1</sup> we hereby notify Maine DEP of the following.

*Date of Receipt of the Certification Request:* May 8, 2025.

<sup>1</sup> The unique identification number for documents relating to this environmental review is EAXX–019–20–000–1725634364.

<sup>1</sup> 18 CFR 4.201(e).

*Reasonable Period of Time To Act on the Certification Request:* One year, May 8, 2026.

If Maine DEP fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(41) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2025-09601 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2325-100]

#### **Brookfield White Pine Hydro, LLC; Notice of Reasonable Period of Time for Water Quality Certification Application**

On May 13, 2025, Brookfield White Pine Hydro, LLC submitted to the Federal Energy Regulatory Commission (Commission) documentation from the Maine Department of Environmental Protection (Maine DEP) that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Brookfield White Pine Hydro, LLC, in conjunction with the above captioned project on May 8, 2025. Pursuant to the Commission's regulations,<sup>1</sup> we hereby notify Maine DEP of the following.

*Date of Receipt of the Certification Request:* May 8, 2025.

*Reasonable Period of Time To Act on the Certification Request:* One year, May 8, 2026.

If Maine DEP fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**

*Secretary.*

[FR Doc. 2025-09599 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. CP25-60-000]

#### **Mountain Valley Pipeline, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Mountain Valley Pipeline Southgate Amendment 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 Mountain Valley Pipeline (MVP) Southgate Amendment Project (Amendment Project) involving construction and operation of facilities by Mountain Valley Pipeline, LLC (MVP) in Pittsylvania County, Virginia and Rockingham County, North Carolina. The Commission will use this environmental document in its decision-making process to determine whether the Amendment Project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the Amendment 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 Certificate of Public Convenience and Necessity. 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 June 21, 2025. 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 Amendment Project to the Commission before the opening of this docket on February 3, 2025, you will need to file those comments in Docket No. CP25-60-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Amendment Project. State and local government representatives should notify their constituents of this proposed Amendment 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 proposed 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 Amendment 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.

MVP provided landowners with a fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" which 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](http://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

<sup>1</sup> 18 CFR 4.201(e).

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](mailto: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](http://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](http://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";

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the Amendment Project docket number (CP25-60-000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852; or

(4) In lieu of sending written comments, the Commission invites you to attend one of the public scoping sessions its staff will conduct in the Amendment Project area, scheduled as follows:

Date and time	Location
Monday, June 16, 2025, 5:00 to 8:00 p.m.	Olde Dominion Agricultural Complex, 19783 U.S. Highway 29, Chatham, VA 24531, 434-432-8026.
Tuesday, June 17, 2025, 5:00 to 8:00 p.m.	Rockingham County Community College, ADT Auditorium, 560 County Home Road, Wentworth, NC 27375, 336-342-4261.

The primary goal of these scoping sessions 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.

Each scoping session is scheduled from 5:00 p.m. to 8:00 p.m. Eastern Time. 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, starting at 5:00 p.m. Comments will be taken until 8:00 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 7:30 p.m. Please see Appendix 1 for additional information on the session format and conduct.<sup>1</sup> Your oral comments will be recorded by a court reporter (with FERC staff or FERC 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 of 5 minutes may be implemented for each commentor. 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 MVP will also be present to answer project-specific questions.

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.

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

<sup>1</sup> 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](http://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](mailto:FercOnlineSupport@ferc.gov) or call toll free, (866) 208-3676 or TTY (202) 502-8659.

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, community organizations, 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](mailto:OPP@ferc.gov).

### Summary of the Proposed Amendment Project

In February 2020, FERC issued a final Environmental Impact Statement (EIS) that analyzed the Southgate Project. On June 18, 2020, the Commission authorized the Southgate Project. MVP further evaluated the Southgate Project and proposes modifications as part of the Amendment Project.<sup>2</sup> On February 3, 2025, MVP filed an application with FERC for the Amendment Project in Docket No. CP25-60-000.

The Amendment Project includes the following modifications to the previously authorized Southgate Project.

- The Lambert Compressor Station has been removed and is no longer proposed;
- The length of the pipeline has decreased from 75.1 miles to 31.3 miles;
- The pipeline diameter would increase from 16- and 24-inch diameters to 30-inch diameter;
- The pipeline's operating capacity would increase from 375,000 dekatherms per day (Dth/d) to 550,000 Dth/d;
- The Southgate Project included four meter (interconnect) stations. The Amendment Project would also include four meter (interconnect) stations, one of which would include a pig launcher and one which would include a pig receiver. Two of the four meter stations are new facilities identified for the Amendment Project, but are entirely located within Southgate Project certificated workspace;<sup>3</sup>
- Six route deviations from the Southgate Project (totaling 3.1 miles) have been incorporated into the Amendment Project. Centerline shifts for the route deviations generally range

<sup>2</sup> Construction of the Southgate Project has not yet started.

<sup>3</sup> A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

from 25 feet to about 1,410 feet, for engineering and environmental reasons;

- Eight mainline valves were in the Southgate Project; four have been removed and are no longer proposed;
- Four cathodic protection groundbeds were in the Southgate Project; two have been removed and are no longer proposed;
- 13.5 acres of additional temporary workspaces were added;
- Two new contractor yards were added; and
- 3.8 acres of temporary access roads were added.

The general location of the Amendment Project facilities is shown in Appendix 2.

### Land Requirements for Construction

The modifications associated with the Amendment Project would result in a total impact footprint of approximately 51.0 acres of land outside of the workspace that was previously certificated for the Southgate Project. This includes the pipeline; additional temporary workspaces; contractor yards; and new or improved access roads. The modifications associated with the Amendment Project would result in 11.3 acres of permanent impact for operation of the Amendment Project. The Southgate Project, as approved by the Commission in 2020, would have affected 1,465.9 acres for construction and 450.0 acres for operation.

### NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed Amendment 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;
- air quality and noise; and
- reliability and safety.

Commission staff have already identified several issues that deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by MVP. This preliminary list of issues may change based on your comments and our analysis:

- waterbodies and wetlands;
- forested areas;
- cumulative impacts;
- pipeline safety associated with the increased diameter and capacity.

Commission staff will also evaluate reasonable alternatives to the proposed

Amendment Project or portions of the Amendment 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.

Following this scoping period, Commission staff will 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 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 decision regarding the proposed Amendment Project. If Commission staff prepares an EIS, a "Notice of Intent to Prepare an EIS/Notice of Schedule" will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which 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 eLibrary<sup>4</sup> 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 of this Amendment Project to formally cooperate in the preparation of the environmental document.<sup>5</sup> 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. Fish and Wildlife Service's Virginia and North Carolina Ecological Services Field Offices have expressed their

intention to participate as a cooperating agency 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 Amendment Project's potential effects on historic properties.<sup>6</sup> The environmental document for this Amendment Project will document 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; environmental and public interest groups; Native American Tribes; newspapers; libraries; and other interested parties. 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 Amendment Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Amendment 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 proposed Amendment 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](mailto:GasProjectAddressChange@ferc.gov) stating your request. You must include the docket number CP25-60-000 in your request. If you are requesting a change to your address, please be sure

<sup>4</sup> For instructions on connecting to eLibrary, refer to the last page of this notice.

<sup>5</sup> Cooperating agency responsibilities are addressed in section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

<sup>6</sup> The Advisory Council on Historic Preservation's regulations are at 36 CFR 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.

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).

#### Additional Information

Additional information about the Amendment Project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at [www.ferc.gov](http://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](mailto:FercOnlineSupport@ferc.gov) or (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: May 22, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09669 Filed 5-28-25; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 14861-002]

#### FFP Project 101, LLC; Notice of Meeting

a. *Project Name and Number:* Goldendale Energy Storage Project No. 14861-002.

b. *Applicant:* FFP Project 101, LLC.

c. *Date and Time of Meeting:* Wednesday, June 4, 2025, from 11:00 a.m. to 1:00 p.m. Eastern Standard Time (8:00 a.m. to 10:00 a.m. Pacific Standard Time).

d. *FERC Contact:* Michael Tust, (202) 502-6522, [michael.tust@ferc.gov](mailto:michael.tust@ferc.gov).

e. *Purpose of Meeting:* As requested by the Advisory Council on Historic Preservation (Advisory Council), Commission staff will hold a meeting with representatives from the Advisory Council, Washington State Historic Preservation Office (Washington SHPO),

Oregon State Historic Preservation Office (Oregon SHPO), and affected Native American Tribes to discuss revisions to Commission staff's draft Programmatic Agreement (PA) for the proposed Goldendale Energy Storage Project pursuant to section 106 of the National Historic Preservation Act. Specifically, Commission staff will discuss revisions made to the draft PA since the last meeting was held on May 7, 2025. The meeting will be held virtually via Microsoft Teams.

f. Intervenor in the referenced proceeding may attend the meeting as observers; however, participation will be limited to representatives from the Advisory Council, Washington SHPO, Oregon SHPO, Tribes, and Commission staff. If meeting attendees decide to disclose information about a specific location which could create a risk or harm to an archaeological site or Native American cultural resource, attendees other than the Advisory Council, Washington SHPO, Oregon SHPO, Tribal representatives, and Commission staff will be excused for that portion of the meeting. A summary of the meeting will be placed in the public record of this proceeding. As appropriate, the meeting summary will include both a public, redacted version that excludes any information about the specific location of the archeological site or Native American cultural resource and an unredacted privileged version. Intervenor planning to attend the meeting should notify Michael Tust at (202) 502-6522 or [michael.tust@ferc.gov](mailto:michael.tust@ferc.gov) by Monday June 2, 2025, to RSVP and to receive specific instructions for logging in to the meeting.

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09605 Filed 5-28-25; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP23-968-000]

#### Elwood Energy LLC v. ANR Pipeline Company; Notice of Withdrawal of Complaint

Take notice that the sole complainant in this proceeding, Elwood Energy LLC, filed an unopposed notice of withdrawal of its complaint on April 10, 2025. On April 25, 2025, ANR Pipeline Company filed comments supporting the withdrawal. In the absence of a motion in opposition or a Commission

order disallowing the withdrawal, the withdrawal became effective on April 25, 2025, by operation of Rule 216(b) of the Commission's Rules of Practice and Procedure, 18 CFR 385.216(b) (2024). Accordingly, this proceeding is terminated.

Dated: May 21, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09606 Filed 5-28-25; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2242-159]

#### Eugene Water & Electric Board; Notice of Application To Install a Load Bank in Lieu of Turbine Bypass Valve Required Under Article 3 Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Capacity Amendment of License.

b. *Project No:* 2242-159.

c. *Date Filed:* June 21, 2021, May 16, 2024, July 3, 2024 and April 21, 2025.

d. *Applicant:* Eugene Water & Electric Board.

e. *Name of Project:* Carmen-Smith Hydroelectric Project.

f. *Location:* The project is located on the McKenzie and Smith Rivers in Lane and Linn counties, near McKenzie Bridge, Oregon, and occupies about 574 acres within the Willamette National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Patricia A. Boyle; P.O. Box 10148, Eugene, OR 97440-2148; [Patty.Boyle@eweb.org](mailto:Patty.Boyle@eweb.org); Phone: (541) 685-7406.

i. *FERC Contact:* Erich Gaedeke; Phone: (503) 552-2716; [erich.gaedeke@ferc.gov](mailto:erich.gaedeke@ferc.gov).

j. *Cooperating agencies:* With this notice, the Commission is inviting Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the

preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests:* June 23, 2025.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <https://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@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, 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P-2242-159. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request:* Eugene Water & Electric Board proposes to install an electrical load bank rather than a turbine bypass valve to minimize spill from Smith Dam and protect habitat improvement measures in the Smith Bypassed Reach. Construction of the load bank will allow for the continuous use of the Carmen Power Plant during transmission line outages to convey the required minimum flow of 800 cubic feet per second (cfs) into Trail Bridge Reservoir rather than the Smith Bypassed Reach. The load bank will dissipate electricity produced at the Carmen Power Plant equivalent to the 800 cfs required to be diverted from the Smith Bypassed Reach to protect public health and the environment against spill

events from Smith Dam. In addition, the licensee's request proposes clerical and minor substantive edits to various sections of the Aquatics Management Plan in Exhibit B of the license order to reflect the load bank alternative.

m. *Locations of the Application:* This filing may be viewed on the Commission's website at <https://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. You may also register online at <https://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. 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, 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](mailto:OPP@ferc.gov).

Dated: May 22, 2025.

**Debbie-Anne A. Reese,**  
Secretary.

[FR Doc. 2025-09670 Filed 5-28-25; 8:45 am]

**BILLING CODE 6717-01-P**

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## FEDERAL MARITIME COMMISSION

### Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984.

Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at [Secretary@fmc.gov](mailto:Secretary@fmc.gov), or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of the agreements are available through the Commission's website ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202)-523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 201429-002.

*Agreement Name:* Gemini Cooperation Agreement.

*Parties:* Hapag-Lloyd AG and Hapag-Lloyd USA, LLC (acting as a single party); Maersk A/S.

*Filing Party:* Wayne Rohde, Cozen O'Connor.

*Synopsis:* The amendment clarifies the use of space to transport dual use and military cargoes. It also adds India to the geographic scope of the Agreement.

*Proposed Effective Date:* 7/3/2025.

*Location:* <https://www2.fmc.gov/FMC/Agreements.Web/Public/AgreementHistory/86566>.

*Agreement No.:* 201454.

*Agreement Name:* The AWC-APX Vessel Sharing Agreement.

*Parties:* Korea Marine Transport Co., Ltd.; Sea Lead Shipping Pte. Ltd.; TS Container Lines Pte. Ltd.

*Filing Party:* Wayne Rohde, Cozen O'Connor.

*Synopsis:* The Agreement authorizes the parties to share vessels in the trade

between ports in China and South Korea on the one hand and Los Angeles/Long Beach on the other hand.

*Proposed Effective Date:* 5/22/2025.

*Location:* <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/88621>.

Dated: May 23, 2025.

**Alanna Beck,**

*Federal Register Alternate Liaison Officer.*

[FR Doc. 2025-09682 Filed 5-28-25; 8:45 am]

**BILLING CODE 6730-02-P**

## FEDERAL RESERVE SYSTEM

### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice, request for comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Consumer Complaint Form (FR 1379c), and Interagency Appraisal Complaint Form (FR 1379d) (collectively FR 1379; OMB No. 7100-0135).

**DATES:** Comments must be submitted on or before July 28, 2025.

**ADDRESSES:** You may submit comments, identified by FR 1379, by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/>. Follow the instructions for submitting comments, including attachments. *Preferred method.*

- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

- *Hand Delivery/Courier:* Same as mailing address.

- *Other Means:* [publiccomments@frb.gov](mailto:publiccomments@frb.gov). You must include the OMB number or the FR number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at <https://www.federalreserve.gov/apps/proposals/> without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in

Room M-4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

#### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, [nuha.elmaghrabi@frb.gov](mailto:nuha.elmaghrabi@frb.gov), (202) 452-3884.

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/review> or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 1379. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

#### Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collections, which are being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collections of information are necessary for the proper performance of the Board's

functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collections, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

#### Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collections

*Collection title:* Consumer Complaint Form (FR 1379c) and Interagency Appraisal Complaint Form (FR 1379d).

*Collection identifiers:* FR 1379c and FR 1379d.

*OMB control number:* 7100-0135.

*General description of collection:* The FR 1379c form is for consumers to submit a complaint against a financial institution. The FR 1379d form collects information about complaints regarding a regulated institution's non-compliance with the appraisal independence standards and the Uniform Standards of Professional Appraisal Practice, including complaints from appraisers, individuals, and other entities. The information is used to respond to consumer complaints and inquiries regarding practices by banks and other financial institutions supervised by the Board.

*Frequency:* Event-generated.

*Respondents:* Appraisers, individuals, financial institutions, and other entities.

*Total estimated number of respondents:* FR 1379c, 7,005; FR 1379d, 4.

*Estimated average hours per response:* FR 1379c, 0.17; FR 1379d, 0.33.

*Total estimated annual burden hours:* FR 1379c, 1,191; FR 1379d, 1.

Board of Governors of the Federal Reserve System, May 23, 2025.

**Benjamin W. McDonough,**

*Deputy Secretary and Ombuds of the Board.*

[FR Doc. 2025-09661 Filed 5-28-25; 8:45 am]

**BILLING CODE 6210-01-P**

**FEDERAL RESERVE SYSTEM****Proposed Agency Information Collection Activities; Comment Request**

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice, request for comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Payments Research Survey (FR 3067; OMB No. 7100–0355).

**DATES:** Comments must be submitted on or before July 28, 2025.

**ADDRESSES:** You may submit comments, identified by FR 3067, by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/>. Follow the instructions for submitting comments, including attachments. *Preferred method.*
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- *Hand Delivery/Courier:* Same as mailing address.
- *Other Means:* [publiccomments@frb.gov](mailto:publiccomments@frb.gov). You must include the OMB number or the FR number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at <https://www.federalreserve.gov/apps/proposals/> without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M–4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

**FOR FURTHER INFORMATION CONTACT:** Federal Reserve Board Clearance Officer—Nuha Elmghrabi—Office of

the Chief Data Officer, Board of Governors of the Federal Reserve System, [nuha.elmaghrabi@frb.gov](mailto:nuha.elmaghrabi@frb.gov), (202) 452–3884.

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/review> or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 3067. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

**Request for Comment on Information Collection Proposal**

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;
- b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- c. Ways to enhance the quality, utility, and clarity of the information to be collected;
- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and
- e. Estimates of capital or startup costs and costs of operation, maintenance,

and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

**Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection**

*Collection title:* Payments Research Survey.

*Collection identifier:* FR 3067.

*OMB control number:* 7100–0355.

*General description of collection:* The Board uses this ad hoc collection to obtain information, as needed, on specific and time-sensitive issues, related to payments research, which may provide insights that augment the Federal Reserve System's effectiveness within the payments system.

*Frequency:* On occasion.

*Respondents:* Respondents may consist of depository institutions, including bank holding companies, savings and loan holding companies, Edge or agreement corporations, and intermediate holding companies and agencies of foreign banks. Other respondents may include financial and nonfinancial businesses, for-profit and nonprofit enterprises, federal, state, and local governments, individual consumers, or households.

*Total estimated number of respondents:* 10,000.

*Total estimated annual burden hours:* 30,000.

Board of Governors of the Federal Reserve System, May 23, 2025.

**Benjamin W. McDonough,**

*Deputy Secretary and Ombuds of the Board.*

[FR Doc. 2025–09664 Filed 5–28–25; 8:45 am]

**BILLING CODE 6210–01–P**

**FEDERAL RESERVE SYSTEM****Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than June 30, 2025.

*A. Federal Reserve Bank of Minneapolis* (Mark Nagle, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291. Comments can also be sent electronically to [MA@mpls.frb.org](mailto:MA@mpls.frb.org):

1. *PSB Financial Shares, Inc., Prinsburg, Minnesota*; to acquire First Community Bank, Lester Prairie, Minnesota.

Board of Governors of the Federal Reserve System.

**Erin Cayce,**

*Assistant Secretary of the Board.*

[FR Doc. 2025-09648 Filed 5-28-25; 8:45 am]

**BILLING CODE P**

## FEDERAL RESERVE SYSTEM

### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Notice, request for comment.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the

Interchange Transaction Fees Survey (FR 3064; OMB No. 7100-0344).

**DATES:** Comments must be submitted on or before July 28, 2025.

**ADDRESSES:** You may submit comments, identified by FR 3064, by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/>. Follow the instructions for submitting comments, including attachments. *Preferred method.*

- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

- *Hand Delivery/Courier:* Same as mailing address.

- *Other Means:* [publiccomments@frb.gov](mailto:publiccomments@frb.gov). You must include the OMB number or the FR number in the subject line of the message.

Comments received are subject to public disclosure. In general, comments received will be made available on the Board's website at <https://www.federalreserve.gov/apps/proposals/> without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure. Public comments may also be viewed electronically or in person in Room M-4365A, 2001 C St. NW, Washington, DC 20551, between 9 a.m. and 5 p.m. during Federal business weekdays.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

#### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, [nuha.elmaghrabi@frb.gov](mailto:nuha.elmaghrabi@frb.gov), (202) 452-3884.

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to

solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/review> or may be requested from the agency clearance officer, whose name appears above. On the page displayed at the link above, you can find the supporting information by referencing the collection identifier, FR 3064. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

#### Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

#### Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

*Collection title:* Interchange Transaction Fees Survey.

*Collection identifier:* FR 3064.

*OMB control number:* 7100-0344.

*General description of collection:* The Debit Card Issuer Survey (FR 3064a) collects data from issuers of debit cards (including general-use prepaid cards) that, together with their affiliates, have assets of \$10 billion or more, including information regarding the volume and value of debit card transactions; chargebacks and returns; costs of authorization, clearance, and settlement of debit card transactions; other costs incurred in connection with particular debit card transactions; fraud prevention costs and fraud losses; and interchange fee revenue. The Payment Card Network Survey (FR 3064b) collects data from payment card networks, including the volume and value of debit card transactions; interchange fees; network fees; and payments and incentives paid by networks to acquirers, merchants, and issuers.

The data from the FR 3064a and FR 3064b are used to fulfill a statutory requirement that the Board disclose certain information regarding debit card transactions on a biennial basis. In addition, the Board uses data from the Payment Card Network Survey (FR 3064b) to publicly report on an annual basis the extent to which networks have established separate interchange fees for exempt and covered issuers.

*Frequency:* Annual.

*Respondents:* Debit card issuers and payment card networks.

*Total estimated number of respondents:* FR 3064a, 531; FR 3064b, 15.

*Estimated average hours per response:* FR 3064a, 160; FR 3064b, 75.

*Total estimated annual burden hours:* FR 3064a, 84,960; FR 3064b, 1,125.

Board of Governors of the Federal Reserve System, May 23, 2025.

**Benjamin W. McDonough,**

*Deputy Secretary and Ombuds of the Board.*

[FR Doc. 2025-09662 Filed 5-28-25; 8:45 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0150]

#### Revocation of Four Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Pfizer Inc. for the Lucira COVID-19 All-In-One Test Kit and Lucira CHECK-IT COVID-19 Test Kit, MAWD Laboratories for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, and Nuclein, LLC (merged with Molecular Diagnostics Inc.) for the DASH SARS-CoV-2/S Test. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

**DATES:** The revocation of the Authorization for the Pfizer Inc.'s Lucira COVID-19 All-In-One Test and Lucira CHECK-IT COVID-19 Test Kit was effective as of April 2, 2025. MAWD Laboratories' MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR was effective as of April 2, 2025, and Nuclein, LLC's (following merger with Molecular Diagnostics Inc.) DASH SARS-CoV-2/S Test was effective as of April 3, 2025.

**ADDRESSES:** Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

**FOR FURTHER INFORMATION CONTACT:** Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product

or an unapproved use of an approved medical product in certain situations.

On November 17, 2020, FDA issued the Authorization to Lucira Health, Inc. for the Lucira COVID-19 All-In-One Test Kit, subject to the terms of the Authorization.<sup>1</sup> Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act.

On April 9, 2021, FDA issued the Authorization to Lucira Health, Inc. for the Lucira CHECK-IT COVID-19 Test Kit, subject to the terms of the Authorization.<sup>2</sup> Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040), as required by section 564(h)(1) of the FD&C Act.

On October 13, 2023, FDA issued the Authorization to MAWD Laboratories for the MAWD Laboratories' SARS-CoV-2 Dual Target by RT-PCR, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on January 25, 2024 (89 FR 4952), as required by section 564(h)(1) of the FD&C Act.

On March 15, 2022, FDA issued the Authorization to Minute Molecular Diagnostics, Inc. (merged with Nuclein, LLC) for the DASH SARS-CoV-2/S Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 22, 2022 (87 FR 43877), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

##### II. Authorizations Revocation Requests

In a request received by FDA on March 14, 2025, Pfizer Inc. requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira COVID-19 All-In-One Test Kit. Pfizer Inc. notified FDA that it did not distribute the Pfizer Inc.'s

<sup>1</sup> Ownership of the EUA for the Lucira COVID-19 All-In-One Test Kit was transferred from Lucira Health, Inc. to Pfizer Inc.

<sup>2</sup> Ownership of the EUA for the Lucira CHECK-IT COVID-19 Test Kit was transferred from Lucira Health, Inc. to Pfizer Inc.

Lucira COVID-19 All-In-One Test Kit, and requested FDA revoke the Pfizer Inc.'s Lucira COVID-19 All-In-One Test Kit. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on March 14, 2025, Pfizer Inc., requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the Pfizer Inc.'s Lucira CHECK-IT COVID-19 Test Kit. Pfizer Inc. notified FDA that it did not distribute the Pfizer Inc.'s Lucira CHECK-IT COVID-19 Test Kit, and requested FDA revoke the Pfizer Inc.'s Lucira CHECK-IT COVID-19 Test Kit. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on March 17, 2025, MAWD Laboratories requested the revocation of, and on April 2, 2025, FDA revoked, the Authorization for the MAWD Laboratories' MAWD Laboratories

SARS-CoV-2 Dual Target by RT-PCR. MAWD Laboratories notified FDA that it had discontinued use of the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR as of April 2, 2025, and requested FDA revoke the MAWD Laboratories' MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on March 17, 2025, Nuclein, LLC (following merger with Minute Molecular Diagnostics, Inc.), requested the revocation of, and on April 3, 2025, FDA revoked, the Authorization for the Nuclein, LLC's DASH SARS-CoV-2/S Test. Nuclein, LLC notified FDA that it had ceased manufacture of the authorized Nuclein, LLC's DASH SARS-CoV-2/S Test as of January 1, 2025, and requested FDA revoke the Nuclein, LLC's DASH SARS-CoV-2/S Test. FDA has determined that it is

appropriate to protect the public health or safety to revoke this Authorization.

### III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/>.

### IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the Pfizer Inc.'s Lucira CHECK-IT COVID-19 Test Kit and Lucira COVID-19 All-In-One Test Kit, MAWD Laboratories' MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, and Nuclein, LLC's DASH SARS-CoV-2/S Test. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

**BILLING CODE 4164-01-P**



April 2, 2025

Elizabeth Mauro  
Director, Global Regulatory Science  
Pfizer Inc.  
66 Hudson Boulevard East  
New York, NY 10001  
**Re: Revocation of EUA202920**

Dear Elizabeth Mauro:

This letter is in response to the request from Pfizer Inc., in letter dated March 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira COVID-19 All-In-One Test Kit issued on November 17, 2020, amended on September 23, 2021, and July 28, 2022, and revised and reissued on November 15, 2022, and June 14, 2023. Pfizer Inc. indicated that they did not distribute the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Lucira COVID-19 All-In-One Test Kit reagents in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Pfizer Inc. has requested that FDA revoke the EUA for the Lucira COVID-19 All-In-One Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202920 for the Lucira COVID-19 All-In-One Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira COVID-19 All-In-One Test Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Ellen J. Flannery, J.D.  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and Radiological Health  
Food and Drug Administration



April 2, 2025

Elizabeth Mauro  
Director, Global Regulatory Science  
Pfizer Inc.  
66 Hudson Boulevard East  
New York, NY 10001  
**Re: Revocation of EUA210196**

Dear Elizabeth Mauro:

This letter is in response to the request from Pfizer Inc., in letter dated March 14, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Lucira CHECK-IT COVID-19 Test Kit issued on April 9, 2021, amended on September 23, 2021, July 28, 2022, and December 12, 2022, and revised and reissued on June 29, 2023. Pfizer Inc. indicated that they did not distribute the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Lucira CHECK-IT COVID-19 Test Kit reagents in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Pfizer Inc. has requested that FDA revoke the EUA for the Lucira CHECK-IT COVID-19 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210196 for the Lucira CHECK-IT COVID-19 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Lucira CHECK-IT COVID-19 Test Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

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Ellen J. Flannery, J.D.  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and Radiological Health  
Food and Drug Administration



April 2, 2025

Philip Adam, Ph.D., HCLD/CC(ABB)  
MAWD Pathology Group, P.A.  
Infectious Diseases Section Director  
MAWD Laboratories  
11070 Strang Line Rd.  
Lenexa, KS 66215

**Re: Revocation of EUA210691**

Dear Dr. Adam:

This letter is in response to the request from MAWD Laboratories, in a letter received March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR issued on October 13, 2023. MAWD Laboratories indicated that as of the date of this letter they have discontinued use of the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR test at MAWD Laboratories, located at 11070 Strang Line Rd., Lenexa, KS 66215.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because MAWD Laboratories has requested that FDA revoke the EUA for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210691 for the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MAWD Laboratories SARS-CoV-2 Dual Target by RT-PCR is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and Radiological Health  
Food and Drug Administration



April 3, 2025

Steve Back  
 Chief Operating Officer  
 Nuclein, LLC  
 8305 Cross Park Drive  
 Austin, TX 78754  
**Re: Revocation of EUA210603**

Dear Steve Back:

This letter is in response to the request from Nuclein, LLC (following Nuclein, LLC's December 27, 2024, merger with, and assumption of responsibility for, the original EUA holder, Minute Molecular Diagnostics, Inc.), in a letter dated March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the DASH SARS-CoV-2/S Test issued on March 15, 2022, and amended on July 28, 2022. Nuclein, LLC indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable DASH SARS-CoV-2/S Test reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Nuclein, LLC has requested that FDA revoke the EUA for the DASH SARS-CoV-2/S Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210603 for the DASH SARS-CoV-2/S Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DASH SARS-CoV-2/S Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

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Ellen J. Flannery, J.D.  
 Deputy Center Director for Policy  
 Director, Office of Policy  
 Center for Devices and Radiological Health  
 Food and Drug Administration

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation,  
 and International Affairs.*

[FR Doc. 2025-09678 Filed 5-28-25; 8:45 am]

BILLING CODE 4164-01-C

**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-N-5302]**

**Michael Dominic Diaz: Final Debarment  
 Order**

**AGENCY:** Food and Drug Administration,  
 HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Michael Dominic Diaz for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Diaz was convicted of one felony count under Federal law. The factual basis supporting Mr. Diaz's conviction, as described below, is conduct relating

to the importation into the United States of a drug or controlled substance. Mr. Diaz was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of May 16, 2024 (30 days after receipt of the notice), Mr. Diaz had not responded. Mr. Diaz's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable May 29, 2025.

**ADDRESSES:** Any application by Mr. Diaz for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

#### *Electronic Submissions*

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

- **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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All applications must include the Docket No. FDA-2023-N-5302. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On November 27, 2023, Mr. Diaz was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Western District of Texas-San Antonio Division when the court accepted his plea of guilty and entered judgment against him for the felony offense of Conspiracy to Defraud the United States and Violate 21 U.S.C. 331—Introduction of Misbranded Drugs into Interstate Commerce in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information from his case, beginning no later than August 2019 and continuing to on or about June 2022, Mr. Diaz was involved in the operation of multiple businesses and associated websites, including Proximo Research and Gulf Coast Chems. The websites for these businesses allowed end consumers to place orders for misbranded prescription drugs, which would be shipped to them via the U.S. Postal Service and other common carriers. The websites offered various drugs for sale, including Clonazepam, Flubromazepam, Fluclotizolam, O-Desmethyl-cis-tramadol (ODSMT) and 2-Methyl-AP-237 (2MAP); these drugs are not approved by FDA for any use in the United States and, during the time Mr. Diaz was involved in operating the Proximo Research and Gulf Coast Chems websites, were not controlled under the Controlled Substances Act. At least some of the drugs offered on the websites for these businesses were purchased by Mr. Diaz, and others, in bulk quantities from sellers located outside the United States, primarily from China. Once orders were placed through the websites, Mr. Diaz, assisted by others, would repackage the drugs into consumer-size containers and ship them to customers at various locations throughout the United States. Mr. Diaz did not require evidence or submission of lawful prescriptions before accepting payment for and shipping the drugs. Despite Mr. Diaz's awareness that individuals were buying the drugs for personal use, he misbranded the drugs being sold with disclaimers that they were "for research purposes only" and "not for human consumption" in an attempt to evade FDA's regulatory oversight and authority.

FDA sent Mr. Diaz, by certified mail, on April 10, 2024, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Diaz's felony conviction under Federal law for conspiracy to defraud

the United States and Violate 21 U.S.C. 331—Introduction of Misbranded Drugs into Interstate Commerce in violation of 18 U.S.C. 371, was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Diaz illegally imported unapproved drugs from sellers located outside of the United States, including in China, and introduced misbranded drug products into interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Diaz's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Diaz of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Diaz received the proposal and notice of opportunity for a hearing on April 16, 2024. Mr. Diaz failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Division of Field Enforcement, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Michael Dominic Diaz has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Diaz is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Diaz is a prohibited act.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09649 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-5056]

#### Justin Cole Henry: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Justin Cole Henry for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Henry was convicted of a felony under Federal law for possession with intent to distribute a Schedule III controlled substance. The factual basis supporting Mr. Henry's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Henry was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of February 24, 2025 (30 days after receipt of the notice), Mr. Henry had not responded. Mr. Henry's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable May 29, 2025.

**ADDRESSES:** Any application by Mr. Henry for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

#### *Electronic Submissions*

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All applications must include the Docket No. FDA-2024-N-5056. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:**

Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act (21 U.S.C. 335a(b)(3)(C)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On August 23, 2024, Mr. Henry was convicted as defined in section 306(l)(1) of the FD&C Act (21 U.S.C. 335a(l)(1)), in the U.S. District Court for the Middle District of Tennessee when the court accepted his plea of guilty and entered judgment against him for the offense of Possession with Intent to Distribute a Schedule III Controlled Substance in violation of 21 U.S.C. 841(a)(1). The underlying facts supporting the conviction are as follows: As contained in the Information, and in the Plea Agreement from his case, Mr. Henry owned and operated a gym called Power Athletics. In 2022 Mr. Henry purchased large volumes of anabolic steroids, including testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one), a Schedule III controlled substance, from mostly overseas wholesale vendors. Mr. Henry then repackaged the drugs and sold them to customers under his own label, American Muscle Labs. On October 21, 2022, law enforcement officers executed a search warrant at Mr. Henry's gym, which included a hidden room housing his steroid laboratory. Mr. Henry admitted that on October 21, 2022, he possessed more than 60,000 units of Schedule III controlled substances, including testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one), which he intended to use himself and sell to his customers.

FDA sent Mr. Henry, by certified mail, on January 2, 2025, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act (21 U.S.C. 335a(b)(3)(C)) that Mr. Henry's

felony conviction under Federal law for Possession with Intent to Distribute a Schedule III Controlled Substance in violation of 21 U.S.C. 841(a)(1) was for conduct relating to the importation of any drug or controlled substance into the United States because you illegally imported the controlled substances at issue, including testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one), and sold them to customers. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act (21 U.S.C. 335a(c)(3)) that it considered applicable to Mr. Henry's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Henry of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Henry received the proposal and notice of opportunity for a hearing on January 24, 2025. Mr. Henry failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

**II. Findings and Order**

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act (21 U.S.C. 335a(b)(3)(C)), under authority delegated to the Director, Division of Enforcement, finds that Mr. Justin Cole Henry has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act (21 U.S.C. 335a(c)(2)(A)(iii)).

As a result of the foregoing finding, Mr. Henry is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Henry is a prohibited act.

Dated: May 25, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09646 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-P-0168]

**Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information; Extension of Comment Period; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for information; extension of comment period; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on April 9, 2025. The document announced the extension of the comment period for the request for information entitled "Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids." The notice published with an error in the **ADDRESSES** section. This document corrects the error.

**FOR FURTHER INFORMATION CONTACT:**

Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Wednesday, April 9, 2025 (90 FR 15243), in FR Doc. 2025-06049, on page 15244, in the first column, in the third sentence of the **ADDRESSES** section, the date until which the <https://www.regulations.gov> electronic filing system will accept comments is corrected to read "June 16, 2025."

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09681 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-5308]

#### Carlton Reico Mallard Jr.: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Carlton Reico Mallard Jr. for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Mallard was convicted of one felony count under Federal law for introduction into interstate commerce a misbranded drug, with the intent to defraud and mislead, and one felony count of illegal importation of merchandise. The factual bases supporting Mr. Mallard's convictions, as described below, are for conduct relating to the importation into the United States of a drug or controlled substance. Mr. Mallard was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of February 23, 2025 (30 days after receipt of the notice), Mr. Mallard had not responded. Mr. Mallard's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable May 29, 2025.

**ADDRESSES:** Any application by Mr. Mallard for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

#### Electronic Submissions

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

- 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All applications must include the Docket No. FDA-2024-N-5308. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

#### FOR FURTHER INFORMATION CONTACT:

Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On July 23, 2024, Mr. Mallard was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Middle District of Florida when the court accepted his plea of guilty and entered judgment against him for the offenses of Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud and Mislead in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act) and of Illegal Importation of Merchandise in violation of 18 U.S.C. 545. The underlying facts supporting the conviction are as follows: As contained in the Information, and in the Plea Agreement from his case, Mr. Mallard was the president and director of Inspiring Estates, Inc., and an owner of Golden Royal Honey USA (GRH). Mr. Mallard also operated the website [www.goldenroyalhoneyusa.com](http://www.goldenroyalhoneyusa.com) on behalf of GRH to market and offer for sale misbranded drugs, specifically male enhancement products. Mr. Mallard was a client of Fulfillment Company 1 (FC-1), a marketing and online order fulfillment service, and used FC-1 to receive shipments of these misbranded drug products unlawfully imported into the United States from foreign nations. Between May 2020 and February 2021, several packages addressed to GRH were seized by the United States Customs and Border Protection (CBP). Mr. Mallard also received notices from the FDA and/or CBP about the violative nature of the

products he was importing from China and other foreign countries.

On or about August 5, 2020, a Special Agent from the FDA's Office of Criminal Investigations (OCI), while undercover, purchased items through the GRH website. The three products were called "Leopard Miracle Honey," "Vitamax Double Shot Honey," and "Golden Royal Honey VIP." After receiving the products, OCI sent them for laboratory analyses at the FDA Forensic Chemistry Center (FCC). The FCC testing and analyses confirmed that sildenafil was present in the "Leopard Miracle Honey" while tadalafil was present in both the "Vitamax Double Shot Honey" and "Golden Royal Honey VIP."

On or about February 27, 2021, Mr. Mallard was interviewed by CBP officers. He confirmed that he operated an online business that distributed honey products. CBP officers discovered Mr. Mallard received text messages from DHL about incoming foreign parcels between February 24, 2021, and February 26, 2021. On or about April 16, 2021, a search and seizure warrant for GRH inventory was executed at FC-1. During the execution of the warrant agents discovered hundreds of products violative of the FDCA that were imported into the United States from foreign countries. Thirty-eight (38) items were submitted to the FCC for testing. Approximately thirty (30) tested positive for sildenafil and/or tadalafil, all of which were violative of the FD&C Act. Fulfillment and shipping records provided by FC-1 revealed that in 2020, FC-1 received 13,000 shipments on behalf of GRH and it processed and shipped out over 12,000 orders. During 2020, Mr. Mallard received approximately \$764,749.64 for the sale of misbranded drugs that lacked the required FDA approval.

FDA sent Mr. Mallard, by certified mail, on January 2, 2025, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Mallard's felony convictions under Federal law for Introduction into Interstate Commerce of Misbranded Drugs with Intent to Defraud and Mislead in violation of 21 U.S.C. 331(a) and 333(a)(2) (sections 301(a) and 303(a)(2) of the FD&C Act) and of Illegal Importation of Merchandise in violation of 18 U.S.C. 545, were for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Mallard illegally imported and introduced misbranded drug products into interstate commerce. In proposing a

debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Mallard's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Mallard of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Mallard received the proposal and notice of opportunity for a hearing on January 24, 2025. Mr. Mallard failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Carlton Reico Mallard Jr. has been convicted of multiple felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years, with the maximum possible period of debarment as provided by section 306(c)(2)(A)(iii) of the FD&C Act for each felony count to run consecutively.

As a result of the foregoing finding, Mr. Mallard is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Mallard is a prohibited act.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09651 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1774]

#### Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program." This guidance document provides an overview of the mechanisms available to submitters through which they can request interactions with FDA related to medical device submissions. This guidance supersedes the document entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" issued on June 2, 2023, and provides clarification and additional information on the scope of Q-Submission (Q-Sub) types, better delineation of how to obtain feedback for different types of questions (*i.e.*, informal communication vs. Pre-Submission or other Q-Sub types), and improved examples.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 29, 2025.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time 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-2018-D-1774 for “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

As part of the Medical Device User Fee Amendments of 2022, the Agency committed to issuing a final guidance to provide additional information to assist in identifying the circumstances in which an applicant’s question is most appropriate for informal communication instead of a Pre-Submission. This final guidance reflects such additional information and further clarifies other elements of the Q-Sub Program.

This guidance provides an overview of the mechanisms available to submitters through which they can

request interactions with FDA, including written feedback and/or a meeting regarding medical device Investigational Device Exemption applications, Premarket Approval applications, Humanitarian Device Exemption applications, De Novo requests, 510(k) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Applications, Dual 510(k) and CLIA Waiver by Application submissions, Accessory Classification Requests, and certain Investigational New Drug applications and Biologics License Applications submitted to the Center for Biologics Evaluation and Research. FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be deregulatory in nature.

A notice of availability of the draft guidance appeared in the **Federal Register** of March 15, 2024 (89 FR 18947). FDA considered comments received and revised the guidance as appropriate in response to the comments, including expanded examples of Pre-Submission topics and questions, and minor clarifications.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive

an electronic copy of the document. Please use the document number GUI00001677 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to

review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form or collection instrument	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
Form FDA 3601 “Medical Device User Fee Cover Sheet”; form FDA 3601(a), the “Device Facility User Fee Cover Sheet”; “FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act”.	Medical Device User Fee Cover Sheet and Device Facility User Fee Cover Sheet—Form FDA 3601 and Form 3601(a); 513(g) Request for Information.	0910–0511
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
“Administrative Procedures for CLIA Categorization” and “Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
“Medical Device Accessories—Describing Accessories and Classification Pathways”.	Accessories	0910–0823
“Center for Devices and Radiological Health Appeals Processes”.	Appeals Process	0910–0738
“Authorization of Medical Products for Use Emergencies”	Emergency Use Authorization	0910–0595
312	Investigational New Drug Application	0910–0014
601	Biologics License Application	0910–0338
FDA’s web page: Total Product Life Cycle Advisory Program (TAP) ( <a href="https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap">https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap</a> ).	TAP Pilot	0910–0930

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09618 Filed 5–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–N–2602]

**Second Annual Animal Drug User Fee Educational Conference; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following educational conference (public meeting) entitled “Second Annual Animal Drug User Fee Educational Conference.” This is the second of five annual educational conferences FDA will host as described in the “Animal Drug User Fee Act Reauthorization Performance Goals and

Procedures Fiscal Years 2024 Through 2028.” The purpose of this series of conferences is to provide educational sessions for stakeholders who are interested in the new animal drug approval process.

**DATES:** The second educational conference will be held on July 15, 2025, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. You may submit comments at any time for this series of educational conferences. We request that you submit either electronic or written comments by 90 days after each annual educational conference to ensure that the Agency considers your comment on a topic discussed at that conference.

**ADDRESSES:** The second educational conference will be available in person and virtually. The in-person conference will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Great Room Conference Center, Silver Spring, MD 20993–0002. Entrance for conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed.

Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to <https://www.dhs.gov/real-id/real-id-faqs>. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>. Persons interested in attending this educational conference must register at: [https://www.surveymonkey.com/r/ADUFAV\\_2025](https://www.surveymonkey.com/r/ADUFAV_2025).

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-2602 for “Second Annual Animal Drug User Fee Educational Conference.” Received comments 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:** Walter Ellenberg, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-796-0885, [adufa\\_v\\_edu\\_conference@fda.hhs.gov](mailto:adufa_v_edu_conference@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Animal Drug User Fee Act (Pub. L. 108-130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency’s funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency’s mission to protect and promote human and animal health.

The Animal Drug User Fee Amendments of 2023 (ADUFA V), the most recent reauthorization of the Act, authorizes FDA to collect user fees through fiscal year 2028. “The Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028” (Performance Goals Letter) sets forth the Agency’s performance goals for the period covered by ADUFA V. Among other goals, the document commits the Agency to hosting triannual meetings (three meetings per calendar year) with Animal Health Institute (AHI) members, one of which will consist of an educational conference of up to 8 hours for the animal drug industry. This

notice announces the second of these annual Animal Drug User Fee Educational Conferences. These conferences are open to the public.

##### II. Topics for Discussion at the Educational Conference

As described in the Performance Goals Letter, FDA will plan a series of topics for the educational conferences during the 5 years of ADUFA V. While the agenda for each educational conference is determined by the Agency with input from AHI, all stakeholders are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This second conference will focus on the following topics:

- (1) Overview of User Fees and Waivers
- (2) Foreign Data
- (3) Real World Data/Evidence
- (4) What Makes a High-Quality Submission?
- (5) Adaptive Study Designs

The conference will also contain Q&A sessions during which FDA will address specific questions from the in-person and virtual audience as time allows. Questions and comments received during each annual conference and comments submitted to the docket will inform the conversation and topics considered in subsequent conferences.

##### III. Participating in the Educational Conference

*Registration:* This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, and email. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend in person. Registrants will receive confirmation when their registration has been received and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at [https://www.surveymonkey.com/r/ADUFAV\\_2025](https://www.surveymonkey.com/r/ADUFAV_2025) no later than July 8, 2025. Onsite registration will be provided on the day of the conference on a first-come, first-served basis, until the room capacity is

reached. No overflow seating will be provided. Onsite registration will open at the conference site at 8 a.m. on July 15, 2025.

If you need special accommodations due to a disability, please contact Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**) no later than July 8, 2025.

*Recording of Conference:* Please be advised that as soon as a recording of this conference is available, it will be accessible at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings>.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09584 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-N-0030]

#### Quality Poultry and Seafood, Incorporated: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarment Quality Poultry and Seafood, Incorporated (QPS) for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that QPS was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. QPS was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of March 15, 2025 (30 days after receipt of the notice), QPS has not responded. QPS' failure to respond and request a hearing constitutes a waiver of its right to a hearing concerning this matter.

**DATES:** This order is applicable May 29, 2025.

**ADDRESSES:** Any application by QPS for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

#### Electronic Submissions

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

- **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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All applications must include the Docket No. FDA-2025-N-0030. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application.

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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

#### FOR FURTHER INFORMATION CONTACT:

Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar a person, including a firm or corporation, from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the person has been convicted of a felony for conduct relating to the importation into the United States of any food.

On December 11, 2024, QPS was convicted as defined in section 306(l)(1)(A) of the FD&C Act in the U. S. District Court for the Southern District of Mississippi when the court accepted its plea of guilty and entered judgment against it for the offense of Conspiracy to Commit Misbranding and Wire Fraud in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information, whose facts alleged therein QPS admitted to in QPS' Plea Agreement, QPS is a Mississippi corporation operating in Biloxi as a wholesale supplier of poultry and seafood to restaurants, casinos, and retail markets. It also sold poultry and seafood to the general public from its

retail outlet and served meals to customers at its cafe. QPS, along with coconspirators, entered into a conspiracy to mislabel foreign seafood and sell it as local varieties of seafood. Through QPS' employees, QPS would purchase frozen seafood from foreign countries, with the intent to advertise and sell the seafood as local premium species of seafood, when in fact the fish was not local and not species they were advertised to be. On at least one occasion, while standing in QPS' large freezer, QPS' sales manager handed to a coconspirator, packages of three different fish suggesting that the coconspirator sample each and decide which would be best to substitute for the local premium species on the conspirator's menu. On a separate occasion QPS sold fish to a customer; QPS represented the fish to be local premium Red Snapper but which genetic analysis determined was not Red Snapper but was instead an imported species of lesser value. Later, one of QPS' seafood purchasing agents notified some of QPS' other employees that due to a shortage on snapper, QPS would be substituting triple tail for all snapper. Triple tail was not a local fish, and QPS had in fact imported it from South America. During a search of QPS facilities in September 2018, two of QPS' employees, its sales manager and business manager, made multiple false statements to FDA investigators, including, that any mislabeling of fish by QPS was inadvertent and that if anyone in QPS' retail market was mislabeling fish with other than its true name, it was happening without approval. Even after the September 2018 search of QPS facilities, QPS continued selling mislabeled seafood to customers in lieu of local varieties of seafood for at least another year.

As a result of this conviction, FDA sent QPS, by certified mail, on February 10, 2025, a notice proposing to debar it for a 5-year period from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that QPS' felony conviction under Federal law for Conspiracy to Commit Misbranding and Wire Fraud in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of an article of food because QPS entered into a scheme to purchase foreign seafood which it then would either mislabel itself and sell it directly to its retail customers or would sell it to its retail customers in order for the retail customers to mislabel it and sell it as local varieties of seafood to

consumers. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to QPS' offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed QPS of the proposed debarment and offered it an opportunity to request a hearing, providing QPS 30 days from the date of receipt of the letter in which to file the request, and advised it that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. QPS received the proposal and notice of opportunity for a hearing on February 13, 2025. QPS failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived its opportunity for a hearing and waived any contentions concerning its debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that QPS has been convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food and that it is subject to a 5-year period of debarment.

FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, QPS is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (See **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of QPS is a prohibited act.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09652 Filed 5-28-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-D-1082]

#### Electronic Submission Template for Medical Device Q-Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Electronic Submission Template for Medical Device Q-Submissions." FDA is issuing this draft guidance to introduce submitters of certain Q-Submissions (Q-Subs), specifically Pre-Submissions (Pre-Subs) to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), to the current resources and associated content developed and made publicly available to support Pre-Sub electronic submissions to FDA. This draft guidance, when finalized, is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by July 28, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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-2025-D-1082 for “Electronic Submission Template for Medical Device Q-Submissions.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Electronic Submission Template for Medical Device Q-Submissions” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is issuing this draft guidance document to introduce submitters of Pre-Subs to CDRH and CBER to the current resources and associated content developed and made publicly available to support Pre-Sub electronic submissions to FDA. This draft guidance is intended to represent one of several steps in meeting FDA’s commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in

the review process. When finalized, this guidance will also facilitate the implementation of the FDA’s mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52), to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

FDA’s guidance document “Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act” (hereafter referred to as the “745A(b) device parent guidance”) provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. When finalized, this guidance will provide such information for Pre-Sub electronic submissions solely in electronic format.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this draft guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.*, standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA’s good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see § 10.115(d)). To the extent that this draft guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued consistent with FDA’s good guidance practices regulation (§ 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies

the requirements of the applicable statutes and regulations. This draft guidance, when finalized, will contain both binding and nonbinding provisions.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Medical Device Q-Submissions” may send an email request to [CDRH-Guidance@](mailto:CDRH-Guidance@fda.hhs.gov)

[fda.hhs.gov](mailto:fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007041 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA Form	Topic	OMB control No.
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09615 Filed 5–28–25; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

**FOR FURTHER INFORMATION CONTACT:** CAPT George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, HHS by mail at 5600 Fishers Lane, 08–W25A, Rockville, Maryland 20857; or call (301) 443–9350.

**SUPPLEMENTARY INFORMATION:** Section 100.2 of the VICP’s implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of HHS (the Secretary), is effective upon its delivery by the

Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. The Secretary delegated this responsibility to the Director of the Division of Injury Compensation Programs. This figure is calculated using the most recent Medical Expenditure Panel Survey–Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation Employer Health Benefits Survey.

In 2024, the Medical Expenditure Panel Survey–Insurance Component, available at [www.meeps.ahrq.gov](http://www.meeps.ahrq.gov), published the annual 2023 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$8,182. This figure is divided by 12 to determine the cost per month of \$681.83. The \$681.83 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at [www.kff.org](http://www.kff.org). The increase from 2023 to 2024 was six percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is \$722.74.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$722.74 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the

Secretary to the Court. Such notice was delivered to the Court on January 7, 2025.

**George Reed Grimes,**

*Director, Division of Injury Compensation Programs.*

[FR Doc. 2025–09694 Filed 5–28–25; 8:45 am]

**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; Small Business: Bioengineering, Device Development and Neurosurgery.

*Date:* June 25–26, 2025.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Cristina Backman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, (301) 480-9069, [cbackman@mail.nih.gov](mailto:cbackman@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PA/PAR Career Development Awards: Health Interventions and Clinical Care.

*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Karen Nieves Lugo, Ph.D., MPH, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave., Ste. 533, Bethesda, MD 20892, 301-402-1366, [karen.nieveslugo@nih.gov](mailto:karen.nieveslugo@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: Complement-ARIE New Approach Methodologies (NAMs) Technology Development Centers (UM1).

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, (301) 435-1047, [krishna@csr.nih.gov](mailto:krishna@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; Bacterial-Host Interactions Study Section.

*Date:* June 26–27, 2025.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-1398, [uma.basavanna@nih.gov](mailto:uma.basavanna@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Infectious Disease Drug Development and Molecular Pharmacology.

*Date:* June 26–27, 2025.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Ekaterina Mikhailovna Nestorovich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-1367, [ekaterina.nestorovich@nih.gov](mailto:ekaterina.nestorovich@nih.gov).

*Name of Committee:* Applied Immunology and Disease Control Integrated Review Group; Drug Discovery and Molecular Pharmacology A Study Section.

*Date:* June 26–27, 2025.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Bidyottam Mitra, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435-0000, [bidyottam.mitra@nih.gov](mailto:bidyottam.mitra@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Musculoskeletal, Oral, Osteoarthritis and Dermatology.

*Date:* June 26–27, 2025.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, (301) 237-9931, [ansaria@csr.nih.gov](mailto:ansaria@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel-NS-24-038: Human Brain Single-cell Genomics Explorer (U24) Review.

*Date:* June 27, 2025.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [mirahamed.hossain@nih.gov](mailto:mirahamed.hossain@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* May 22, 2025.

**Bruce A. George,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-09610 Filed 5-28-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

*Date:* June 25–26, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Michael Edward Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, 7W634, National Cancer Institute, NIH, Rockville, MD 20850, (240) 276-5735, [mike.lindquist@nih.gov](mailto:mike.lindquist@nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Cellular Immunotherapy of Cancer Study Section.

*Date:* June 26–27, 2025.

*Time:* 8:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Shahana Majid, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, [shahana.majid@nih.gov](mailto:shahana.majid@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Majed M. Hamawy, Ph.D., MBA Scientific Review Officer, Research

Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Dr., Rm. 7w120, Bethesda, MD 20892, 240-276-6457, [mh101v@nih.gov](mailto:mh101v@nih.gov).

*Name of Committee:* Healthcare Delivery and Methodologies Integrated Review Group; Healthcare and Health Disparities Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Tara Roshell Earl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007C, Bethesda, MD 20892, (301) 402-6857, [earltr@MAIL.NIH.GOV](mailto:earltr@MAIL.NIH.GOV).

*Name of Committee:* Infectious Diseases and Immunology A Integrated Review Group; Innate Immunity B Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805-P, Bethesda, MD 20892, (301) 435-0000, [drammehbs@csr.nih.gov](mailto:drammehbs@csr.nih.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; Etiology, Diagnostic, Intervention and Treatment of Infectious Diseases Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Lisa Ann Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2582, [lisa.lewis3@nih.gov](mailto:lisa.lewis3@nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Tumor Host Interactions Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Angela Y. Ng, Ph.D., MBA Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710-C, MSC 7806, Bethesda, MD 20892, (301) 435-1715, [nga@csr.nih.gov](mailto:nga@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Clinical Integrative Cardiovascular and Hematological Sciences Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Marie-Luise Brennan, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-0732, [marie-luise.brennan@nih.gov](mailto:marie-luise.brennan@nih.gov).

*Name of Committee:* Infectious Diseases and Immunology B Integrated Review Group; Immunity and Host Defense Study Section.

*Date:* June 26–27, 2025.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4203, Bethesda, MD 20892, (301) 435-3566, [mulky@mail.nih.gov](mailto:mulky@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Cardiovascular Differentiation and Development.

*Date:* June 26, 2025.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4136, Bethesda, MD 20892, 301-435-0904, [sara.ahlgren@nih.gov](mailto:sara.ahlgren@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 22, 2025.

**Lauren B. Gibson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-09613 Filed 5-28-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; Translational Investigations of Pulmonary and Immunological Diseases.

*Date:* June 23–24, 2025.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Carl White, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-4835, [carl.white@nih.gov](mailto:carl.white@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-25-242: Mobile Health: Technology and Outcomes in Low and Middle Income Countries Panel A (R21/R33—Clinical Trial Optional).

*Date:* June 24–25, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Gheda Khodr Temsah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-2342, [temshahgk@csr.nih.gov](mailto:temshahgk@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Integrative Myocardial Physiology/Pathophysiology A Study Section.

*Date:* June 25–26, 2025.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301-435-2365, [aitouchea@csr.nih.gov](mailto:aitouchea@csr.nih.gov).

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Guided Interventions and Surgery Study Section.  
*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 6:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Ella Fung Jones, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-0777, [ella.jones@nih.gov](mailto:ella.jones@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: NCI National Clinical Trials Network-Group II.

*Date:* June 26–27, 2025.  
*Time:* 9:00 a.m. to 7:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Robert F. Gahl, BS, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities (DEA), 9606 Medical Center Drive, Room 7w260, National Cancer Institute, NIH, Rockville, MD 20850, 240-276-7869, [robert.gahl@nih.gov](mailto:robert.gahl@nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.  
*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 8:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Andrew Maxwell Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, (301) 402-3019, [andrew.wolfe@nih.gov](mailto:andrew.wolfe@nih.gov).

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Cancer Prevention Study Section.  
*Date:* June 26–27, 2025.

*Time:* 9:00 a.m. to 7:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Byung Min Chung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-4056, [justin.chung@nih.gov](mailto:justin.chung@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Kidney and Urological Sciences.

*Date:* June 26–27, 2025.  
*Time:* 9:00 a.m. to 6:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-827-5467, [ganesan.ramesh@nih.gov](mailto:ganesan.ramesh@nih.gov).

*Name of Committee:* Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

*Date:* June 26–27, 2025.  
*Time:* 9:00 a.m. to 7:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Michael Patrick O'Connell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, [occonnellmp@mail.nih.gov](mailto:occonnellmp@mail.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

*Date:* June 26–27, 2025.  
*Time:* 9:00 a.m. to 7:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Todd Everett White, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-3962, [todd.white@nih.gov](mailto:todd.white@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 22, 2025.

**Bruce A. George,**  
*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-09612 Filed 5-28-25; 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

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

*Comments are invited on:* (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: 988 Suicide & Crisis Lifeline and Crisis Services Program Evaluation—New Package

The Substance Abuse and Mental Health Services Administration (SAMHSA) 988 & Behavioral Health Crisis Coordinating Office (BHCCO) is requesting clearance for the new data collection associated with the evaluation of the SAMHSA 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation (988 Suicide and Crisis Lifeline Evaluation). The collection of this information is critical to successfully oversee operational response and quality of service through the 988 Suicide and Crisis Lifeline to ensure connections to care for individuals in suicidal crisis or emotional distress contacting in for 988 phone, chat, and text support for connecting local, state/territory, and national outcomes and monitoring contractual obligations for current and future 988 Suicide and Crisis Lifeline grant programs. Much of the information is already embedded in the current 988 Suicide and Crisis Lifeline

network administrator grants, the 988 state and territory grant program, or the 988 Tribal Response grant program.

In 2020, Congress designated the three-digit number, 9–8–8 for the Suicide and Crisis Lifeline, and the Suicide and Crisis Lifeline transitioned to the 3-digit number in July 2022. As a part of the federal government's commitment to addressing the mental health and opioid crises in America, unprecedented federal resources have been invested to expand crisis centers in support of 988. Since its launch in July 2022, the 988 Suicide & Crisis Lifeline has answered over 9.6 million contacts (SAMHSA, 2024). Progress recognized in 2023 continues in all areas including crisis line features, crisis center supports, and funding. In FY2024, nearly \$500 million was appropriated in new funding opportunities for the 988 Lifeline Administrator and other grantees on state territorial, Tribal and center levels, as part of the commitment to strengthen crisis care nationally. In Section 1103(a)(2)(B) of the Consolidated Appropriations Act, 2023 (Pub. L. No: 117–328), Congress called for enhanced program evaluation, including performance measures to assess program response and improve readiness and performance of the service, including review of each contact to ensure timely connection of service and quality provision in line with evidence-based care. To meet the standards and requirements set forth in the statute, ongoing communication of key outcomes within this OMB request must be received and reviewed to ensure connection and quality of care through the 988 Suicide and Crisis Lifeline.

The information collected will be used by SAMHSA to conduct an evaluation of the 988 Suicide & Crisis Lifeline and Crisis Services, to ensure individuals in suicidal, mental health and/or substance use crisis can contact 988 Suicide and Crisis Lifeline and are connected to crisis centers providing evidence-based care and are able to receive critical resource referral and linkage, including opportunities for mobile crisis support, crisis receiving and stabilizing facilities, peer respite centers and withdrawal management services. The purpose of the 988 Lifeline and Crisis Services Program Evaluation is to assess the implementation and expansion of the 988 Lifeline in the U.S. The evaluation will provide SAMHSA, grantees, and other interested parties with the information needed to strengthen the Behavioral Health Crisis

Services Continuum (BHSCS) for all people in crisis. The evaluation utilizes multiple studies to conduct the evaluation of the 988 Lifeline and Crisis Services across a 5-year period. The 988 Lifeline and Crisis Services Program Evaluation includes three levels: system-level, client-level, and impact. Embedded within each of the three evaluation levels are inquiries into differences in utilization of 988 Lifeline and BHSCS services and outcomes.

The System-level Evaluation examines the characteristics, collaborations, and structures of the crisis services infrastructure within states, territories, and Tribal jurisdictions that support improved client outcomes. The Systems-level Evaluation includes two studies: the System Composition and Collaboration Study and the System-Level Service Utilization Study. The System Composition and Collaboration Study examines the structure of the 988 Lifeline and the BHSCS at the national, state, territory, and Tribal levels, and the extent to which crisis service agencies work together. The System-level Service Utilization Study investigates whether the 988 Lifeline and BHSCS are successful in creating a behavioral-health-system-first response to crisis events and the resulting reduction in use of non-behavioral health crisis services (e.g., 911, law enforcement, emergency medical services).

The Client-level Evaluation provides critical information about the ways in which the 988 Lifeline and crisis services fulfill their mission to connect those in crisis with the services and supports needed to reduce crisis risk and improve overall behavioral health outcomes. The Client-level Evaluation consists of two studies: The Client-level Service Utilization and Outcome Study and the Client-level Risk Reduction Study. The Client-Level Service Utilization and Outcome Study explores the effectiveness of 988 Lifeline and BHSCSs in linking individuals to referral services following their contact with the crisis system and assesses the relationship between engagement with crisis services and behavioral health outcomes. The Client-Level Risk Reduction Study assesses the efficacy of 988 Lifeline and BHSCS contacts on immediate reductions in risks of suicide, violence toward others, and overdose.

The Impact Evaluation informs SAMHSA's efforts to continue to build the evidence base for suicide prevention

and crisis programming. Specifically, this evaluation will examine the impact of 988 Lifeline and BHSCS on suicide and overdose morbidity and mortality. A quasi-experimental interrupted time series (ITS) design using extant, secondary data sources (e.g., CDC mortality data, Medicaid claims data, data from Healthcare Cost and Utilization Project (HCUP), data from the NSDUH, and SAMHSA's Performance and Accountability Reporting System [SPARS] data) gathered across multiple years to establish longitudinal state-level trends before and after major milestones in the implementation of the 988 Lifeline and BHSCS.

The 988 Lifeline and Crisis Services Program Evaluation engages with the following SAMHSA grant-funded programs that make up the core of the crisis care continuum: 988 State/Territory; 988 Tribal nations; Community Crisis Response Program (CCRP); Crisis Center Follow-Up (CCFU); 988 Administrator; and Certified Community Behavioral Health Clinics (CCBHCs). Additional grant programs which are relevant to the BHSCS, such as the Mental Health Services Block Grant (MHBG), State Opioid Response (SOR), Tribal Opioid Response (TOR), Substance Use Prevention, Treatment and Recovery Services Block Grant (SUPTRS BG), will be included in portions of the evaluation as relevant. In addition, crisis-providing organizations that are not SAMHSA grantees, especially mobile crisis programs, crisis stabilization units, and CCBHCs will also be engaged to participate in the evaluation.

Ultimately, the purpose of the SAMHSA 988 Suicide & Crisis Lifeline and Crisis Services Program is to build the program's knowledge base of effectiveness by thoroughly describing the implementation, outcomes, and impact of a program meant to reduce deaths by suicide.

The total annualized burden is an estimated 16,724 respondents for the 988 Lifeline and Crisis Services Program Evaluation instruments, with a combined hourly estimate to be 8,006.10 hours. Burden estimates are based on the data collection requirements and the number of respondents. The estimated response burden to collect this information associated with the 988 Lifeline and Crisis Services Program Evaluation is as follows annualized over the requested 3-year clearance period is presented below:

**TOTAL ANNUALIZED BURDEN HOURS AND COSTS**  
[Across the 3-year clearance period]

Type of respondent	Instrument	Number of respondents per year	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)	Hourly wage rate (\$)	Total annualized cost (\$)
<b>System Composition and Collaboration Study</b>								
Organizational Staff/Crisis System Administrator <sup>1</sup> .	SIS .....	73	1	73	0.75	54.75	\$78.06	\$4,273.79
Organizational Staff/Crisis Agency Manager <sup>2</sup> .	CCPS .....	1034	1	1034	1.00	1,034.00	58.80	60,799.20
Organizational Staff/Crisis Agency Staff <sup>3</sup> .	KII-CS .....	35	1	35	1.00	35.00	27.46	961.10
Organizational Staff/Crisis Agency Staff <sup>3</sup> .	KII-CS-CSS .....	13	1	13	0.50	6.50	27.46	178.49
<b>Client-Level Service Utilization and Outcome Study</b>								
Organizational Staff/Crisis Agency Staff <sup>3</sup> .	CCDF .....	6,000	1	6,000	0.15	900.00	27.46	24,714.00
Parents/Caregivers <sup>4</sup> .....	CCDF Parent Supplement .....	<sup>5</sup> 1,560	1	1,560	0.10	156.00	7.25	1,131.00
Client <sup>4</sup> .....	CES—Baseline .....	6,000	1	6,000	0.75	4,500.00	7.25	32,625.00
Client <sup>4</sup> .....	CES—3 months .....	1,500	1	1,500	0.65	975.00	7.25	7,068.75
Client <sup>4</sup> .....	CES—6 months .....	375	1	375	0.65	243.75	7.25	1,767.19
Client <sup>4</sup> .....	CES—12 months .....	94	1	94	0.65	61.10	7.25	442.98
<b>Client-Level Risk Reduction Study</b>								
Client <sup>4</sup> .....	C-KII-DC .....	30	1	30	1.00	30.00	7.25	217.50
Client <sup>4</sup> .....	C-KII-TPC .....	10	1	10	1.00	10.00	7.25	72.50
Total .....	16,724 .....				8,006.10		134,251.49	

<sup>1</sup> BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for General and Operations Managers (code 11-1021), <https://www.bls.gov/oes/current/oes111021.htm>.  
<sup>2</sup> BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for Social and Community Service Managers (code 11-9151), <https://www.bls.gov/oes/current/oes119151.htm>.  
<sup>3</sup> BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for Counselors, Social Workers, and Other Community and Social Service Specialists (code 21-1000), [https://www.bls.gov/oes/current/naics5\\_541720.htm#29-0000](https://www.bls.gov/oes/current/naics5_541720.htm#29-0000).  
<sup>4</sup> <https://www.usa.gov/minimum-wage>.  
<sup>5</sup> This number represents an estimate based on the average distribution of monthly contacts by modality, cited in Lifeline Performance Metrics (SAMHSA, April 2024), and assumes that 40% of all individuals who contact 988 through chat or text (as cited in Gould et al., 2021 and Pisani et al., 2022) and 20% of those who contact 988 through phone call are below the age of 18.

Send comments to SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E45, Rockville, MD 20852 OR email a copy at [samhsapra@samhsa.hhs.gov](mailto:samhsapra@samhsa.hhs.gov). Written comments should be received by July 28, 2025.

**Alicia Broadus,**  
Public Health Advisor.

[FR Doc. 2025-09620 Filed 5-28-25; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. CISA-2025-0001]

**Agency Information Collection Activities: Cybersecurity and Infrastructure Security Agency (CISA) Speaker Request Form**

**AGENCY:** Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

**ACTION:** 60-Day notice and request for comments; renewal of extension on the collection with the OMB control number of 1670-0047.

**SUMMARY:** The External Affairs (EA) within Cybersecurity and Infrastructure Security Agency (CISA) submits the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance.

**DATES:** Comments are encouraged and will be accepted until July 28, 2025. Submissions received after the deadline for receiving comments may not be considered.

**ADDRESSES:** You may submit comments, identified by docket number Docket # CISA-2025-0001, by following the instructions below for submitting comment via the Federal eRulemaking Portal at <http://www.regulations.gov>.

*Instructions:* All comments received must include the agency name and docket number Docket # CISA-2025-0001. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Bryana Thomas, 771-217-0728, [bryana.thomas@mail.cisa.dhs.gov](mailto:bryana.thomas@mail.cisa.dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Cybersecurity and Infrastructure Security Agency Act of 2018 (Pub. L. 115-278) created the Cybersecurity and Infrastructure Security Agency (CISA). CISA is responsible for protecting the Nation’s critical infrastructure from physical and cyber threats. This mission requires effective coordination and collaboration from government and private sector organizations. As part of the collaboration efforts, CISA receives requests for CISA employees to give presentations and speeches at various events.

This digital collection of information is necessary to ensure an efficient and timely process to schedule outreach and engagement with CISA stakeholders. This information may be disclosed as generally permitted under 5 U.S.C. 522.

The Speaker Request Form will be the first point of contact between CISA and the public to initiate CISA speaking engagements. The form will be available on [www.cisa.gov](http://www.cisa.gov) and any member of the public can submit a request for a CISA employee to speak at an event. The form

will be used by CISA to track and manage external speaking engagements. The information will also be used to schedule and determine the most appropriate CISA speaker based on date, time, location, presentation format, and topic. The form collects information regarding the requested speaking engagement, *e.g.*, the host organization, the speaking topic, agenda, and additional event details.

The requested information helps CISA determine whether the speaker should attend the engagement and/or how CISA should best prepare for the event. The information is used to determine if accepting the request will further CISA's mission.

The CISA Speakers Bureau team will use the information to identify a speaker and route the Speakers Request Form to that person for consideration. The form will be available on [www.cisa.gov](http://www.cisa.gov) as a fillable pdf and/or webform and will be submitted to the CISA External Affairs Speakers Bureau. The data collected will be stored in an internal SharePoint site.

The CISA Speaker Request Form was previously approved by OMB on July 26, 2022, and is set to expire on July 31, 2025.

This is an extension of an existing information collection.

The Office of Management and Budget is particularly interested in comments which:

1. 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;
2. Evaluate 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;
3. Enhance the quality, utility, and clarity of the information to be collected; and
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, *e.g.*, permitting electronic submissions of responses.

#### Analysis

*Agency:* Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

*Title:* Cybersecurity and Infrastructure Security Agency (CISA) Speaker Request Form.

*OMB Number:* 1670-0047.

*Frequency:* Annually.

*Affected Public:* State, Local, Tribal, Territorial Governments and Public Organizations.

*Number of Respondents:* 1,300.

*Estimated Time per Respondent:* 0.25 hours.

*Total Burden Hours:* 325 hours.

*Total Annualized Respondent Cost:* \$14,813.60.

*Total Annualized Government Cost:* \$26,718.16.

**Robert J. Costello,**

*Chief Information Officer, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.*

[FR Doc. 2025-09688 Filed 5-28-25; 8:45 am]

**BILLING CODE 9111-LF-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[OMB Control Number 1615-NEW]

#### Agency Information Collection Activities; New Collection: Generic Clearance for the Collection of Certain Biographic and Employment Identifiers on Immigration Forms

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 60-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments. This collection of information is necessary to comply with section 2 of the Executive order (E.O.) 14161 entitled "Protecting the United States from Foreign Terrorists and Other National Security and Public Safety Threats" to establish enhanced screening and vetting standards and procedures to enable USCIS to assess an alien's eligibility to receive an immigration-related benefit. This data collection also is used to help validate an applicant's identity and to determine

whether such grant of a benefit poses a security or public-safety risk to the United States.

**DATES:** Comments are encouraged and will be accepted for 60 days until July 28, 2025.

**ADDRESSES:** All submissions received must include the Office of Management and Budget (OMB) Control Number 1615-NEW in the body of the letter, the agency name and Docket ID USCIS-2025-0006. Submit comments via the Federal eRulemaking Portal website at <https://www.regulations.gov> under e-Docket ID number USCIS-2025-0006.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Jerry Rigdon, Acting Chief, telephone number (240) 721-3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <https://www.uscis.gov>, or call the USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).

#### SUPPLEMENTARY INFORMATION:

##### Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: <https://www.regulations.gov> and entering USCIS-2025-0006 in the search box. Comments must be submitted in English, or an English translation must be provided. All submissions will be posted, without change, to the Federal eRulemaking Portal at <https://www.regulations.gov> and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <https://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

- (1) 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;

(2) Evaluate 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(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, e.g., permitting electronic submission of responses.

### Background

E.O. 14161, "Protecting the United States from Foreign Terrorists and Other National Security and Public Safety Threats," directs implementation of uniform vetting standards and necessitates the collection of all information necessary for a rigorous vetting and screening of all grounds of inadmissibility and removability or bases for the denial of immigration-related benefits. See 90 FR 8451 (Jan. 20, 2025). Implementation of the directives provided in the E.O. requires U.S. Citizenship and Immigration Services (USCIS) to collect standard data on immigration forms and/or information collection systems. This data will be collected from certain populations of individuals on applications for immigration-related benefits and is necessary for the enhanced identity verification, vetting, and national security screening and inspection conducted by USCIS and required under the E.O.

This collection of information is necessary to comply with section 2 of the E.O. to establish screening and vetting standards and procedures to enable USCIS to assess an alien's eligibility to receive an immigration-related benefit from USCIS. This data collection is also used to validate an applicant's identity and to help determine whether such grant of a benefit poses a security or public-safety threat to the United States.

USCIS will collect biographic information on immigration information collection instruments and systems. USCIS will update its forms and systems to collect additional information from individuals who seek admissibility or other benefits when that information is not already collected.

### New Information To Be Collected

U.S. Government departments and agencies involved in screening and vetting, to include USCIS, identified 24 data elements that would constitute a new baseline threshold of data to be collected for improved identity verification and national security vetting. These 24 core data elements were published in the **Federal Register** at 90 FR 11326 on March 3, 2025. These six (6) new data elements are in addition to and separate from the data elements for which USCIS requested comments in the March 3, 2025, generic clearance notice, but they are also needed for further identification and national security vetting and will be added to certain immigration benefit request forms where the information is not already collected.

The following six (6) data elements are biographic and employment identifiers used to help USCIS confirm both an individual's identity as it relates to the submitted application and to other records. These biographic identifiers are also used by USCIS and screening partners to help confirm or disprove a relevant association between an applicant and information of interest and the strength of that association in the context of the underlying information.

1. Beneficiary/Applicant/Petitioner Social Security Number
2. Family Member (parent(s), spouse, sibling(s), and child(ren)) Social Security Number
3. Business/Employer Name
4. Business/Employer Physical Address
5. Business/Employer Mailing Address
6. Business Federal Employer Identification Number

### Programs Affected, OMB Control Numbers

- OMB No. 1615-0052—Form N-400, Application for Naturalization
- OMB No. 1615-0013—Form I-131, Application for Travel Document
- OMB No. 1615-0017—Form I-192, Application for Advance Permission to Enter as a Nonimmigrant
- OMB No. 1615-0023—Form I-485, Application to Register Permanent Residence or Adjust status
- OMB No. 1615-0067—Form I-589, Application for Asylum and for Withholding of Removal
- OMB No. 1615-0068—Form I-590, Registration for Classification as Refugee
- OMB No. 1615-0037—Form I-730, Refugee/Asylee Relative Petition
- OMB No. 1615-0038—Form I-751, Petition to Remove Conditions on Residence

- OMB No. 1615-0045—Form I-829, Petition by Entrepreneur to Remove Conditions on Permanent Resident Status

Applicant information is collected to maintain a record of persons applying for specific immigration benefits, and to help determine whether these applicants are eligible to receive the benefits for which they are applying. The information provided through USCIS forms is also analyzed—along with other information that the Secretary of Homeland Security determines is necessary, including information about other persons included on the USCIS forms—against various security and law enforcement databases to identify those applicants who may pose a security or public-safety risk to the United States.

### Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Generic Clearance for the Collection of Certain Biographic and Employment Identifiers on Immigration Forms.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* GC-2025-0006; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. E.O. 14161, "Protecting the United States from Foreign Terrorists and Other National Security and Public Safety Threats," directs implementation of uniform vetting standards and necessitates collection of all information necessary for a rigorous vetting and screening of all grounds of inadmissibility and removability or bases for the denial of immigration-related benefits. Implementation of the directives in the E.O. requires USCIS to collect standard data on immigration forms and/or information collection systems. This data will be collected from certain populations of individuals on applications for immigration-related benefits and is necessary for the enhanced identity verification, vetting and national security screening, and inspection conducted by USCIS and required under the E.O.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

- The estimated total number of respondents for the information collection N-400 is 909,700 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–131 is 1,073,059 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–192 is 68,050 and the estimated hour burden per response is 2.08 hours.

- The estimated total number of respondents for the information collection I–485 is 1,060,585 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–589 is 203,379 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–590 is 106,200 and the estimated hour burden per response is 2.08 hours.

- The estimated total number of respondents for the information collection I–730 is 13,000 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–751 is 140,000 and the estimated hour burden per response is 2 hours.

- The estimated total number of respondents for the information collection I–829 is 1,010 and the estimated hour burden per response is 2 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 7,163,906 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$0. No additional costs to the public are anticipated due to this action. Any costs to the respondents associated with the specific form filed are captured in those approved information collections.

Dated: May 22, 2025.

**Jerry L. Rigdon,**

*Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2025–09585 Filed 5–28–25; 8:45 am]

**BILLING CODE 9111–97–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0008]

#### Agency Information Collection Activities; Revision of a Currently Approved Collection: Biographic Information (for Deferred Action)

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 60-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

**DATES:** Comments are encouraged and will be accepted for 60 days until June 30, 2025.

**ADDRESSES:** All submissions received must include the OMB Control Number 1615–0008 in the body of the letter, the agency name and Docket ID USCIS–2005–0024. Submit comments via the Federal eRulemaking Portal website at <https://www.regulations.gov> under e-Docket ID number USCIS–2005–0024.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Jerry Rigdon, Acting Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <https://www.uscis.gov>, or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

#### SUPPLEMENTARY INFORMATION:

##### Comments

You may access the information collection instrument with instructions

or additional information by visiting the Federal eRulemaking Portal site at: <https://www.regulations.gov> and entering USCIS–2005–0024 in the search box. Comments must be submitted in English, or an English translation must be provided. All submissions will be posted, without change, to the Federal eRulemaking Portal at <https://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <https://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) 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;

(2) Evaluate 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(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, *e.g.*, permitting electronic submission of responses.

#### Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Biographic Information (for Deferred Action).

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–325A; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. USCIS uses Form G–325A

to collect biographic information from individuals requesting deferred action for certain military service members and their family members, or for non-military deferred action (other than deferred action based on Deferred Action for Childhood Arrivals (DACA), Violence Against Women Act, A-3, G-5 nonimmigrants, and T and U nonimmigrant visas).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection G-325A is 7,500 and the estimated hour burden per response is 2.31 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total annual hour burden associated with this collection is 17,325 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$187,500.

Dated: May 22, 2025.

**Jerry L. Rigdon,**

*Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2025-09616 Filed 5-28-25; 8:45 am]

BILLING CODE 9111-97-P

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[Docket No. FWS-R1-ES-2022-0029; ES1114010000-256-FF01E0000]

#### Record of Decision for the Final Environmental Impact Statement and Habitat Conservation Plan for the Elliott State Research Forest in Coos and Douglas Counties, Oregon

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; record of decision.

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**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service) announce the availability of a record of decision (ROD) for the issuance of a permit under the Endangered Species Act (ESA) for certain activities at the Elliott State Research Forest supported by a habitat conservation plan (HCP) in Coos and Douglas Counties, Oregon. The ROD documents the Service's decision to issue an incidental take permit (ITP) to the Oregon Department of State Lands (DSL) in response to their permit

application. As summarized in the ROD, the Service has selected the proposed action alternative, which is issuance of an 80-year ITP authorizing take of species listed under the ESA that may occur incidental to research and management activities over the permit term implemented consistent with the HCP.

**ADDRESSES:** You may obtain copies of the ROD and other documents associated with the decision by any of the following methods:

- **Internet:** <https://www.regulations.gov> (search for Docket No. FWS-R1-ES-2022-0029) or at <https://www.fws.gov/project/elliott-state-research-forest-habitat-conservation-plan>.

- **Phone:** You may call Shauna Everett at 503-231-6949, to request alternative formats of the documents.

**FOR FURTHER INFORMATION CONTACT:** Shauna Everett, U.S. Fish and Wildlife Office, Oregon Fish and Wildlife Office (see **ADDRESSES**), by telephone at 503-231-6949, or by email at [shauna\\_everett@fws.gov](mailto:shauna_everett@fws.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.

**SUPPLEMENTARY INFORMATION:** We, the Service, announce the availability of a ROD for the issuance of a permit under section 10(a)(1)(B) of the ESA, as amended (16 U.S.C. 1531 *et seq.*) to the DSL for research and forest management activities on the Elliott State Research Forest, as supported and implemented under DSL's HCP. In compliance with the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*), the Service prepared an environmental impact statement (EIS) analyzing effects to the human environment associated with the proposed action and alternatives. The ROD documents the Service's decision to select Alternative 2, the proposed action, which includes issuance of an 80-year ITP authorizing take of the threatened northern spotted owl (*Strix occidentalis caurina*) and threatened marbled murrelet (*Brachyramphus marmoratus*) that may occur incidental to research and management activities in the permit area over the permit term.

The Service and National Marine Fisheries Service (NMFS) make independent decisions regarding authorization for incidental take of the

species under their respective jurisdictions. NMFS's decision regarding authorization of take of the threatened Oregon Coast coho salmon (*Oncorhynchus kisutch*) is not addressed in the Service's ROD.

### Background

As described in the HCP, DSL requested authorization for take of the northern spotted owl, marbled murrelet, and Oregon Coast coho salmon (together, the covered species) that may occur incidental to a variety of research and management activities, including forest research treatments, timber removal, forest and species research projects, supporting management activities, supporting infrastructure management, and activities identified in the conservation strategy and monitoring program of the HCP. These activities and the effects on covered species and the human environment are described further in the HCP and final EIS. Measures to minimize and mitigate impacts on covered species are described in the HCP for each species as conservation measures and conditions on covered activities, guided by goals and objectives in the conservation strategy of the HCP. DSL will monitor implementation of these measures for compliance and effectiveness.

The Service published a notice of intent in the **Federal Register** to develop an EIS for this project on May 5, 2022 (87 FR 26778). The Service published a notice of availability (NOA) for the draft EIS on November 18, 2022 (87 FR 69291), followed by an extension of the comment period (December 20, 2022, 87 FR 77877). Next, the Service published an NOA for the final EIS on January 10, 2025 (90 FR 1013). The EIS analyzed the environmental consequences of the proposed action (also described as the preferred alternative), a no action alternative, and two alternatives to the proposed action. All alternatives analyzed in detail include forest management activities (*i.e.*, timber harvest and reforestation, thinning, and supporting management activities and infrastructure); however, the implementation of these activities would vary by alternative, as described in the final EIS.

The Service prepared the draft EIS and final EIS pursuant to the Council on Environmental Quality's (CEQ's) implementing NEPA regulations at 40 CFR 1500-1508, effective as of May 20, 2022 (87 FR 23453; April 20, 2022). On February 25, 2025, in response to President Trump's Executive Order (E.O.) 14154, CEQ issued an interim final rule removing all its NEPA regulations (90 FR 10610, effective April

11, 2025). The Service prepared this ROD considering this change and related E.O.s, including E.O. 14154, “Unleashing American Energy,” as discussed in the ROD.

### Rationale for Decision

We have made the determination that DSL’s application, including the HCP, meet the statutory permit issuance criteria set forth in section 10(a)(2)(B) (16 U.S.C. 1539(a)(2)(B)). Our assessment of the application was conducted in accordance with the requirements of section 10(a)(1)(B) of the ESA and its implementing regulations. Based on our review of the alternatives and their environmental consequences as described in the final EIS, we selected the proposed action because issuance of the ITP and implementation of the HCP best fulfill the Service’s statutory mission and responsibilities while meeting our purpose and need. This decision is described further in the ROD.

### Authority

We provide this notice pursuant to NEPA (42 U.S.C. 4321 *et seq.*) and Department of the Interior guidance (318 DM 3).

### Bridget Fahey,

*Acting Regional Director, Pacific Region.*

[FR Doc. 2025–09636 Filed 5–28–25; 8:45 am]

BILLING CODE 4333–15–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2024–0006; EEEE500000 256E1700D2 ET1SF0000.EAQ000; OMB Control Number 1014–0003]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Oil and Gas Production Safety Systems

**AGENCY:** Bureau of Safety and Environmental Enforcement, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act (PRA) of 1995, the Bureau of Safety and Environmental Enforcement (BSEE, we) proposes to renew an information collection.

**DATES:** Interested persons are invited to submit comments. To be considered, your comments must be received on or before June 30, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent to [www.reginfo.gov/public/do/PRAMain](http://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 Kelly Odom, Acting BSEE ICCO, 45600 Woodland Road, Sterling, VA 20166; or by email to [kelly.odom@bsee.gov](mailto:kelly.odom@bsee.gov). Please reference OMB Control Number 1014–0003 in the subject line of your comments.

### FOR FURTHER INFORMATION CONTACT:

Kelly Odom by email at [kelly.odom@bsee.gov](mailto:kelly.odom@bsee.gov), or by telephone at (703) 787–1775. 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 PRA 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 August 30, 2024, (89 FR 70664). 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:** The regulations at 30 CFR part 250, subpart H concern oil and gas production safety systems and are the subject of this collection. The authority and responsibility for issuing these regulations are among those delegated to BSEE. This request also covers any related notices to lessees and operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

BSEE uses the information collected under subpart H to:

- review safety system designs prior to installation to ensure that minimum safety standards will be met;
- evaluate equipment and/or procedures used during production operations;
- review records of erosion control to ensure that erosion control programs are effective;
- review plans to ensure safety of operations when more than one activity is being conducted simultaneously on a production facility;
- review records of safety devices to ensure proper maintenance during the useful life of that equipment; and
- verify proper performance of safety and pollution prevention equipment.

**Title of Collection:** 30 CFR part 250, subpart H, “Oil and Gas Production Safety Systems.”

**OMB Control Number:** 1014–0003.

**Form Number:** None.

**Type of Review:** Extension of a currently approved collection.

**Respondents/Affected Public:** Potential respondents include Federal Outer Continental Shelf (OCS) oil, gas,

and sulfur lessees and/or operators and holders of pipeline rights-of-way.

**Total Estimated Number of Annual Respondents:** Currently there are approximately 60 oil and gas drilling and production operators on the OCS. Not all the potential respondents will submit information in any given year, and some may submit multiple times.

**Total Estimated Number of Annual Responses:** 7,454.

**Estimated Completion Time per Response:** Varies from .5 hour to 41 hours, depending on activity.

**Total Estimated Annual Nonhour Burden Hours:** 91,250.

**Respondent's Obligation:** Responses are mandatory.

**Frequency of Collection:** Submissions are generally on occasion.

**Total Estimated Annual Nonhour Burden Cost:** \$11,455,906.

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.*).

**Kirk Malstrom,**

*Chief, Regulations and Standards Branch.*

[FR Doc. 2025-09583 Filed 5-28-25; 8:45 am]

**BILLING CODE 4310-VH-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1394]

### Certain Liquid Coolers for Electronic Components in Computers, Components Thereof, Devices for Controlling Same, and Products Containing Same; Notice of a Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review in part a final initial determination ("ID") of the presiding administrative law judge ("ALJ"), Chief Judge Cheney. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government

agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

#### FOR FURTHER INFORMATION CONTACT:

Edward S. Jou, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-3316. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). General information concerning the Commission may also be obtained by accessing its internet server at <https://www.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 instituted this investigation on March 21, 2024, based on a complaint filed on behalf of Cooler Master Co., Ltd. of Taiwan; CMI USA, Inc. of Claremont, California; and CMC Great USA, Inc. of San Jose, California (collectively, "Complainants"). 89 FR 20247-48 (Mar. 21, 2024). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain liquid coolers for electronic components in computers, components thereof, devices for controlling same, and products containing same by reason of infringement of claims 1-3 and 14 of U.S. Patent No. 10,509,446 ("the '446 patent"); claims 1-4 of U.S. Patent No. 11,061,450 ("the '450 patent"); and the claim of U.S. Patent No. D856,941 ("the '941 design patent"). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents SilverStone Technology Co., Ltd. of Taiwan; SilverStone Technology, Inc. of Chino, California; Enermax Technology Corp. of Taiwan; Enermax USA of Chino, California; Shenzhen Apaltek Co., Ltd. of China; and Guangdong Apaltek Liquid Cooling Technology Co., Ltd. of China (collectively, "Respondents"). *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

The '941 design patent was terminated from the investigation by withdrawal of the complaint. Order No.

7 (Sept. 6, 2024), *unreviewed by* Comm'n Notice (Sept. 30, 2024).

A claim construction hearing was held on July 22, 2024, and a claim construction order issued on November 20, 2024. Order No. 10 (Nov. 20, 2024). An evidentiary hearing was held on December 2-5, 2024.

On March 21, 2025, the ALJ issued the subject ID. Respondents filed a petition for review of the ID on April 4, 2025. Complainants filed their response on April 14, 2025.

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, and the petition for review and response thereto, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the ID's analysis of the limitation "defining a heat exchange chamber" in the asserted claims of the '446 patent and the '450 patent in the context of invalidity, infringement, and the technical prong of the domestic industry requirement. The Commission has also determined to review the ID's findings on the economic prong of the domestic industry requirement. The Commission has determined not to review the ID's findings on other issues.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) Did the ID apply the plain and ordinary meaning of the claim limitation "defining a heat exchange chamber" in the context of the '446 patent and '450 patent with respect to invalidity, infringement, and the technical prong of the domestic industry requirement? If you disagree with the ID's interpretation of this limitation, please explain what meaning should have been applied and identify where you raised such arguments before the ALJ.

(2) Did the ID consistently apply the scope of the "defining a heat exchange chamber" limitation to the prior art, the accused products, and the domestic industry products? If you contend that there are inconsistencies in the ID, please explain how the limitation should have been consistently applied and identify where you raised such arguments before the ALJ.

(3) What is the amount of the domestic industry investments in dispute with respect to the remote controller addressed in the ID at pages 118-20? Are the domestic industry activities related to the remote controller limited to certain employees, a certain timeframe, or certain domestic

industry products? Can the domestic industry investments in this investigation be allocated or otherwise modified to exclude all investments related to the remote controller? How would exclusion of these investments affect the ID's determination regarding the existence of a domestic industry?

(4) Is there any evidence in the record that shows how many employees or subcontractors of Complainants work on any aspect of the domestic industry products worldwide, including manufacturing activities? If so, please identify the number of worldwide employees or subcontractors and the labor costs attributable to the domestic industry products for those worldwide employees or subcontractors.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

*Written Submissions:* The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding.

In their initial submission, Complainants are also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. All initial written submissions, from the parties and/or third parties/interested government agencies, and proposed remedial orders from the parties must be filed no later than close of business on June 5, 2025. All reply submissions must be filed no later than the close of business on June 12, 2025. Opening submissions from the parties are limited to 40 pages. Reply submissions from the parties are limited to 30 pages. All submissions from third parties and/or interested government agencies are limited to 10 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (Inv. No. 337-TA-1394) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, [https://www.usitc.gov/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf)). Persons with questions

regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. 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. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on May 22, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 22, 2025.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2025-09655 Filed 5-28-25; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–764–766 and 731–TA–1747–1749 (Preliminary)]

### Hardwood and Decorative Plywood From China, Indonesia, and Vietnam; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–764–766 and 731–TA–1747–1749 (Preliminary) pursuant to the Tariff Act of 1930 (“the Act”) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of hardwood and decorative plywood from China, Indonesia, and Vietnam, provided for in subheadings 4412.31.06, 4412.31.25, 4412.31.26, 4412.31.40, 4412.31.41, 4412.31.42, 4412.31.45, 4412.31.48, 4412.31.51, 4412.31.52, 4412.31.60, 4412.31.61, 4412.31.91, 4412.31.92, 4412.32.05, 4412.32.06, 4412.32.25, 4412.32.26, 4412.32.31, 4412.32.32, 4412.32.56, 4412.32.57, 4412.33.06, 4412.33.26, 4412.33.32, 4412.33.57, 4412.34.26, 4412.34.32, 4412.34.57, 4412.39.40, 4412.39.50, 4412.41.00, 4412.42.00, 4412.51.10, 4412.51.31, 4412.51.41, 4412.52.10, 4412.52.31, 4412.52.41, 4412.91.06, 4412.91.10, 4412.91.31, 4412.91.41, 4412.92.07, 4412.92.11, 4412.92.31, 4412.92.42, 4412.94.10, 4412.94.31, 4412.94.41, 4412.99.06, 4412.99.10, 4412.99.31, 4412.99.41, 4412.99.51, and 4412.99.57 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the governments of China, Indonesia, and Vietnam. Unless the Department of Commerce (“Commerce”) extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by July 7, 2025. The Commission’s views must be transmitted to Commerce within five business days thereafter, or by July 14, 2025.

**DATES:** May 22, 2025.

### FOR FURTHER INFORMATION CONTACT:

Calvin Chang ((202) 205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission’s TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these investigations may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>.

### SUPPLEMENTARY INFORMATION:

**Background.**—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to petitions filed on May 22, 2025, by the Coalition for Fair Trade in Hardwood Plywood, the members of which are Columbia Forest Products, Greensboro, North Carolina; Commonwealth Plywood Co., Ltd., Whitehall, New York; Manthei Wood Products, Petoskey, Michigan; States Industries LLC, Eugene, Oregon; and Timber Products Company, Springfield, Oregon.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

**Participation in the investigations and public service list.**—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission’s rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

**Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO)**

**and BPI service list.**—Pursuant to § 207.7(a) of the Commission’s rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

**Conference.**—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on June 12, 2025. Requests to appear at the conference should be emailed to [preliminaryconferences@usitc.gov](mailto:preliminaryconferences@usitc.gov) (DO NOT FILE ON EDIS) on or before noon on June 10, 2025. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission’s Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission’s deliberations may request permission to participate by submitting a short statement.

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.

**Written submissions.**—As provided in §§ 201.8 and 207.15 of the Commission’s rules, any person may submit to the Commission on or before 5:15 p.m. on June 17, 2025, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on June 11, 2025. All written submissions must conform with the provisions of § 201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s *Handbook on Filing Procedures*, available on the Commission’s website at

[https://www.usitc.gov/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf), elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Certification.**—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, 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. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: May 22, 2025.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2025-09656 Filed 5-28-25; 8:45 am]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF LABOR

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Securities Lending by Employee Benefit Plans, Prohibited Transaction Exemption 2006-16

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Department of Labor (DOL) is submitting this Employee Benefits Security Administration

(EBSA)-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 June 30, 2025.

**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](http://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:** Michael Howell by telephone at 202-693-6782, or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** In 2006, the Department promulgated a final class exemption, PTE 2006-16, which amended and replaced the exemptions previously provided under PTE 81-6 and PTE 82-63. The final exemption incorporates the exemptions into one renumbered exemption and expands the categories of exempted transactions to include securities lending to foreign banks and foreign broker-dealers that are domiciled in specified countries and to allow the use of additional forms of collateral, all subject to specified conditions outlined in the exemption.

Among other conditions, the class exemption requires a bank or broker-dealer that borrows securities from a plan to provide the lending fiduciary with its most recent audited financial statement and its most recent unaudited statement if the unaudited statement is more recent than the audited financial statement. The borrower must also represent, at the time the loan is negotiated, that there has been no material adverse change in its financial condition since the date of the most recent financial statement provided to the plan that has not been disclosed to the lending fiduciary. The exemption also requires the loan be made pursuant to a written loan agreement. Individual agreements are not required for each transaction; rather the compensation agreement may be made in the form of a master agreement covering a series of transactions. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 6, 2025 (90 FR 671).

**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-EBSA.

**Title of Collection:** Securities Lending by Employee Benefit Plans, Prohibited Transaction Exemption 2006-16.

**OMB Control Number:** 1210-0065.

**Affected Public:** Private sector.

**Total Estimated Number of Respondents:** 208.

**Total Estimated Number of Responses:** 8,320.

**Total Estimated Annual Time Burden:** 450 hours.

**Total Estimated Annual Other Costs Burden:** \$93,683.

(Authority: 44 U.S.C. 3507(a)(1)(D))

**Michael Howell,**

*Senior Paperwork Reduction Act Analyst.*

[FR Doc. 2025-09587 Filed 5-28-25; 8:45 am]

**BILLING CODE 4510-29-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219-0054]

### Proposed Extension of Information Collection: Underground Coal Mine Fire Protection

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. 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 can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection entitled Underground Coal Mine Fire Protection.

**DATES:** All comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA–2025–0015.

- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at [MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Legal Authority*

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act) as amended, 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its

duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal and nonmetal mines.

The Paperwork Reduction Act governs paperwork burdens imposed by Federal agencies on the public for using identical questions to collect information from 10 or more persons. Paperwork burden is defined in 44 U.S.C. 3502(2) as time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, policies and procedures of information collection are established to control paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

*B. Information Collection*

To fulfill the statutory mandate of promoting miners' health and safety, MSHA requires information under the information collection request (ICR) titled "Underground Coal Mine Fire Protection." The information collection is intended for MSHA to ensure mine operators keep proper records for the examination and testing of firefighting equipment, automatic fire sensor and warning device systems, fire hydrants and fire hoses, and fire suppression devices. It is also intended to ensure that mine operators certify the emergency response training for the designated responsible persons and maintain mine emergency evacuation and firefighting programs of instruction.

Burden and costs associated with this ICR include:

1. examining chemical extinguishers and recording dates;
2. updating maps or schematic with locations of sensors of automatic fire warning devices;
3. functional testing the warning signals and calibrating sensors in automatic fire sensor and warning device systems;
4. testing each fire hydrant and fire hose;
5. certifying mine emergency evacuation response training; and
6. submitting mine emergency evacuation and firefighting program of instruction for MSHA approval.

Below are described the relevant safety and information collection requirements.

1. Examining Chemical Extinguishers and Recording

Under 30 CFR 75.1100–3, all firefighting equipment must be maintained in a usable and operative condition. Chemical extinguishers must be examined every 6 months and the date of the examination must be written on a permanent tag attached to the extinguisher.

2. Updating Maps or Schematic With Locations of Sensors of Automatic Fire Warning Devices

Under 30 CFR 75.1103–5(a), when the carbon monoxide level reaches 10 parts per million above the established ambient level at any sensor location, automatic fire sensor and warning device systems must provide an effective warning signal at the following locations: (1) At working sections and other work locations where miners may be endangered from a fire in the belt entry; and (2) At a manned surface location where personnel have an assigned post of duty.

Under 30 CFR 75.1103–5(a)(2)(ii), the manned surface location must have a map or schematic that shows the locations of sensors and the intended air flow direction at the sensor locations. This map or schematic must be updated within 24 hours of any change in the content.

3. Functional Testing the Warning Signals and Calibrating Sensors in Automatic Fire Sensor and Warning Device Systems

Under 30 CFR 75.1103–8(a), automatic fire sensor and warning device systems must be examined at least once each shift, when belts are operated as part of a production shift. A functional test of the warning signals must be made at least once every seven days. Examination and maintenance of the systems must be done by a qualified person.

Under 30 CFR 75.1103–8(b), a record of the functional test must be maintained by the operator and kept for a period of one year.

Under 30 CFR 75.1103–8(c), sensors must be calibrated in accordance with the manufacturer's calibration instructions at intervals not to exceed 31 days. A record of the sensor calibrations must be maintained by the operator and kept for a period of one year.

4. Testing Fire Hydrants and Fire Hoses

Under 30 CFR 75.1103–11, each fire hydrant must be tested by opening to ensure that it is in operating condition, and each fire hose must be tested, at intervals not exceeding 1 year. A record

of these tests must be maintained at an appropriate location.

#### 5. Certifying Mine Emergency Response Training

Under 30 CFR 75.1501(a), for each shift that miners work underground, there must be in attendance a responsible person designated by the mine operator to take charge during mine emergencies involving a fire, explosion, or gas or water inundation.

Under 30 CFR 75.1501(a)(2), the responsible person must be trained annually in a course of instruction in mine emergency response, as prescribed by MSHA's Office of Educational Policy and Development. Further, under 75.1051(a)(3), the operator must certify by signature and date after each responsible person has completed the training and keep the certification at the mine for 1 year.

#### 6. Submitting Mine Emergency Evacuation and Firefighting Program of Instruction for MSHA Approval

Under 30 CFR 75.1502, each operator of an underground coal mine must adopt and follow a mine emergency evacuation and firefighting program that instructs all miners in the proper procedures they must follow if a mine emergency occurs.

Under 30 CFR 75.1502(a), the operator must submit the program of instruction, and any revisions, for approval to the District Manager in which the mine is located. Within 30 days of approval, the operator must conduct training in accordance with the revised program.

Additionally, under 30 CFR 75.1502(b), before implementing any new or revised approved provision in the program of instruction, the operator must instruct miners regarding the change.

### II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection titled "Underground Coal Mine Fire Protection". MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

The information collection request will be available on <https://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on <https://www.regulations.gov> and <https://www.reginfo.gov>.

The public may also examine publicly available documents at DOL-MSHA, Office of Standards, Regulations and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202-693-9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

### III. Current Actions

This information collection request concerns provisions for Underground Coal Mine Fire Protection. MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

*Type of Review:* Extension, without change, of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219-0054.

*Affected Public:* Business or other for-profit.

*Number of Annual Respondents:* 148.

*Frequency:* On occasion.

*Number of Annual Responses:* 143,039.

*Annual Time Burden:* 15,878 hours.

*Annual Other Burden Costs:* \$63.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at <https://www.reginfo.gov>.

**Song-ae Aromie Noe,**

*Certifying Officer, Mine Safety and Health Administration.*

[FR Doc. 2025-09594 Filed 5-28-25; 8:45 am]

**BILLING CODE 4510-43-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219-0150]

#### Proposed Extension of Information Collection: Pattern of Violations

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. 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 can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection titled Pattern of Violations.

**DATES:** All comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA-2025-0013.

- *Mail/Hand Delivery:* DOL-MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202-693-9455 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at [MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); (202) 693-9440 (voice); or (202) 693-9441 (facsimile). These are not toll-free numbers.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act) as amended, 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal and nonmetal mines.

The Paperwork Reduction Act (PRA) governs paperwork burdens imposed by Federal agencies on the public for using identical questions to collect information from 10 or more persons. Paperwork burden is defined in 44 U.S.C. 3502(2) as time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, policies and procedures of information collection are established for controlling paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

### B. Information Collection

To fulfill the statutory mandates to promote miners' health and safety, MSHA requires information under the information collection request (ICR) titled "Pattern of Violations". The information collection is intended to use the written corrective action programs (CAP) developed by mine operators to monitor the progress and effectiveness of operators' efforts to avoid the issuance of pattern of violations (POV) and to restore safe and healthful working conditions in their mines.

The Mine Act requires mine operators to take the ultimate responsibility of ensuring the safety and health of miners. Under 30 CFR part 104, the criteria and procedures to determine whether a mine operator has established a recurring pattern of significant and substantial (S&S) violations of mandatory health and safety standards at the mine. An S&S violation is a type of violation that is regarded to be reasonably likely to result in a serious injury or illness. 30 CFR part 104 implements section 104(e) of the Mine Act, 30 U.S.C. 814(e), regarding POV by addressing mines with an inspection history of recurrent S&S violations that demonstrate a mine operator's disregard

for the health and safety of miners. MSHA uses the POV provisions to effectively restore safe and healthy conditions at mines with an established pattern of S&S violations.

Burden costs associated with the ICR includes:

1. Mine operators developing and reviewing caps for MSHA approval and progress review;
2. MSHA issuing POV notices and withdrawal orders;
3. Mine operators posting POV notices; and
4. MSHA posting POV criteria.

Authorization and the associated rule text are described below.

#### 1. Mine Operators Developing and Reviewing CAPs for MSHA Approval and Progress Review

Under 30 CFR 104.2(a), at least once each year, MSHA will review the compliance and accident, injury, and illness records of mines to determine if any mines meet the POV criteria. MSHA's review to identify mines with a pattern of S&S violations will include:

- (i) Citations for S&S violations;
- (ii) Orders under section 104(b) of the Mine Act for not abating S&S violations;
- (iii) Citations and withdrawal orders under section 104(d) of the Mine Act, resulting from the mine operator's unwarrantable failure to comply;
- (iv) Imminent danger orders under section 107(a) of the Mine Act;
- (v) Orders under section 104(g) of the Mine Act requiring withdrawal of miners who have not received training and who MSHA declares to be a hazard to themselves and others;
- (vi) Enforcement measures, other than section 104(e) of the Mine Act, that have been applied at the mine;
- (vii) Other information that demonstrates a serious safety or health management problem at the mine, such as accident, injury, and illness records; and

(viii) Mitigating circumstances.

A POV notice could result in a temporary closure of the mine or sections of the mine. When a mine operator determines that the mine is likely to be issued a POV notice soon (a POV calculator is available on MSHA website, <https://www.msha.gov/data-and-reports/data-sources-and-calculators/pov-calculator>), the operator usually chooses to work with MSHA to develop and submit a written CAP to the District Manager for approval.

An approved CAP is one of the mitigating circumstances of 30 CFR 104.2(a)(8) that MSHA considers when determining whether to issue a POV notice. The CAP is submitted to MSHA to demonstrate planned actions by the

operator to address known health and safety violations. The CAP encourages operators to take proactive measures to bring their mines into compliance. Positive CAP results in reducing S&S violations will allow MSHA to monitor demonstrated progress of operator efforts to restore safe and healthful conditions.

#### 2. MSHA Issuing POV Notices and Withdrawal Orders

Under 30 CFR 104.3(a), when a mine has a POV, the District Manager will issue a POV notice to the mine operator that specifies the basis for the Agency's action. The District Manager will also provide a copy of this notice to the representative of miners.

Under 30 CFR 104.3(c), if MSHA finds any S&S violation within 90 days after issuance of the POV notice, MSHA will issue an order for the withdrawal of all persons from the affected area, except those exempted persons referred to in section 104(c) of the Mine Act, until the violation has been abated.

Under 30 CFR 104.3(d), if a withdrawal order is issued, any subsequent S&S violation will result in a withdrawal order that will remain in effect until MSHA determines that the violation has been abated.

#### 3. Mine Operators Posting POV Notices

Under 30 CFR 104.3(b), the mine operator must post the POV notice on the mine bulletin board. The POV notice must remain posted at the mine until terminated by MSHA.

#### 4. MSHA Posting POV Criteria

Under 30 CFR 104.2(b), MSHA will post the specific pattern criteria on its website. The criteria has been posted (<https://www.msha.gov/compliance-and-enforcement/pattern-violations-pov>) and no further cost is involved.

## II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection titled "Pattern of Violations". MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

The information collection request is available on <https://www.regulations.gov>. MSHA cautions commenters against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on <https://www.regulations.gov> and <https://www.reginfo.gov>.

The public may also examine publicly available documents at DOL–MSHA, Office of Standards, Regulations and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

### III. Current Actions

This information collection request concerns provisions for Pattern of Violations. MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

*Type of Review:* Extension, without change, of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219–0150.

*Affected Public:* Business or other for-profit.

*Number of Annual Respondents:* 15.

*Frequency:* On occasion.

*Number of Annual Responses:* 21.

*Annual Time Burden:* 1,664 hours.

*Annual Other Burden Costs:* \$2,801.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at <https://www.reginfo.gov>.

#### Song-ae Aromie Noe,

*Certifying Officer, Mine Safety and Health Administration.*

[FR Doc. 2025–09596 Filed 5–28–25; 8:45 am]

BILLING CODE 4510–43–P

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219–0011]

#### Proposed Extension of Information Collection: Respirable Coal Mine Dust Sampling

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. 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 can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection titled “Respirable Coal Mine Dust Sampling”.

**DATES:** All comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:*

<https://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA–2025–0026.

- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at [MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

## SUPPLEMENTARY INFORMATION:

### I. Background

#### A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act) as amended, 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal and nonmetal mines.

The Paperwork Reduction Act (PRA) governs paperwork burdens imposed by Federal agencies on the public for using identical questions to collect information from 10 or more persons. Paperwork burden is defined in 44 U.S.C. 3502(2) as time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, policies and procedures of information collection are established for controlling paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

#### B. Information Collection

To fulfill the statutory mandates to promote miners’ health and safety, MSHA requires information under the information collection request (ICR) titled “Respirable Coal Mine Dust Sampling”. The information collection is intended to ascertain coal mine dust levels and to ensure coal miners are not exposed to excessive levels of respirable coal mine dust.

Chronic excessive exposure to respirable coal mine dust causes lung diseases including coal workers’ pneumoconiosis (CWP), emphysema, silicosis, and chronic bronchitis. These diseases, known collectively as “black lung,” are debilitating and can result in severe disability and premature death. While considerable progress has been made in lowering dust levels over time, severe cases of black lung continue to be identified. Information from the federally funded Coal Workers’ Health Surveillance Program administered by the National Institute for Occupational Safety and Health (NIOSH) indicates that black lung remains an occupational health risk among coal miners.

MSHA’s standards in 30 CFR parts 70 and 71 require each operator of

underground and surface coal mines to protect miners from exposure to excessive respirable coal mine dust levels for the miners' health and safety. Under 30 CFR parts 70 and 71, coal mine operators are required to continuously maintain the average concentration of respirable coal mine dust in the atmosphere where miners normally work or travel at or below 1.5 milligrams per cubic meter of air (mg/m<sup>3</sup>). Each coal mine operator is also required to continuously maintain the average concentration of respirable dust in intake airways at underground mines at or below 0.5 mg/m<sup>3</sup>.

Additionally, MSHA's standards in 30 CFR part 90 require that for coal mine employees who have exercised the option described in section 30 CFR 90.3 (hereafter referred to as part 90 miners<sup>1</sup>), the mine operator must place them in a work area of the mine where the average concentration of respirable dust in the mine atmosphere is at or below 0.5 mg/m<sup>3</sup>.

To ensure coal mine operators comply with the applicable dust standards specified in 30 CFR parts 70, 71, and 90, coal mine operators are required to sample respirable coal mine dust quarterly and submit these samples to MSHA for analysis.

Underground coal mine operators must take the following samples quarterly with an approved Continuous Personal Dust Monitor (CPDM) unless notified by MSHA that they may use an approved Coal Mine Dust Personal Sampling Unit (CMDPSU) to conduct sampling:

- The Designated Occupations (DO) and Other Designated Occupations (ODO) associated with each Mechanized Mining Unit (MMU), and
- Each Designated Area (DA) location specified in the operator's approved mine ventilation plan.

At surface coal mines and surface work areas of underground coal mines, operators must take quarterly samples of the Designated Work Positions (DWP) with an approved CMDPSU unless notified by MSHA that they may use an approved CPDM to conduct sampling.

Furthermore, at both surface and underground coal mines each part 90 miner may only be sampled with an approved CPDM unless notified by

MSHA that they may use an approved CMDPSU.

This information collection request summarizes recordkeeping and reporting burden, and costs associated with respirable coal mine dust sampling, which includes six components:

#### 1. Records Related to Sampling

This component covers the information collection costs related to activities that mine operators are required to conduct and submit to MSHA for sampling, but are not direct costs of sampling, and MSHA's responses to those reports. These recordkeeping activities include mine operators:

- i. Recording lengths of shifts for each MMU, DWP, and part 90 miner;
- ii. Submitting dates and times of when sampling will be conducted for MSHA's review;
- iii. Submitting samples taken for purposes other than fulfilling the sampling requirements;
- iv. Reporting changes in the status of a mine, MMU, DA, DWP, or part 90 miner that affects sampling requirements for MSHA's review;
- v. Recording production at underground coal mines to establish a normal production shift; and
- vi. Submitting work position lists that identify where DWP samples are collected at surface coal mines and surface work areas of underground coal mines.

#### 2. CMDPSU Sampling

This component covers the information collection costs related to CMDPSU sampling, including:

- i. Mine operators collecting, certifying, and submitting CMDPSU samples;
- ii. MSHA processing CMDPSU samples and reporting results to mine operators; and
- iii. Mine operators posting MSHA's CMDPSU sampling results on mine bulletin boards.

#### 3. CPDM Sampling

This component covers the information collection costs related to CPDM sampling, mostly at underground coal mines, including:

- i. Mine operators collecting, certifying, and submitting CPDM samples;
- ii. MSHA processing CPDM samples and reporting results to mine operators; and
- iii. Mine operators posting CPDM Dust Data Cards and MSHA's sampling results on mine bulletin boards.

#### 4. Part 90 Miner Sampling

This component covers the information collection costs related to part 90 miner sampling, including:

- i. Mine operators collecting, certifying, and submitting samples from part 90 miners;
- ii. MSHA processing samples from part 90 miners and reporting results to part 90 miners; and
- iii. Mine operators providing part 90 miners with Dust Data Cards and MSHA's sampling results.

#### 5. Recording and Certifying Corrective Actions

This component covers the information collection costs related to corrective actions taken after a sample meets or exceeds the Excessive Concentration Value (ECV), or after the issuance of a citation for violation, including:

- i. Recording and certifying corrective actions taken after a valid sample meets or exceeds the ECV; and
- ii. Recording and certifying corrective actions taken after a citation for violation is issued.

#### 6. Abatement Activities after Corrective Actions

This component covers the information collection costs related to all abatement activities after corrective actions are taken, including:

- i. Mine operators collecting, certifying, and submitting abatement samples;
- ii. MSHA processing abatement samples and reporting results to mine operators or part 90 miners;
- iii. Mine operators posting Dust Data Cards and MSHA's abatement sampling results, and providing copies to part 90 miners;
- iv. Mine operators submitting new or revised mine ventilation plans or dust control plans for MSHA's review;
- v. Mine operators notifying miners' representatives of new or revised mine ventilation plans or dust control plans and providing copies to miner's representatives and part 90 miners; and
- vi. Mine operators posting new or revised mine ventilation plans or dust control plans.

Authorization and the associated rule text as well as detailed requirements associated with respirable coal mine dust sampling are described below.

#### 1. Records Related to Sampling

##### i. Recording Lengths of Shifts Underground Coal Mines

Under 30 CFR 70.201(e), records showing the length of each production shift for each MMU must be made and

<sup>1</sup> Under 30 CFR 90.3(a), any miner employed at a coal mine who has evidence of the development of pneumoconiosis, based on a chest X-ray or other medical examinations, must be afforded the option to work in an area of a mine where the average concentration of respirable dust in the mine atmosphere during each shift to which that miner is exposed is continuously maintained at or below the applicable standard. Each of these miners must be notified in writing of eligibility to exercise the option.

retained for at least 6 months and must be made available for inspection by authorized representatives of the Secretary, the representative of miners, and submitted to the District Manager when requested in writing.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.201(d), records showing the length of each normal work shift for each DWP must be made and retained for at least 6 months and must be made available for inspection by authorized representatives of the Secretary, the representative of miners, and submitted to the District Manager when requested in writing.

#### Part 90 Miners

Under 30 CFR 90.201(f), records showing the length of each shift for each part 90 miner must be made and retained for at least 6 months and must be made available for inspection by authorized representatives of the Secretary and submitted to the District Manager when requested in writing.

#### ii. Submitting Sampling Dates and Times

##### Underground Coal Mines

Under 30 CFR 70.201(f), upon request from the District Manager, the operator must submit the date and time any respirable dust sampling will begin. This information must be submitted at least 48 hours prior to the scheduled sampling.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.201(e), upon request from the District Manager, the operator must submit the date and time any respirable dust sampling will begin. This information must be submitted at least 48 hours prior to scheduled sampling.

Under 30 CFR 71.201(f), upon written request by the operator, the District Manager may waive the rain restriction for a normal work shift as defined in 30 CFR 71.2 for a period not to exceed 2 months, if the District Manager determines that: The operator will not have reasonable opportunity to complete the respirable dust sampling without the waiver because of the frequency of rain, and the operator did not have reasonable opportunity to complete the required respirable dust sampling prior to requesting the waiver.

#### Part 90 Miners

Under 30 CFR 90.201(g), upon request from the District Manager, the operator must submit the date and time any required respirable dust sampling will

begin. This information must be submitted at least 48 hours prior to scheduled sampling.

#### iii. Submitting Samples Taken for Purposes Other Than Fulfilling the Sampling Requirements

##### Underground Coal Mines

Under 30 CFR 70.210(d), all respirable dust samples collected by the operator will be considered taken to fulfill the sampling requirements of parts 70, 71, or 90, unless the sample has been identified in writing by the operator to the District Manager, prior to the intended sampling shift, as a sample to be used for purposes other than required by 30 CFR parts 70, 71, or 90.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.207(d), all respirable dust samples collected by the operator will be considered taken to fulfill the sampling requirements of parts 70, 71, or 90, unless the sample has been identified in writing by the operator to the District Manager, prior to the intended sampling shift, as a sample to be used for purposes other than required by 30 CFR parts 70, 71, or 90.

#### Part 90 Miners

Under 30 CFR 90.208(d), all respirable dust samples collected by the operator will be considered taken to fulfill the sampling requirements of parts 70, 71, or 90, unless the sample has been identified in writing by the operator to the District Manager, prior to the intended sampling shift, as a sample to be used for purposes other than required by 30 CFR parts 70, 71, or 90.

#### iv. Reporting Status Changes

##### Underground Coal Mines

Under 30 CFR 70.212(a), if there is a change in operational status that affects the respirable dust sampling requirements, the operator must report the change in operational status of the mine, MMU, or DA to the MSHA District Office or to any other MSHA office designated by the District Manager. Status changes must be reported in writing or electronically within 3 working days after the status change has occurred. Operational status is classified as producing, nonproducing, and abandoned.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.209(a), if there is a change in operational status that affects the respirable dust sampling requirements, the operator must report the change in operational status of the

mine or DWP to the MSHA District Office or to any other MSHA office designated by the District Manager. Status changes must be reported in writing or electronically within 3 working days after the status change has occurred. Operational status is classified as producing, nonproducing, and abandoned.

#### Part 90 Miners

Under 30 CFR 90.210, if there is a change in the status of a part 90 miner (such as entering a terminated, injured, or ill status, or returning to work), the operator must report the change in the status of the part 90 miner to the MSHA District Office or to any other MSHA office designated by the District Manager. Status changes must be reported in writing or by electronic means within 3 working days after the status change has occurred.

#### v. Recording Production at Underground Coal Mines

##### Underground Coal Mines

Under 30 CFR 70.201(g), to establish a normal production shift the operator must record the amount of run-of-mine material produced by each MMU during each shift to determine the average production for the most recent 30 production shifts, or for all production shifts if fewer than 30 shifts of production data are available. Production records must be retained for at least 6 months and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

#### vi. Submitting Work Position Lists of DWP Samples at Surface Coal Mines and Surface Work Areas of Underground Coal Mine

##### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.206(d), operators with multiple specified work positions must sample the DWP exposed to the greatest respirable dust concentration in each work position performing the same activity or task at the same location at the mine and exposed to the same dust generation source. Specified work positions include bulldozer operators (MSHA occupation code 368) and other work positions designated by the District Manager for sampling where a concentration of respirable dust exceeding 50 percent of the standard in effect at the time the sample is taken, or a concentration of respirable dust exceeding 50 percent of the standard has been measured by one or more MSHA valid representative samples. Each operator must provide the District

Manager with a list identifying the specific work positions where DWP samples will be collected for active mines, new mines, and DWPs with a change in operational status that increases or reduces the number of active DWPs.

Under 30 CFR 71.206(m), The District Manager may designate additional work positions for sampling where a concentration of respirable dust exceeding 50 percent of the standard in effect at the time the sample is taken, or a concentration of respirable dust exceeding 50 percent of the standard has been measured by one or more MSHA valid representative samples.

## 2. CMDPSU Sampling

### i. Collecting, Certifying, and Submitting CMDPSU Samples

After conducting quarterly sampling and notating irregular flowrate or other events, all mine operators using CMDPSUs must certify and submit these samples to MSHA.

#### Underground Coal Mines

Under 30 CFR 70.201(b)(2), DAs identified by the operator under section 75.371(t) must be sampled quarterly with an approved CMDPSU, unless the operator notifies the District Manager in writing that only an approved CPDM will be used for all DA sampling at the mine. The notification must be received at least 90 days before the beginning of the quarter in which CPDMs will be used to collect the DA samples.

Under 30 CFR 70.209(a), if using a CMDPSU, the operator must sample quarterly each DA on consecutive production shifts until five valid representative samples are taken.

Under 30 CFR 70.205(b)(2), if using a CMDPSU, each approved sampling device must be examined each shift by a person certified in sampling during the last hour of operation to assure that the sampling device is operating properly and at the proper flowrate. If the proper flow rate is not maintained, the respirable dust sample must be transmitted to MSHA with a notation by the certified person on the back of the dust data card stating that the proper flowrate was not maintained. Other events occurring during the collection of respirable dust samples that may affect the validity of the sample, such as dropping of the sampling head assembly onto the mine floor, must also be noted on the back of the dust data card.

Under 30 CFR 70.210(c), a person certified in sampling must properly complete the dust data card that is provided by the manufacturer for each filter cassette. The card must have an

identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and must include that person's MSHA Individual Identification Number (MIIN). Respirable dust samples with data cards not properly completed may be voided by MSHA.

Under 30 CFR 70.210(a), if using a CMDPSU the operator must transmit within 24 hours after the end of the sampling shift all samples collected for compliance, including control filters, in containers provided by the manufacturer of the filter cassette to MSHA, or to any other address designated by the District Manager.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.201(a), each operator must take representative samples of the concentration of respirable dust in the active workings of the mine only with an approved CMDPSU. The operator may use an approved CPDM if the operator notifies the District Manager in writing that only an approved CPDM will be used for all DWP sampling at the mine. The notification must be received at least 90 days before the beginning of the quarter in which CPDMs will be used to collect the DWP samples.

Under 30 CFR 71.206(a), if using a CMDPSU, each operator must take one valid representative sample from the DWP during each quarterly period.

Under 30 CFR 71.205(b)(2), if using a CMDPSU, each sampling device must be examined each shift by a person certified in sampling during the last hour of operation to assure that it is operating properly and at the proper flowrate. If the proper flowrate is not maintained, the respirable dust sample must be transmitted to MSHA with a notation by the certified person on the back of the dust data card stating that the proper flowrate was not maintained. Other events occurring during the collection of respirable dust samples that may affect the validity of the sample, such as dropping of the sampling head assembly onto the mine floor, must also be noted on the back of the dust data card.

Under 30 CFR 71.206(e), each DWP sample must be taken on a normal work shift. If a normal work shift is not achieved, the respirable dust sample must be transmitted to MSHA with a notation by the person certified in sampling on the back of the dust data card stating that the sample was not

taken on a normal work shift. When a normal work shift is not achieved, the sample for that shift may be voided by MSHA. However, any sample, regardless of whether a normal work shift was achieved, that exceeds the applicable standard by at least 0.1 mg/m<sup>3</sup> must be used in the determination of the equivalent concentration for that occupation.

Under 30 CFR 71.207(c), a person certified in sampling must properly complete the dust data card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and must include that person's MIIN. Respirable dust samples with data cards not properly completed may be voided by MSHA.

Under 30 CFR 71.207(a), if using a CMDPSU, the operator must transmit within 24 hours after the end of the sampling shift all required samples, including control filters, in containers provided by the manufacturer of the filter cassette to MSHA.

### ii. MSHA Processing CMDPSU Samples and Reporting Results to Mine Operators

#### Underground Coal Mines

Under 30 CFR 70.211(a), MSHA will provide the operator a report on respirable dust samples submitted. The report will include the concentration of respirable dust, the average equivalent concentration of respirable dust for all valid samples, the occupation code (where applicable), and the reason for voiding any sample.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.208(a), MSHA will provide the operator a report on respirable dust samples submitted. The report will include the concentration of respirable dust, the average equivalent concentration of respirable dust for all valid samples, the occupation code, and the reason for voiding any sample.

### iii. Posting MSHA's CMDPSU Sampling Results

#### Underground Coal Mines

Under 30 CFR 70.211(b), upon receipt, the operator must post MSHA's report with data on respirable dust samples submitted or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.208(b), upon receipt, the operator must post MSHA's report with data on respirable dust samples submitted or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

#### 3. CPDM Sampling

##### i. Collecting, Certifying, and Submitting CPDM Samples

After conducting quarterly sampling and notating irregular flowrate or other events, mine operators must certify and submit CPDM samples to MSHA.

##### Underground Coal Mines

Under 30 CFR 70.201(a), DOs in each MMU must be sampled quarterly with an approved CPDM and an approved CMDPSU cannot be used, unless notified by the Secretary to continue to use an approved CMDPSU to conduct quarterly sampling.

Under 30 CFR 70.201(b)(1), DAs associated with an MMU must be redesignated as ODO. ODOs must be sampled quarterly with an approved CPDM and an approved CMDPSU must not be used, unless notified by the Secretary to continue to use an approved CMDPSU to conduct quarterly sampling.

Under 70.208(a), the operator must sample each calendar quarter: the DO in each MMU and each ODO in each MMU on consecutive normal production shifts until 15 valid representative samples are taken.

Under 30 CFR 70.210(c), a person certified in sampling must properly complete the dust data card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and must include that person's MIIN. Respirable dust samples with data cards not properly completed may be voided by MSHA.

Under 30 CFR 70.210(f)(1), if using a CPDM, the person certified in sampling must validate, certify, and transmit electronically to MSHA within 24 hours after the end of each sampling shift all sample data file information collected and stored in the CPDM, including the sampling status conditions encountered when sampling. Under 30 CFR 70.210(f)(2), the person certified in sampling must not tamper with the CPDM or its components in any way

before, during, or after it is used to sample for compliance or alter any sample data files. All CPDM data files transmitted electronically to MSHA must be maintained by the operator for at least 12 months.

##### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.201(a), each operator must take representative samples of the concentration of respirable dust in the active workings of the mine only with an approved CMDPSU. The operator may use an approved CPDM if the operator notifies the District Manager in writing that only an approved CPDM will be used for all DWP sampling at the mine. The notification must be received at least 90 days before the beginning of the quarter in which CPDMs will be used to collect the DWP samples.

Under 30 CFR 71.207(c), a person certified in sampling must properly complete the dust data card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and must include that person's MSHA MIIN. Respirable dust samples with data cards not properly completed may be voided by MSHA.

Under 30 CFR 71.207(f), if using a CPDM, the person certified in sampling must (1) validate, certify, and transmit electronically to MSHA within 24 hours after the end of each sampling shift all sample data file information collected and stored in the CPDM, including the sampling status conditions encountered when sampling each DWP; and (2) not tamper with the CPDM or its components in any way before, during, or after it is used to sample for compliance, or alter any sample data files. All CPDM data files transmitted electronically to MSHA must be maintained by the operator for at least 12 months.

##### ii. MSHA Processing CPDM Samples and Reporting Results to Mine Operators

##### Underground Coal Mines

Under 30 CFR 70.211(a), MSHA will provide the operator a report on respirable dust samples submitted physically or transmitted electronically if using a CPDM. The report will include the concentration of respirable dust, the average equivalent concentration of respirable dust for all

valid samples, the occupation code (where applicable), and the reason for voiding any sample.

##### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.208(a), MSHA will provide the operator a report on respirable dust samples submitted physically or transmitted electronically if using a CPDM. The report will include the concentration of respirable dust, the average equivalent concentration of respirable dust for all valid samples, the occupation code, and the reason for voiding any sample.

##### iii. Posting CPDM Dust Data Cards and MSHA's Sampling Results

##### Underground Coal Mines

Under 30 CFR 70.211(b), upon receipt of a MSHA's report, the operator must post the report with data on respirable dust samples submitted physically or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

Under 30 CFR 70.211(c), if using a CPDM, the person certified in sampling must, within 12 hours after the end of each sampling shift, print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of the sample run. This hard-copy record must include the data entered when the sample run was first programmed and key information such as the concentration of respirable dust and the shift length.

Under 30 CFR 70.211(d), the information must remain posted until the receipt of the MSHA report covering the respirable dust samples.

Under 30 CFR 70.201(j), anthracite mines using the full box, open breast, or slant breast mining method may use either a CPDM or a CPMDPSU to conduct the required sampling. The mine operator must notify the District Manager in writing of its decision to not use a CPDM.

##### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.208(b), upon receipt of a MSHA's report, the operator must post the report with data on respirable dust samples submitted physically or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

Under 30 CFR 71.208(c), if using a CPDM, the person certified in sampling must, within 12 hours after the end of each sampling shift, print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of each sample run. This hard-copy record must include the data entered when the

sample run was first programmed and key information such as the concentration of respirable dust and the shift length.

Under 30 CFR 71.208(d), the information must remain posted until the receipt of the MSHA report covering the respirable dust samples.

#### 4. Part 90 Miner CPDM Sampling

##### i. Collecting, Certifying, and Submitting Samples From Part 90 Miners

Under 30 CFR 90.201(a), part 90 miners must be sampled only with an approved CPDM, and an approved CMDPSU cannot be used unless notified by the Secretary to continue to use an approved CMDPSU to conduct quarterly sampling.

Under 30 CFR 90.207(a), each operator must take five valid representative samples every calendar quarter from the environment of each part 90 miner while performing normal work duties. Part 90 miner samples must be collected on consecutive workdays.

Under 30 CFR 90.205(b)(2), if using a CMDPSU, each approved sampling device must be examined each shift, by a person certified in sampling during the last hour of operation to assure that the sampling device is operating properly and at the proper flowrate. If the proper flowrate is not maintained, the respirable dust sample must be transmitted to MSHA with a notation by the certified person on the back of the dust data card stating that the proper flowrate was not maintained. Other events that occurred during the collection of respirable dust samples that may affect the validity of the sample, such as dropping of the sampling head assembly onto the mine floor, must be noted on the back of the dust data card.

Under 30 CFR 90.208(c), a person certified in sampling must properly complete the dust data card that is provided by the manufacturer for each filter cassette. The card must have an identification number identical to that on the cassette used to take the sample and be submitted to MSHA with the sample. Each card must be signed by the certified person who actually performed the required examinations during the sampling shift and must include that person's MIIN. Respirable dust samples with data cards not properly completed may be voided by MSHA.

Under 30 CFR 90.208(a), if using a CMDPSU, the operator must transmit within 24 hours after the end of the sampling shift all samples collected for compliance, including control filters, in containers provided by the

manufacturer of the filter cassette, to MSHA or to any other address designated by the District Manager.

Under 30 CFR 90.208(f), if using a CPDM, the person certified in sampling must validate, certify, and transmit electronically to MSHA within 24 hours after the end of each sampling shift all sample data file information collected and stored in the CPDM, including the sampling status conditions encountered when sampling each part 90 miner. The person certified in sampling must not tamper with the CPDM or its components in any way before, during, or after it is used to fulfill the requirements, or alter any data files. All CPDM data files transmitted electronically to MSHA must be maintained by the operator for at least 12 months.

Under 30 CFR 90.201(j), anthracite mines using the full box, open breast, or slant breast mining method may use either a CPDM or a CMDPSU to conduct the required sampling. The mine operator must notify the District Manager in writing of its decision to not use a CPDM.

##### ii. MSHA Processing Samples From Part 90 Miners and Reporting Results to Part 90 Miners

Under 30 CFR 90.209(a), MSHA will provide the operator a report on respirable dust samples submitted physically or transmitted electronically, if using a CPDM, to the part 90 miner.

##### iii. Providing Part 90 Miners With Dust Data Cards and MSHA's Sampling Results

Under 30 CFR 90.209(b), upon receipt of MSHA's report on respirable dust samples, the operator must provide a copy of the report to the part 90 miner. The operator must not post the original or a copy of this report on the mine bulletin board.

Under 30 CFR 90.209(c), if using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within one hour after the start of the part 90 miner's next work shift. This hard-copy record must include the data entered when the sample run was first programmed and key information such as the concentration of respirable dust, the shift length, and the part 90 miner's MIIN.

Under 30 CFR 90.209(d), the operator must not post data on respirable dust samples for part 90 miners on the mine bulletin board.

#### 5. Recording and Certifying Corrective Actions

##### i. Recording and Certifying Corrective Actions After a Valid Sample Meets or Exceeds the ECV

###### Underground Coal Mines

Under 30 CFR 70.208(e)(2), when a valid representative sample meets or exceeds the ECV in Table 70-1 (Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements) that corresponds to the applicable standard and particular sampling device used, the operator must immediately take corrective action to lower the concentration of respirable dust to at or below the applicable dust standard.

Under 30 CFR 70.208(e)(3), the operator must make a record of the corrective action taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

Under 30 CFR 70.209(c)(2), when a valid representative sample meets or exceeds the ECV in Table 70-1 that corresponds to the applicable standard and particular sampling device used, the operator must immediately take corrective action to lower the concentration of respirable dust to at or below the applicable respirable dust standard.

Under 30 CFR 70.209(c)(3), the operator must make a record of the corrective action taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.206(h)(2), when a valid representative sample meets or exceeds the ECV in Table 71–1 (Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements) that corresponds to the applicable standard and particular sampling device used, the operator must immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the applicable standard.

Under 30 CFR 71.206(h)(3), the operator must make a record of the corrective actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

### Part 90 Miners

Under 30 CFR 90.207(c)(2), when a valid representative sample meets or exceeds the ECV in Table 90–1 (Excessive Concentration Values (ECV) Based on Single, Full-Shift CMDPSU/CPDM Concentration Measurements) that corresponds to the applicable standard and particular sampling device used, the operator must immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the applicable standard.

Under 30 CFR 90.207(c)(3), the operator must make a record of the corrective actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the part 90 miner.

### ii. Recording and Certifying Corrective Actions After a Citation for Violation Is Issued

#### Underground Coal Mines

Under 30 CFR 70.208(h)(2), upon the issuance of a citation for violation of the applicable standard for MMUs, the operator must immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the applicable standard.

Under 30 CFR 70.208(h)(3), the operator must make a record of the corrective action taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman's or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

Under 30 CFR 70.209(f)(2), upon issuance of a citation for a violation of the applicable standards for DAs, the operator must immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the applicable standard.

Under 30 CFR 70.209(f)(3), the operator must make a record of the corrective actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.206(k)(2), upon issuance of a citation for violation of the applicable standard for DWPs, the operator must immediately take corrective action to lower the concentration of respirable coal mine dust to at or below the applicable standard.

Under 30 CFR 71.206(k)(3), the operator must make a record of the corrective actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the representative of miners.

### Part 90 Miners

Under 30 CFR 90.207(f)(2), upon issuance of a citation for a violation of the applicable standard for part 90 miners, the operator must immediately take corrective action to lower the concentration of respirable dust to at or below the applicable standard.

Under 30 CFR 90.207(f)(3), the operator must make a record of the corrective actions taken. The record must be certified by the mine foreman or equivalent mine official, no later than the end of the mine foreman or equivalent official's next regularly scheduled working shift. The record must be made in a secure book or electronically in a computer system, both of which must be secure and not susceptible to alteration. Such records must be retained at a surface location at the mine for at least 1 year and must be made available for inspection by authorized representatives of the Secretary and the part 90 miner.

### 6. Abatement Activities After Corrective Actions

#### i. Collecting, Certifying, and Submitting Abatement Samples

##### Underground Coal Mines

Under 30 CFR 70.208(h)(4), after the issuance of a citation for violation of the applicable standard for MMUs and taking correct actions, the operator must begin sampling, within 8 calendar days after the date the citation is issued, the environment of the affected occupation in the MMU on consecutive normal production shifts until five valid representative samples are taken.

Under 30 CFR 70.208(i)(1), a citation for violation of the applicable standard will be terminated by MSHA when each of the five valid representative samples is at or below the applicable standard, and the operator has submitted a revised mine ventilation plan approved by MSHA.

Under 30 CFR 70.209(f)(4), after the issuance of a citation for violation of the applicable standard for DAs and taking correct actions, the operator must begin sampling, within 8 calendar days after the date the citation is issued, the environment of the affected DA on consecutive normal production shifts until five valid representative samples are taken.

Under 30 CFR 70.209(g)(1), a citation for violation of the applicable standard will be terminated by MSHA when each of the five valid representative samples is at or below the applicable standard, and the operator has submitted a revised mine ventilation plan approved by MSHA.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.206(k)(4), after the issuance of a citation for violation of the standard for DWPs and taking corrective actions, the operator must begin sampling, within 8 calendar days after the date the citation is issued, the environment of the affected DWP on consecutive normal work shifts until five valid representative samples are taken.

Under 30 CFR 71.206(l), a citation for violation of the applicable standard will be terminated by MSHA when the equivalent concentration of each of the five valid representative samples is at or below the standard.

Under 30 CFR 71.206(g), upon notification from MSHA that any valid representative sample taken from a DWP exceeds the applicable standard, the operator must, within 15 calendar days of notification, sample that DWP each normal work shift until five valid representative samples are taken. The operator must begin sampling on the first normal work shift following receipt of notification.

#### Part 90 Miners

Under 30 CFR 90.207(f)(2)(i), if the corrective action involves reducing the respirable dust levels in the work position of the part 90 miner identified in the citation, the operator must implement the proposed corrective actions and begin sampling the affected miner within 8 calendar days after the date the citation is issued, until five valid representative samples are taken.

Under 30 CFR 90.207(g), a citation for a violation of the applicable standard must be terminated by MSHA when the equivalent concentration of each of the five valid representative samples is at or below the applicable standard.

#### ii. MSHA Processing Abatement Samples and Reporting Results to Mine Operators or Part 90 Miners

Under 30 CFR 70.211(a), MSHA will provide the operator a report on respirable dust samples taken from underground locations in coal mines and submitted. The report includes the concentration of respirable dust, the average equivalent concentration of respirable dust for all valid samples, the occupation code (where applicable), and the reason for voiding any sample.

Under 30 CFR 71.208(a), MSHA will provide the operator a report on respirable dust samples taken from surface locations in coal mines and submitted. The report includes the concentration of respirable dust, the average equivalent concentration of respirable dust for all valid samples, the occupation code (where applicable), and the reason for voiding any sample.

Under 30 CFR 90.209(a), MSHA will provide the operator a report on respirable dust samples taken from part 90 miners and submitted or transmitted electronically, if using a CPDM.

#### iii. Posting Dust Data Cards and MSHA's Abatement Sampling Results and Providing Copies to Part 90 Miners

##### Underground Coal Mines

Under 30 CFR 70.211(b), upon receipt of MSHA's report, the operator must post the report with data on respirable dust samples submitted physically or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

Under 30 CFR 70.211(c), if using a CPDM, the person certified in sampling must, within 12 hours after the end of each sampling shift, print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of the sample run. This hard-copy record must include the data entered when the sample run was first programmed and key information such as the concentration of respirable dust and the shift length.

Under 30 CFR 70.211(d), the information must remain posted until the receipt of the MSHA report covering these respirable dust samples.

##### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.208(b), upon receipt of MSHA's report, the operator must post the report with data on respirable dust samples submitted physically or transmitted electronically if using a CPDM for at least 31 days on the mine bulletin board.

Under 30 CFR 71.208(c), if using a CPDM, the person certified in sampling

must, within 12 hours after the end of each sampling shift, print, sign, and post on the mine bulletin board a paper record (Dust Data Card) of each sample run. This hard-copy record must include the data entered when the sample run was first programmed and key information such as the concentration of respirable dust and the shift length.

Under 30 CFR 71.208(d), the information must remain posted until the receipt of the MSHA report covering these respirable dust samples.

#### Part 90 Miners

Under 30 CFR 90.209(b), upon receipt of MSHA's report on respirable dust samples, the operator must provide a copy of the report to the part 90 miner. The operator must not post the original or a copy of this report on the mine bulletin board.

Under 30 CFR 90.209(c), if using a CPDM, the person certified in sampling must print, sign, and provide to each part 90 miner, a paper record (Dust Data Card) of the sample run within one hour after the start of the part 90 miner's next work shift. This hard-copy record must include the data entered when the sample run was first programmed and key information such as the concentration of respirable dust, the shift length, and the part 90 miner's MIIN.

Under 30 CFR 90.209(d), the operator must not post data on respirable dust samples for part 90 miners on the mine bulletin board.

#### iv. Submitting New or Revised Mine Ventilation Plans or Dust Control Plans for MSHA Review

##### Underground Coal Mines

Under 30 CFR 70.208(i)(2), in order to terminate a citation for violation of the applicable standard for MMUs by MSHA, the operator must submit to the District Manager revised dust control parameters as part of the mine ventilation plan applicable to the MMU in the citation and the changes have been approved by the District Manager. The revised parameters must reflect the control measures used by the operator to abate the violation.

Under 30 CFR 70.209(g)(2), in order to terminate a citation for violation of the applicable standard for DAs by MSHA, the operator must submit to the District Manager revised dust control parameters as part of the mine ventilation plan applicable to the DA in the citation, and the changes have been approved by the District Manager. The revised parameters must reflect the control measures used by the operator to abate the violation.

### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.300(a), within 15 calendar days after the termination date of a citation for violation of the applicable standard for DWPs, the operator must submit to the District Manager for approval a written respirable dust control plan applicable to the DWP identified in the citation. The respirable dust control plan and its revisions must be suitable to the conditions and the mining system of the coal mine and must be adequate to continuously maintain respirable dust to at or below the applicable standard at the DWP identified in the citation.

### Part 90 Miners

Under 30 CFR 90.300(a), if an operator abates a violation of the applicable standard by reducing the respirable dust level in the position of the part 90 miner, the operator must submit to the District Manager for approval a written respirable dust control plan for the part 90 miner in the position identified in the citation within 15 calendar days after the citation is terminated. The respirable dust control plan and its revisions must be suitable to the conditions and the mining system of the coal mine and must be adequate to continuously maintain respirable dust to at or below the applicable standard for that part 90 miner.

### v. Notifying Miners' Representatives of New or Revised Mine Ventilation Plans or Dust Control Plans and Providing Copies

#### Underground Coal Mines

Under 30 CFR 75.370(a)(3)(i), the mine operator must notify the representative of miners at least 5 days prior to the submission to MSHA of a mine ventilation plan and any revision to a mine ventilation plan. If requested, the mine operator must provide a copy to the representative of miners at the time of notification. In the event of a situation requiring immediate action on a revision of the mine ventilation plan, notification of the revision must be given, and if requested, a copy of the revision must be provided, to the representative of miners by the operator at the time of submittal.

Under 30 CFR 75.370(a)(3)(ii), a copy of the proposed ventilation plan, and a copy of any proposed revision, submitted to MSHA for approval must be made available for inspection by the representative of miners.

Under 30 CFR 75.370(f)(1), the approved ventilation plans and any revisions must be provided upon request to the representative of miners

by the operator following notification of approval from MSHA.

Under 30 CFR 75.370(f)(2), the approved ventilation plans and any revisions must be made available for inspection by the representative of miners.

#### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.300(a)(1), the mine operator must notify the representative of miners at least 5 days prior to submission to MSHA of a respirable dust control plan and any revision to a dust control plan. If requested, the mine operator must provide a copy to the representative of miners at the time of notification.

Under 30 CFR 71.300(a)(2), a copy of the proposed respirable dust control plan, and a copy of any proposed revision, submitted to MSHA for approval must be made available for inspection by the representative of miners.

Under 30 CFR 71.301(d)(1), the approved respirable dust control plan and any revisions must be provided upon request to the representative of miners by the operator following notification of approval from MSHA.

Under 30 CFR 71.301(d)(2), the approved respirable dust control plan and any revisions must be made available for inspection by the representative of miners.

### Part 90 Miners

Under 30 CFR 90.301(d), the operator must provide a copy of the current respirable dust control plan to the part 90 miner. The operator must not post the original or a copy of the plan on the mine bulletin board.

### vi. Posting New or Revised Mine Ventilation Plans or Dust Control Plans

#### Underground Coal Mines

Under 30 CFR 75.370(a)(3)(iii), a copy of the proposed ventilation plan, and a copy of any proposed revision, submitted to MSHA for approval must be posted on the mine bulletin board at the time of submittal. The proposed plan or proposed revision must remain posted until it is approved, withdrawn or denied.

Under 30 CFR 75.370(f)(3), the approved ventilation plan and any revisions must be posted on the mine bulletin board within 1 working day following notification of approval from MSHA. The approved plan and revisions must remain posted on the bulletin board for the period that they are in effect.

### Surface Coal Mines and Surface Work Areas of Underground Coal Mines

Under 30 CFR 71.300(a)(3), a copy of the proposed respirable dust control plan, and a copy of any proposed revision, submitted to MSHA for approval must be posted on the mine bulletin board at the time of submittal. The proposed plan or proposed revision must remain posted until it is approved, withdrawn, or denied.

Under 30 CFR 71.301(d)(3), the approved respirable dust control plan and any revisions must be posted on the mine bulletin board within 1 working day following notification of approval from MSHA and must remain posted for the period that the plan is in effect.

### vii. MSHA Providing Mine Operators With Copies of Comments on Plans

Under 30 CFR 71.300(a)(4), following receipt of the proposed respirable dust control plan or proposed revision, the representative of miners may submit timely comments to the District Manager, in writing, for consideration during the review process. Upon request, a copy of these comments must be provided to the operator by the District Manager.

Under 30 CFR 75.370(b), following receipt of the proposed mine ventilation plan or proposed revision, the representative of miners may submit timely comments to the District Manager, in writing, for consideration during the review process. A copy of these comments must also be provided to the operator by the district manager upon request.

## II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection titled "Respirable Coal Mine Dust Sampling". MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
  - Suggest methods to 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.

The information collection request will be available on <https://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on <https://www.regulations.gov> and <https://www.reginfo.gov>.

The public may also examine publicly available documents at DOL–MSHA, Office of Standards, Regulations and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

### III. Current Actions

This information collection request concerns provisions for Respirable Coal Mine Dust Sampling. MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

*Type of Review:* Extension, without change, of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219–0011.

*Affected Public:* Business or other for-profit.

*Number of Annual Respondents:* 701.

*Frequency:* On occasion.

*Number of Annual Responses:* 989,403.

*Annual Time Burden:* 69,765 hours.

*Annual Other Burden Costs:* \$29,813.

*MSHA Form:* Mine Operator Dust Data Card.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at <https://www.reginfo.gov>.

#### Song-ae Aromie Noe,

*Certifying Officer, Mine Safety and Health Administration.*

[FR Doc. 2025–09592 Filed 5–28–25; 8:45 am]

BILLING CODE 4510–43–P

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219–0083]

#### Proposed Extension of Information Collection: Daily Inspection of Surface Coal Mine; Certified Person; Reports of Inspection (Pertains to Surface Coal Mines)

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. 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 can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection titled “Daily Inspection of Surface Coal Mine; Certified Person; Reports of Inspection (Pertains to Surface Coal Mines).”

**DATES:** All comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA–2025–0016.

- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at

[MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act) as amended, 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal and nonmetal mines.

The Paperwork Reduction Act (PRA) governs paperwork burdens imposed by Federal agencies on the public for using identical questions to collect information from 10 or more persons. Paperwork burden is defined in 44 U.S.C. 3502(2) as time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, policies and procedures of information collection are established for controlling paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

###### B. Information Collection

To fulfill the statutory mandates to promote miners’ health and safety, MSHA requires information under the information collection request (ICR) titled “Daily Inspection of Surface Coal Mine; Certified Person; Reports of Inspection (Pertains to Surface Coal Mines).” The information collection is intended to be used by MSHA operators and inspectors to ensure that corrective actions are taken to address any hazards found in active work areas to prevent injuries or deaths of miners.

Surface coal mines and facilities present a number of potential hazards. Highwalls, mining equipment, travelways, and the handling of mining materials present potentially hazardous conditions. Before daily examinations of working areas and surface installations were required, numerous miners lost their lives or were seriously injured in areas covered in the standard. The majority of these fatalities and injuries resulted from hazardous conditions that were not detected and immediately

corrected in these areas. Mine operators ensure a safe working environment for miners by complying with the standards and conducting on shift examinations for hazardous conditions in working areas and surface installations.

Burden and costs associated with the ICR includes:

1. conducting daily inspections;
2. creating inspection records; and
3. signing or countersigning records.

Authorization and the associated rule text are described below.

#### 1. Conducting Daily Inspections

Under 30 CFR 77.1713(a), at least once during each working shift, or more often if necessary for safety, each active working area and each active surface installation must be examined by a certified person designated by the operator to conduct examinations for hazardous conditions and any hazardous conditions noted during the examinations must be reported to the operator and must be corrected by the operator.

Under 30 CFR 77.1713(b), if any hazardous condition noted during an examination creates an imminent danger, the person conducting the examination must notify the operator and the operator must withdraw all persons from the area affected, except those exempted persons referred to in section 104(c) of the Mine Act, 30 U.S.C. 814(c), until the danger is abated.

#### 2. Creating Inspection Records

Under 30 CFR 77.1713(c), after each examination, each certified person who conducted all or any part of the required examination must enter with ink or indelible pencil in a book approved by the Secretary the date and a report of the condition of the mine or any area of the mine which he has inspected together with a report of the nature and location of any hazardous condition found to be present at the mine. The book in which the entries are made must be kept in an area at the mine designated by the operator to minimize the danger of destruction by fire or other hazard.

#### 3. Signing or Countersigning Records

Under 30 CFR 77.1713(d), all recorded examination reports must include a report of the action taken to abate hazardous conditions and must be signed or countersigned each day by at least one of the following persons:

- (1) The surface mine foreman;
- (2) The assistant superintendent of the mine;
- (3) The superintendent of the mine;
- (4) The person designated by the operator as responsible for health and safety at the mine; or,

- (5) An equivalent mine official.

## II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection titled "Daily Inspection of Surface Coal Mine; Certified Person; Reports of Inspection (Pertains to Surface Coal Mines)." MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

The information collection request will be available on <https://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on <https://www.regulations.gov> and <https://www.reginfo.gov>.

The public may also examine publicly available documents at DOL-MSHA, Office of Standards, Regulations and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202-693-9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

## III. Current Actions

This information collection request concerns provisions for Daily Inspection of Surface Coal Mine; Certified Person; Reports of Inspection (Pertains to Surface Coal Mines). MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

*Type of Review:* Extension, without change, of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219-0083.

*Affected Public:* Business or other for-profit.

*Number of Annual Respondents:* 771.

*Frequency:* On occasion.

*Number of Annual Responses:* 188,812.

*Annual Time Burden:* 286,365 hours.

*Annual Other Burden Costs:* \$0.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at <https://www.reginfo.gov>.

**Song-ae Aromie Noe,**

*Certifying Officer, Mine Safety and Health Administration.*

[FR Doc. 2025-09595 Filed 5-28-25; 8:45 am]

**BILLING CODE 4510-43-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

[OMB Control No. 1219-0039]

#### Proposed Extension of Information Collection: Gamma Radiation Surveys

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for public comments.

**SUMMARY:** The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program for all information collections, to provide the public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. 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 can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection titled Gamma Radiation Surveys.

**DATES:** All comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments concerning the information collection requirements of this notice may be sent by any of the

methods listed below. Please note that comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal:* <https://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA–2025–0014.

- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at [MSHA.information.collections@dol.gov](mailto:MSHA.information.collections@dol.gov) (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

#### SUPPLEMENTARY INFORMATION:

### I. Background

#### A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act) as amended, 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal, and nonmetal mines.

The Paperwork Reduction Act (PRA) governs paperwork burdens imposed by Federal agencies on the public for using identical questions to collect information from 10 or more persons. Paperwork burden is defined in 44 U.S.C. 3502(2) as time, effort, or financial resources expended to generate, maintain, or provide information to or for a Federal agency. Under 44 U.S.C. 3507, policies and procedures of information collection are established for controlling paperwork burdens imposed by Federal agencies on the public, including evaluating public comments.

#### B. Information Collection

To fulfill the statutory mandates to promote miners' health and safety,

MSHA requires information under the information collection request (ICR) titled "Gamma Radiation Surveys." The information collection is intended to ensure that mine operators monitor and maintain records of employee exposures to gamma rays so to minimize the negative health effects on miners.

Gamma radiation occurs where radioactive materials are present. Natural sources of gamma radiation include uranium and other radioactive elements that can be found in rocks, soils, and ground water. Gamma radiation may also be found near equipment with radiation sources in surface and underground mine operations where gamma rays are used to measure the level and density of liquids, slurries, or solids. The equipment includes X-ray machines, weightometers, nuclear gauges, and diffraction units that are mounted outside tanks, pipes, bins, hoppers, or other types of vessels, and contain radioactive materials.

The adverse health effects from exposure to gamma radiation vary depending upon the energy level of the radiation, the cumulative length of exposure, and the type of cell affected. Gamma rays penetrate the body and can cause cell death or damage in their path which can affect many of the body's organs. If a radioactive element is inhaled or ingested, gamma radiation can also be emitted and absorbed internally. As a result, gamma radiation can cause many types of cancer.

Burden costs associated with the ICR include:

1. conducting annual gamma radiation surveys; and
2. recording cumulative individual gamma radiation exposure.

Authorization and the associated rule text are described below.

#### 1. Conducting Gamma Radiation Surveys

Under section 103(c) of the Mine Act, 30 U.S.C. 813(c), MSHA is required to issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under the Act.

Under 30 CFR 57.5047(a), mine operators are required to conduct gamma radiation surveys annually in all underground mines where radioactive ores are mined. Under 30 CFR 57.5047(b), surveys must be conducted in accordance with American National Standards Institute (ANSI) Standard N13.8–1973, titled "Radiation

Protection in Uranium Mines", which is incorporated by reference.

#### 2. Recording Cumulative Gamma Radiation Exposure

Under 30 CFR 57.5047(c), where average gamma radiation measurements are in excess of 2.0 milliroentgens per hour in the working place, gamma radiation dosimeters must be provided for all persons affected, and records of cumulative individual gamma radiation exposure must be kept. Under 30 CFR 57.5047(d), an annual individual gamma radiation exposure cannot exceed 5 rems.

### II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Gamma Radiation Surveys. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

The information collection request will be available on <https://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on <https://www.regulations.gov> and <https://www.reginfo.gov>.

The public may also examine publicly available documents at DOL–MSHA, Office of Standards, Regulations and Variances, 200 Constitution Avenue NW, Room C3522, Washington, DC 20210. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

### III. Current Actions

This information collection request concerns provisions for Gamma Radiation Surveys. MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

*Type of Review:* Extension, without change, of a currently approved collection.

*Agency:* Mine Safety and Health Administration.

*OMB Number:* 1219–0039.

*Affected Public:* Business or other for-profit.

*Number of Annual Respondents:* 4.

*Frequency:* On occasion.

*Number of Annual Responses:* 4.

*Annual Time Burden:* 8 hours.

*Annual Other Burden Costs:* \$0.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at <https://www.reginfo.gov>.

**Song-ae Aromie Noe,**

*Certifying Officer, Mine Safety and Health Administration.*

[FR Doc. 2025–09593 Filed 5–28–25; 8:45 am]

**BILLING CODE 4510–43–P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2025–024]

### Freedom of Information Act (FOIA) Advisory Committee Meeting

**AGENCY:** Office of Government Information Services (OGIS), National Archives and Records Administration (NARA).

**ACTION:** Notice of meeting.

**SUMMARY:** We are announcing an upcoming Freedom of Information Act (FOIA) Advisory Committee meeting in accordance with the Federal Advisory Committee Act and the second United States Open Government National Action Plan.

**DATES:** The meeting will be on June 12, 2025, from 10 a.m. to Noon EDT. You must register to attend. (See registration information below.)

**ADDRESSES:** This meeting will be a virtual meeting. We will send access instructions for the meeting to those who register according to the instructions below.

**FOR FURTHER INFORMATION CONTACT:** Kirsten Mitchell, Designated Federal

Officer for this committee, by email at [foia-advisory-committee@nara.gov](mailto:foia-advisory-committee@nara.gov), or by telephone at 202.741.5770.

#### SUPPLEMENTARY INFORMATION:

*Agenda and meeting materials:* We will post all meeting materials, including the agenda, at <https://www.archives.gov/ogis/foia-advisory-committee/2024-2026-term>.

This meeting will be the fifth of the 2024–2026 committee term. The purpose of the meeting will be to hear reports from and discuss any recommendations from each of the three subcommittees: Statutory Reform, Volume and Frequency, and Implementation.

*Procedures:* This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. 1001–1014). If you wish to offer oral public comments during the public comments periods of the meeting, you must register in advance at [https://www.zoomgov.com/webinar/register/WN\\_jp21CP9oTAeuobFloMxWrw](https://www.zoomgov.com/webinar/register/WN_jp21CP9oTAeuobFloMxWrw). You will be provided with information to access the meeting online. Public comments will be limited to three minutes per individual. Written public comments may be submitted at any time to <https://www.archives.gov/ogis/public-comments> and will be posted if they meet OGIS's posting policy. We will also live-stream the meeting on the National Archives YouTube channel, <https://www.youtube.com/live/59PYN88FCpw> and include a captioning option. To request additional accommodations, email [foia-advisory-committee@nara.gov](mailto:foia-advisory-committee@nara.gov) or call 202.741.5770. Those who are unable to register online, and those who require special accommodations, should contact Kirsten Mitchell (contact information listed above).

**Merrily Harris,**

*Committee Management Officer.*

[FR Doc. 2025–09676 Filed 5–28–25; 8:45 am]

**BILLING CODE 7515–01–P**

## POSTAL REGULATORY COMMISSION

**[Docket Nos. MC2025–1429 and K2025–1428; MC2025–1430 and K2025–1429; MC2025–1431 and K2025–1430; MC2025–1432 and K2025–1431; MC2025–1433 and K2025–1432; MC2025–1434 and K2025–1433; MC2025–1435 and K2025–1434; MC2025–1436 and K2025–1435; MC2025–1437 and K2025–1436; MC2025–1438 and K2025–1437]**

### 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:* May 30, 2025.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <https://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. Public Proceeding(s)
- III. Summary Proceeding(s)

### I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

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.<sup>1</sup>

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such 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 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular

<sup>1</sup> 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).

point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. 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 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. See 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)-(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

## II. Public Proceeding(s)

1. *Docket No(s)*.: MC2025-1429 and K2025-1428; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 763 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Arif Hafiz; *Comments Due*: May 30, 2025.

2. *Docket No(s)*.: MC2025-1430 and K2025-1429; *Filing Title*: USPS Request to Add Priority Mail Contract 833 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Jennaca Upperman; *Comments Due*: May 30, 2025.

3. *Docket No(s)*.: MC2025-1431 and K2025-1430; *Filing Title*: USPS Request to Add Priority Mail Contract 834 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing*

*Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory Stanton; *Comments Due*: May 30, 2025.

4. *Docket No(s)*.: MC2025-1432 and K2025-1431; *Filing Title*: USPS Request to Add Priority Mail Contract 835 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory Stanton; *Comments Due*: May 30, 2025.

5. *Docket No(s)*.: MC2025-1433 and K2025-1432; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 764 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Arif Hafiz; *Comments Due*: May 30, 2025.

6. *Docket No(s)*.: MC2025-1434 and K2025-1433; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 765 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Christopher Mohr; *Comments Due*: May 30, 2025.

7. *Docket No(s)*.: MC2025-1435 and K2025-1434; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1371 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Christopher Mohr; *Comments Due*: May 30, 2025.

8. *Docket No(s)*.: MC2025-1436 and K2025-1435; *Filing Title*: USPS Request to Add Priority Mail Contract 836 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Maxine Bradley; *Comments Due*: May 30, 2025.

9. *Docket No(s)*.: MC2025-1437 and K2025-1436; *Filing Title*: USPS Request to Add Priority Mail Contract 837 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Maxine Bradley; *Comments Due*: May 30, 2025.

10. *Docket No(s)*.: MC2025-1438 and K2025-1437; *Filing Title*: USPS Request to Add Priority Mail Contract 838 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 21, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory Stanton; *Comments Due*: May 30, 2025.

## III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,  
Secretary.

[FR Doc. 2025-09586 Filed 5-28-25; 8:45 am]

BILLING CODE 7710-FW-P

## POSTAL REGULATORY COMMISSION

[Docket Nos. CP2024-520; K2025-22; MC2025-1440 and K2025-1439; MC2025-1441 and K2025-1440; MC2025-1442 and K2025-1441; MC2025-1443 and K2025-1442]

### 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*: June 2, 2025.

**ADDRESSES**: Submit comments electronically via the Commission's Filing Online system at <https://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:

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- I. Introduction
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#### I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may

propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

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.<sup>1</sup>

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such 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 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. 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 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. See 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR

3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)-(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

## II. Public Proceeding(s)

1. *Docket No(s)*: CP2024-520; *Filing Title*: USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 224, with Materials Filed Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative*: Jennaca Upperman; *Comments Due*: June 2, 2025.

2. *Docket No(s)*: K2025-22; *Filing Title*: USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 436, with Materials Filed Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative*: Gregory Stanton; *Comments Due*: June 2, 2025.

3. *Docket No(s)*: MC2025-1440 and K2025-1439; *Filing Title*: USPS Request to Add Priority Mail Contract 839 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Kenneth Moeller; *Comments Due*: June 2, 2025.

4. *Docket No(s)*: MC2025-1441 and K2025-1440; *Filing Title*: USPS Request to Add Priority Mail Contract 840 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Arif Hafiz; *Comments Due*: June 2, 2025.

5. *Docket No(s)*: MC2025-1442 and K2025-1441; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 766 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Gregory Stanton; *Comments Due*: June 2, 2025.

6. *Docket No(s)*: MC2025-1443 and K2025-1442; *Filing Title*: USPS Request to Add Priority Mail Contract 841 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: May 22, 2025; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public*

*Representative*: Maxine Bradley; *Comments Due*: June 2, 2025.

## III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

**Erica A. Barker**,  
*Secretary*.

[FR Doc. 2025-09687 Filed 5-28-25; 8:45 am]

BILLING CODE 7710-FW-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103105; File No. SR-CBOE-2025-037]

### Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules To Clarify the Timing Requirements of When Fees Must Be Submitted With an Application and When the Application Will Be Deemed To Be Automatically Withdrawn

May 22, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on May 14, 2025, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") 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 Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder.<sup>4</sup> 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

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend its rules to clarify the timing requirements of when fees must be submitted with an application and when the application will be deemed to be automatically withdrawn. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's

<sup>1</sup> 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).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, 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 Exchange proposes amendments to Rule 3.10, to update when fees for an application for prospective Trading Permit Holders ("TPHs") are due and when an application for a TPH should be considered automatically withdrawn. The Exchange's current Rule 3.10(b) requires that application fees are filed within the application and by doing so, assumes that application fees are submitted via a check, which is generally no longer the case. The Exchange proposes to update this Rule to allow for payment to be submitted within a reasonable time of submitting the application (to be determined by the Exchange)—this allows for applicants to have flexibility and timing to ensure another method of payment (e.g., a wire) gets to the Exchange in a timely manner, while understanding that it may take time for an applicant to remit payment when not using a check. The Exchange proposes to have the timing be in the Exchange's discretion to prevent a hard stop in the processing of an application in the event there is a delay in payment. The Exchange typically requires payment within 30 days of receipt of an application but would still request that it has the flexibility to extend this when needed as to not prevent additional work by requiring an applicant to resubmit its application if it pays on day 31.

The Exchange's current Rule 3.10(i) requires that if the application process is not completed within 6 months of the submission of the application and the

appropriate fees, that the application shall be deemed to be automatically withdrawn. The Exchange proposes to modify this Rule to clearly set the 6-month timer to begin at the time of the application submission by removing the requirement that the fee has also been remitted. In the aforementioned circumstance, where payment is submitted via wire and may come 30 days after the initial submission of the application, this revised Rule 3.10 makes it clear that the timer should start upon the Exchange's receipt of an application.

#### 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>5</sup> Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>6</sup> 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>7</sup> requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,<sup>8</sup> which provides that the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's TPHs and persons associated with its TPHs with the Act, the rules and regulations thereunder, and the rules of the Exchange.

In particular, the Exchange believes the proposed amendments provide clarity for its prospective TPHs by making it clear what the expectations are regarding the timing of payment with an application and when a prospective TPH must complete its

application process by. These updates are intended to align with current practices and manage expectations of applications.

The proposed changes also apply uniformly to all prospective TPHs that submit applications to the Exchange. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

### 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 that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the proposed change will apply uniformly to all prospective TPHs that submit applications to the Exchange. Further, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it merely clarifies the Exchange's internal process requirements for applicants inline with current business practices.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>9</sup> and Rule 19b-4(f)(6)<sup>10</sup> 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

<sup>5</sup> 15 U.S.C. 78f(b).

<sup>6</sup> 15 U.S.C. 78f(b)(5).

<sup>7</sup> *Id.*

<sup>8</sup> 15 U.S.C. 78f(b)(1).

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f)(6).

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 will institute proceedings 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 (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2025-037 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-CBOE-2025-037. 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 (<http://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 such 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-CBOE-2025-037 and should be submitted on or before June 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Sherry R. Haywood,**  
*Assistant Secretary.*

[FR Doc. 2025-09623 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103108; File No. SR-CboeBZX-2025-069]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the Canary Staked TRX ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

May 22, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on May 12, 2025, Cboe BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change to list and trade shares of the Canary Staked TRX ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change is described in Items I, II, and III 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

Cboe BZX Exchange, Inc. ("BZX" or the "Exchange") is filing with the Securities and Exchange Commission ("Commission" or "SEC") a proposed rule change to list and trade shares of the Canary Staked TRX ETF (the "Trust"),<sup>3</sup> under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares.

The text of the proposed rule change is also available on the Exchange's website ([http://markets.cboe.com/us/equities/regulation/rule\\_filings/bzx/](http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/)), at the Exchange's Office of the Secretary,

<sup>11</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> The Trust was formed as a Delaware statutory trust on February 27, 2025, and is operated as a C corporation. The Trust has no fixed termination date.

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 Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4),<sup>4</sup> which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.<sup>5</sup> Canary Capital Group LLC is the sponsor of the Trust (the "Sponsor"). The Shares will be registered with the Commission by means of the Trust's registration statement on Form S-1 (the "Registration Statement").<sup>6</sup> According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,<sup>7</sup> nor a commodity pool for purposes of the Commodity Exchange Act ("CEA"), and neither the Trust nor the Sponsor is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

<sup>4</sup> The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR-BATS-2011-018).

<sup>5</sup> Any of the statements or representations regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values, or the applicability of Exchange listing rules specified in this filing to list a series of Other Securities (collectively, "Continued Listing Representations") shall constitute continued listing requirements for the Shares listed on the Exchange.

<sup>6</sup> See the Registration Statement on Form S-1, dated April 18, 2025, submitted by the Sponsor on behalf of the Trust. The descriptions of the Trust, the Shares, and the Pricing Benchmark (as defined below) contained herein are based, in part, on information in the Registration Statement. The Registration Statement is not yet effective, and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

<sup>7</sup> 15 U.S.C. 80a-1.

Since 2017, the Commission has approved or disapproved exchange filings to list and trade series of Trust Issued Receipts, including spot-based Commodity-Based Trust Shares, on the basis of whether the listing exchange has in place a comprehensive surveillance sharing agreement with a regulated market of significant size related to the underlying commodity to be held (the “Winklevoss Test”).<sup>8</sup> The Commission has also consistently recognized that this not the *exclusive* means by which an ETP listing exchange can meet this statutory obligation.<sup>9</sup> A listing exchange could, alternatively, demonstrate that “other means to prevent fraudulent and manipulative acts and practices will be sufficient” to justify dispensing with a surveillance-sharing agreement with a regulated market of significant size.<sup>10</sup>

<sup>8</sup> See Securities Exchange Act Release Nos. 78262 (July 8, 2016), 81 FR 78262 (July 14, 2016) (the “Winklevoss Proposal”). The Winklevoss Proposal was the first exchange rule filing proposing to list and trade shares of an ETP that would hold spot bitcoin (a “Spot Bitcoin ETP”). It was subsequently disapproved by the Commission. See Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (the “Winklevoss Order”); 99306 (January 10, 2024), 89 FR 3008 (January 17, 2024) (Self-Regulatory Organizations; NYSE Arca, Inc.; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units) (the “Spot Bitcoin ETP Approval Order”); 100224 (May 23, 2024), 89 FR 46937 (May 30, 2024) (Self-Regulatory Organizations; NYSE Arca, Inc.; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Shares of Ether-Based Exchange-Traded Products) (the “Spot ETH ETP Approval Order”).

<sup>9</sup> See Winklevoss Order, 83 FR at 37580; see Spot Bitcoin ETP Approval Order, 89 FR at 3009; see Spot ETH ETP Approval Order 89 FR at 46938.

<sup>10</sup> The Exchange notes that that the Winklevoss Test was first applied in 2017 in the Winklevoss Order, which was the first disapproval order related to an exchange proposal to list and trade a Spot Bitcoin ETP. All prior approval orders issued by the Commission approving the listing and trading of series of Trust Issued Receipts included no specific analysis related to a “regulated market of significant size.” In the Winklevoss Order and the Commission’s prior orders approving the listing and trading of series of Trust Issued Receipts have noted that the spot commodities and currency markets for which it has previously approved spot ETPs are generally unregulated and that the Commission relied on the underlying futures market as the regulated market of significant size that formed the basis for approving the series of Currency and Commodity-Based Trust Shares, including gold, silver, platinum, palladium, copper, and other commodities and currencies. The Commission specifically noted in the Winklevoss Order that the approval order issued related to the first spot gold ETP “was based on an assumption that the currency market and the spot gold market were largely unregulated.” See Winklevoss Order at 37592. As such, the regulated market of significant size test does not require that the spot market be regulated in order for the Commission to approve this

The Commission recently issued orders granting approval for proposals to list bitcoin- and ether-based commodity trust shares and bitcoin-based, ether-based, and a combination of bitcoin- and ether-based trust issued receipts (these proposed funds are nearly identical to the Trust, but proposed to hold bitcoin and/or ether, respectively, instead of TRX) (“Spot Bitcoin ETPs” and “Spot ETH ETPs”). In both the Spot Bitcoin ETP Approval Order and Spot ETH ETP Approval Order, the Commission found that sufficient “other means” of preventing fraud and manipulation had been demonstrated that justified dispensing with a surveillance-sharing agreement of significant size. Specifically, the Commission found that while the Chicago Mercantile Exchange (“CME”) futures market for both bitcoin and ether were not of “significant size” related to the spot market, the Exchange demonstrated that other means could be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the proposals.

As further discussed below, both the Exchange and the Sponsor believe that this proposal and the included analysis are sufficient to establish that the proposal is consistent with the Act itself and, additionally, that there are sufficient “other means” of preventing fraud and manipulation that warrant dispensing of the surveillance-sharing agreement with a regulated market of significant size, as was done with both Spot Bitcoin ETPs and Spot ETH ETPs, and that this proposal should be approved.

## Background

TRX is the native cryptographic token of the Tron Network, a permissionless and decentralized blockchain platform launched in 2017. The Tron Network is designed to facilitate high-speed, low-cost transactions and support the creation of decentralized applications, with a particular emphasis on content sharing and entertainment services. TRX serves multiple functions within the Tron Network, including securing the network through staking, enabling governance participation, and

proposal, and precedent makes clear that an underlying market for a spot commodity or currency being a regulated market would actually be an exception to the norm. These largely unregulated currency and commodity markets do not provide the same protections as the markets that are subject to the Commission’s oversight, but the Commission has consistently looked to surveillance sharing agreements with the underlying futures market in order to determine whether such products were consistent with the Act.

facilitating the payment of transaction fees.

The Tron Network utilizes a delegated proof-of-stake consensus mechanism in which TRX token holders vote to elect 27 “super representatives” who are responsible for validating transactions and producing blocks. These super representatives are elected every six hours, and TRX holders can vote by staking their tokens, thereby participating in the Tron Network’s governance. This mechanism enhances scalability and efficiency, aligning validator incentives with network security.

Unlike proof-of-work systems used by networks like Bitcoin, the delegated proof-of-stake consensus mechanism employed by the Tron Network is designed to be energy-efficient while enabling high transaction throughput. The Tron Network can process up to 2,000 transactions per second, making it suitable for applications requiring high throughput, such as gaming and multimedia platforms.

The Tron Network employs a dual-resource model (*i.e.*, bandwidth and energy) to manage transaction costs and computational resource consumption. Bandwidth is used to cover the cost of simple transactions, while energy is consumed when executing more complex operations such as smart contract executions. Users can obtain these resources by freezing TRX, which temporarily locks the tokens in exchange for resource credits and staking rights.

Unlike digital assets such as bitcoin, which are created through a progressive mining process, 100 billion TRX were pre-mined and created prior to the launch of the Tron. TRX does not have a fixed supply cap and is subject to an inflationary model that may be adjusted over time by community governance. The issuance of TRX as staking rewards follows the delegated proof-of-stake consensus mechanism, with a current block reward fixed at sixteen TRX per block, though this rate is subject to change through protocol updates or governance decisions.

As noted above, this proposal is to list and trade shares of the Trust that would hold spot TRX and, as described below, cause the Trust to stake a portion of its TRX.

## Section 6(b)(5) and the Applicable Standards

The Commission has approved numerous series of Trust Issued Receipts,<sup>11</sup> including Commodity-Based

<sup>11</sup> See Exchange Rule 14.11(f).

Trust Shares,<sup>12</sup> to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) the requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices;<sup>13</sup> and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that potential policy concerns under the Act are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

More recently, the Commission has applied the Winklevoss Test while also recognizing that the "regulated market of significant size" standard is not the only means for satisfying Section 6(b)(5) of the Act. In the specifically providing that a listing exchange could demonstrate that "other means to prevent fraudulent and manipulative acts and practices" are sufficient to

<sup>12</sup> Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

<sup>13</sup> Much like bitcoin and ETH, the Exchange believes that TRX is resistant to price manipulation and that "other means to prevent fraudulent and manipulative acts and practices" exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of TRX trading render it difficult and prohibitively costly to manipulate the price of TRX. The fragmentation across platforms and the capital necessary to maintain a significant presence on each trading platform make manipulation of TRX prices through continuous trading activity challenging. To the extent that there are trading platforms engaged in or allowing wash trading or other activity intended to manipulate the price of TRX on other markets, such pricing does not normally impact prices on other trading platforms because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between TRX markets and the presence of arbitrageurs in those markets means that the manipulation of the price of TRX on any single venue would require manipulation of the global TRX price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular trading platforms or OTC platform. Further, the speed and relatively inexpensive nature of transactions on the Tron Network allow arbitrageurs to quickly move capital between trading platforms where price dislocations may occur. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

justify dispensing with the requisite surveillance-sharing agreement.<sup>14</sup> While there are currently several futures markets for TRX, in the Spot Bitcoin ETF Approval Order and Spot ETH ETF Approval Order the Commission determined that the CME bitcoin futures market and CME ETH futures market, respectively, were not of "significant size" related to the spot market. Instead, the Commission found that sufficient "other means" of preventing fraud and manipulation had been demonstrated that justified dispensing with a surveillance-sharing agreement of significant size. The Exchange and Sponsor believe that this proposal provides for other means of preventing fraud and manipulation justify dispensing with a surveillance-sharing agreement of significant size.

Over the past several years, U.S. investor exposure to TRX has grown into billions of dollars with a fully diluted market cap of greater than \$24 billion. The Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to TRX in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors.

The policy concerns that the Exchange Act is designed to address are also otherwise mitigated by the fact that the size of the market for the underlying reference asset (\$24+ billion fully diluted value) and the nature of the TRX ecosystem reduces its susceptibility to manipulation. The geographically diverse and continuous nature of TRX trading makes it difficult and prohibitively costly to manipulate the price of TRX and, in many instances, the TRX market can be less susceptible to manipulation than the equity, fixed income, and commodity futures markets. There are a number of reasons this is the case, including that there is not inside information about revenue, earnings, corporate activities, or sources of supply; manipulation of the price on any single venue would require manipulation of the global TRX price in order to be effective; a substantial over-the-counter market provides liquidity and shock-absorbing capacity; TRX's 24/7/365 nature provides constant arbitrage opportunities across all trading venues;

<sup>14</sup> See Winklevoss Order at 37580. The Commission has also specifically noted that it "is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met." *Id.* at 37582.

and it is unlikely that any one actor could obtain a dominant market share.

Further, TRX is arguably less susceptible to manipulation than other commodities that underlie ETPs; there may be inside information relating to the supply of the physical commodity such as the discovery of new sources of supply or significant disruptions at mining facilities that supply the commodity that simply are inapplicable as it relates to certain cryptoassets, including TRX. Further, the Exchange believes that the fragmentation across TRX trading platforms and increased adoption of TRX, as displayed through increased user engagement and trading volumes, and the Tron Network make manipulation of TRX prices through continuous trading activity more difficult. Moreover, the linkage between the TRX markets and the presence of arbitrageurs in those markets means that the manipulation of the price of TRX price on any single venue would require manipulation of the global TRX price in order to be effective. Arbitrageurs must have funds distributed across multiple TRX trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular TRX trading platform. As a result, the potential for manipulation on a particular TRX trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences. For all of these reasons, TRX is not particularly susceptible to manipulation, especially as compared to other approved ETP reference assets.

#### Canary TRX ETF

CSC Delaware Trust Company is the trustee ("Trustee"). A third party will be the administrator ("Administrator") and transfer agent ("Transfer Agent") and will be responsible for the custody of the Trust's cash and cash equivalents<sup>15</sup> (the "Cash Custodian"). A third-party custodian (the "Custodian") will be responsible for custody of the Trust's TRX.

According to the Registration Statement, each Share will represent a fractional undivided beneficial interest in and ownership of the Trust. The Trust's assets will only consist of TRX, cash, or cash and cash equivalents.

According to the Registration Statement, the Trust will be neither an investment company registered under the Investment Company Act of 1940, as

<sup>15</sup> Cash equivalents are short-term instruments with maturities of less than 3 months.

amended,<sup>16</sup> nor a commodity pool for purposes of the CEA, and neither the Trust nor the Sponsor is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

The Sponsor may stake, or cause to be staked, all or a portion of the Trust's TRX through one or more trusted staking providers ("Staking Providers"). In consideration for any staking activity in which the Trust may engage, the Trust would receive all or a portion of the staking rewards generated through staking activities, which may be treated as income to the Trust. The Trust will not acquire and will disclaim any incidental right ("IR"), or IR asset received, for example as a result of forks or airdrops, and such assets will not be taken into account for purposes of determining NAV.

When the Trust sells or redeems its Shares, it will do so in cash transactions in blocks of 10,000 Shares (a "Creation Basket") at the Trust's net asset value ("NAV"). For creations, authorized participants will deliver cash to the Trust's account with the Cash Custodian in exchange for Shares. Upon receipt of an approved creation order, the Sponsor, on behalf of the Trust, will submit an order to buy the amount of TRX represented by a Creation Basket. Based off TRX executions, the Cash Custodian will request the required cash from the authorized participant; the Transfer Agent will only issue Shares when the authorized participant has made delivery of the cash. Following receipt by the Cash Custodian of the cash from an authorized participant, the Sponsor, on behalf of the Trust, will approve an order with one or more previously onboarded trading partners to purchase the amount of TRX represented by the Creation Basket. This purchase of TRX will normally be cleared through an affiliate of the Custodian (although the purchase may also occur directly with the trading partner) and the TRX will settle directly into the Trust's account at the Custodian.<sup>17</sup> Authorized participants may then offer Shares to the public at prices that depend on various factors, including the supply and demand for Shares, the value of the Trust's assets, and market conditions at the time of a transaction. Shareholders who buy or

sell Shares during the day from their broker may do so at a premium or discount relative to the NAV of the Shares of the Trust.

#### Investment Objective

According to the Registration Statement and as further described below, the Trust's investment objective is to seek to track the performance of TRX, as measured by the CoinDesk TRX USD CCIX 60 min NY Rate ("Pricing Benchmark"), adjusted for the Trust's expenses and other liabilities. In seeking to achieve its investment objective, the Trust will hold TRX and will value its Shares daily as of 4:00 p.m. ET using the same methodology used to calculate the Pricing Benchmark. All of the Trust's TRX will be held by the Custodian.

#### The Pricing Benchmark

As described in the Registration Statement, The Trust will use the Pricing Benchmark to calculate the Trust's NAV. The Trust will determine the TRX Pricing Benchmark price and value its Shares daily based on the value of TRX as reflected by the Pricing Benchmark. The Pricing Benchmark will be calculated daily and aggregates the notional value of TRX trading across major TRX spot trading platforms, as determined by the provider.

#### Net Asset Value

NAV means the total assets of the Trust (which includes all TRX and cash and cash equivalents) less total liabilities of the Trust. The Administrator determines the NAV of the Trust on each day that the Exchange is open for regular trading, as promptly as practical after 4:00 p.m. ET based on the closing value of the Pricing Benchmark. The NAV of the Trust is the aggregate value of the Trust's assets less its estimated accrued but unpaid liabilities (which include accrued expenses). In determining the NAV, the Administrator values the TRX held by the Trust based on the closing value of the Pricing Benchmark as of 4:00 p.m. ET. The Administrator also determines the NAV per Share. The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time.

#### Availability of Information

In addition to the price transparency of the Pricing Benchmark, the Trust will provide information regarding the Trust's TRX holdings as well as additional data regarding the Trust. The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a)

the current NAV per Share daily and the prior business day's NAV per Share and the reported BZX Official Closing Price;<sup>18</sup> (b) the BZX Official Closing Price in relation to the NAV per Share as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV per Share; (c) data in chart form displaying the frequency distribution of discounts and premiums of the BZX Official Closing Price against the NAV per Share, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The aforementioned information will be published as of the close of business and available on the Sponsor's website at <https://canary.capital>, or any successor thereto. The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association ("CTA"). The Trust will also disseminate its holdings on a daily basis on its website.

The Intraday Indicative Value ("IIV") will be updated during Regular Trading Hours to reflect changes in the value of the Trust's TRX holdings during the trading day. The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV may differ from the NAV because NAV is calculated, using the closing value of the Pricing Benchmark, once a day at 4 p.m. ET, whereas the IIV draws prices from the last trade on each constituent platform in an effort to produce a relevant, real-time price). The Trust will provide an IIV per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours through the facilities of the CTA and Consolidated Quotation System (CQS) high speed lines. In addition, the IIV will be available through on-line information services, such as Bloomberg and Reuters.

<sup>18</sup> As defined in Rule 11.23(a)(3), the term "BZX Official Closing Price" shall mean the price disseminated to the consolidated tape as the market center closing trade.

<sup>16</sup> 15 U.S.C. 80a-1.

<sup>17</sup> For redemptions, the process will occur in the reverse order. Upon receipt of an approved redemption order, the Sponsor, on behalf of the Trust, will submit an order to sell the amount of TRX represented by a Creation Basket and the cash proceeds will be remitted to the authorized participant when the 10,000 Shares are received by the Transfer Agent.

The price of TRX will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours.

As noted above, the Pricing Benchmark is calculated every 15 seconds and information about the Pricing Benchmark and Pricing Benchmark value, including index data and key elements of how the Pricing Benchmark is calculated, will be publicly available at a website maintained by the provider of the Pricing Benchmark.

Quotation and last sale information for TRX is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in TRX is available from major market data vendors and from the trading platforms on which TRX are traded. Depth of book information is also available from TRX trading platforms. The normal trading hours for TRX trading platforms are 24 hours per day, 365 days per year.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's BZX Official Closing Price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA.

#### The Custodian

The Custodian's services (i) allow TRX to be deposited from a public blockchain address to the Trust's TRX account; (ii) allow TRX to be withdrawn from the TRX account to a public blockchain address as instructed by the Trust; and (iii) allow TRX to be staked. The custody agreement requires the Custodian to hold the Trust's TRX in cold storage, unless required to facilitate withdrawals as a temporary measure. The Custodian will use segregated cold storage TRX addresses for the Trust which are separate from the TRX addresses that the Custodian uses for its other customers and which are directly verifiable via the TRX blockchain. The Custodian will safeguard the private keys to the TRX associated with the Trust's TRX account. The Custodian will at all times record and identify in its books and records that such TRX constitutes the property of the Trust. The Custodian will not withdraw the Trust's TRX from the Trust's account

with the Custodian, or loan, hypothecate, pledge or otherwise encumber the Trust's TRX, without the Trust's instruction. If the custody agreement terminates, the Sponsor may appoint another custodian, and the Trust may enter into a custodian agreement with such custodian.

#### Creation and Redemption of Shares

When the Trust sells or redeems its Shares, it will do so in cash transactions in 10,000 Share increments (a Creation Basket) that are based on the amount of TRX held by the Trust on a per Creation Basket basis. According to the Registration Statement, on any business day, an authorized participant may place an order to create one or more Creation Baskets. Purchase orders must be placed by 4:00 p.m. ET, or the close of regular trading on the Exchange, whichever is earlier. The day on which an order is received is considered the purchase order date. The total deposit of cash required is based on the combined NAV of the number of Shares included in the Creation Baskets being created determined as of 4:00 p.m. ET on the date the order to purchase is properly received. The Administrator determines the quantity of TRX associated with a Creation Basket for a given day by dividing the number of TRX held by the Trust as of the opening of business on that business day, adjusted for the amount of TRX constituting estimated accrued but unpaid fees and expenses of the Trust as of the opening of business on that business day, by the quotient of the number of Shares outstanding at the opening of business divided by the number of Shares in a Creation Basket.

The authorized participants will deliver only cash to create Shares and will receive only cash when redeeming Shares. Further, authorized participants will not directly or indirectly purchase, hold, deliver, or receive TRX as part of the creation or redemption process or otherwise direct the Trust or a third party with respect to purchasing, holding, delivering, or receiving TRX as part of the creation or redemption process.

The Trust will create Shares by receiving TRX from a third party that is not the authorized participant and the Trust—not the authorized participant—is responsible for selecting the third party to facilitate the delivery of TRX. Further, the third party will not be acting as an agent of the authorized participant with respect to the delivery of the TRX to the Trust or acting at the direction of the authorized participant with respect to the delivery of the TRX to the Trust. When fulfilling a redemption request, the Trust will

redeem shares by delivering TRX to a third party that is not the authorized participant and the Trust—not the authorized participant—is responsible for selecting such third party to receive the TRX. Further, the third party will not be acting as an agent of the authorized participant with respect to the receipt of the TRX from the Trust or acting at the direction of the authorized participant with respect to the receipt of the TRX from the Trust.

The procedures by which an authorized participant can redeem one or more Creation Baskets mirror the procedures for the creation of Creation Baskets.

The Sponsor will maintain ownership and control of TRX in a manner consistent with good delivery requirements for spot commodity transactions.

#### Rule 14.11(e)(4)—Commodity-Based Trust Shares

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange represents that, for initial and continued listing, the Trust must be in compliance with Rule 10A-3 under the Act. A minimum of 100,000 Shares will be outstanding at the commencement of listing on the Exchange. The Exchange will obtain a representation that the NAV will be calculated daily and that the NAV and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) issued by a trust that holds (1) a specified commodity<sup>19</sup> deposited with the trust, or (2) a specified commodity and, in addition to such specified commodity, cash; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity and/or cash; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity and/or cash.

Upon termination of the Trust, the Shares will be removed from listing. The Trustee, CSC Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that

<sup>19</sup>For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act.

no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker ("Market Maker") in the Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (see, e.g., Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

The Exchange is able to obtain information regarding trading in the Shares and the underlying TRX or any other TRX derivative through members acting as registered Market Makers, in connection with their proprietary or customer trades.

As a general matter, the Exchange has regulatory jurisdiction over its Members and their associated persons, which include any person or entity controlling a Member. To the extent the Exchange may be found to lack jurisdiction over a subsidiary or affiliate of a Member that does business only in commodities or futures contracts, the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

#### Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which trading is not occurring in the TRX underlying the Shares; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

If the IIV or the value of the Pricing Benchmark is not being disseminated as required, the Exchange may halt trading during the day in which the interruption to the dissemination of the IIV or the value of the Pricing Benchmark occurs. If the interruption to the dissemination of the IIV or the value of the Pricing Benchmark persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption.

In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

#### Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's

existing rules governing the trading of equity securities. BZX will allow trading in the Shares during all trading sessions on the Exchange. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a) the minimum price variation for quoting and entry of orders in securities traded on the Exchange is \$0.01 where the price is greater than \$1.00 per share or \$0.0001 where the price is less than \$1.00 per share. The Shares of the Trust will conform to the initial and continued listing criteria set forth in BZX Rule 14.11(e)(4).

#### Surveillance

The Exchange represents that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. FINRA conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares or any other TRX derivative with other markets and other entities that are members of the ISG, and the Exchange, or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares or any other TRX derivative from such markets and other entities.<sup>20</sup> The Exchange may obtain information regarding trading in the Shares or any other TRX derivative via ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

The Sponsor has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance

<sup>20</sup> For a list of the current members and affiliate members of ISG, see [www.isgportal.com](http://www.isgportal.com).

with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

#### Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) the procedures for the creation and redemption of Creation Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the IIV and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares outside of Regular Trading Hours<sup>21</sup> when an updated IIV will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information. The Information Circular will also reference the fact that there is no regulated source of last sale information regarding TRX, and that the Commission has no jurisdiction over the trading of TRX as a commodity.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

#### 2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act<sup>22</sup> in general and Section 6(b)(5) of the Act<sup>23</sup> in particular in that it is 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 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.

The Commission has approved numerous series of Trust Issued Receipts,<sup>24</sup> including Commodity-Based Trust Shares,<sup>25</sup> to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) the requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices;<sup>26</sup> and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that potential policy concerns under the Act are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

<sup>24</sup> See Exchange Rule 14.11(f).

<sup>25</sup> Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

<sup>26</sup> Much like bitcoin and ETH, the Exchange believes that TRX is resistant to price manipulation and that "other means to prevent fraudulent and manipulative acts and practices" exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of TRX trading render it difficult and prohibitively costly to manipulate the price of TRX. The fragmentation across platforms and the capital necessary to maintain a significant presence on each trading platform make manipulation of TRX prices through continuous trading activity challenging. To the extent that there are trading platforms engaged in or allowing wash trading or other activity intended to manipulate the price of TRX on other markets, such pricing does not normally impact prices on other trading platforms because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between TRX markets and the presence of arbitrageurs in those markets means that the manipulation of the price of TRX on any single venue would require manipulation of the global TRX price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular trading platforms or OTC platform. Further, the speed and relatively inexpensive nature of transactions on the Tron Network allow arbitrageurs to quickly move capital between trading platforms where price dislocations may occur. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

More recently, the Commission has applied the Winklevoss Test while also recognizing that the "regulated market of significant size" standard is not the only means for satisfying Section 6(b)(5) of the Act. In the specifically providing that a listing exchange could demonstrate that "other means to prevent fraudulent and manipulative acts and practices" are sufficient to justify dispensing with the requisite surveillance-sharing agreement.<sup>27</sup> While there are currently several futures markets for TRX, in the Spot Bitcoin ETF Approval Order and Spot ETH ETF Approval Order the Commission determined that the CME bitcoin futures market and CME ETH futures market, respectively, were not of "significant size" related to the spot market. Instead, the Commission found that sufficient "other means" of preventing fraud and manipulation had been demonstrated that justified dispensing with a surveillance-sharing agreement of significant size. The Exchange and Sponsor believe that this proposal provides for other means of preventing fraud and manipulation justify dispensing with a surveillance-sharing agreement of significant size.

The Exchange believes that the proposal is designed to protect investors and the public interest. Over the past several years, U.S. investor exposure to TRX has grown into billions of dollars with a fully diluted market cap of greater than \$24 billion. The Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to TRX in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors.

The Exchange believes that the policy concerns are mitigated by the fact that the size of the market for the underlying reference asset (\$24+ billion fully diluted value) and the nature of the TRX ecosystem reduces its susceptibility to manipulation. The geographically diverse and continuous nature of TRX trading makes it difficult and prohibitively costly to manipulate the price of TRX and, in many instances, the TRX market can be less susceptible to manipulation than the equity, fixed income, and commodity futures markets. There are a number of reasons

<sup>27</sup> See Winklevoss Order at 37580. The Commission has also specifically noted that it "is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met." *Id.* at 37582.

<sup>21</sup> Regular Trading Hours is the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

<sup>22</sup> 15 U.S.C. 78f.

<sup>23</sup> 15 U.S.C. 78f(b)(5).

this is the case, including that there is not inside information about revenue, earnings, corporate activities, or sources of supply; manipulation of the price on any single venue would require manipulation of the global TRX price in order to be effective; a substantial over-the-counter market provides liquidity and shock-absorbing capacity; TRX's 24/7/365 nature provides constant arbitrage opportunities across all trading venues; and it is unlikely that any one actor could obtain a dominant market share.

Further, TRX is arguably less susceptible to manipulation than other commodities that underlie ETPs; there may be inside information relating to the supply of the physical commodity such as the discovery of new sources of supply or significant disruptions at mining facilities that supply the commodity that simply are inapplicable as it relates to certain cryptoassets, including TRX. Further, the Exchange believes that the fragmentation across TRX trading platforms and increased adoption of TRX, as displayed through increased user engagement and trading volumes, and the Tron Network make manipulation of TRX prices through continuous trading activity more difficult. Moreover, the linkage between the TRX markets and the presence of arbitrageurs in those markets means that the manipulation of the price of TRX price on any single venue would require manipulation of the global TRX price in order to be effective. Arbitrageurs must have funds distributed across multiple TRX trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular TRX trading platform. As a result, the potential for manipulation on a particular TRX trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences. For all of these reasons, TRX is not particularly susceptible to manipulation, especially as compared to other approved ETP reference assets.

#### Commodity-Based Trust Shares

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable

federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and listed TRX derivatives via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

#### Availability of Information

In addition to the price transparency of the Pricing Benchmark, the Trust will provide information regarding the Trust's TRX holdings as well as additional data regarding the Trust. The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) the current NAV per Share daily and the prior business day's NAV per Share and the reported BZX Official Closing Price;<sup>28</sup> (b) the BZX Official Closing Price in relation to the NAV per Share as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV per Share; (c) data in chart form displaying the frequency distribution of discounts and premiums of the BZX Official Closing Price against the NAV per Share, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The aforementioned information will be published as of the close of business and available on the Sponsor's website at [www.canary.capital](http://www.canary.capital), or any successor thereto. The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be

disseminated through the facilities of the CTA. The Trust will also disseminate its holdings on a daily basis on its website.

The Intraday Indicative Value ("IIV") will be updated during Regular Trading Hours to reflect changes in the value of the Trust's TRX holdings during the trading day. The IIV may differ from the NAV because NAV is calculated, using the closing value of the Pricing Benchmark, once a day at 4:00 p.m. Eastern time whereas the IIV draws prices from the last trade on each constituent platform to produce a relevant, real-time price. The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The Trust will provide an IIV per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours through the facilities of the CTA and CQS high speed lines. In addition, the IIV will be available through on-line information services such as Bloomberg and Reuters.

The price of TRX will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours.

As noted above, the Pricing Benchmark is calculated every 15 seconds and information about the Pricing Benchmark and Pricing Benchmark value, including index data and key elements of how the Pricing Benchmark is calculated, will be publicly available at a website maintained by the provider of the Pricing Benchmark.

Quotation and last sale information for TRX is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters. Information relating to trading, including price and volume information, in TRX is available from major market data vendors and from the trading platforms on which TRX are traded. Depth of book information is also available from TRX trading platforms. The normal trading hours for TRX trading platforms are 24 hours per day, 365 days per year.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's BZX Official Closing

<sup>28</sup> As defined in Rule 11.23(a)(3), the term "BZX Official Closing Price" shall mean the price disseminated to the consolidated tape as the market center closing trade.

Price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA.

In sum, the Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act, that on the whole the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by investor protection issues that would be resolved by approving this proposal.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

#### *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 that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

- A. by order approve or disapprove such proposed rule change, or
- B. institute proceedings to determine whether the proposed rule change should be 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](mailto:rule-comments@sec.gov). Please include file number SR-CboeBZX-2025-069 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-CboeBZX-2025-069. 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-CboeBZX-2025-069 and should be submitted on or before June 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>29</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09632 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>29</sup> 17 CFR 200.30-3(a)(12).

## **SECURITIES AND EXCHANGE COMMISSION**

[OMB Control No. 3235-0633]

### **Submission for OMB Review; Comment Request; Extension: Rule 0-4**

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for approval of the collection of information discussed below.

Rule 0-4 (17 CFR 275.0-4) under the Investment Advisers Act of 1940 ("Act" or "Advisers Act") (15 U.S.C. 80b-1 *et seq.*) entitled "General Requirements of Papers and Applications," prescribes general instructions for filing an application seeking exemptive relief with the Commission.

The requirements of rule 0-4 are designed to provide Commission staff with the necessary information to assess whether granting the Orders of exemption are necessary and appropriate in the public interest and consistent with the protection of investors and the intended purposes of the Act.

Applicants for Orders under the Advisers Act can include registered investment advisers, affiliated persons of registered investment advisers, and entities seeking to avoid investment adviser status, among others. Commission staff estimates that it receives up to 7 applications per year submitted under rule 0-4 of the Act seeking relief from various provisions of the Advisers Act. Although each application typically is submitted on behalf of multiple applicants, the applicants in the vast majority of cases are related entities and are treated as a single respondent for purposes of this analysis. Most of the work of preparing an application is performed by outside counsel and, therefore, imposes no hourly burden on respondents. The cost outside counsel charges applicants depends on the complexity of the issues covered by the application and the time required. Based on conversations with applicants and attorneys, the cost for applications ranges from approximately \$15,259.94 for preparing a well-precedented, routine (or otherwise less involved) application to approximately \$238,761.88 to prepare a complex or

novel application. We estimate that the Commission receives 1 of the most time-consuming applications annually, 3 applications of medium difficulty, and 3 of the least difficult applications subject to rule 0–4. This distribution gives a total estimated annual cost burden to applicants of filing all applications of \$440,387.38 [(1 × \$238,761.88) + (3 × \$51,948.56) + (3 × \$15,259.94)]. The estimate of annual cost burden is made solely for the purposes of the Paperwork Reduction Act and is not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms.

The requirements of this collection of information are required to obtain or retain benefits. Responses will not be kept confidential.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the 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 respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

The public may view and comment on this information collection request at: [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202501-3235-021](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202501-3235-021) or email comment to [MBX.OMB.OIRA.SEC\\_desk\\_officer@omb.eop.gov](mailto:MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov) within 30 days of the day after publication of this notice, by June 30, 2025.

Dated: May 22, 2025.

**Sherr R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025–09634 Filed 5–28–25; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103104; File No. SR–CBOE–2025–022]

### Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Permit the Exchange To List and Trade Options With P.M.-Settlement That Overlie the S&P 500 Equal Weight Index

May 22, 2025.

#### I. Introduction

On March 20, 2020, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) <sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule change to list and trade p.m.-settled S&P 500 Equal Weight Index options that have standard third Friday-of-the-month, nonstandard, and quarterly expirations. The proposed rule change was published for comment in the **Federal Register** on April 8, 2025.<sup>3</sup> On April 29, 2025, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and superseded the proposed rule change as originally filed.<sup>4</sup> The Commission received no comments on the proposed rule change. The Commission is publishing this Notice and Order to solicit comment on Amendment No. 1 in Sections II and III below, which sections are being published verbatim as filed by the Exchange, and to approve the proposed rule change, as modified and superseded by Amendment No. 1, on an accelerated basis.

#### II. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to amend certain rules to permit the Exchange to list and trade options with p.m.-settlement that overlie the S&P 500 Equal Weight Index (based on both the full value and one-tenth the value of the index) (“SPEQF options” and “SPEQX options,” respectively). The text of the proposed rule change is provided in Exhibit 5.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 102752 (April 2, 2025), 90 FR 15189.

<sup>4</sup> See Amendment No. 1, available at <https://www.sec.gov/comments/sr-cboe-2025-022/sr-cboe2025022.htm>.

The text of the proposed rule change is also available on the Exchange’s website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

#### III. 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 this proposed rule change is to amend certain rules to permit the Exchange to list and trade SPEQF and SPEQX options that are p.m.-settled. Specifically, the Exchange proposes to (1) amend Rule 4.13, Interpretation and Policy .13 to permit the listing of P.M.-settled <sup>5</sup> SPEQF and SPEQX options that expire on the standard third Friday-of-the-month (“Expiration Friday”); <sup>6</sup> (2) amend Rule 4.13(c) to permit the Exchange to open for trading Quarterly Index Expirations (“QIXs”) on SPEQF and SPEQX options; <sup>7</sup> and (3) permit the Exchange

<sup>5</sup> An option with P.M.-settlement has its exercise settlement value derived from the closing prices on the expiration date.

<sup>6</sup> Rule 4.13, Interpretation and Policy .13 currently permits the Exchange to list P.M.-settled SPX and XSP options, as well as options on the Russell 2000 Index (“RUT options”) and the Mini-Russell 2000 Index (“MRUT” options), that expire on Expiration Fridays. Amendment No. 1 also amends Rule 4.13, Interpretation and Policy .13 to clarify that provision relates specific to p.m.-settled index options that expire on the third Friday-of-the-month. This rule provision previously included such language, which was inadvertently deleted by SR–CBOE–2024–034. This rule provision has always related specifically to classes for which the Exchange may list p.m.-settled series that expire on the third Friday-of-the-month; therefore, this proposed rule change has no impact on the application of the rule and merely provides clarity and transparency.

<sup>7</sup> QIXs are index option contracts that expire on the last business day of a calendar quarter. Rule 4.13(c) currently permits the Exchange to list QIXs for SPX and XSP options, as well as RUT options,

Continued

to list SPEQF and SPEQX options with Nonstandard Expirations pursuant to Rule 4.13(e).<sup>8</sup>

The S&P 500 Equal Weight Index is the equal-dollar weighted version of the S&P 500 Index (which is capitalization-weighted). The S&P 500 Index measures the performance of approximately 500 of the largest capitalization stocks in the United States. The constituents of the S&P 500 Equal Weight Index are the same as those of the S&P 500 Index; the difference between the two indexes is that each constituent is allocated a fixed weight with respect to the S&P 500 Equal Weight Index rather than a capitalization weight as is the case for the S&P 500 Index. Therefore, the index that underlies options on the S&P 500 Index (“SPX options”), as well as the Mini-S&P 500 Index (“XSP options”), for which the Exchange may currently list p.m.-settled options on Expiration Fridays, with Nonstandard Expirations, and as QIXs, is comprised of the same constituents as the underlying index for SPEQF and SPEQX options.

The Exchange currently is permitted to list p.m.-settled series that expire on Expiration Friday, with Nonstandard Expirations, and QIXs for several different broad-based index options, including SPX and XSP options. This proposed rule change would permit the Exchange to list p.m.-settled SPEQF and SPEQX options that expire on Expiration Fridays, with Nonstandard Expirations, and QIXs. The availability of p.m.-settled SPEQF and SPEQX options with these various expirations will provide market participants with opportunities to trade those options in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging strategies related to the S&P 500 Equal Weight Index and manage their portfolios. In particular, the proposed rule change will allow market participants to roll their positions in SPEQF and SPEQX options with regularity and more precision, to spread risk across more trading days, and incorporate daily, weekly, monthly, and quarterly changes

MRUT options, and options on the S&P 100 Index. Amendment No. 1 also deletes an extra space from the rule text in Rule 4.13(c).

<sup>8</sup> Rule 4.13(e) permits the Exchange to open for trading Weekly Expirations on any broad-based index eligible for standard options trading on any Monday, Tuesday, Wednesday, Thursday, or Friday (other than Expiration Fridays or days that coincide with an end-of-month (“EOM”) expiration) or EOM expirations on any broad-based index eligible for standard options trading. While the Exchange believes it has the authority under this rule to list SPEQF and SPEQX options with Nonstandard Expirations, Commission staff informed the Exchange that it must submit a rule filing pursuant to Section 19(b)(2) under the Act before it may list Nonstandard Expirations for these classes.

in the markets, which may reduce the premium cost of hedging.

In connection with the proposed change to Rule 4.13, Interpretation .13, Exchange also proposes to amend Rule 5.1, which governs trading days and hours, in conjunction with the proposed addition of SPEQF and SPEQX p.m.-settled options that expire on Expiration Friday. Rule 5.1(b)(2)(C) currently provides that on their last trading day, Regular Trading Hours for expiring p.m.-settled SPX, XSP, RUT, MRUT options, as well as Index Options with Nonstandard Expirations and QIXs, may be effected on the Exchange between 9:30 a.m. and 4:00 p.m. Eastern Time<sup>9</sup> (as opposed to the 9:30 a.m. to 4:15 p.m. Regular Trading Hours for options with those expirations that are non-expiring). The proposed rule change amends Rule 5.1(b)(2)(C) to include SPEQF and SPEQX P.M.-settled options that expire on Expiration Friday.<sup>10</sup> The primary listing markets for the component securities that comprise the S&P 500 Equal Weight Index close trading in those securities at 4:00 p.m., just as the primary listing markets for the component securities that comprise the S&P 500 and Russell 2000 Indexes close trading at 4:00 p.m. (as noted above, the components of the S&P 500 Index are identical to the components of the S&P 500 Equal Weight Index). The primary listing exchanges for the component securities disseminate closing prices for the component securities, which are used to calculate the exercise settlement value of broad-based indexes on which the Exchange lists options. The Exchange believes that, under normal trading circumstances, the primary listing markets have sufficient bandwidth to prevent any data queuing that may cause any trades that are executed prior to the closing time from being reported after 4:00 p.m. If trading in expiring SPEQF and SPEQX p.m.-settled options that expire on Expiration Fridays continued an additional fifteen minutes until 4:15 p.m. on their last trading day, these expiring options would be trading after the settlement index value for those expiring options

<sup>9</sup> See Rule 1.6, which states that unless otherwise specified, all times in the Rules are Eastern Time.

<sup>10</sup> As noted above, Rule 5.1(b)(2)(C) already applies to p.m.-settled series of SPEQF and SPEQX options with Nonstandard Expirations and QIXs. Therefore, while the proposed rule change amends this Rule only with respect to p.m.-settled SPEQF and SPEQX options that expire on Expiration Friday, on their last trading day, Regular Trading Hours for all expiring p.m.-settled SPEQF and SPEQX options with all permissible expirations (including Nonstandard Weekly and End-of-Month Expirations and QIXs) will end at 4:00 p.m.

was calculated.<sup>11</sup> Therefore, in order to mitigate potential investor confusion and the potential for increased costs to investors as a result of potential pricing divergence at the end of the trading day, the Exchange believes that it is appropriate to cease trading in the expiring SPEQF and SPEQX p.m.-settled options that expire on Expiration Fridays at 4:00 p.m., as it already does for expiring p.m.-settled SPX and XSP options (as well as RUT and MRUT options) that expire on Expiration Fridays and for expiring broad-based indexes with Nonstandard Expirations (which are p.m.-settled) for the same aforementioned reasons.<sup>12</sup> The Exchange does not believe that the proposed rule change will impact volatility on the underlying cash markets comprising broad-based indexes at the close on Expiration Fridays, as it already closes trading on the last trading day for expiring p.m.-settled options at 4:00 p.m. (including SPX and XSP options, which have the same underlying cash markets as those of SPEQF and SPEQX options), which the Exchange does not believe has had an adverse impact on fair and orderly markets on Expiration Fridays for the underlying stocks comprising the

<sup>11</sup> Further, the Exchange expects that SPEQF and SPEQX p.m.-settled options (as the Exchange understands is the case for P.M.-settled SPX, XSP, RUT, and MRUT options that expire on Expiration Friday and all broad-based index options with Nonstandard Expirations, QIXs, and other p.m.-settled options) will typically be priced in the market based on corresponding futures values. If trading in expiring SPEQF and SPEQX p.m.-settled options that expire on Expiration Friday continued until 4:15 p.m. on their last trading day, these expiring options could not be priced on corresponding futures values but rather would have to be priced on the known cash value. At the same time, the prices of non-expiring SPEQF and SPEQX p.m.-settled options series that expire on a future Expiration Friday would continue to move and likely be priced in response to changes in corresponding futures prices. As a result, a potential pricing divergence could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring SPEQF and SPEQX p.m.-settled options that expire on Expiration Friday (e.g., a switch from pricing off of futures to cash). The Exchange understands that the switch from pricing off of futures to cash can be a difficult and risky crossover for liquidity providers. As a result, if expiring p.m.-settled contracts closed at 4:15 p.m., Market-Makers may react by widening spreads in order to compensate for the additional risk.

<sup>12</sup> See Securities Exchange Act Release Nos. 68888 (February 8, 2013), 78 FR 10668 (February 14, 2013) (SR-CBOE-2012-120) (“SPXPM Pilot Approval Order”); 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR-CBOE-2013-055) (“XSPM Pilot Approval Order”); 91067 (February 5, 2021), 86 FR 9108 (February 11, 2021) (SR-CBOE-2020-116) (“MRUTPM Pilot Approval Order”); and 101197 (September 26, 2024), 89 FR 20291 (October 2, 2024) (SR-CBOE-2024-034) (“RUT Pilot Approval Order”).

corresponding indexes (as further discussed below).<sup>13</sup>

The Exchange notes, as is the case for other p.m.-settled options, that SPEQF and SPEQX options will be aggregated with all other option contracts for those options for purposes of determining compliance with the applicable position (and exercise) limit, as well as determining position limit reporting requirements.<sup>14</sup>

SPEQF and SPEQX p.m.-settled options will trade in the same manner as other p.m.-settled index options that trade on the Exchange. The Exchange Rules that currently apply to the listing and trading of p.m.-settled index options on the Exchange, including, for example, Rules that govern listing criteria, expirations, exercise prices, minimum increments, position and exercise limits, margin requirements, customer accounts, and trading halt procedures, will apply to the listing and trading of p.m.-settled SPEQF and SPEQX options on the Exchange in the same manner as they apply to other p.m.-settled index options that are listed and traded on the Exchange.

The Exchange has analyzed its capacity and represents that it believes the Exchange has the necessary systems capacity to handle the additional message traffic associated with the listing of new series that would result from the introduction of the SPEQF and SPEQX options up to the proposed number of possible p.m.-settled expirations. The Options Price Reporting Authority (“OPRA”) also informed the Exchange it believes it has the necessary systems capacity to handle the additional traffic associated

with the listing of new series that would result from this proposed rule change. The Exchange believes the equal weighting of the components of the index underlying SPEQF and SPEQX options presents a value proposition to the market that has generated investor demand for p.m.-settled SPEQF and SPEQX options, including Weekly Expirations. As further discussed below, equal-weighted index options can provide market participants with the ability to gain broad exposure to the stocks comprising the underlying index in a manner less impacted by a shift in concentration and market momentum than options overlying capitalization-weighted index that are more impacted by the stocks with largest capitalization. However, as the proposal is limited to two classes, the Exchange believes any additional traffic that would be generated from the introduction of p.m.-settled SPEQF and SPEQX options with the permissible expirations will be manageable.

The S&P 500 Equal Weight Index consists of the same components as the S&P 500 Index, as noted above. Because of the relationship between the S&P 500 Equal Weight Index and the S&P 500 Index, both of which market participants may use as hedging vehicles to meet their investment needs in connection with S&P 500 Index-related products and cash positions, the Exchange believes it is appropriate to permit the same expirations and settlement for SPEQF and SPEQX options as SPX and XSP options. The Exchange understands that investors often use S&P 500 Index-related products to diversify their portfolios and benefit from market trends. The Exchange believes that investors will benefit from the availability of p.m.-settled SPEQF and SPEQX options, as it will expand investing tools offering exposure to the U.S. equities market.

If the Commission approves the proposed rule change, the Exchange will provide the Commission with the following data on an annual basis for a period of five years following the initial listings of p.m.-settled SPEQF and SPEQX options series. This data will permit evaluation of any impact of these options on the component securities that comprise the underlying index, as well as other linked markets (e.g., hedging instruments for SPEQF and SPEQX options), such as the E-mini S&P 500 Equal Weight Index futures, to the extent possible:<sup>15</sup>

(1) number of exercised contracts for all expirations (i.e., Monday, Tuesday, Wednesday, Thursday, and Friday Weekly Expirations; EOM Expirations; a.m.- and p.m.-settled Expiration Fridays; and QIXs);

(2) monthly trading volume aggregated for E-mini S&P 500 Equal Weight Index futures that trade on the Chicago Mercantile Exchange (to the extent such data is available); and

(3) month-end open interest aggregated for all expirations of the E-mini S&P 500 Equal Weight Index futures.

The Exchange will also include analysis of this data. Further, the Exchange will provide the Commission with any additional data and analysis the Commission requests during this five-year period if the Commission [sic] such data necessary for purposes of its evaluation of any potential impact the listing of the proposed options has on the market. The Exchange would make all of this data analysis available in machine-readable format and publicly on its website.

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>16</sup> Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>17</sup> 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>18</sup> requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

500 Index (which are the same securities that comprise the S&P 500 Equal Weight Index) and whether listing and trading p.m.-settled SPX options would increase volatility around the market close in linked-markets, as well as its underlying component securities.

<sup>16</sup> 15 U.S.C. 78f(b).

<sup>17</sup> 15 U.S.C. 78f(b)(5).

<sup>18</sup> *Id.*

<sup>13</sup> See Securities Exchange Act Release Nos. 98454 (September 20, 2023), 88 FR 66103 (September 26, 2023) (SR-CBOE-2023-005) (“SPXPM Permanent Approval Order”); and 98455 (September 20, 2023), 88 FR 66073 (September 26, 2023) (SR-CBOE-2023-019) (“XSPPM and MRUTPM Permanent Approval Order”).

<sup>14</sup> See Rules 8.31(b), 8.35(b) and (d), and 8.42(b) and (g). Pursuant to current Rules, the position and exercise limits for SPEQF and SPEQX options are 25,000 contracts. The Exchange has a separate rule filing pending to eliminate position limits for SPEQF and SPEQX options (other broad-based index options, including SPX and XSP options, currently have no position limits). See Securities Exchange Act Release No. 102720 (March 25, 2025), 90 FR 14297 (March 31, 2025) (SR-CBOE-2025-020). If the Commission separately approves that filing, then SPEQF and SPEQX options (including those proposed in this rule filing) would have no position limits. Other rules regarding position and exercise limits would continue to apply. For example, Rule 8.35(b) requires Trading Permit Holders to report certain information regarding FLEX positions in FLEX index options that are subject to no position limits if they maintain in excess of 100,000 contracts in those options. Additionally, Rule 8.43 imposes various reporting obligations with respect to options (including index options), even for index options subject to no position limits.

<sup>15</sup> As discussed below, the Exchange and Commission analyzed various data to study, among other things, the impact, if any, of p.m.-settlement on the underlying securities that comprise the S&P

In particular, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors, because it will provide investors with additional means to manage their risk exposures and carry out their investment objectives with more flexibility. By offering SPEQF and SPEQX p.m.-settled options that expire on Expiration Fridays, with Nonstandard Expirations, and QIXs, the proposed rule change will allow market participants to purchase options on additional indexes available for trading on the Exchange in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging strategies related to the S&P 500 Equal Weight Index and manage their portfolios. In particular, the proposed rule change will allow market participants to roll their positions in SPEQF and SPEQX options with more regularity and precision, to spread risk across more trading days, and to incorporate daily, weekly, monthly, and quarterly changes in the markets, which may reduce the premium cost of hedging.

The Exchange further believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because it will permit the Exchange to make available to investors series with the same expirations and settlement in SPEQF and SPEQX options as are available for SPX and XSP options. As noted above, the constituent stocks of the S&P 500 Index are exactly the same as the constituent stocks of the S&P 500 Equal Weight Index. However, the Exchange believes that SPEQF and SPEQX options are designed to provide different, additional opportunities for investors to hedge the market risk associated with this index and to gain directional exposure to the index by listing options directly on this index. The U.S. equity markets have experienced increased levels of concentration in recent years. SPEQF and SPEQX options provide market participants with alternative tools to manage their risk and diversify their exposure to the stocks comprising the S&P 500 Index. Specifically, these options permit market participants to gain broad exposure to these stocks using options that would be less impacted by a shift in concentration and market momentum. Because capitalization-weighted indexes such as the S&P 500 Index are more impacted by

overlying an equal-weighted index (such as the S&P 500 Equal Weight Index) would permit investors to hedge against potential swings in the largest stocks comprising the S&P 500 Index while maintaining the ability to hedge across the entire span of S&P 500 constituent securities. The Exchange believes the significant liquidity of the components of the S&P 500 Equal Weight Index can withstand any additional trading as a result of listing options on an index comprised of components that also comprise other indexes underlying listed options (including unwinding of options positions into underlying stock positions). The proposed rule change will provide market participants looking to gain broad exposure to the stocks underlying the S&P 500 Index in a manner less impacted by a shift in concentration and market momentum with hedging tools with the same level of precision currently available to market participants that look to gain broad exposure to these stocks more impacted by the stocks with largest capitalization. As a result, market participants will have greater trading opportunities, regardless of in which index option market they participate.

The Exchange initially listed certain options that were p.m.-settled, including SPX and XSP options, that expire on Expiration Fridays and with Nonstandard Expirations pursuant to pilot programs,<sup>19</sup> so the Commission could monitor the impact of p.m.-settlement of cash-settled index derivatives on the underlying cash markets. When permanently approving these programs, the Commission recognized that listing p.m.-settled SPX and XSP options that expire on Expiration Fridays and with Nonstandard Expirations were consistent with the Act.<sup>20</sup> The Commission noted that these p.m.-settled index options had “benefitted investors and other market participants by providing more flexible trading and hedging opportunities while also having no disruptive impact on the market.”<sup>21</sup>

<sup>19</sup> While QIXs were not part of these pilot programs, we believe any conclusions applicable to Nonstandard Expirations, which include EOMs, would apply to QIXs, as the last calendar days of quarters represent a subset of the last calendar days of months.

<sup>20</sup> See SPXPM and XSPPM Pilot Approval Orders (the Commission also recognized that these risks may have been mitigated given enhanced closing procedures in use in the primary equity markets); SPXPM and XSPPM and MRUTPM Permanent Approval Orders; and Securities Exchange Act Release No. 98456 (September 20, 2023), 88 FR 66091 (September 26, 2023) (SR-CBOE-2023-020) (“Nonstandard Permanent Approval Order”).

<sup>21</sup> See SPXPM Permanent Approval Order at 66106; XSPPM and MRUTPM Permanent Approval

The Exchange believes p.m.-settled SPEQF and SPEQX options will provide the same benefits to investors and other market participants with respect to these products.

As noted above, the S&P 500 Equal Weight Index is comprised of the same underlying components as the S&P 500 Index (which underlies SPX and XSP options). While the Commission’s prior determination was based on data specific to SPX options, the Exchange believes it is appropriate to extrapolate the data to apply to p.m.-settled SPEQF and SPEQX options with the same expirations.<sup>22</sup> Therefore, the Exchange believes extrapolating the data results (in combination with ongoing review of the data the Exchange will provide to the Commission, as discussed above) to an index comprised of the same components is more than appropriate, as the Commission has already considered the impact of p.m.-settled options on futures overlying an index with the same components, another index with the same components, and the exact index components, concluding p.m.-settled options had minimal economic impact on that future, index, and constituents.<sup>23</sup> Overall, the Commission concluded that the “analysis of pilot data did not identify any significant economic impact on the underlying component securities surrounding the close as a result of expiring p.m.-settled options, nor did it indicate a deterioration in market quality . . . for an existing product when a new p.m.-settled expiration was introduced. Further significant changes in closing procedures in the decades since index options moved to a.m. settlement may also serve to mitigate the potential impact of p.m.-settled index options on the underlying cash markets.”<sup>24</sup>

Order at 66076; and Nonstandard Approval Order at 66094 (citing data the Commission reviewed in connection with the pilot programs).

<sup>22</sup> See XSPPM and MRUTPM Permanent Approval at n. 31; and Nonstandard Permanent Approval Order at n. 37 (at the time of that approval order, the Exchange had listed Nonstandard Expirations for RUT and MRUT options) (“The Commission agrees it is appropriate to extrapolate the data to [p.m.-settled third Friday-of-the-month XSP and MRUT options], as the Exchange’s analysis examines liquidity and volatility dynamics around the market close, which may be associated with typical hedging activities tied to expiring p.m.-settled index options.”) Ultimately, the Commission found that the Exchange’s filing, pilot data, and analysis demonstrated these p.m.-settled products had no significant economic impact on the respective underlying indexes or other products. See *id.*

<sup>23</sup> See XSPPM and MRUTPM Permanent Approval at 66075; and Nonstandard Permanent Approval Order at 66093–66094.

<sup>24</sup> See XSPPM and MRUTPM Permanent Approval at 66076; and Nonstandard Permanent Approval Order at 66094.

With respect to markets linked to these options, such as instruments investors may use to hedge SPEQF and SPEQX options (e.g., securities underlying the index, futures overlying the same index, and ETFs designed to track the same index), the Exchange believes these markets can withstand any additional pressure on [sic] derivatives products may place on these markets. The securities underlying SPEQF and SPEQX options must be significantly liquid to satisfy the Exchange's listing and maintenance criteria in Rule 4.10(f) and (g).<sup>25</sup> The Exchange believes these requirements demonstrate the constituents would not be materially impacted by any additional pressure resulting from the listing of these options given their significant market capitalization and liquidity. The Exchange understands that investors may use other instruments (such as futures overlying the same index and ETFs designed to track the same index) to hedge their positions in options overlying this index given potential investment challenges and risk, as well as cost, of hedging with the underlying constituents (which would entail obtaining positions in each of the over 500 individual stocks that comprise the index). The corresponding futures trade on the same market as the futures often used to hedge SPX options.<sup>26</sup> As there are currently no options overlying the S&P 500 Equal Weight Index,<sup>27</sup> the Exchange believes the established futures market trading on the same market in the same manner as the futures overlying the S&P 500 Equal Weight Index can withstand any additional pressure the listing of SPEQF and SPEQX options may have. Similarly, RSP has significant assets under management (approximately \$70 billion as of April 15) and trading volume (average daily trading volume of over 13 million shares in the previous 30 days). The Exchange believes this market is more than sufficient to withstand any additional pressure that may result from the listing of these

<sup>25</sup> These listing and maintenance criteria include: (1) component securities that account for at least 95% of the weight of the index have a market capitalization of at least \$75 million, except that component securities that account for at least 65% of the weight of the index have a market capitalization of at least \$100 million; and (2) each component security that accounts for at least 1% of the weight of the index has an average daily trading volume of at least 90,000 shares during the last six-month period.

<sup>26</sup> CME launched the futures over a year ago, making it an established product on that market.

<sup>27</sup> The Exchange understands it is possible investors may use the futures for hedging other products, such as options overlying ETFs designed to track the same index (e.g., the Invesco S&P 500 Equal Weight ETF ("RSP")).

options. The Exchange has identified no reason why the difference in weighting of the S&P 500 Index and the S&P 500 Equal Weight Index would cause p.m.-settled options overlying the S&P 500 Equal Weight Index to have a measurable impact on the same underlying cash markets or linked markets when p.m.-settled options overlying the S&P 500 Index did not. Therefore, the Exchange believes permitting p.m.-settled series of SPEQF and SPEQX options will offer investors the same opportunities as those offered by p.m.-settled SPX and XSP options with the same lack of material impact on the market and the component securities.

The Exchange further believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors, because it will provide investors with additional means for additional index options to manage their risk exposures and carry out their investment objectives. By offering SPEQF and SPEQX p.m.-settled options that expire on Expiration Fridays, with Nonstandard Expirations, and QIXs, the proposed rule change will allow market participants to purchase options on an additional index option [sic] available for trading on the Exchange in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging strategies related to the S&P 500 Equal Weight Index and manage their portfolios. In particular, the proposed rule change will allow market participants to roll their positions in SPEQF and SPEQX options with regularity, thus with more precision, to spread risk across trading days, and to incorporate daily, weekly, monthly, and quarterly changes in the markets, which may reduce the premium cost of hedging.

In addition, the Exchange believes that the proposal to end trading at 4:00 p.m. on the last trading day for transactions in expiring SPEQF and SPEQX P.M.-settled options that expire on Expiration Fridays will prevent continued trading in a product after the exercise settlement value has been fixed, thereby mitigating potential investor confusion and the potential for increased costs to investors as a result of potential pricing divergence at the end of the trading day. This is consistent with the trading hours on the last trading day for transactions in other p.m.-settled options, including SPX and XSP options.<sup>28</sup>

<sup>28</sup> As noted above, while the proposed rule change amends this Rule only with respect to p.m.-

The Exchange represents that it has the necessary systems capacity to support the proposed new option series given [sic]. The Exchange believes that its existing surveillance and reporting safeguards (including with respect to p.m.-settled index option series) in place are adequate to deter and detect possible manipulative behavior which might arise from listing and trading p.m.-settled SPEQF and SPEQX options (as the Exchange currently applies to other p.m.-settled broad-based index options, including SPX and XSP options with the same expirations) and will support the protection of investors and the public interest.<sup>29</sup> Additionally, the Exchange is a member of the Intermarket Surveillance Group ("ISG") under the Intermarket Surveillance Group Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets. In addition to obtaining information from its affiliated markets, the Exchange would be able to obtain information from other markets through ISG. In addition, Cboe has a Regulatory Services Agreement with the Financial Industry Regulatory Authority ("FINRA") for certain market surveillance, investigation and examinations functions. Pursuant to a multi-party 17d-2 joint plan, all options exchanges allocate amongst themselves and FINRA responsibilities to conduct certain options-related market surveillance that are common to rules of all options exchanges.<sup>30</sup> The Exchange further notes that current Exchange Rules that apply to the trading of other p.m.-settled index options traded on the Exchange,

settled SPEQF and SPEQF options that expire on Expiration Friday, on their last trading [sic], Regular Trading Hours for all expiring p.m.-settled SPEQF and SPEQX options with all permissible expirations (including Nonstandard Weekly and End-of-Month Expirations and QIXs) will end at 4:00 p.m.

<sup>29</sup> The surveillance program includes surveillance patterns for price and volume movements as well as patterns for potential manipulation (e.g., spoofing and marking the close).

<sup>30</sup> Section 19(g)(1) of the Act, among other things, requires every self-regulatory organization ("SRO") registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d-2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO ("common members"). Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

such as SPX and XSP options, would also apply to the trading of p.m.-settled SPEQF and SPEQX options, such as, for example, Exchange Rules governing customer accounts, margin requirements, position and exercise limits,<sup>31</sup> and trading halt procedures, which are designed to prevent fraudulent and manipulative acts.

#### *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 that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because p.m.-settled SPEQF and SPEQX options that expire on Expiration Fridays, with Nonstandard Expirations, and QIXs will be equally available to all market participants via Cboe Trading Permit Holders who wish to trade such options. Additionally, the proposed trading hours for expiring options on their expiration dates will be the same for all market participants. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because p.m.-settlement with these expirations (and the trading hours for expiring options on their expiration dates) are consistent with those of similar index products, such as SPX and XSP options (which overlie an index comprised of the same components) and competitive products.<sup>32</sup> Additionally, options on equities, including options on certain

<sup>31</sup> As noted above, pursuant to current Rules, the position and exercise limits for SPEQF and SPEQX options are 25,000 contracts. The Exchange has a separate rule filing pending to eliminate position limits for SPEQF and SPEQX options (other broad-based index options, including SPX and XSP options, currently have no position limits). See Securities Exchange Act Release No. 102720 (March 25, 2025), 90 FR 14297 (March 31, 2025) (SR-CBOE-2025-020). If the Commission separately approves that filing, then SPEQF and SPEQX options (including those proposed in this rule filing) would have no position limits. Other rules regarding position and exercise limits would continue to apply. For example, Rule 8.35(b) requires Trading Permit Holders to report certain information regarding FLEX positions in FLEX index options that are subject to no position limits if they maintain in excess of 100,000 contracts in those options. Additionally, Rule 8.43 imposes various reporting obligations with respect to options (including index options), even for index options subject to no position limits.

<sup>32</sup> See, e.g., Nasdaq PHLX, LLC Options 4A, Section 12(a)(6) (permitting p.m. settlement for options on the Nasdaq-100 and Nasdaq-100 Micro Indexes that expire on Expiration Fridays).

ETFs that track the S&P 500 Index and the S&P 500 Equal Weight Index, are p.m.-settled. To the extent that the advent of p.m.-settled SPEQF and SPEQX options trading on the Exchange makes the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received written comments on the proposed rule change.

#### **IV. Discussion and Commission Findings**

After careful review, the Commission finds that the Exchange's proposal, as modified and superseded by Amendment No. 1 ("Amended Proposal"), is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>33</sup> In particular, the Commission finds that the Amended Proposal is consistent with Section 6(b)(1) of the Act,<sup>34</sup> which requires, among other things, that the Exchange be so organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by its members and persons associated with its members with the provisions of the Act, Commission rules and regulations thereunder, and its own rules; and Section 6(b)(5) of the Act,<sup>35</sup> which requires that the proposal be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.

The Amended Proposal does not raise unique regulatory concerns. Options on broad-based indexes with p.m. settlement and third Friday-of-the-month, nonstandard, and quarterly expirations are not novel. The Exchange's rules already permit, for certain broad-based index options, including SPX and XSP options, the listing of p.m.-settled series with third Friday-of-the-month, nonstandard, and quarterly expirations, as well as trading days and hours that are the same as

<sup>33</sup> In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>34</sup> 15 U.S.C. 78f(b)(1).

<sup>35</sup> 15 U.S.C. 78f(b)(5).

would apply to p.m.-settled SPEQF and SPEQX options.<sup>36</sup> P.M.-settled SPEQF and SPEQX options with third Friday-of-the-month, nonstandard, and quarterly expirations also would be subject to the same rules that presently govern the trading of all index options on the Exchange, including, among others, rules governing customer accounts, sales practices, margin requirements, and trading practices, which are designed to protect investors and prevent fraudulent and manipulative acts.<sup>37</sup> In addition, the constituents of the S&P 500 Index and S&P 500 Equal Weight Index are the same.<sup>38</sup> As such, the Amended Proposal would not expose any index constituents to options trading with p.m. settlement and third Friday-of-the-month, nonstandard, and quarterly expirations that are not already exposed to such settlement and expirations in the SPX and XSP classes. Moreover, other options exchanges permit the listing and trading of certain broad-based index options with p.m. settlement and third Friday-of-the-month, nonstandard, and quarterly expirations.<sup>39</sup> Further, already available in the marketplace are futures contracts overlying the S&P 500 Equal Weight Index and an ETF (RSP) that is designed to track the S&P 500 Equal Weight Index, which could be important hedging instruments for market makers and other market participants that establish positions in p.m.-settled SPEQF and SPEQX options.<sup>40</sup>

Permitting the trading of options on an index of securities enables investors to participate in the price movements of the index's underlying securities and allows investors holding positions in some or all such securities to hedge the risks associated with their portfolios. The Exchange's proposal to permit the listing and trading of SPEQF and

<sup>36</sup> See *supra* Section III. The generic listing standards for broad-based index options require a.m. settlement. See, e.g., Exchange Rule 4.10(f). Accordingly, the listing of a class of broad-based index options with nonstandard expirations and p.m. settlement pursuant to Exchange Rule 4.13(e) requires the filing of a proposed rule change to that effect for the specific broad-based index option, which proposed rule change must be approved by the Commission under Section 19(b) of the Act. See *supra* note 8.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> See, e.g., Nasdaq ISE, LLC Options 4A, Section 12 and Supplementary Material (Nasdaq-100 Index options); MIAAX Rule 1809 and Interpretation and Policies (Bloomberg 500 Index options).

<sup>40</sup> See *supra* Section III. According to the Exchange, the Chicago Mercantile Exchange launched the S&P 500 Equal Weight Index futures product over a year ago, and it is an established product on that exchange. The Exchange also points out that the futures product often used to hedge SPX options trades on that same market. *Id.*

SPEQX options with p.m. settlement and third Friday-of-the-month, nonstandard, and quarterly expirations could benefit investors by providing them with additional investment and hedging alternatives on a broad-based index that offers exposure to the U.S. equities market.

Specifically, each constituent in the S&P 500 Equal Weight Index is allocated a fixed weight rather than, as is the case for S&P 500 Index constituents, a capitalization weight.<sup>41</sup> In light of this difference, the Amended Proposal could provide market participants with alternative tools to manage their risk and diversify their exposure to the stocks comprising the S&P 500 Index. P.M.-settled SPEQF and SPEQX options with the expirations set forth in the Amended Proposal could permit market participants to gain broad exposure to S&P 500 Index component stocks using options that would be less impacted by a shift in concentration and market momentum. Because capitalization-weighted indexes such as the S&P 500 Index are more impacted by larger capitalized stocks, options overlying an equal-weighted index, such as SPEQX and SPEQF options, could enable investors to hedge against potential price swings in the largest stocks comprising the S&P 500 Index while maintaining the ability to hedge across the entire span of S&P 500 constituent securities.

Furthermore, the availability of p.m.-settled SPEQF and SPEQX options with third Friday-of-the-month, nonstandard, and quarterly expirations could benefit investors and remove impediments to a free and open market by allowing market participants to establish option positions in a manner more aligned with each individual participant's specific timing needs and to roll a participant's positions on more trading days, which may enable the market participant to more precisely spread risk across more trading days and incorporate daily changes in the markets. Because the proposed p.m. settlement feature would permit trading in SPEQF and SPEQX options throughout the expiration day, market participants should be able to trade out of their positions up until the time the contract settles, which could permit market participants to more effectively manage overnight risk and reduce residual risk on the day of expiration.

The Commission has considered the potential for adverse market impact presented by the Amended Proposal in the underlying cash markets as well as the markets for linked products,

including in light of the fact that the constituent securities of the S&P 500 Equal Weight Index and S&P 500 Index are the same. The Commission believes that the significant liquidity of these constituent securities should help mitigate against such potential for adverse market impact. The constituent securities underlying SPEQF and SPEQX options (as well as SPX and XSP options) must be significantly liquid to satisfy the Exchange's listing and maintenance criteria in Exchange Rule 4.10(f) and (g).<sup>42</sup> The Commission believes that the satisfaction of these requirements helps demonstrate that the constituent securities and linked products, such as E-mini S&P 500 Equal Weight Index futures and RSP, would not be materially impacted by additional derivative pressure resulting from the listing of SPEQF and SPEQX options as proposed in the Amended Proposal.<sup>43</sup>

Relatedly, and importantly, the Exchange has committed to providing specific data on an annual basis for five years following the initial listing of p.m.-settled SPEQF and SPEQX options series.<sup>44</sup> This data will be coupled with analysis by the Exchange, and the Exchange represents that it will provide the Commission with any additional data and analysis that the Commission requests during this five-year period if the Commission deems such data to be necessary for purposes of its evaluation of any potential impact the listing of the proposed options has on the market.<sup>45</sup> The Exchange also has committed to make all of this data analysis available in machine-readable format and publicly on its website.<sup>46</sup> These Exchange commitments are designed to protect investors and the public interest, as they should provide the Commission with data and analysis that sheds light on the development of the market for p.m.-settled SPEQF and SPEQX options and enables the Commission to monitor for and assess any potential adverse market effects arising from the trading of such options.

The Commission also believes that the potential risks of trading p.m.-settled SPEQF and SPEQX options with third Friday-of-the-month, nonstandard, and quarterly expirations are mitigated by the Exchange's surveillances mechanisms, consistent with Sections 6(b)(1) and 6(b)(5) of the Act.<sup>47</sup> The Exchange represents that its existing

surveillance and reporting safeguards (including with respect to p.m.-settled index option series) in place are adequate to deter and detect possible manipulative behavior which might arise from listing and trading p.m.-settled SPEQF and SPEQX options and will support the protection of investors and the public interest.<sup>48</sup> Additionally, the Exchange is a member of ISG, whose members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets.<sup>49</sup> Further, the Exchange has a Regulatory Services Agreement with FINRA for certain market surveillance, investigation and examinations functions.<sup>50</sup> And pursuant to a multi-party Rule 17d-2 joint plan, all options exchanges allocate amongst themselves and FINRA responsibilities to conduct certain options-related market surveillance that are common to rules of all options exchanges.<sup>51</sup>

In light of the foregoing, the Commission believes that the Amended Proposal is consistent with Sections 6(b)(1) and 6(b)(5) of the Act.<sup>52</sup>

#### V. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 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](mailto:rule-comments@sec.gov). Please include file number SR-CBOE-2025-022 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-CBOE-2025-022 on the subject line. 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

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> 15 U.S.C. 78f(b)(1), 78f(b)(5).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> 15 U.S.C. 78f(b)(1), 78f(b)(5).

<sup>41</sup> *Id.*

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-CBOE-2025-022 on the subject line, and should be submitted on or before June 20, 2025.

#### VI. Accelerated Approval of Proposed Rule Change, as Modified and Superseded by Amendment No. 1

The Commission finds good cause to approve the Amended Proposal prior to the 30th day after the date of publication of Amendment No. 1 in the **Federal Register**. Amendment No. 1 does not change the original purpose of the proposal, which was, and remains under Amendment No. 1, to permit the Exchange to list and trade p.m.-settled SPEQF and SPEQX options with third Friday-of-the-month, nonstandard and quarterly expirations. In addition, the original proposal has been subject to public comment and no comments have been received.

Amendment No. 1 sets forth additional support for and detail regarding the original filing, and clarifies certain rule text provisions.<sup>53</sup> Among other things, Amendment No. 1 clarifies that p.m.-settled SPEQF and SPEQX options will trade in the same manner as and be subject to the same Exchange Rules that apply to other p.m.-settled index options that trade on the Exchange. In addition, Amendment No. 1 includes the Exchange's commitment to provide data and accompanying analysis of such data, annually or upon

Commission request, for a period of five years following the initial listing of p.m.-settled SPEQF and SPEQX options series to permit evaluation of any impact of these options on the component securities that comprise the underlying index, as well as other linked markets. The Commission believes that Amendment No. 1, without altering the purpose of the original proposal, strengthens the original proposal by providing additional clarity, support, and data commitments, as explained above and set forth fully in Sections II and III above.

The Commission therefore finds that Amendment No. 1 raises no novel regulatory issues that have not previously been subject to comment and is reasonably designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. Accordingly, pursuant to Section 19(b)(2) of the Act,<sup>54</sup> the Commission finds good cause to approve the Amended Proposal on an accelerated basis prior to the 30th day after publication of notice of the filing of Amendment No. 1 in the **Federal Register**.

#### VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,<sup>55</sup> that the proposed rule change (SR-CBOE-2025-022), as modified and superseded by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>56</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09622 Filed 5-28-25; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103114; File No. SR-CboeBZX-2025-020]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Bitwise XRP ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

May 22, 2025.

#### I. Introduction

On February 6, 2025, Cboe BZX Exchange, Inc. ("BZX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to list and trade shares ("Shares") of the Bitwise XRP ETF ("Trust") under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on February 24, 2025.<sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> This order institutes proceedings under Section 19(b)(2)(B) of the Act<sup>6</sup> to determine whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice,<sup>7</sup> the Exchange proposes to list and trade the Shares of the Trust under BZX Rule 14.11(e)(4), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is to seek to track the performance of

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 102438 (Feb. 18, 2025), 90 FR 10525 ("Notice"). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-cboebzx-2025-020/sr-cboebzx2025020.htm>.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 102601, 90 FR 12426 (Mar. 17, 2025). The Commission designated May 25, 2025, as the date by which the Commission shall approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> See Notice, *supra* note 3.

<sup>53</sup> Amendment No. 1 corrects a prior, inadvertent deletion of language from Exchange Rule 4.13, Interpretation and Policy .13, by clarifying that that provision applies specifically to p.m.-settled index options that expire on the third Friday-of-the-month. See *supra* note 6.

<sup>54</sup> 15 U.S.C. 78s(b)(2).

<sup>55</sup> 15 U.S.C. 78s(b)(2).

<sup>56</sup> 17 CFR 200.30-3(a)(12).

XRP,<sup>8</sup> as measured by the CME CF Ripple-Dollar Reference Rate—New York Variant (“Pricing Benchmark”), adjusted for the Trust’s expenses and other liabilities.<sup>9</sup> In seeking to achieve its investment objective, the Trust will hold XRP and will value its Shares daily as of 4:00 p.m. ET using the same methodology used to calculate the Pricing Benchmark.<sup>10</sup> The Trust’s assets will only consist of XRP, cash, and cash equivalents.<sup>11</sup> When the Trust sells or redeems its Shares, it will do so in cash transactions with authorized participants in blocks of 10,000 Shares.<sup>12</sup>

### III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2025–020 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act<sup>13</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>14</sup> the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices” and “to protect investors and the public interest.”<sup>15</sup>

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of

the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal to list and trade Shares of the Trust, which would hold XRP, is designed to prevent fraudulent and manipulative acts and practices or raises any new or novel concerns not previously contemplated by the Commission.

### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.<sup>16</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person’s submission must file that rebuttal by July 3, 2025.

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](mailto:rule-comments@sec.gov). Please include file number SR–CboeBZX–2025–020 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–CboeBZX–2025–020. 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–CboeBZX–2025–020 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025–09630 Filed 5–28–25; 8:45 am]

**BILLING CODE 8011–01–P**

<sup>8</sup> The Exchange states that XRP is a digital asset that is created and transmitted through the operations of the XRP Ledger, a decentralized ledger upon which XRP transactions are processed and settled. *See id.* at 10526.

<sup>9</sup> *See id.* at 10528. Bitwise Investment Advisers, LLC is the sponsor of the Trust, Delaware Trust Company is the trustee, and a third-party custodian will be responsible for custody of the Trust’s XRP. *See id.* at 10525, 10528.

<sup>10</sup> *See id.* at 10528.

<sup>11</sup> *See id.*

<sup>12</sup> *See id.*

<sup>13</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>14</sup> *Id.*

<sup>15</sup> 15 U.S.C. 78f(b)(5).

<sup>16</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

<sup>17</sup> 17 CFR 200.30–3(a)(57).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103109; File No. SR–CboeBZX–2025–025]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend the Rules Governing the Listing and Trading of Shares of the 21Shares Core Ethereum ETF To Permit Staking Under Rule 14.11(e)(4) (Commodity-Based Trust Shares)

May 22, 2025.

#### I. Introduction

On February 12, 2025, Cboe BZX Exchange, Inc. (“BZX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule change to amend the rules governing the listing and trading of shares (“Shares”) of the 21Shares Core Ethereum ETF (“Trust”) under BZX Rule 14.11(e)(4). The proposed rule change was published for comment in the **Federal Register** on February 25, 2025.<sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> This order institutes proceedings under Section 19(b)(2)(B) of the Act<sup>6</sup> to determine whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice,<sup>7</sup> the Exchange proposes to amend the rules governing the listing and trading of the Shares of the Trust under BZX Rule 14.11(e)(4).<sup>8</sup>

Specifically, the Exchange proposes to amend certain representations regarding the Trust in order to permit staking of the ether held by the Trust. According to the Exchange, except for these proposed amendments, all other representations relied upon by the Commission in approving the listing and trading of the Shares of the Trust will remain unchanged and will continue to constitute continued listing requirements.

#### III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2025–025 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act<sup>9</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>10</sup> the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to allow staking of the Trust’s ether. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.<sup>11</sup>

#### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission

invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.<sup>12</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person’s submission must file that rebuttal by July 3, 2025.

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](mailto:rule-comments@sec.gov). Please include file number SR–CboeBZX–2025–025 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–CboeBZX–2025–025. 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

<sup>12</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 102450 (Feb. 19, 2025), 90 FR 10645 (“Notice”).

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 102598, 90 FR 12385 (Mar. 17, 2025). The Commission designated May 26, 2025, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> See Notice, *supra* note 3.

<sup>8</sup> BZX Rule 14.11(e)(4) governs the listing and trading of Commodity-Based Trust Shares. The Commission approved the Exchange’s proposal to list and trade the Shares of the Trust on May 23, 2024. See Securities Exchange Act Release No.

100224 (May 23, 2024), 89 FR 46937 (May 30, 2024).

<sup>9</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>10</sup> *Id.*

<sup>11</sup> 15 U.S.C. 78f(b)(5).

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-CboeBZX-2025-025 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

**Sherry R. Haywood,**  
Assistant Secretary.

[FR Doc. 2025-09633 Filed 5-28-25; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103103; File No. SR-MRX-2025-11]

### Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Methodology for Its Options Regulatory Fee as of January 2, 2026

May 22, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on May 20, 2025, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission (the "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 MRX's Pricing Schedule at Options 7, Section 5C, Options Regulatory Fee, to

amend its current methodology of collection.

While the changes proposed herein are effective upon filing, the Exchange has designated the proposed rule change to be operative on January 2, 2026.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/mrx/rulefilings>, 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

MRX proposes to amend its current methodology of assessment and collection of the Options Regulatory Fee or "ORF" to assess ORF only for options transactions that occur on MRX that are cleared in the Customer<sup>3</sup> range at The Options Clearing Corporation ("OCC"). With this proposal MRX would not assess ORF for transactions that occur on other exchanges. Below is a more detailed description of the proposal.

###### Background on Current ORF

Today, MRX assesses its ORF for each Customer option transaction that is either: (1) executed by a Member<sup>4</sup> on

<sup>3</sup> Currently, the ORF is assessed by MRX and collected via the OCC from Priority Customers, Professional Customers, and Broker-Dealers that are not affiliated with a clearing member. These market participants clear in the "C" range at OCC. ORF will continue to be assessed and collected from these market participants under the new methodology. On MRX, a "Priority Customer" is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq MRX Options 1, Section 1(a)(36); a "Professional Customer" is a person or entity that is not a broker/dealer and is not a Priority Customer; and a "Broker-Dealer" order is an order submitted by a Member for a broker-dealer account that is not its own proprietary account.

<sup>4</sup> The term "Member" means an organization that has been approved to exercise trading rights

MRX; or (2) cleared by an MRX Member at OCC in the Customer range, even if the transaction was executed by a non-Member of MRX, regardless of the exchange on which the transaction occurs.<sup>5</sup> If the OCC clearing member is an MRX Member, ORF is assessed and collected on all ultimately cleared Customer contracts (after adjustment for CMTA<sup>6</sup>); and (2) if the OCC clearing member is not an MRX Member, ORF is collected only on the cleared Customer contracts executed at MRX, taking into account any CMTA instructions which may result in collecting the ORF from a non-Member.<sup>7</sup> The current MRX ORF is \$0.0004 per contract side.

Today, in the case where a Member both executes a transaction and clears the transaction, the ORF will be assessed to and collected from that Member. Today, in the case where a Member executes a transaction and a different Member clears the transaction, the ORF will be assessed to and collected from the Member who clears the transaction and not the Member who executes the transaction. Today, in the case where a non-Member executes a transaction at an away market and a Member clears the transaction, the ORF will be assessed to and collected from the Member who clears the transaction. Today, in the case where a Member executes a transaction on MRX and a non-Member clears the transaction, the ORF will be assessed to the Member that executed the transaction on MRX and collected from the non-Member who cleared the transaction. Today, in the case where a Member executes a transaction at an away market and a non-Member ultimately clears the transaction, the ORF will not be assessed to the Member who executed the transaction or collected from the

associated with Exchange Rights. See General 1, Section 1(a)(14).

<sup>5</sup> The Exchange uses reports from OCC when assessing and collecting the ORF. Market participants must record the appropriate account origin code on all orders at the time of entry of the order. The Exchange represents that it has surveillances in place to verify that members mark orders with the correct account origin code.

<sup>6</sup> CMTA or Clearing Member Trade Assignment is a form of "give-up" whereby the position will be assigned to a specific clearing firm at OCC.

<sup>7</sup> By way of example, if Broker A, an MRX Member, routes a Customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by MRX from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than MRX, it was cleared by an MRX Member in the member's OCC clearing account in the Customer range, therefore there is a regulatory nexus between MRX and the transaction. If Broker A was not an MRX Member, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on MRX nor was it cleared by an MRX Member.

<sup>13</sup> 17 CFR 200.30-3(a)(57).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

non-Member who cleared the transaction because the Exchange does not have access to the data to make absolutely certain that ORF should apply. Further, the data does not allow the Exchange to identify the Member executing the trade at an away market.

#### ORF Revenue and Monitoring of ORF

Today, the Exchange monitors the amount of revenue collected from the ORF ("ORF Regulatory Revenue") to ensure that it, in combination with other regulatory fees and fines, does not exceed Options Regulatory Costs.<sup>8</sup> In determining whether an expense is considered an Options Regulatory Cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset Options Regulatory Cost.

ORF Regulatory Revenue, when combined with all of the Exchange's other regulatory fees and fines, is designed to recover the Options Regulatory Costs to the Exchange of the supervision and regulation of member Customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Options Regulatory Costs include direct regulatory expenses and certain indirect expenses in support of the regulatory function. The direct expenses include in-house and third-party service provider costs to support the day-to-day regulatory work such as surveillance, investigations and examinations. The indirect expenses are only those expenses that are in support of the regulatory functions, such areas include Office of the General Counsel, technology, finance, and internal audit. Indirect expenses will not exceed 35% of the total Options Regulatory Costs, in which case direct expenses could be 65% or more of total Options Regulatory Costs.<sup>9</sup>

#### Proposal for January 2, 2026

MRX has been reviewing its methodologies for the assessment and

<sup>8</sup>The regulatory costs for options comprise a subset of the Exchange's regulatory budget that is specifically related to options regulatory expenses and encompasses the cost to regulate all Members' options activity ("Options Regulatory Cost").

<sup>9</sup>Direct and indirect expenses are based on the Exchange's 2025 Regulatory Budget.

collection of ORF. As a result of this review, MRX proposes to modify its current ORF to continue to assess ORF for options transactions cleared by OCC in the Customer range, however ORF would be assessed to each MRX Member for executions that occur on MRX. Specifically, the ORF would continue to be collected by OCC on behalf of MRX from MRX Members and non-Members for all Customer transactions executed on MRX. ORF would be assessed and collected on all ultimately cleared Customer contracts, taking into account adjustments for CMTA that were provided to MRX the same day as the trade.<sup>10</sup>

Further, the Exchange would bill ORF according to the clearing instructions provided on the execution. More specifically, MRX proposes to assess ORF based on the clearing instruction provided on the execution on trade date and would not take into consideration CMTA changes or transfers that occur at OCC.<sup>11</sup> As a result of this proposed rule change, if a Member executes a Customer transaction on MRX and is the clearing member on record on the transaction on MRX, the ORF will be assessed to that Member. With this proposal, in the case where a Member executes a Customer transaction on MRX and a different Member is the clearing member on record on the transaction on MRX, the ORF will be assessed to and collected from the Member who is the clearing member on record on the transaction and not the Member who executes the transaction. Additionally, in the case where a Member executes a Customer transaction on MRX and a non-MRX Member is the clearing member on record on the transaction on MRX, the ORF will be assessed to the non-MRX Member who is the clearing member on record on the transaction and not the Member who executes the transaction. With this proposal, in the case where a Member executes a Customer transaction on a non-MRX exchange, MRX will not assess an ORF, regardless of how the transaction is cleared. As is the case today, OCC will collect ORF from OCC clearing members on behalf of MRX based on MRX's instructions.

With this proposal, the current MRX ORF of \$0.0010 per contract side would

<sup>10</sup> Adjustments to CMTA that occur at OCC would not be taken into account.

<sup>11</sup> Adjustments that were made the same day as the trade on MRX will be taken into account.

be increased to \$0.0139 per contract side. With this proposal, the Exchange will endeavor to ensure that ORF Regulatory Revenue generated from ORF will not exceed 82% of Options Regulatory Cost. MRX will continue to ensure that ORF Regulatory Revenue does not exceed Options Regulatory Cost. As is the case today, the Exchange will notify Members via an Options Trader Alert of any change in the amount of the fee at least 30 calendar days prior to the effective date of the change. In this case, the Exchange will notify Members via an Options Trader Alert of these changes at least 30 calendar days prior to January 2, 2026.

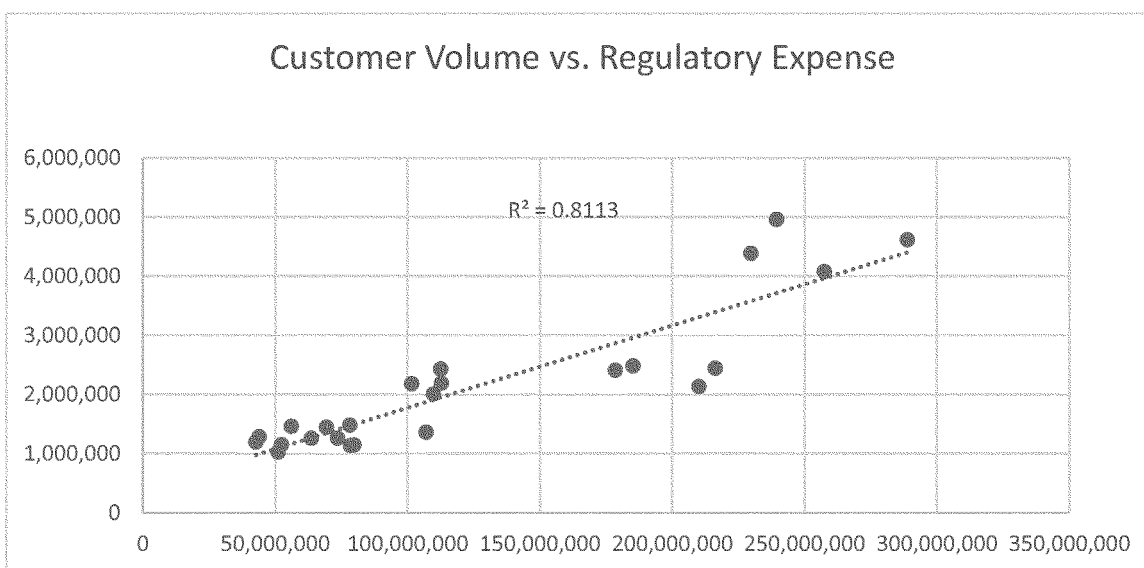
The Exchange utilized historical and current data from its affiliated options exchanges to create a new regression model that would tie expenses attributable to regulation to a respective source.<sup>12</sup> To that end, the Exchange plotted Customer volumes from each exchange<sup>13</sup> against Options Regulatory Cost from each exchange for the Time Period. Specifically, the Exchange utilized standard charting functionality to create a linear regression. The charting functionality yields a "slope" of the line, representing the marginal cost of regulation, as well as an "intercept," representing the fixed cost of regulation.<sup>14</sup> The Exchange considered using non-linear models, but concluded that the best R<sup>2</sup> ("R-Squared")<sup>15</sup> results came from a standard  $y = Mx + B$  format for regulatory expense. The R-Squared for the charting method ranged from 80% to 90% historically. As noted, the plots below represent the Time Period. The X-axis reflects Customer volumes by exchange, by quarter and the Y-axis reflects regulatory expense by exchange.

<sup>12</sup> This model seeks to relate Options Regulatory Cost to historical volumes on each Nasdaq affiliated exchange by market participant. In creating this model, the Exchange did not rely on data from a single SRO as it had in the past.

<sup>13</sup> The Exchange utilized data from all Nasdaq affiliated options exchanges to create this model from data for the 2024 calendar year ("Time Period").

<sup>14</sup> The Exchange utilized data from Time Period to calculate the slope and intercept.

<sup>15</sup> R-Squared is a statistical measure that indicates how much of the variation of a dependent variable is explained by an independent variable in a regression model. The formula for calculating R-squared is:  $R^2 = 1 - \text{Unexplained Variation} / \text{Total Variation}$ .



The results of this modelling indicated a high correlation and intercept for the baseline cost of regulating the options market as a whole. Specifically, the regression model indicated that (1) the marginal cost of regulation is measurable, and significantly attributable to Customer activity; and (2) the fixed cost of setting up a regulatory regime should arguably be dispersed across the industry so that all options exchanges have substantially similar revenue streams to satisfy the "intercept" element of cost. When seeking to offset the "set-up" cost of regulation, the Exchange attempted several levels of attribution.<sup>16</sup> This led the Exchange to utilize a model with a two-factor regression on a quarterly basis for the 2024 calendar year of volumes relative to the pool of expense data for the six Nasdaq affiliated options exchanges. Once again, standard spreadsheet functionality (including the Data Analysis Packet) was used to determine the mathematics for this model.<sup>17</sup>

Utilizing the new regression model, and assumptions in the proposal, the model demonstrates that Customer volumes are directly attributable to marginal cost. Applying the regression coefficient values historically, the

<sup>16</sup> Of note, through analysis of the results of this regression model, there was no positive correlation that could be established between Customer away volume and regulatory expense. The most successful attribution was related to industry wide Firm Proprietary and Broker-Dealer Transaction volume which accounted for approximately 3–4% of the regulatory expense both on-exchange and away.

<sup>17</sup> The Exchange notes that various exchanges negotiate their respective contracts independently with FINRA creating some variability. Additionally, an exchange with a floor component would create some variability.

Exchange established a "normalization" by per options exchange. The primary driver of this need for "normalization" are negotiated regulatory contracts that were negotiated at different points in time, yielding differences in per contract regulatory costs by exchange. Normalization is therefore the average of a given exchange's historical period (all four quarters in 2024) ratio of regulatory expense to revenue when using the regressed values (for Customer ORF) that yields an effective rate by exchange. The "normalization" was then multiplied to a "targeted collection rate" of approximately 82% to arrive at ORF rates for Customer. Of note, when comparing the ORF rates generated from this method, historically, there appears to be a very tight relationship between the estimated modeled collection and actual expense and the regulatory expenses for that same period.

One other important aspect of this modeling is the input of Options Regulatory Costs. The Exchange notes that in defining Options Regulatory Costs it accounts for the nexus between the expense and options regulation. By way of example, the Exchange excludes certain indirect expenses such as payroll expenses, accounts receivable, accounts payable, marketing, executive level expenses and corporate systems.

The Exchange will continue to monitor ORF Regulatory Revenue to ensure that it, in combination with other regulatory fees and fines, does not exceed Options Regulatory Costs. In determining whether an expense is considered an Options Regulatory Cost, the Exchange will continue to review all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes

that fines collected by the Exchange in connection with a disciplinary matter will continue to offset Options Regulatory Cost.

As is the case today, ORF Regulatory Revenue is designed to recover a material portion of the Options Regulatory Costs to the Exchange for the supervision and regulation of Members' transactions, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. As discussed above, Options Regulatory Costs include direct regulatory expenses<sup>18</sup> and certain indirect expenses in support of the regulatory function.<sup>19</sup>

Finally, the Exchange notes that this proposal will sunset on February 1, 2026, at which point the Exchange would revert back to the ORF methodology and rate (\$0.0004 per contract side) that was in effect prior to this rule change.<sup>20</sup>

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>21</sup> Specifically,

<sup>18</sup> The direct expenses include in-house and third-party service provider costs to support the day-to-day regulatory work such as surveillances, investigations and examinations.

<sup>19</sup> The indirect expenses include support from such areas as Office of the General Counsel, technology, finance and internal audit.

<sup>20</sup> The Exchange proposes to reconsider the sunset date in 2026 and determine whether to proceed with the proposed ORF structure at that time.

<sup>21</sup> 15 U.S.C. 78f(b).

the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,<sup>22</sup> which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its members, and other persons using its facilities. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>23</sup> requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed ORF to be assessed on January 2, 2026, is reasonable, equitable and not unfairly discriminatory for various reasons. First, the Exchange believes that continuing to assess only Customers an ORF is reasonable because Customer transactions account for a material portion of MRX's Options Regulatory Cost.<sup>24</sup> A large portion of the Options Regulatory Cost relates to Customer allocation because obtaining Customer information may be more time intensive. For example, non-Customer market participants are subject to various regulatory and reporting requirements which provides the Exchange certain data with respect to these market participants. In contrast, Customer information is known by Members of the Exchange and is not readily available to MRX.<sup>25</sup> The Exchange may have to take additional steps to understand the facts surrounding particular trades involving a Customer which may require requesting such information from a broker-dealer. Further, Customers require more Exchange regulatory services based on the amount of options business they conduct. For example, there are Options Regulatory Costs associated with main office and branch office examinations (*e.g.*, staff expenses), as well as investigations into

Customer complaints and the terminations of registered persons. As a result, the Options Regulatory Costs associated with administering the Customer component of the Exchange's overall regulatory program are materially higher than the Options Regulatory Costs associated with administering the non-Customer component when coupled with the amount of volume attributed to such Customer transactions. Utilizing the new regression model, and assumptions in the proposal, it appears that MRX's Customer regulation occurs to a large extent on Exchange. Utilizing the new regression model, and assumptions in the proposal, the Exchange does not believe that significant Options Regulatory Costs result from activity attributed to Customers that may occur across options markets. To that end, with this proposal, the amount of Options Regulatory Cost allocated to on-exchange Customer transactions is significant. Also, with respect to Customer transactions, options volume continues to surpass volume from other options participants. Additionally, there are rules in the Exchange's Rulebook that deal exclusively with Customer transactions, such as rules involving doing business with a Customer, which would not apply to Firm Proprietary and Broker-Dealer Transactions.<sup>26</sup> For these reasons, regulating Customer trading activity is "much more labor-intensive" and therefore, more costly.

Second, while the Exchange acknowledges that there is a cost to regulate Market Makers, unlike other market participants, Market Makers have various regulatory requirements with respect to quoting as provided for in Options 2, Section 4. Specifically, Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. Primary Market Makers are obligated to quote in the Opening Process and intra-day.<sup>27</sup> Additionally, Market Makers may enter quotes in the Opening Process to open an option series and they are required to quote intra-day.<sup>28</sup> Further, unlike other market participants, Primary Market Makers and Market Makers have obligations to compete with other Market Makers to improve the market in all series of options classes to which the Market Maker is appointed and to update market quotations in response to changed market conditions in all series of options classes to which the Market

Maker is appointed.<sup>29</sup> Also, Primary Market Makers and Market Makers incur other costs imposed by the Exchange related to their quoting obligations in addition to other fees paid by other market participants. Market Makers are subject to a number of fees, unlike other market participants. Market Makers pay CMM Trading Right Fees<sup>30</sup> in addition to other fees paid by other market participants. These liquidity providers are critical market participants in that they are the only market participants that are required to provide liquidity to MRX and are necessary for opening the market. Excluding Market Maker transactions from ORF allows these market participants to manage their costs and consequently their business model more effectively thus enabling them to better allocate resources to other technologies that are necessary to manage risk and capacity to ensure that these market participants continue to compete effectively on MRX in providing tight displayed quotes which in turn benefits markets generally and market participants specifically. Permitting these market participants to utilize their resources to quote tighter in the market. Tighter quotes benefits Customers as well as other market participants who interact with that liquidity. Finally, the Exchange notes that Market Makers may transact orders in addition to submitting quotes on the Exchange. This proposal would except orders submitted by Market Makers, in addition to quotes, for purposes of ORF. Market Makers utilize orders in their assigned options series to sweep the order book. The Exchange believes the quantity of orders utilized by Market Makers in their assigned series is de minimis. In their unassigned options series, Market Makers utilize orders to hedge their risk or respond to auctions. The Exchange notes that the number of orders submitted by Market Makers in their unassigned options series are far below the cap<sup>31</sup> and therefore de minimis.

Additionally, while the Exchange acknowledges that there is a cost to regulate Firm Proprietary and Broker-Dealer transactions, the Exchange notes that these market participants do not entail significant volume when compared to Customer transactions. The Exchange notes that Firm Proprietary

<sup>22</sup> 15 U.S.C. 78f(b)(4).

<sup>23</sup> 15 U.S.C. 78f(b)(5).

<sup>24</sup> The Exchange notes that the regulatory costs relating to monitoring Members with respect to Customer trading activity are generally higher than the regulatory costs associated with Members that do not engage in customer trading activity, which tends to be more automated and less labor-intensive. By contrast, regulating Members that engage in Customer trading activity is generally more labor intensive and requires a greater expenditure of human and technical resources as the Exchange needs to review not only the trading activity on behalf of Customers, but also the Member's relationship with its Customers via more labor-intensive exam-based programs. As a result, the costs associated with administering the Customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-Customer component of the regulatory program.

<sup>25</sup> The Know Your Customer or "KYC" provision is the obligation of the broker-dealer.

<sup>26</sup> See MRX Options 10 Rules.

<sup>27</sup> See MRX Options 3, Section 8 and Options 2, Section 5.

<sup>28</sup> *Id.*

<sup>29</sup> See MRX Options 2, Section 4(b)(1) and (3).

<sup>30</sup> See MRX Options 7, Section 6, B.

<sup>31</sup> See MRX Options 2, Section 6. The total number of contracts executed during a quarter by a Market Maker in options classes to which it is not appointed may not exceed twenty-five percent (25%) of the total number of contracts traded. In the Exchange's experience, Market Maker's are generally below the 25% cap.

and Broker-Dealer market participants are more sophisticated. There are not the same protections in place for Firm Proprietary and Broker-Dealer Transactions as compared to Customer transactions. The regulation of Firm Proprietary and Broker-Dealer transactions is less resource intensive than the regulation of Customer transactions and accounts for a small percentage of Options Regulatory Costs.

Third, assessing ORF on Customer executions that occur on MRX is reasonable, equitable and not unfairly discriminatory because it will avoid overlapping ORFs that would otherwise be assessed by MRX and other options exchanges that also assess an ORF. With this proposal, Customers executions that occur on other exchanges would no longer be subject to an MRX ORF. Further, the Exchange believes that collecting 82% of Options Regulatory Cost is appropriate and correlates to the degree of regulatory responsibility and Options Regulatory Cost borne by the Exchange with respect to Customer transactions. The Exchange's proposal continues to ensure that Options Regulatory Revenue, in combination with other regulatory fees and fines, does not exceed Options Regulatory Costs. Fines collected by the Exchange in connection with a disciplinary matter will continue to offset Options Regulatory Cost. Capping ORF collected at 82% of Options Regulatory Cost, commencing January 2, 2026, is reasonable, equitable and not unfairly discriminatory as the Options Regulatory Revenue collected will offset the corresponding Options Regulatory Cost associated with on-exchange Customer transactions. The Exchange will review the ORF Regulatory Revenue and would amend the ORF if it finds that its ORF Regulatory Revenue exceeds its projections.<sup>32</sup>

The proposed sunset date of February 1, 2026 is reasonable, equitable and not unfairly discriminatory. If all options exchanges have adopted a similar ORF model, the Exchange notes that it would not sunset the proposal on February 1, 2026. The Exchange proposes to reconsider the sunset date in early 2026 and determine whether to proceed with the proposed ORF structure at that time.

#### *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 intra-market competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposed changes to ORF do not impose an undue burden on inter-market competition because ORF is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange notes, however, the proposed change is not designed to address any competitive issues. The Exchange is obligated to ensure that the amount of ORF Regulatory Revenue, in combination with its other regulatory fees and fines, does not exceed ORF Regulatory Cost.

Continuing to assess ORF only on Customer executions that occur on MRX does not impose an undue burden on intra-market competition. Customer transactions account for a large portion of the Exchange's surveillance expense. With respect to Customer transactions, options volume continues to surpass volume from other options participants. Additionally, there are rules in the Exchange's Rulebook that deal exclusively with Customer transactions, such as rules involving doing business with a Customer, which would not apply to Non-Customer transactions.<sup>33</sup> For these reasons, regulating Customer trading activity is "much more labor-intensive" and therefore, more costly. Further, the Exchange believes that a large portion of the Options Regulatory Cost relates to Customer allocation because obtaining Customer information may be more time intensive. For example, non-Customer market participants are subject to various regulatory and reporting requirements which provides the Exchange certain data with respect to these market participants. In contrast, Customer information is known by Members of the Exchange and is not readily available to MRX.<sup>34</sup> The Exchange may have to take additional steps to understand the facts surrounding particular trades involving a Customer which may require requesting such information from a broker-dealer. Further, Customers require more Exchange regulatory services based on the amount of options business they conduct. For example, there are Options Regulatory Costs associated with main office and branch office examinations (e.g., staff expenses), as well as investigations into Customer complaints and the terminations of registered persons. As a result, the Options Regulatory Costs associated with administering the Customer component of the Exchange's overall regulatory program are materially higher than the Options Regulatory Costs associated

with administering the non-Customer component when coupled with the amount of volume attributed to such Customer transactions. Not attributing significant Options Regulatory Costs to Customers for activity that may occur across options markets does not impose an undue burden on intra-market competition because the data in the regression model demonstrates that MRX's Customer regulation occurs to a large extent on Exchange.

The Exchange believes that not assessing ORF on Market Makers does not impose an undue burden on intra-market competition because these liquidity providers are critical market participants in that they are the only market participants that are required to provide liquidity to MRX and are necessary for opening the market. Excluding Market Maker transactions from ORF does not impose an intra-market burden on competition, rather it allows these market participants to manage their costs and consequently their business model more effectively thus enabling them to better allocate resources to other technologies that are necessary to manage risk and capacity to ensure that these market participants continue to compete effectively on MRX in providing tight displayed quotes which in turn benefits markets generally and market participants specifically. Unlike other market participants, Market Makers have various regulatory requirements with respect to quoting as provided for in Options 2, Section 4. Specifically, Market Makers have certain quoting requirements with respect to their assigned options series as provided in Options 2, Section 5. Primary Market Makers are obligated to quote in the Opening Process and intra-day.<sup>35</sup> Additionally, Market Makers may enter quotes in the Opening Process to open an option series and they are required to quote intra-day.<sup>36</sup> Further, unlike other market participants, Primary Market Makers and Market Makers have obligations to compete with other Market Makers to improve the market in all series of options classes to which the Market Maker is appointed and to update market quotations in response to changed market conditions in all series of options classes to which the Market Maker is appointed.<sup>37</sup> Primary Market Makers and Market Makers incur other costs imposed by the Exchange related to their quoting obligations in addition to other fees paid by other market

<sup>32</sup> MRX would submit a rule change to the Commission to amend ORF rates.

<sup>33</sup> See MRX Options 10 Rules.

<sup>34</sup> The Know Your Customer or "KYC" provision is the obligation of the broker-dealer.

<sup>35</sup> See MRX Options 3, Section 8 and Options 2, Section 5.

<sup>36</sup> *Id.*

<sup>37</sup> See MRX Options 2, Section 4(b)(1) and (3).

participants. Market Makers are subject to a number of fees, unlike other market participants. Market Makers pay CMM Trading Right Fees<sup>38</sup> in addition to other fees paid by other market participants. Finally, the Exchange notes that Market Makers may transact orders on the Exchange in addition to submitting quotes. The Exchange's proposal to except orders submitted by Market Makers, in addition to quotes, for purposes of ORF does not impose an undue burden on intra-market competition because Market Makers utilize orders in their assigned options series to sweep the order book. Further, the Exchange believes the quantity of orders utilized by Market Makers in their assigned series is de minimis. In their unassigned options series, Market Makers utilize orders to hedge their risk or respond to auctions. The Exchange notes that the number of orders submitted by Market Makers in their unassigned options series are far below the cap<sup>39</sup> and therefore de minimis.

The Exchange believes that not assessing ORF on Firm Proprietary and Broker-Dealer market participants does not impose an undue burden on intra-market competition because the regulation of Firm Proprietary and Broker-Dealer transactions is less resource intensive than the regulation of Customer transactions. The volume generated from Firm Proprietary and Broker-Dealer transactions does not entail significant volume when compared to Customer transactions. Therefore, excluding Firm Proprietary and Broker-Dealer transactions from ORF does not impose an undue burden on intra-market competition as Customer transactions account for a material portion of MRX's Options Regulatory Cost.<sup>40</sup>

<sup>38</sup> See MRX Options 7, Section 6, B.

<sup>39</sup> See MRX Options 2, Section 6(b)(1) and (2). The total number of contracts executed during a quarter by a Competitive Market Maker in options classes to which it is not appointed may not exceed twenty-five percent (25%) of the total number of contracts traded by such Competitive Market Maker in classes to which it is appointed and with respect to which it was quoting pursuant to Options 2, Section 5(e)(1). The total number of contracts executed during a quarter by a Primary Market Maker in options classes to which it is not appointed may not exceed twenty-five percent (25%) of the total number of contracts traded per each Primary Market Maker Membership.

<sup>40</sup> The Exchange notes that the regulatory costs relating to monitoring Members with respect to customer trading activity are generally higher than the regulatory costs associated with Members that do not engage in customer trading activity, which tends to be more automated and less labor-intensive. By contrast, regulating Members that engage in customer trading activity is generally more labor intensive and requires a greater expenditure of human and technical resources as the Exchange needs to review not only the trading activity on behalf of customers, but also the

The Exchange's proposal to assess ORF only on Customer executions that occur on MRX does not impose an intra-market burden on competition because the amount of activity surveilled across exchanges is small when compared to the overall number of Exchange rules that are surveilled by MRX for on-Exchange activity. Limiting the amount of ORF assessed to activity that occurs on MRX avoids overlapping ORFs that would otherwise be assessed by MRX and other options exchanges that also assess an ORF. Further, capping ORF collected at 82% of Options Regulatory Cost commencing January 2, 2026, does not impose an intra-market burden on competition as this collection accounts for the collection only on Customer executions. The Exchange will review the ORF Regulatory Revenue and would amend the ORF if it finds that its ORF Regulatory Revenue exceeds its projections.<sup>41</sup>

### 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) of the Act<sup>42</sup> and paragraph (f) of Rule 19b-4<sup>43</sup> 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. If the Commission takes such action, the Commission shall institute proceedings 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.

Member's relationship with its customers via more labor-intensive exam-based programs. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component of the regulatory program.

<sup>41</sup> MRX would submit a rule change to the Commission to amend ORF rates.

<sup>42</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>43</sup> 17 CFR 240.19b-4(f).

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](mailto:rule-comments@sec.gov). Please include file number SR-MRX-2025-11 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-2025-11. 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-2025-11 and should be submitted on or before June 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>44</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09621 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>44</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103107; File No. SR–CboeBZX–2025–050]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Franklin Bitcoin ETF, the Franklin Ethereum ETF, and the Franklin Crypto Index ETF To Permit In-Kind Creations and Redemptions

May 22, 2025.

On April 2, 2025, Cboe BZX Exchange, Inc. (“Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule change to amend the rule governing the listing and trading of shares of the Franklin Bitcoin ETF, the Franklin Ethereum ETF, and the Franklin Crypto Index ETF to permit in-kind creations and redemptions. The proposed rule change was published for comment in the **Federal Register** on April 11, 2025.<sup>3</sup>

Section 19(b)(2) of the Act<sup>4</sup> provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is May 26, 2025. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,<sup>5</sup> designates July 10, 2025, as the date by which the Commission shall either approve or disapprove, or institute

proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CboeBZX–2025–050).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>6</sup>

Sherry R. Haywood,  
Assistant Secretary.

[FR Doc. 2025–09625 Filed 5–28–25; 8:45 am]

BILLING CODE 8011–01–P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103115; File No. SR–CboeBZX–2025–022]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Canary XRP Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

May 22, 2025.

#### I. Introduction

On February 6, 2025, Cboe BZX Exchange, Inc. (“BZX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule change to list and trade shares (“Shares”) of the Canary XRP Trust (“Trust”) under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on February 25, 2025.<sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> This order institutes proceedings under Section 19(b)(2)(B) of the Act<sup>6</sup> to determine

whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice,<sup>7</sup> the Exchange proposes to list and trade the Shares of the Trust under BZX Rule 14.11(e)(4), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

The investment objective of the Trust is to seek to track the performance of XRP,<sup>8</sup> as measured by the CoinDesk XRP USD CCIX 30min NY Rate (“Pricing Benchmark”), adjusted for the Trust’s expenses and other liabilities.<sup>9</sup> In seeking to achieve its investment objective, the Trust will hold XRP and will value its Shares daily as of 4:00 p.m. ET using the same methodology used to calculate the Pricing Benchmark.<sup>10</sup> The Trust’s assets will only consist of XRP, cash, and cash equivalents.<sup>11</sup> When the Trust sells or redeems its Shares, it will do so in cash transactions with authorized participants in blocks of 10,000 Shares.<sup>12</sup>

#### III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2025–022 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act<sup>13</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>14</sup> the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for

<sup>6</sup> 17 CFR 200.30–3(a)(31).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 102449 (Feb. 19, 2025), 90 FR 10647 (“Notice”). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-cboebzx-2025-022/sr-cboebzx2025022.htm>.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 102596, 90 FR 12409 (Mar. 17, 2025). The Commission designated May 26, 2025, as the date by which the Commission shall approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> See Notice, *supra* note 3.

<sup>8</sup> The Exchange states that XRP is a digital asset that is created and transmitted through the operations of the XRP Ledger, a decentralized ledger upon which XRP transactions are processed and settled. See *id.* at 10648.

<sup>9</sup> See *id.* at 10650. Canary Capital Group LLC is the sponsor of the Trust, CSC Delaware Trust Company is the trustee, and a third-party custodian will be responsible for custody of the Trust’s XRP. See *id.* at 10648, 10650.

<sup>10</sup> See *id.* at 10650–51.

<sup>11</sup> See *id.* at 10650.

<sup>12</sup> See *id.*

<sup>13</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>14</sup> *Id.*

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 102776 (Apr. 7, 2025), 90 FR 15499. The Commission has received no comments on the proposed rule change.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> 15 U.S.C. 78s(b)(2).

additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices" and "to protect investors and the public interest."<sup>15</sup>

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal to list and trade Shares of the Trust, which would hold XRP, is designed to prevent fraudulent and manipulative acts and practices or raises any new or novel concerns not previously contemplated by the Commission.

#### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.<sup>16</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by July 3, 2025.

<sup>15</sup> 15 U.S.C. 78f(b)(5).

<sup>16</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

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](mailto:rule-comments@sec.gov). Please include file number SR-CboeBZX-2025-022 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-CboeBZX-2025-022. 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-CboeBZX-2025-022 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Sherry R. Haywood,**  
Assistant Secretary.

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**BILLING CODE 8011-01-P**

<sup>17</sup> 17 CFR 200.30-3(a)(57).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103110; File No. SR-CboeBZX-2025-023]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend the Rules Governing the Listing and Trading of Shares of the Fidelity Wise Origin Bitcoin Fund and the Fidelity Ethereum Fund To Permit In-Kind Creations and Redemptions Under Rule 14.11(e)(4) (Commodity-Based Trust Shares)

May 22, 2025.

#### I. Introduction

On February 7, 2025, Cboe BZX Exchange, Inc. ("BZX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to amend the rules governing the listing and trading of shares ("Shares") of the Fidelity Wise Origin Bitcoin Fund ("Bitcoin Trust") and the Fidelity Ethereum Fund ("ETH Trust" and, together with the Bitcoin Trust, the "Trusts") under BZX Rule 14.11(e)(4). The proposed rule change was published for comment in the **Federal Register** on February 25, 2025.<sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> This order institutes proceedings under Section 19(b)(2)(B) of the Act<sup>6</sup> to determine whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice,<sup>7</sup> the Exchange proposes to amend the rules governing the listing

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 102451 (Feb. 19, 2025), 90 FR 10664 ("Notice"). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-cboebzx-2025-023/sr-cboebzx2025023.htm>.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 102595, 90 FR 12376 (Mar. 17, 2025). The Commission designated May 26, 2025, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> See Notice, *supra* note 3.

and trading of the Shares of the Trusts under BZX Rule 14.11(e)(4).<sup>8</sup> Specifically, the Exchange proposes to amend certain representations regarding the Trusts' creation and redemption processes in order to permit in-kind creations and redemptions. According to the Exchange, except for these proposed amendments, all other representations relied upon by the Commission in approving the listing and trading of the Shares of the Trusts will remain unchanged and will continue to constitute continued listing requirements.

### III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2025–023 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act<sup>9</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>10</sup> the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to allow for in-kind creation and redemption of the Trusts' bitcoin and ether. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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.<sup>11</sup>

### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.<sup>12</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by July 3, 2025.

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](mailto:rule-comments@sec.gov). Please include file number SR–CboeBZX–2025–023 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–CboeBZX–2025–023. 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–CboeBZX–2025–023 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

**Sherry R. Haywood,**  
Assistant Secretary.

[FR Doc. 2025–09626 Filed 5–28–25; 8:45 am]

BILLING CODE 8011–01–P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103111; File No. SR–CboeBZX–2025–049]

### Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Various Provisions of Exchange Rule 14.11

May 22, 2025.

On March 31, 2025, Cboe BZX Exchange, Inc. (“BZX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b–4 thereunder,<sup>2</sup> a proposed rule

<sup>8</sup> BZX Rule 14.11(e)(4) governs the listing and trading of Commodity-Based Trust Shares. The Commission approved the Exchange's proposal to list and trade the Shares of the Bitcoin Trust on January 10, 2024. See Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024). Separately, the Commission approved the Exchange's proposal to list and trade the Shares of the ETH Trust on May 23, 2024. See Securities Exchange Act Release No. 100224 (May 23, 2024), 89 FR 46937 (May 30, 2024).

<sup>9</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>10</sup> *Id.*

<sup>11</sup> 15 U.S.C. 78f(b)(5).

<sup>12</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

<sup>13</sup> 17 CFR 200.30–3(a)(57).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

change to amend various provisions of BZX Rule 14.11 that would modify specific requirements relating to registered Market Makers in a UTP Derivative Security or a Derivative Security listed on the Exchange. The proposed rule change was published for comment in the **Federal Register** on April 17, 2025.<sup>3</sup> The Commission has received no comments regarding the proposed rule change.

Section 19(b)(2) of the Act<sup>4</sup> provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is June 1, 2025. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,<sup>5</sup> designates July 16, 2025, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR-CboeBZX-2025-049).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>6</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09627 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103113; File No. SR-NASDAQ-2025-012]

### Self-Regulatory Organizations; Nasdaq Stock Market LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the CoinShares XRP ETF Under Nasdaq Rule 5711(d) (Commodity Based Trust Shares)

May 22, 2025.

#### I. Introduction

On February 7, 2025, The Nasdaq Stock Market LLC (“Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to list and trade shares (“Shares”) of the CoinShares XRP ETF (“Trust”) under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on February 25, 2025.<sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act,<sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>5</sup> This order institutes proceedings under Section 19(b)(2)(B) of the Act<sup>6</sup> to determine whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice,<sup>7</sup> the Exchange proposes to list and trade the Shares of the Trust under Nasdaq Rule 5711(d), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

According to the Exchange, the investment objective of the Trust is for the Shares to reflect the performance of

the value of XRP<sup>8</sup> as represented by the Compass Crypto Reference Index XRP—4 p.m. NY Time (“Index”), less the Trust’s liabilities and expenses.<sup>9</sup> In seeking to achieve its investment objective, the Trust will hold XRP and will value its Shares daily based on the value of XRP as reflected by the Index.<sup>10</sup> The Trust holds only XRP and cash.<sup>11</sup> When the Trust sells or redeems its Shares, it will do so in cash transactions with authorized participants in blocks of 5,000 Shares.<sup>12</sup>

#### III. Proceedings To Determine Whether To Approve or Disapprove SR-NASDAQ-2025-012 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act<sup>13</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>14</sup> the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices” and “to protect investors and the public interest.”<sup>15</sup>

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, which are set forth in the Notice, in addition to any other

<sup>8</sup> The Exchange states that XRP is a digital asset that is created and transmitted through the operations of the “XRP Ledger,” a decentralized ledger upon which XRP transactions are processed and settled. *See id.* at 10668.

<sup>9</sup> *See id.* CoinShares Co. is the sponsor of the Trust, CSC Delaware Trust Company is the trustee, and a third-party custodian will be responsible for the custody of the Trust’s XRP. *See id.* at 10667.

<sup>10</sup> *See id.* at 10668. The Index is representative of the XRP trading activity on selected trading platforms and is calculated by Compass Financial Technologies. *See id.* at 10668, 10670.

<sup>11</sup> *See id.* at 10667-68.

<sup>12</sup> *See id.* at 10668.

<sup>13</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>14</sup> *Id.*

<sup>15</sup> 15 U.S.C. 78f(b)(5).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> *See* Securities Exchange Act Release No. 102443 (Feb. 19, 2025), 90 FR 10667 (“Notice”). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-012/srnasdaq2025012.htm>.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> *See* Securities Exchange Act Release No. 102604, 90 FR 12422 (Mar. 17, 2025). The Commission designated May 26, 2025, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> *See* Notice, *supra* note 3.

<sup>3</sup> *See* Securities Exchange Act Release No. 102843 (April 11, 2025), 90 FR 16222.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> 15 U.S.C. 78s(b)(2).

<sup>6</sup> 17 CFR 200.30-3(a)(31).

comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal to list and trade Shares of the Trust, which would hold XRP, is designed to prevent fraudulent and manipulative acts and practices or raises any new or novel concerns not previously contemplated by the Commission.

#### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.<sup>16</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by July 3, 2025.

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](mailto:rule-comments@sec.gov). Please include file number SR-NASDAQ-2025-012 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-2025-012. 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-2025-012 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09629 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-103106; File No. SR-OCC-2025-006]

### Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change by The Options Clearing Corporation Concerning the Adoption of the Amended and Restated Participant Exchange Agreement ("New RPEA") Between OCC and Each of the National Securities Exchanges That List Equity Options

May 22, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act" or "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on May 13, 2025, The Options Clearing Corporation ("OCC" or "Corporation") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change is designed to replace the current Restated Participant Exchange Agreement ("Existing RPEA") with the New RPEA to (1) enhance the operational and business practices between the parties, (2) account for any intervening amendments and changes to relevant law and/or OCC By-Laws and Rules, and (3) eliminate provisions that are out-of-date.

The proposed changes are included as Exhibit 5 to File No. SR-OCC-2025-006. This proposed rule change does not require any changes to the text of OCC's By-Laws or Rules. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the New RPEA or OCC's By-Laws and Rules.<sup>3</sup>

#### II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the

<sup>16</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

<sup>17</sup> 17 CFR 200.30-3(a)(57).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> OCC's By-Laws and Rules can be found on OCC's public website at <https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules>.

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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

*(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

OCC is the sole clearing agency for standardized equity options listed on national securities exchanges registered with the Commission. With limited exceptions, OCC's Rules and By-Laws largely are directed at (i) establishing guidelines related to OCC's governance and clearing operations and (ii) the rights and obligations of OCC's Clearing Members. In contrast, OCC's relationship with the national securities exchanges that list options (each an "Exchange," and collectively, the "Exchanges") is largely governed by an agreement between OCC and the Exchanges. This agreement sets out the terms and conditions under which OCC will provide clearing services to the Exchanges for the options listed on the Exchanges. The agreement was last amended in 2007, and as a result, it contains certain provisions that are not current or do not address current interactions between OCC and the Exchanges and are no longer appropriate to include in the agreement governing OCC's clearance and settlement services for the Exchanges. Consequently, OCC proposes to update the agreement to (a) reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, which may address technology or industry changes or developments that necessitate new or updated agreement terms or incorporate adopted best practices for contract terms, (b) align the agreement with current law and/or OCC's rules, (c) eliminate provisions that are out of date or update provisions to reflect current industry terminology, (d) acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement, and (e) improve overall readability of the document through the incorporation of intervening amendments and changes into the agreement. This proposal is not intended to affect the rights or obligations of Clearing Members or other market participants.

1. Purpose

Pursuant to Article VIIA, Section 4 and Article VIIB, Section 4 of the OCC By-Laws,<sup>4</sup> prior to clearing through OCC, each Exchange must enter into an agreement with OCC and each of the other Exchanges.<sup>5</sup> This agreement is referred to as the "participant exchange agreement" within OCC By-Laws and Rules. The participant exchange agreement establishes the terms and conditions pursuant to which OCC provides clearing services to the Exchanges. More specifically, among other things, the participant exchange agreement: (i) governs the business relationships between the Exchanges and OCC, and the relationships among the Exchanges themselves, in respect of such matters as the listing, registration, clearance, issuance, and exercise of option contracts traded on the respective Exchanges and the preparation of options disclosure documents; (ii) provides for indemnification by each Exchange of OCC, its officers and directors and the other Exchanges and their respective governors, directors, and officers with respect to information about an Exchange contained in any registration statement of OCC or other document required to be filed by OCC with any regulatory authority, or in any options disclosure document; (iii) provides for indemnification by OCC of the Exchanges and their respective governors, directors, and officers with respect to information contained in any registration statement of OCC or other document required to be filed by OCC with any regulatory authority, or in any options disclosure document; and (iv) specifies certain areas of authority reserved to OCC and the Exchanges, respectively.

In addition to OCC's By-Laws, OCC is subject to the Commission's 2016 covered clearing agency rules ("CCA's"),<sup>6</sup> which establish additional

<sup>4</sup> See note 1 *supra*.

<sup>5</sup> Article VIIA, Section 4 of OCC's By-Laws applies to "Equity Exchanges," which are Exchanges that are OCC shareholders. Article VIIB, Section 4 of OCC's By-Laws applies to "Non-Equity Exchanges," which do not own shares in OCC, but rather, have purchased a promissory note of OCC. See OCC's By-Laws *supra* note 1. Both types of Exchanges are required to enter into a participant exchange agreement with OCC and the other Exchanges prior to becoming an OCC participant Exchange. The participant exchange agreement for Non-Equity Exchanges is required to be of substantially the same tenor as the participant exchange agreement entered into by each of the Equity Exchanges. Accordingly, OCC has entered into one participant exchange agreement with both the Equity Exchanges and the Non-Equity Exchanges (collectively, the "participant exchanges").

<sup>6</sup> 17 CFR 240.17Ad-22(e).

standards that OCC must meet as a clearing agency designated as a Systemically Important Financial Market Utility. Among other things, these rules require OCC to establish, implement, maintain, and enforce policies and procedures reasonably designed to:

identify, monitor, and manage risks related to any link<sup>7</sup> the covered clearing agency establishes with one or more . . . trading markets.<sup>8</sup>

OCC initially entered into a participant exchange agreement in January 1975. The participant exchange agreement was restated in July 1983 and five stand-alone amendments subsequently were executed through 2007, establishing the Existing RPEA. This proposed rule change would amend and update the Existing RPEA to (1) reflect current, enhanced, or implied but not specifically stated practices between OCC and the Exchanges, (2) align the agreement with current law and/or OCC's rules, (3) eliminate provisions that are out of date or update terms to reflect current industry terminology, (4) acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement, thereby aligning legal and regulatory requirements with the New RPEA, and (5) improve overall readability of the document through the incorporation of intervening amendments and changes into the agreement.

Proposed Changes to the Existing RPEA

General changes throughout the New RPEA include (i) changing references from "the Corporation" to "OCC" to align the New RPEA with OCC's current brand identity and (ii) changing references to exchanges from "Participating Exchange" to "Exchange." The remaining changes are described below.

Introductory Paragraphs

The introductory paragraphs of the Existing RPEA are changed to note that the New RPEA amends and supersedes the Existing RPEA and subsequent amendments. The Existing RPEA also sets forth the parties to the RPEA as of

<sup>7</sup> 17 CFR 240.17Ad-22(a)(8). A "link" for purposes of SEC Rule 17Ad-22(e)(20) means "a set of contractual and operational arrangements between two or more clearing agencies, financial market utilities, or trading markets that connect them directly or indirectly for the purposes of participating in settlement, cross margining, expanding their services to additional instruments or participants, or for any other purposes material to their business."

<sup>8</sup> 17 CFR 240.17Ad-22(e)(20).

July 1983, which was the last time the Existing RPEA was restated in its entirety. OCC proposes to remove the names of the specific Exchanges that are parties to the participant exchange agreement so that new Exchanges may be added to the agreement without necessitating a change to the introductory paragraphs.

Lastly, OCC intends to incorporate references to OCC's By-Laws to clarify that the New RPEA applies to Equity and Non-Equity Exchanges in satisfaction of the requirements in both Article VIIA and Article VIIB of OCC's By-Laws.<sup>9</sup>

#### Section 1—Exchange Authority To Trade Options

OCC proposes to amend Section 1 to remove the provision allowing national securities associations to become parties to the New RPEA. No parties to the Existing RPEA are national securities associations and the parties do not anticipate that any such entity will become a party to the agreement in the future. OCC also proposes to add a threshold representation from both OCC and the Exchanges that OCC and each Exchange is and will remain in compliance with the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and its own Exchange rules, and each party will use reasonable efforts to come back into compliance in the event a party can no longer make the representation. Lastly, OCC proposes to (i) clarify that, in addition to its By-Laws, OCC issues options pursuant to its Rules and (ii) add a defined term for the OCC Rules and By-Laws.

#### Section 2—Registration and Qualification of Options To Be Renamed "Selection of Underlying Interests"

OCC proposes to delete Section 2 of the Existing RPEA in its entirety as the provisions are out of date and no longer necessary. Section 2 of the Existing RPEA describes OCC's obligations to register options listed for trading by the Exchanges pursuant to the Exchange Act and the Securities Act of 1933, as amended (the "Securities Act"). However, the Commission's 2003 adoption of Securities Act Rule 238 and Exchange Act Rule 12a-9, provided that Securities Act and Exchange Act registrations are not required for standardized options.<sup>10</sup> In addition, the

provisions in Section 2(g) of the Existing RPEA related to registration of listed options under state blue sky laws are no longer necessary due to 1996 amendments to Section 18 of the Securities Act.<sup>11</sup> Section 18, as amended, exempts "covered securities" from state regulation.<sup>12</sup> The term "covered securities" includes listed options.<sup>13</sup>

Section 3 of the Existing RPEA, which relates to the selection of underlying securities on which the Exchanges may list options for trading, would be renumbered as Section 2 in the New RPEA. OCC proposes to clarify in subsection (a) that an (i) Exchange must list options in accordance with the relevant Exchange's rules, and (ii) that such options also must be addressed in the Options Disclosure Document.<sup>14</sup> Such clarifications incorporate into the agreement the legal and regulatory basis of requirements Exchanges must meet before OCC may issue and clear specific products. Subsection (a) also defines the term "Underlying Interests" for those underlying securities on which the Exchanges may list options. OCC proposes to update the list of permitted Underlying Interests to (i) add types of underlying interests not explicitly listed in the Existing RPEA because such interests, some of which did not exist at the time when the Existing RPEA was first executed such as exchange traded funds, were not contemplated for listed options at that time but have since become acceptable underlying securities to listed options, and (ii) remove from the list those interests which currently do not underlie listed options because such interests do not align with interest types OCC is prepared to clear. Specifically, OCC proposes to remove the following from the list of permitted Underlying Interests: U.S. Treasury bonds, notes, or bills; top tier bank certificates of deposit; mortgage pass-through securities guaranteed by the Government National Mortgage Association; and corporate debt securities listed on national securities exchanges. Further, OCC proposes to add the following to the list of permitted Underlying Interests: exchange trades

provisions of the Securities Act and from the registration requirements of the Exchange Act).

<sup>11</sup> See Securities Exchange Act Release Nos. 53799 (May 12, 2006), 71 FR 29195 (May 19, 2006) and 54071 (June 29, 2006), 71 FR 38922 (July 10, 2006).

<sup>12</sup> 15 U.S.C 77r(a).

<sup>13</sup> 15 U.S.C 77r(b)(1).

<sup>14</sup> The June 2024 version of *Characteristics and Risks of Standardized Options*, also referred to as the "Options Disclosure Document" ("ODD"), is located at: <https://www.theocc.com/getmedia/a151a9ae-d784-4a15-bdeb-23a029f50b70/riskstoc.pdf>.

funds; American Depository Receipts; American Depository Shares; exchange traded notes; and securities indexes. The Existing RPEA allows OCC to expand the list of permitted Underlying Interests. OCC proposes to require that such expansion be only to securities or financial instruments conforming to the requirements of the RPEA. The purpose of this change is to eliminate provisions that are out of date while also reflecting the current operational and business practices between OCC and the Exchanges to address industry developments, such as new underlying interests that were not available in 1983. This will modernize the list of underlying interests and provide greater certainty to the Exchanges concerning the types of options contracts OCC has the authority to clear and settle. These updated terms retain the flexibility found in the Existing RPEA by allowing for other underlying interests when approved by the Board of Directors of the OCC pursuant to Section 3(a)(viii).

OCC proposes to delete and replace existing subparagraph (b). OCC proposes to delete subparagraph (b) because it is out of date as it relates to OCC's former obligation to register options for trading. OCC proposes to add a new subsection (b) to specifically articulate that OCC has the authority to disapprove for clearing purposes any new options an Exchange proposes to list that materially impacts OCC's risk profile, that presents new risk, impacts OCC's risk models, or creates third party risks (defined as "New Product Risk"). New subparagraph (b) requires OCC to work with the Exchange to mitigate any such risk, if feasible, and to otherwise notify an Exchange of a disapproval of a new product. These proposed changes reflect current and enhanced operational and business practices between OCC and the Exchanges to address industry changes in terms of risk assessment and management of new products. Finally, OCC proposes to add a provision in new Section 2 to recognize that Exchanges must submit new products to OCC in accordance with the Options Listing Procedure Plan.<sup>15</sup> This proposed change

<sup>15</sup> OCC and the Exchanges have entered into the 'PLAN FOR THE PURPOSE OF DEVELOPING AND IMPLEMENTING PROCEDURES DESIGNED TO FACILITATE THE LISTING AND TRADING OF STANDARDIZED OPTIONS SUBMITTED PURSUANT TO SECTION 11A(a)(3)(B) OF THE SECURITIES EXCHANGE ACT OF 1934,' which also is referred to as "The Options Listing Procedure Plan" or "OLPP." The OLPP generally describes (i) the process related to the selection of option classes and new option series, (ii) Exchanges' rights to review the eligibility of a new option class, (iii) the process related to selecting option classes for the Penny Interval Program, (iv) the process related to adjustments to option classes.

Continued

<sup>9</sup> See note 3 *supra*.

<sup>10</sup> See Exemption for Standardized Options From Provisions of the Securities Act of 1933 and From the Registration Requirements of the Securities Exchange Act of 1934, Release Nos. 33-8171 and 34-47082, 68 FR 188 (Jan. 2, 2003) (File No. S7-29-02) (exemption for standardized options from

acknowledges the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges because the OLPP serves as the national market plan that establishes the requirements Exchanges must follow when they submitting a new option class to OCC. OCC also proposes minor conforming changes to the remainder of new Section 2.

#### Section 3—Expiration Dates, Exercise Prices and Units of Trading

Section 4 of the Existing RPEA, which describes the process related to establishing expiration dates, exercise prices, and units of trading will be renumbered to Section 3. OCC proposes to remove references to specific times by which Exchanges must notify OCC when opening new series of options for trading because such timeframes were necessary decades prior when adding new series and notifying other exchanges of newly added series was a much more manual process but are now no longer needed. Technology advancements now allow for an ease and quickness to the series adds process with Exchanges utilizing OCC system functionality to add or view new series. These removals eliminate provisions that are out of date. Additionally, the New RPEA will state that each Exchange, rather than the Securities Committee,<sup>16</sup> is responsible for determining units of trading and that each Exchange must communicate this information to OCC. Prior to 2018, panels of the Securities Committee were convened to make contract adjustment determinations for option contracts whose underlying securities were subject to a corporate action event, for example a merger or stock split. These panels voted to create non-standard option deliverables in response to certain corporate actions. As a result, these panels determined the unit of trading in certain situations, and the inclusion of this provision in the current RPEA was an acknowledgement of the role of the Securities Committee established in Article VI, Section 11 of the OCC By-Laws. With the implementation of an OCC rule change in 2018, the authority to make contract adjustment determination transferred from panels of the Securities Committee

to the OCC.<sup>17</sup> Consequently, the removal of the reference to the Securities Committee removes a provision that is out dated. OCC proposes to replace Securities Committee with the Exchanges because Section 3 of the New RPEA will address those option characteristics that are determined by Exchanges at the time an option is opened for trading, and unit of trade is one such characteristic. Consequently, the proposed change reflects the current business practice between OCC and the Exchanges. The proposed change also acknowledges that, as the standard for the industry, the unit of trading will ordinarily be 100 at the time an option is opened for trading, and that a deviation from the standard may not necessarily be permissible under the OCC's Rules and By-Laws absent an amendment.

#### Section 4—List of Options

Existing Section 5 will be renumbered to Section 4, along with minor clarifying and conforming changes related to the defined terms “Participating Exchange,” “underlying securities,” and “the Clearing Corporation.” Additionally, with the expansion of the number of expirations available outside of the standard monthly expiration cycle, the reference to “expiration months” has been changed to “expiration dates.” Finally, the requirement that Exchanges make available product lists “in reasonable quantities” upon request has been removed as out of date because of the electronic manner in which the Exchanges currently provide such information to OCC. These proposed changes will remove provisions of the Existing RPEA that are out-of-date and will support intervening amendments and changes to relevant OCC By-Laws and Rules.

#### Section 5—Delisting of Options

OCC proposes to add a new Section 5 to set forth conditions the Exchanges will establish before seeking to delist an option. Other than as required in the OLPP, each Exchange will agree to continue to list and make trading for that option available until all open interest is closed out at OCC for those options. This provision will enhance the operational and business practices between OCC and the Exchanges by

reducing the risk that Clearing Members could have open interest in options with no mechanism to close out those positions.

#### Section 6—Singly Listed Options

OCC proposes to add a new Section 6 to set forth the conditions for options that are listed on only one Exchange. This proposed addition will reflect enhanced operational and business practices between OCC and the Exchanges to address the situation in which an underlying price may not be available or accurate. Such situations may be disruptive to the functioning of the options industry, and the proposed language will allow OCC to seek the help of the listing exchange to determine an accurate settlement price. As a result, where only one Exchange is the listing entity for an option and the settlement price for such a singly listed option is deemed by OCC to be inaccurate, unreliable, unavailable, or inappropriate, that Exchange agrees to work with OCC to determine reliable settlement prices in accordance with OCC By-Laws and Rules. Such Exchanges may seek out additional information about the underlying security from the primary listing market. Finally, in new Section 6 the Exchanges will agree to use commercially reasonable efforts to list a singly listed options until all open interest is closed out at OCC. Under the proposed RPEA, an Exchange would be required to notify OCC when it concludes that it can no longer list a singly listed option that has open interest and must take reasonable steps to permit listing and trading on an alternate Exchange.

#### Section 7—Exchange Data

The amount and speed of the flow of data between OCC and the Exchanges has grown substantially since the Existing RPEA was first executed due to technological advancements and the growth of the industry. As a result, OCC receives a substantial amount of data from Exchanges currently. OCC also processes and sends out data based on data received from Exchanges. Consequently, OCC proposes adding new Section 7 to govern the use of “Exchange Data” because such new language will reflect current operational and business practices between OCC and the Exchanges. Proposed Exhibit A to the New RPEA contains a description of such Exchange Data, which includes real time and daily values of options and Underlying Interests, and the final settlement value of Underlying Interests. New Section 7 would grant OCC a license in Exchange Data for purposes of (i) performing clearing services for the

(v) the admission of Exchanges as “Plan Sponsors” of the OLPP, and (vi) the loss of eligibility for an Exchange as a Plan Sponsor of the OLPP.

<sup>16</sup> The Securities Committee is established under Article VI, Section 11 of the By-Laws to make certain recommendations with respect to cleared contracts, such as statements of policy or interpretations having general application to specified types of contract adjustments.

<sup>17</sup> See Securities Exchange Act Release No. 34–69977 (July 11, 2013), 78 FR 42815 (July 17, 2013). Although the amendment to the OCC By-Laws was approved in 2013, its implementation was delayed until an amendment to the Options Disclosure Document (ODD) reflecting the change to the adjustment determination authority was made. The ODD amendment was effective on October 31, 2018, as referenced in OCC Information Memo 43927.pdf (theocc.com)

Exchanges, (ii) performing investor education activities, and (iii) complying with OCC's regulatory obligations. The Exchanges also agree to provide OCC with a final settlement value when OCC is not able to determine the value.

The proposed language also establishes the term Derived Data and defines the ways in which OCC may use Derived Data based on data received from the Exchanges. Additionally, the Reporting Authority will be those entities identified in the OCC By-Laws and Rules. The proposed language also states that Exchanges will provide the Daily Values of Underlying Interests and Options and that such values are transferred to OCC on each Trading Day. Reference to Exercise Settlement Amount is included in the agreement and the requirement that Exchanges determine such amount aligns with the process established in the OCC By-Laws. These proposed additions reflect current operational and business practices between OCC and the Exchanges while also acknowledging the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges, namely the pricing structure and requirements established in the OCC By-Laws and Rules.

New Section 7 adds the requirement that an Exchange will make Exchange Data available to OCC for Options while open interest exists for a specific option listed by the Exchange. This requirement will reflect enhanced operational and business practices between OCC and the Exchanges and help ensure the continued proper functioning of the market for an option by requiring that the Exchanges that list an option continue to provide the pricing needed to support an option while open interest exists on the option.

New Section 7 places certain limitations on OCC's use of Exchange Data. More specifically, OCC may not use Exchange Data to create or calculate any index or other financial instrument, investment product, or investment strategy without an Exchange's prior consent. OCC may redistribute Exchange Data to third parties (as described in proposed Exhibit B to the New RPEA), but only pursuant to a written market data agreement that is consistent with the provisions of new Section 7. Market data agreements must contain a disclaimer of warranties, waivers of liability for the contents of the Exchange Data, and indemnification provisions. Under the proposed RPEA OCC would be limited to certain third parties to whom OCC can redistribute data (e.g., Clearing Members) and the kind of data that OCC would be

permitted to redistribute (e.g., no real-time data). OCC would be obligated to stop redistributing Exchange Data to third parties that fail to comply with the limitations of new Section 7. The Exchanges also would retain the right to audit OCC's use and redistribution of Exchange Data.

New Section 7 provides that Exchange Data, including intellectual property rights therein, remains the property of the Exchanges. OCC will acknowledge the proprietary nature of the Exchange Data and that the Exchange Data remains the property of the Exchanges. New Section 7 also states that the New RPEA will not modify any existing data agreements between OCC and an Exchange. To incorporate adopted best practices for contract terms, new Section 7 states that Exchanges may make changes to Exchange Data and establishes that an Exchange will give OCC at least 60 days notice in advance of such change, in most cases. The notice period will provide OCC with the time to prepare for the change, and OCC will cooperate with an Exchange in addressing any such change.

#### Section 8—Comparison of Options Transactions

OCC proposes to renumber Section 6 to Section 8 in the New RPEA. OCC also proposes to delete the option for an Exchange to retain OCC to provide comparison services as out of date because OCC has not been retained by the Exchanges to perform such services. Since the Exchanges have not previously requested this service, OCC proposes to remove this provision. Section 8 also creates a defined terms for "Trading Day," *i.e.*, a day on which an Exchange is open for trading, and "Matched Trade(s)," which replaces the previously used term, "matched trades."<sup>18</sup> Although the change to "Matched Trade(s)" is stylistic, the addition of "Trading Day" is intended to reflect current industry terminology for clarification purposes. OCC also proposes to add a new provision to Section 8 that would require OCC to provide at least 60 days' prior notice to the Exchanges of a change to the time by which an Exchange must report comparisons to OCC in order to enhance operational practices between OCC and the Exchanges by providing the Exchanges with sufficient notice to prepare for the change. OCC also proposes minor clarifying and conforming changes to Section 8 with

<sup>18</sup> The meaning of "Matched Trades" under the New RPEA would be the same as the meaning of "matched trades" under the Existing RPEA. Only the capitalization of the term would change.

respect to use of the terms "the Clearing Corporation" and "underlying security."

#### Section 9—Clearance of Options Transactions

OCC proposes to renumber Section 7 to Section 9 in the New RPEA, along with minor clarifying and conforming changes related to use of the terms "the Clearing Corporation," "underlying security," "matched trades," and "Clearing Member."

#### Section 10—Acceptance of Options Transactions

OCC proposes to renumber Section 8 to Section 10 in the New RPEA. OCC also proposes to remove the condition, "provided it shall have received payment of the premiums due," in respect of which options transactions OCC clears because the provision is out of date. OCC accepts all transactions for clearance until such time as a Clearing Member terminates its membership or OCC declares a Clearing Member to be in default. Payment of an options premium is not a prerequisite for OCC's acceptance of transactions.<sup>19</sup>

#### Section 11—Issuance of Options

OCC proposes to renumber Section 9 to Section 11, along with one minor conforming change related to use of the term "the Clearing Corporation."

#### Section 12—No Unfair Discrimination

OCC proposes to renumber Section 10 to Section 12, along with minor conforming and clarifying changes, which include changing the title of Section 12 from "Non-Discrimination" to "No Unfair Discrimination" and a change in the reference to Article VII of the By-Laws to Articles VIIA and VIIB. OCC proposes the use of "No Unfair Discrimination" as a stylistic change to avoid any indication that OCC is prohibited from amending its By-Laws and Rules in a way that may permit different treatment of an Exchange that may no longer meet the requirements to be a participant at OCC.

#### Section 13—Limitations of Authority

OCC proposes to renumber Section 11 to Section 13 in the New RPEA, along with minor changes, which include conforming references to other sections of the RPEA and OCC By-Laws. Similarly, OCC proposes to add cross

<sup>19</sup> With the implementation of Encore as OCC's clearing system in 2002, OCC began receiving and processing trades at various times throughout the day. With this technological capability, trade premiums were settled by the morning of the next business day. Consequently, payment of premiums was not a prerequisite to trade acceptance.

references within new Section 13 to other sections within the new RPEA to improve readability without changing the terms of the RPEA. Separately OCC proposes to add a new provision stating that OCC may calculate position limits at the request of the Exchanges even though OCC is generally precluded from establishing or enforcing position limits or exercise limits. OCC began calculating position limits in 2003 at the request of the Exchanges and continues to provide position limits on the OCC website.<sup>20</sup> This new provision is not designed to change OCC's rights or obligations but is merely included for the avoidance of doubt and reflects the current business practice between OCC and the Exchanges. Similarly, OCC propose to add a parenthetical noting that the general limit precluding OCC from determining when to open or restrict trading would not limit OCC's other rights and obligations under the RPEA.<sup>21</sup>

#### Section 14—Margin Requirements of OCC

OCC proposes to renumber Section 12 to Section 14 in the New RPEA, along with minor conforming changes related to the use of the terms “the Clearing Corporation” and “underlying security.”

#### Section 15—Financial Requirements for Clearing Members

OCC proposes to renumber Section 13 to Section 15 in the New RPEA. OCC proposes to change the defined term “management authority” to “Management Authority.”<sup>22</sup> OCC also proposes to update the currently outdated text of the Existing RPEA to include a reference to “Regulatory Services Agreement” to recognize that some Exchanges now outsource surveillance of Clearing Member financial responsibility standards to third parties. OCC proposes to remove language that requires Exchanges to notify OCC when a Clearing Member is not in compliance with OCC's financial responsibility standards because the

Exchanges have indicated that they do not incorporate OCC's financial responsibility standards into their Exchange monitoring processes. OCC also proposed to add to the statement that Exchanges will notify OCC of a financial condition of a Clearing Member that must be reported to the Securities Investor Protection Corporation by including the phrase “or any other resolution authority”. This proposed addition acknowledges that other authorities may require reporting of such financial conditions. Separately, OCC proposes to remove reference to in-person delivery of documents and telephone calls as out of date because electronic communications are the primary method currently used to transfer information between OCC and the Exchanges. OCC also proposes to add clarifying language that an Exchange is required to furnish materials to OCC with respect to a Clearing Member that is also a member of the Exchange. This addition is for clarification purposes. OCC further proposes to change the time requirement for submission of material from 2:00 p.m. Central Time to 3:00 p.m. Central Time to reflect enhanced business practices between OCC and the Exchanges. Additionally, OCC proposes to change the requirement of reporting materials from “immediately” to “promptly” to incorporate adopted best practices for contract terms. Finally, OCC proposes to replace the outdated reference to OCC's Chairman or any Vice President to a “Financial Risk Management officer” to reflect OCC's current designation of authority.

#### Section 16—Customer Accounts

OCC proposes to renumber Section 14 to Section 16 in the New RPEA, along with one minor conforming change related to use of the term “the Clearing Corporation.”

#### Existing RPEA Section 16—Maintenance of Offices

OCC proposes to delete Section 16 in the Existing RPEA in its entirety as outdated. Existing RPEA Section 16 requires OCC to maintain an office in each of the cities in which the Exchanges are located. Given the widespread use of electronic communications in financial services, the increase in the number and various locations of Exchanges over time, and the ability for Exchanges and OCC to send and receive information quickly via electronic means, the requirement for OCC to maintain an office in such locations is outdated.

#### Section 17—Operations

OCC proposes to renumber Section 15 to Section 17 and retitle Section 17 “Operations.” OCC proposes amendments to Section 17 to remove outdated systems scalability reporting and OCC response protocols. Instead, the New RPEA would require the Exchanges to agree to provide OCC with supporting documentation, data files, and reports to OCC as needed in support of its clearing activities. The New RPEA would also require Exchanges to make representatives available to discuss any additional OCC information and data needs and to use commercially reasonable efforts to provide the same.

Under the current RPEA, OCC is obligated to use its best efforts to maintain sufficient operational capacity to clear new options on behalf of the Exchanges. OCC proposes to remove details related to interactions regarding lack of operational capacity to clear a new underlying and replace the requirement to use best efforts with a requirement to use commercially reasonable efforts which would allow OCC to conduct its operations in a manner that is economically justified and in accordance with commonly accepted commercial practices. OCC also proposes to change the timing requirement from “as expeditiously as possible” to “as soon as reasonably practicable” and to incorporate adopted best practices for contract terms. OCC also will agree to use commercially reasonable efforts, as opposed to best efforts as required by the Existing RPEA, to expand operations capabilities as warranted to facilitate an Exchange's ability to clear new options which serves to enhance operational and business practices between OCC and the Exchanges.<sup>23</sup> Finally, the Exchanges will agree to comply with OCC operational specifications for options, including during extended trading hours, which would address the current state of the industry in which certain trading in extended and overnight trading hours occurs. By acknowledging that Exchanges will comply with the OCC's operational specifications for options, the New RPEA will reflect the current operational practice between OCC and the Exchanges. OCC also proposes to add a 60-day notice requirement in advance of implementation or changes to specifications for such trading to enhance the business practices between

<sup>23</sup> Consistent with the Existing RPEA, the New RPEA will not permit OCC to clear new options for another Exchange until it has the capacity to clear options on behalf of the Exchange that made the first request.

<sup>20</sup> See OCC Information Memo #19050.

<sup>21</sup> Such rights and obligations are reflected in Sections 9, 10, and 11 in the New RPEA through references to provisions in the OCC By-Laws and Rules in general. For example, in concert with the clearance of trades, OCC Rule 401(a)(1) provides the required information that an Exchange must send to OCC for a trade to be accepted. The parenthetical addition to Section 13 (g) of the New RPEA is included to ensure that OCC's authority regarding the acceptance of trades from Exchanges is not diminished.

<sup>22</sup> The meaning of “Management Authority” under the New RPEA would be the same as the meaning of “management authority” under the Existing RPEA. Only the capitalization of the term would change.

OCC and the Exchanges by incorporating adopted best practices for contract terms.

#### Section 18—Financials

OCC proposes to add a new Section 18 to the New RPEA to enhance the operational and business practices between OCC and the Exchanges by establishing certain financial requirements for Exchanges and to allow OCC to monitor for going concern risk. Exchanges that are a party to the New RPEA as of the effective date will be required to provide to OCC annual audited financial reports, Form 10K, and Form 10Q, as applicable. Any Exchange that becomes a party to the New RPEA after the effective date will be required to provide to OCC quarterly unaudited financial statements, or Form 10K and Form 10Q, as the case may be, for a period of three years from the date the Exchange becomes a party to the New RPEA.

Under the New RPEA, Exchanges would be required to notify OCC if they experience a 25% or more decrease in shareholder equity or losses exceeding 25% of shareholder equity. Following such a loss, OCC would be authorized to request that any such Exchange provide OCC with quarterly financial reports. Additionally, given the sensitivity of the information involved, OCC proposes to add confidentiality provisions in this section that references Section 32 for clarity purposes.

#### Section 19—Information Technology and Security

Given the widespread use of ever evolving and improving electronic systems, along with related security concerns since the time the Existing RPEA became effective, OCC proposes to enhance the operational and business practices between OCC and the Exchanges by adding a new Section 19 in the New RPEA to strengthen information security. The New RPEA requires Exchanges to provide to OCC, and requires OCC to provide to the Exchanges, contact information, including emergency contact information, for Exchange and OCC operational and technology personnel, respectively, to support information technology issues. OCC and the Exchanges will be obligated to notify the other party of incidents that could impact a party's ability to provide (*i.e.*, OCC) or receive (*i.e.*, an Exchange) services.

Section 19 of the New RPEA would also require the parties' to take commercially reasonable steps to comply with applicable cybersecurity

regulations, including Regulation SCI.<sup>24</sup> If an Exchange notifies OCC of a cyber-related disruption or intrusion to a SCI System that could reasonably be expected to materially affect OCC's ability to perform the services for the Exchange, or if OCC has a reasonable basis to believe that any such disruption is occurring that could materially impact OCC's ability to perform services for the Exchange, under the terms of the New RPEA, OCC is permitted to take steps to mitigate any effects to OCC's operations, including suspending its obligations for that Exchange under the New RPEA, until OCC determines the incident has been resolved. Any OCC suspension would not impact trades accepted by OCC prior to the time of the suspension. OCC and an Exchange experiencing such a disruption are obligated to consult with each other to determine an appropriate course of action that could resolve the incident. OCC also proposes to include that it will use commercially reasonable efforts to maintain performance of its obligations when addressing an incident to reflect implied business practices between the parties whereby OCC would make efforts to continue to support clearance and settlement.

Lastly, under Section 19, the Exchanges agree to accommodate OCC's connectivity requirements. This includes the maintenance of point-to-point connections to OCC and redundant connectivity. The parties also will agree to provide at least 60 days' notice to each other if connectivity or related requirements change.

#### Section 20—Exercise Restrictions

OCC proposes to renumber section 17 to Section 20 in the New RPEA, along with minor clarifying changes. OCC proposes to replace "index options" with "Options that are cash settled" and "other options" with "Options that are physically settled" to utilize industry terminology that is broader and more descriptive of the products subject to the provisions. OCC also proposes to add a provision to allow for an Exchange or OCC to restrict exercises in the case of government mandated restrictions, such as in the case of a sanctioned entity or underlying security.

#### Section 21—Deadlines for Exercise of Options

OCC proposes to renumber Section 18 to Section 21 in the New RPEA, along with minor conforming changes to use of the terms "Participating Exchange" and "the Clearing Corporation."

#### Section 22—Allocation of Exercise Notices

OCC proposes to renumber Section 19 to Section 22 in the New RPEA, along with one minor conforming change related to use of the term "Participating Exchange."

#### Section 23—Financial Arrangements

OCC proposes to renumber Section 20 to Section 23 in the New RPEA. OCC also proposes to remove the requirements for local banking relationships as of out date in light of the current electronic and global nature of banking.

#### Section 24—Services, Programs and Projects

OCC proposes to renumber Section 21 to Section 24 in the New RPEA. OCC proposes changes to Section 24 to clarify that services OCC develops for any Clearing Member or group of Clearing Members, or programs or projects developed at OCC's own cost will be offered to all Clearing Members on the same terms and conditions and at the same cost. The terms of the New RPEA would grant sole and absolute discretion to OCC for determining whether to undertake programs or projects for a particular Exchange. These changes reflect the current or enhanced operational and business practices between OCC and the Exchanges. Additionally, OCC proposes language to provide further detail on development costs. The Existing RPEA requires that the Exchange must pay all associated costs for such programs or projects. OCC proposes to include new language to clarify that such costs include staffing to reflect enhanced business practices between OCC and the Exchanges.

#### Section 25—Access to Books and Records of OCC

OCC proposes to renumber Section 22 to Section 25 in the New RPEA, along with minor conforming and clarifying changes to use of the term "the Clearing Corporation" and "Participating Exchange." Additionally, the New RPEA would state that an Exchange will not have a right to view another Exchange's Confidential Information so as to reflect current business practices between OCC and the Exchanges.

#### Section 26—Indemnification

OCC proposes to renumber Section 23 to Section 26 in the New RPEA, along with minor conforming and clarifying changes related to use of the terms "the Clearing Corporation," "participating Exchange," "Clearing Fund," "Clearing Member." OCC also proposed to add "or noteholder agreement" to occurrences of

<sup>24</sup> 17 CFR 242.1000–242.1007.

“stockholders agreement” in this section since certain exchanges are subject to the shareholders agreement while other are subject to the noteholders agreement.<sup>25</sup> The proposed changes all update references to OCC Rules and references to section in the New RPEA.

#### Section 27—Additional Parties

OCC proposes to renumber Section 24 to Section 27 in the New RPEA, along with one minor conforming change to the title of the New RPEA.

#### Section 28—Notices

OCC proposes to renumber Section 25 to Section 28 in the New RPEA, along with other minor conforming and clarifying changes related to the contact information of the parties to the New RPEA. OCC also proposes to remove the address information of each party because such information, as contained in the Existing RPEA, is out of date, such information can change over time, and notices may be given via email. Consequently, the New RPEA excludes providing physical addresses of each party.

#### Section 29—Miscellaneous

OCC proposes to renumber Section 26 to Section 29 in the New RPEA. The proposed changes to new Section 29 are intended to reflect either current or implied business practices between OCC and the Exchanges to incorporate adopted best practices for contract terms. OCC proposes to clarify in Section 29 that the New RPEA may be assigned by a party only with the prior written consent of OCC in the case of assignment by an Exchange or all Exchanges in the case of assignment by OCC. OCC proposes to remove references to assignment in Section 29(b) and update assignment provision in Section 29(c). The New RPEA would also allow for assignment without written consent in the case of a corporate reorganization or sale of OCC.<sup>26</sup>

OCC also proposes to add a new provision related to the use of the parties’ names, tradenames, logos, and trademarks (collectively, “Marks”). More specifically, OCC proposes to add a provision granting the Exchanges a license to use OCC’s Marks and granting

OCC a license to use the Exchanges’ Marks. By signing the New RPEA, the parties would acknowledge the other parties’ ownership in their Marks. Licenses will remain in effect until the termination of the New RPEA, or sooner if a party notifies the other party that they elect to terminate a license. The Marks are licensed “as-is” and without warranties and must bear the appropriate trademark symbols where required. Lastly, use of Marks must comply with applicable laws and regulations and must not be used for objectionable purposes.

#### Section 30—Breach of Agreement—Termination

OCC proposes to renumber Section 27 to Section 30 in the New RPEA. OCC also proposes to add a provision permitting OCC to suspend its obligations to an Exchange whenever, in OCC’s judgment, a suspension is necessary to comply with, or give full effect to, any waiver or suspension of OCC’s By-Laws, Rules, policies and procedures, or any other rules issued by OCC.<sup>27</sup> OCC is obligated to notify the SEC if OCC takes any such action. The New RPEA would also require OCC to provide notice to each Exchange of such a suspension. The proposed additions will acknowledge the regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement, thereby aligning legal and regulatory requirements contained in the OCC By-Laws and Rules with the New RPEA.

Proposed changes to Section 30 would provide additional clarification as to whom at OCC shall approve a suspension by naming the Chief Executive Officer (“OCC CEO”) as the individual with this authority or in the event that the OCC CEO is unavailable, the Chief Operating Officer (“OCC COO”) would have this authority. In the event that neither the OCC CEO nor the OCC COO are available, the Chief Security Officer would have this authority. OCC also proposes to include a statement that the parties will work together in good faith to minimize a suspension. These changes are intended to enhance the operational and business practices between the parties by

incorporating best practices for contract terms for clarity purposes.

OCC further proposes to update which provisions of the New RPEA an Exchange must breach for OCC to cease providing clearing services to that Exchange to conform to any renumbering required by the changes described above. OCC also proposes to include a catch-all provision to allow termination in those circumstances where OCC has a reasonable basis to believe the issuance, clearance, or settlement of options of an Exchange or the continued performance of services for the Exchange would cause OCC to be in breach of the Securities Act or Exchange Act.

OCC also proposes to state that OCC will not be obligated to clear transactions for an Exchange if the Exchange ceases to (i) be registered as an exchange, (ii) materially abide by the Securities Act or the Exchange Act, or (iii) be an OCC noteholder or stockholder until such breach is corrected. OCC proposes this change to acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges to ensure that the New RPEA will align the Securities Act or the Exchange Act and OCC’s By-Laws and Rules. Additionally, OCC proposes to remove, as outdated, a provision allowing it to terminate the RPEA with an Exchange that ceases to be registered as a national securities association because, as noted above, OCC is proposing to remove the provision allowing national securities associations to become parties to the RPEA. Further, OCC also proposes to specify that termination requires delivery of a written notice to the Exchange to reflect enhanced business practices between OCC and the Exchanges by incorporate adopted best practices for contract terms.

#### Section 31—Options Disclosure Document

OCC proposes to renumber Section 28 to Section 31 in the New RPEA. Consistent with the changes described above, OCC proposes to delete, as outdated, references to text related to OCC’s prior obligation to register options for trading.<sup>28</sup> Currently, the RPEA establishes the Listed Options Disclosure Committee (“LDOC”) to oversee amendments to and administration of the ODD and that the LDOC is composed of the Chairman and the Exchange Directors on OCC’s

<sup>25</sup> Pursuant to Article VIIA of the OCC By-Laws, Equity Exchanges are party to the stockholders agreement. Pursuant to Article VIIB, Non-Equity Exchanges are party to the noteholders agreement. Non-Equity Exchanges and the noteholders agreement did not exist when the Existing RPEA was originally executed.

<sup>26</sup> The Existing RPEA already allows for assignment without written consent in the case of a corporate reorganization or sale of an Exchange.

<sup>27</sup> See note 1 *supra*. Article IX, Section 14 of the OCC By-Laws gives OCC the authority to waive or suspend its By-Laws or Rules if (i) an emergency exists and (ii) such suspension, waiver or extension is necessary or advisable for the protection of OCC or otherwise in the public interest for OCC to continue to facilitate the prompt and accurate clearance and settlement of confirmed trades or other transactions and to provide its services in a safe and sound manner.

<sup>28</sup> See note 9 *supra*.

Board.<sup>29</sup> OCC also proposes to change the responsibility for chairing the LDOC from OCC's Chairman of the Board to a designated OCC officer and to replace participation on the LDOC by Exchange Directors of OCC's Board to representatives of each Exchange. These proposed changes reflect the current business practices between OCC and the Exchanges to address industry developments, namely the addition of exchanges, some of which do not have a representative on the OCC Board of Directors. As a result, OCC and the Exchanges have adopted the practice of utilizing an authorized representative from each Exchange to serve on the LODC. In an effort to reflect modernized processes already in use around the manner in which the LODC operates, OCC proposes to include provisions allowing LODC matters to be addressed using electronic correspondence, unless this method of communication would be insufficient, in which case, the Chair of the LODC or two other members of the LODC can call a meeting of the LODC.

Additional proposed changes in Section 31 are intended to restate that an Exchange will notify OCC of proposed changes to an Exchange's rules that would cause information in the ODD to become materially inaccurate, incomplete, or misleading due to the delisting or change in the specifications of certain options products. New text proposed to be included in Section 31 would also require the relevant Exchanges to provide input and feedback when OCC is drafting amendments to the ODD. Changes to Section 31 would further highlight OCC's responsibility to provide drafts of proposed ODD amendments to the Commission for review and feedback prior to final submission to the Commission.<sup>30</sup>

Proposed changes to Section 31 also include removal of the statement that OCC will pay costs associated with the meeting of the LODC. Such a provision is out of date because the LODC does not meet in person. OCC also proposes to revise the indemnification provisions in Section 31 to update the provisions such that they apply to the ODD to reflect enhanced business practices

between OCC and the Exchanges to incorporate adopted practices for contract terms by relocating certain language to Section 31 and applying it specifically to the ODD.

The Existing RPEA establishes that an Exchange will indemnify OCC and other Exchanges for omissions or alleged omissions in the ODD and the indemnification provisions contained in Section 2(g) of the Existing RPEA will govern such indemnification. OCC proposes language that extracts much of the language in Section 2(g) and applies it specifically to the circumstances and requirements of the ODD. OCC will agree to indemnify the Exchanges for untrue statements or omissions of material fact unless such statements are made in writing by an Exchange for use in the ODD or in a case where an Exchange omits a material fact that would make the ODD misleading. Each Exchange will agree to indemnify OCC and the other Exchanges for omissions or written untrue statements of material fact for use in the ODD or in a case where an Exchange omits a material fact that would make the ODD misleading. Section 31 also details the notice obligations for a party seeking indemnification, allows indemnifying parties to participate in any legal proceedings, allows indemnifying parties to assume the defense of any claims, describes which parties are responsible for legal fees under certain circumstances, and allows an indemnifying party to settle a claim as long as the settlement would not require a contribution by an indemnified party.

#### Section 32—Confidentiality

OCC proposes to add a new Section 32 related to confidential information to explain how this term is defined for purposes of the New RPEA and to provide certainty that confidential information shared among the Exchanges and OCC, orally or in writing, may not be released to third parties or the public. Such proposed change is intended to reflect current business practices between OCC and the Exchanges and to adopt best practices for contract terms. OCC proposes to define "Confidential Information" as information, that relates to a party's products and services, operations, customers, members, prospects, know-how, design rights, trade secrets, market information, business affairs, and information provided to the receiving party pursuant to any requirements in the New RPEA. Any documents created using Confidential Information also are considered Confidential Information. Confidential Information will not include information already in the

possession of a receiving party, information already known to the public, information revealed by a third party, information developed independently, and anonymized statistical information compiled by a receiving party using Confidential Information. Recipients of Confidential Information are obligated to exercise the same degree of care over a disclosing party's Confidential Information as is does for its own Confidential Information. Additionally, parties are limited to using Confidential Information solely for purposes of fulfilling their obligations under the New RPEA and are only permitted to disclose Confidential Information to employees and agents who need to know the information.

Section 32 makes clear that a disclosing party retains all intellectual property rights in its Confidential Information. Section 32 also contains a provision prohibiting OCC's disclosure of Exchange Data that identifies an Exchange member except as required by law or regulation, or as part of post-trade processing. A receiving party may disclose Confidential Information to a government entity with jurisdiction over a party, as part of a party's responsibilities to share information with other regulatory bodies, or in response to a valid subpoena.

Section 32 highlights that the parties are required to acknowledge that a disclosing party could suffer harm in the event of a breach of the confidentiality provisions, and that a disclosing party is entitled to seek an injunction, specific performance, and other equitable relief in court against a threatened or continuation of a material breach of the confidentiality provisions in the New RPEA.

Lastly, new Section 32 provides that the receipt of Confidential Information does not restrict a receiving party from providing services to other parties as long as it does not use a disclosing party's Confidential Information to provide services to third parties.

#### Final Paragraph

OCC removed "The 1975 Agreement is hereby terminated, effective as of the date of this Agreement" because it no longer is necessary because the 1975 agreement was terminated by the 1983 agreement. OCC also removed language allowing the agreement to be executed in several counterparts because the language is out of date.

#### 2. Statutory Basis

OCC believes the proposed changes are consistent with the requirements of the Exchange Act and the rules and

<sup>29</sup> See note 11 *supra*. The ODD explains the characteristics and risks of exchange traded options. Investors must read the ODD prior to buying or selling an option. The Commission's Rules require that disclosures about listed options must be furnished to investors in the form of the ODD. See Exchange Act Rule 9b-1.

<sup>30</sup> While OCC would coordinate communications with the Commission, the proposed changes would not remove the right of an Exchange to communicate directly with the Commission on any issues that might arise.

regulations thereunder applicable to a registered clearing agency. In particular, OCC believes the proposed changes are consistent with Section 17A(b)(3)(F) of the Exchange Act, which requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, in general, to protect investors and the public interest.<sup>31</sup> OCC's relationship with the Exchanges is largely governed by the Existing RPEA, which sets out the terms and conditions under which OCC will provide clearing services to the Exchanges for the options listed on the Exchanges. The agreement was last amended 17 years ago, and the proposed changes would bring up to date the agreement and would serve to ensure that the relationship between OCC and the Exchanges is accurately documented to reflect current practices between the parties. Updating the Existing RPEA to reflect current practices will add clarity and eliminate confusion about the roles and responsibilities of the parties to the agreement by integrating amendments into the New RPEA to make one cohesive, more readable document and incorporating existing and modernized practices into the document as well, thereby promoting the prompt and accurate clearance and settlement of securities transactions and, in general, protecting investors and the public interest.

By adopting the New RPEA, the proposed changes would identify, monitor, and manage in an up-to-date manner the risks related to links OCC established with the Exchanges in accordance with 17A(b)(3)(F)<sup>32</sup> of the Exchange Act and Rule 17Ad-22(e)(20) thereunder.<sup>33</sup>

The proposed changes would (i) eliminate provisions that are out of date or update provisions to reflect current industry terminology and/or (ii) reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, which may address technology or industry changes or developments that necessitate new or updated agreement terms or incorporate adopted best practices for contract terms. The proposed changes serving these purposes would: state that national securities exchanges would not become parties to the New RPEA; update the permitted Underlying Interests on which options could be listed; provide OCC with the authority to disapprove for clearing options that

materially impact OCC's risk profile; remove a specified time by which Exchanges may add new series; state that each Exchange is responsible for determining units of trading and communicating this information to OCC and that deviation from the standard unit of trading may not be permitted; remove the requirement that Exchanges make product lists available; establish conditions for Exchanges to delist options; establish requirements for Exchanges in the listing of and the determination of the settlement process for singly listed options; memorialize the manner in which Exchanges make Exchange Data available to OCC and how OCC may use and redistribute Exchange Data, address intellectual property rights, address changes to Exchange Data, and grant a license to OCC to use the Exchange Data; remove provisions related to OCC performing comparison services; create the defined terms "Matched Trade" and "Trading Day"; require OCC to provide notice for any change to the time by which Exchanges must submit comparisons; and remove the prerequisite that payment of premiums be made prior to OCC's acceptance of trades.

Additional changes serving these two purposes would: state that OCC can calculate position limits at the request of the Exchanges; note that the general limitation on OCC from opening or restricting trading would not limit OCC's other rights under the agreement; include references to "Regulatory Services Agreement" for Exchanges that outsource surveillance; remove the obligation for Exchanges to notify OCC when a Clearing Member is not in compliance with OCC's financial standards; add that Exchanges will notify OCC when a Clearing Member must be reported to SIPC or "any other resolution authority"; remove in person document delivery requirements; remove the requirement that OCC maintain an office in every city where Exchanges are located; remove outdated systems scalability reporting and response protocols; require the Exchanges to provide supporting materials, data, and reports needed to support clearing and to make Exchange representatives available to discuss data and information needs; instead of best efforts, require OCC to use commercially reasonable efforts to maintain capacity and expand operations to clear new options; require the Exchanges to comply with OCC's operational specifications for options and require advance notice to change the specifications; establish financial reporting requirements for exchanges

and related confidentiality provisions; strengthen information security; require the parties to take commercially reasonable steps to comply with cybersecurity regulations; allow OCC to suspend its obligations to an Exchange if an Exchange disruption materially impacts OCC; require Exchanges to accommodate OCC's connectivity requirements and provide advance notice of any changes; use industry terminology to describe options as cash settled or physically settled; remove requirements related to providing local banking information; allow notices to be delivered via email; clarify the assignment provisions; grant OCC a license to use the Exchanges' trademarks and grant the Exchanges a license to use OCC trademarks; give OCC the right to suspend its obligations to an Exchange to comply with OCC's Rules or By-Laws, or the Securities Act or Exchange Act; provide that both OCC and the Exchanges are responsible for preparing the ODD and would provide for mutual indemnification for the contents of the ODD; clarify and describe the administration of the LOD Committee; and add confidentiality provisions with respect to both OCC's and the Exchanges' information.

The proposed changes also would align the agreement with current law and/or OCC's By-Laws and Rules by: changing "expiration months" to "expiration dates" to reflect the increased number of expiration cycles; requiring Exchanges to provide values for underlying options and to determine Exercise Settlement Values in alignment with OCC By-Laws; changing the use of "Non-Discrimination" to "No Unfair Discrimination," along with By-Laws references; requiring Exchanges to provide materials for Clearing Members that also are members of the Exchange and change the time requirement for Exchange submissions of materials and reporting materials; and change OCC's designated official for financial purposes to the Financial Risk Management officer.

Lastly, the proposed changes would acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement. As part of the New RPEA, OCC and the Exchanges would: agree to remain in compliance with the Exchange Act and each party's own rules; the Exchanges would agree to list options in accordance with their rules and agree that listings must be addressed in the ODD; agree to submit new products to the OCC in accordance with the OLPP; and allow for exercises

<sup>31</sup> 15 U.S.C. 78q-1(B)(3)(F).

<sup>32</sup> Id.

<sup>33</sup> 17 CFR 240.17Ad-22(e)(20).

to be restricted in the case of a government mandated restrictions.

OCC believes amending the Existing RPEA to reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, align the agreement with current law and/or OCC's By-Laws and Rules, eliminate provisions that are out of date or update provisions to reflect current industry terminology, and acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement will ensure the parties rights and obligations are clear and well documented. This, in turn, will serve the public interest by continuing to promote the prompt and accurate clearance and settlement of transactions because both OCC and the Exchanges will have a clear understanding of their rights and obligations in the agreement.

OCC also believes that the proposed changes are consistent with SEC rules that apply to OCC as a covered clearing agency. Specifically, SEC Rule 17Ad-22(e)(20) requires OCC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to identify, monitor, and manage risks related to any link that OCC establishes with one or more other clearing agencies, financial market utilities, or trading markets.<sup>34</sup> As described in OCC's publicly available disclosure framework for financial market infrastructures, OCC maintains links with the Exchanges that are qualified to participate at OCC. As described above, the Existing RPEA manages the risks associated with OCC's dealings with the Exchanges by establishing the terms and conditions under which OCC will provide clearing services to the Exchanges. The proposed changes to the Existing RPEA are intended to strengthen OCC's links to the Exchanges by reflecting current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, aligning the agreement with current law and/or OCC's By-Laws and Rules, eliminating provisions that are out of date or update provisions to reflect current industry terminology, and acknowledging the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement.

For these reasons, OCC believes the proposed rule change is consistent with

applicable provisions of Section 17A of the Exchange Act and Rule 17Ad-22 thereunder.

*(B) Clearing Agency's Statement on Burden on Competition*

Section 17A(b)(3)(I) of the Act<sup>35</sup> requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. OCC does not believe that the proposal would impose any burden on competition.<sup>36</sup> The New RPEA applies to Equity and Non-Equity Exchanges alike in satisfaction of the requirements in OCC's By-Laws. Accordingly, OCC does not believe that the New RPEA imposes any added burdens on competition on any one Exchange over another.

The primary purpose of the proposed rule change is to (a) reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, (b) align the agreement with current law and/or OCC's By-Laws and Rules, (c) eliminate provisions that are out of date or update provisions to reflect current industry terminology, (d) acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges by recognizing such factors within the agreement, and (e) improve overall readability of the document through the incorporation of intervening amendments and changes into the agreement. Because the proposed rule change is intended to reflect current, enhanced, or implied but not specifically stated operational and business practices between OCC and the Exchanges, OCC anticipates that most, if not all, of the proposed changes related to operational and business practices between OCC and the Exchanges already are in effect, and therefore, will not be overly burdensome on the Exchanges.

The proposed rule change also is intended to align the New RPEA with current law and/or OCC's By-Laws and Rules. OCC anticipates that the Exchanges also are operating in alignment with current law and/or OCC's By-Laws and Rules, and therefore, changes related to this purpose also should not be overly burdensome on the Exchanges.

The proposed rule change would eliminate provisions that are out of date or update provisions to reflect current industry terminology. Changes related to this purpose are intended to ensure

that the parties have engaged in good practices regarding principles related to contracting and that the agreement between OCC and the Exchanges is clear and eliminates confusion around the parties' rights and responsibilities.

Finally, the proposed rule change acknowledges the legal and regulatory landscape of the options industry that affects the interactions between OCC and the Exchanges by recognizing such factors within the agreement. As with the changes related to the other purposes described above, OCC anticipates that changes intended to acknowledge the legal and regulatory landscape of the options industry that affect the interactions between OCC and the Exchanges serve to memorialize existing industry conditions and practices between the parties.

The proposed rule change would not affect any individual participant Exchange's current rights beyond the description provided above or ability to access OCC services or disadvantage or favor any particular Exchange in relationship to another. As such, OCC believes that the proposed changes would not have any impact or impose any burden on competition.

For the foregoing reasons, OCC believes that the proposed rule change is in the public interest, would be consistent with the requirements of the Exchange Act applicable to clearing agencies, and would not have any impact or impose a burden on competition.

*(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

Written comments were not, and are not, intended to be solicited with respect to the proposed change and none have been received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the selfregulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required

<sup>34</sup> 17 CFR 240.17Ad-22(e)(20).

<sup>35</sup> 15 U.S.C. 78q-1(b)(3)(I).

<sup>36</sup> *Id.*

with respect to the proposal are completed.

#### 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-regulations/self-regulatory-organization-rulemaking>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include file number SR-OCC-2025-006 on the subject line.

##### *Paper Comments*

- Send paper comments in triplicate to Vanessa Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-OCC-2025-006. 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 such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at <https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules>.

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-OCC-2025-006 and

should be submitted on or before June 20, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>37</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09624 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

#### **SECURITIES AND EXCHANGE COMMISSION**

**[OMB Control No. 3235-0206]**

#### **Proposed Collection; Comment Request; Extension: Rule 19d-1**

*Upon Written Request, Copies Available From:* Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (SEC or "Commission") is soliciting comments on the proposed collection of information in Rule 19d-1.

Rule 19d-1 prescribes the form and content of notices to be filed with the Commission by self-regulatory organizations ("SROs") for which the Commission is the appropriate regulatory agency concerning the following final SRO actions: (1) disciplinary actions with respect to any person; (2) denial, bar, prohibition, or limitation of membership, participation or association with a member or of access to services offered by an SRO or member thereof; (3) summarily suspending a member, participant, or person associated with a member, or summarily limiting or prohibiting any persons with respect to access to or services offered by the SRO or a member thereof; and (4) delisting a security.

The Rule enables the Commission to obtain reports from the SROs containing information regarding SRO determinations to delist a security, discipline members or associated persons of members, deny membership or participation or association with a member, and similar adjudicated findings. The Rule requires that such actions be promptly reported to the Commission. The Rule also requires that the reports and notices supply sufficient information regarding the background, factual basis and issues involved in the proceeding to enable the Commission: (1) to determine whether the matter should be called up for review on the

Commission's own motion; and (2) to ascertain generally whether the SRO has adequately carried out its responsibilities under the Exchange Act.

It is estimated that approximately seventeen respondents will utilize this application procedure annually, and will file approximately 850 submissions, based upon recent data. The Commission estimates that the average number of hours necessary to comply with the requirements of Rule 19d-1 for each submission is 1 hour. The total annual burden for all respondents is thus 850 hours. The Commission estimates that the internal compliance cost per respondent is approximately \$344 per response. The annual internal cost of compliance for all respondents is thus approximately \$292,400 (17 respondents × 50 responses × \$344 per response).

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the 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 respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comment to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg, 100 F Street NE, Washington, DC 20549 and send it by email to [PaperworkReductionAct@sec.gov](mailto:PaperworkReductionAct@sec.gov) by July 28, 2025.

Dated: May 21, 2025.

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09490 Filed 5-28-25; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>37</sup> 17 CFR 200.30-3(a)(12).

**SECURITIES AND EXCHANGE COMMISSION**

[OMB Control No. 3235-0311]

**Proposed Collection; Comment Request; Extension: Rule 7d-1**

*Upon Written Request, Copies Available*

From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) is soliciting comments on the collection of information discussed below.

Section 7(d) of the Investment Company Act of 1940 (15 U.S.C. 80a-7(d)) (the “Act” or “Investment Company Act”) requires an investment company (“fund”) organized outside the United States (“foreign fund”) to obtain an order from the Commission allowing the fund to register under the Act before making a public offering of its securities through the United States mail or any means of interstate commerce. The Commission may issue an order only if it finds that it is both legally and practically feasible effectively to enforce the provisions of the Act against the foreign fund, and that the registration of the fund is consistent with the public interest and protection of investors.

Rule 7d-1 (17 CFR 270.7d-1) under the Act, which was adopted in 1954, specifies the conditions under which a Canadian management investment company (“Canadian fund”) may request an order from the Commission permitting it to register under the Act. Although rule 7d-1 by its terms applies only to Canadian funds, funds in other jurisdictions generally have agreed to comply with the requirements of rule 7d-1 as a prerequisite to receiving an order permitting the fund’s registration under the Act.

The rule requires Canadian funds that propose to register under the Act to file an application with the Commission that contains various undertakings and

agreements by the fund. The requirement of the Canadian fund to file an application is a collection of information under the Paperwork Reduction Act. Certain of the undertakings and agreements, in turn, impose the following additional information collection requirements:

(1) the fund must file with the Commission agreements between the fund and its directors, officers, and service providers requiring them to comply with the fund’s charter and bylaws, the Act, and certain other obligations relating to the undertakings and agreements in the application;

(2) the fund and each of its directors, officers, and investment advisers that is not a U.S. resident, must file with the Commission an irrevocable designation of the fund’s custodian in the United States as agent for service of process;

(3) the fund’s charter and bylaws must provide that (a) the fund will comply with certain provisions of the Act applicable to all funds, (b) the fund will maintain originals or copies of its books and records in the United States, and (c) the fund’s contracts with its custodian, investment adviser, and principal underwriter, will contain certain terms, including a requirement that the adviser maintain originals or copies of pertinent records in the United States;

(4) the fund’s contracts with service providers will require that the provider perform the contract in accordance with the Act, the Securities Act of 1933 (15 U.S.C. 77a), and the Securities Exchange Act of 1934 (15 U.S.C. 78a), as applicable; and

(5) the fund must file, and periodically revise, a list of persons affiliated with the fund, its investment adviser, and principal underwriter.

As noted above, under section 7(d) of the Act, the Commission may issue an order permitting a foreign fund’s registration only if the Commission finds that “by reason of special circumstances or arrangements, it is both legally and practically feasible effectively to enforce the provisions of the (Act).” The information collection requirements are necessary to ensure

that the substantive provisions of the Act may be enforced as a matter of contract right in the United States or Canada by the fund’s shareholders or by the Commission.

Rule 7d-1 also contains certain information collection requirements that are associated with other provisions of the Act. These requirements are applicable to all registered funds and are outside the scope of this request. The Commission staff estimates that one foreign fund is registered under the Act pursuant to rule 7d-1 and is currently active. The burden hours under the rule associated with the fund’s compliance with the Act’s requirements are reflected in the information collection burdens applicable to those requirements for all registered funds. If a fund were to file an application under rule 7d-1 to register under the Act, the Commission estimates that the rule would impose initial information collection burdens (for example, for filing an application, preparing the specified charter, bylaw, and contract provisions, designations of agents for service of process, and an initial list of affiliated persons, and establishing a means of keeping records in the United States) of approximately 90 hours for the fund and its associated persons. As noted above, after registration, a Canadian fund may file a supplemental application seeking special relief designed for the fund’s particular circumstances. Rule 7d-1 does not mandate these applications. The Commission is not including these applications in its calculation of the annual burden because no fund has applied to register under the Act pursuant to rule 7d-1 in the last three years.

These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of Commission rules. Commission staff estimates the burden of the rule as set forth in Table 1 below:

	Number of affected funds	Internal annual burden hours	Wage rate <sup>1</sup>	Internal time costs	Annual external cost burden <sup>2</sup>
Rule 7d-1 .....	1	5	\$1,910	\$9,550	\$5,256
Total Annual Burden .....	.....	5	.....	9,550	5,256

Cost burden is the cost of goods and services purchased to comply with rule 7d-1, such as legal and accounting services. The cost burden does not

include the hour burden discussed in Item 12 above. As outlined in the table above, we estimate the total external

cost burden to comply with rule 7d-1 to be \$5,256.

If a Canadian or other foreign fund in the future applied to register under the

Act under rule 7d–1, the fund initially might have capital and start-up costs (not including hourly burdens) of an estimated \$20,000 to comply with the rule’s initial information collection requirements. These costs include legal and processing-related fees for preparing the required documentation (such as the application, charter, bylaw, and contract provisions, designations for service of process, and the list of affiliated persons). Other related costs would include fees for establishing arrangements with a custodian or other agent for maintaining records in the United States, copying and transportation costs for records, and the costs of purchasing or leasing computer equipment, software, or other record storage equipment for records maintained in electronic or photographic form.

The Commission expects that the fund and its sponsors would incur these costs immediately, and that the annualized cost of the expenditures would be \$20,000 in the first year. Some expenditures might involve capital improvements, such as computer equipment, having expected useful lives for which annualized figures beyond the first year would be meaningful. These annualized figures are not provided, however, because, in most cases, the expenses would be incurred immediately rather than on an annual basis. As indicated above, a Canadian or foreign fund may file a supplemental application seeking special relief designed for the fund’s particular circumstances. Rule 7d–1 does not mandate these applications. The Commission is not including these costs because no fund has applied made an application under rule 7d–1 in the last three 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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC’s estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the 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 respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comment to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg, 100 F Street NE, Washington, DC 20549 and send it by email to [PaperworkReductionAct@sec.gov](mailto:PaperworkReductionAct@sec.gov) by July 28, 2025.

Dated: May 22, 2025.

**Sherry R. Haywood,**  
Assistant Secretary.

[FR Doc. 2025–09635 Filed 5–28–25; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–103112; File No. SR–NASDAQ–2025–013]

### Self-Regulatory Organizations; Nasdaq Stock Market LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the CoinShares Litecoin ETF Under Nasdaq Rule 5711(d) (Commodity Based Trust Shares)

May 22, 2025.

#### I. Introduction

On February 7, 2025, The Nasdaq Stock Market LLC (“Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) <sup>1</sup> and Rule 19b–4 thereunder, <sup>2</sup> a proposed rule change to list and trade shares (“Shares”) of the CoinShares Litecoin ETF (“Trust”) under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on February 25, 2025. <sup>3</sup>

On March 11, 2025, pursuant to Section 19(b)(2) of the Act, <sup>4</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change. <sup>5</sup> This order institutes proceedings under Section

19(b)(2)(B) of the Act <sup>6</sup> to determine whether to approve or disapprove the proposed rule change.

#### II. Summary of the Proposal

As described in more detail in the Notice, <sup>7</sup> the Exchange proposes to list and trade the Shares of the Trust under Nasdaq Rule 5711(d), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.

According to the Exchange, the investment objective of the Trust is for the Shares to reflect the performance of the value of Litecoin (“LTC”) <sup>8</sup> as represented by the Compass Crypto Reference Index Litecoin—4 p.m. NY Time (“Index”), less the Trust’s liabilities and expenses. <sup>9</sup> In seeking to achieve its investment objective, the Trust will hold LTC and will value its Shares daily based on the value of LTC as reflected by the Index. <sup>10</sup> The Trust holds only LTC and cash. <sup>11</sup> When the Trust sells or redeems its Shares, it will do so in cash transactions with authorized participants in blocks of 5,000 Shares. <sup>12</sup>

#### III. Proceedings To Determine Whether To Approve or Disapprove SR–NASDAQ–2025–013 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act <sup>13</sup> to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

<sup>6</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>7</sup> See Notice, *supra* note 3.

<sup>8</sup> The Exchange states that LTC is a digital asset that is created and transmitted through the operations of the peer-to-peer, decentralized network of computers that operates on cryptographic protocols (“Litecoin Network”). See *id.* at 10657.

<sup>9</sup> See *id.* at 10656–57. CoinShares Co. is the sponsor of the Trust, CSC Delaware Trust Company is the trustee, and a third-party custodian will be responsible for the custody of the Trust’s LTC. See *id.* at 10656.

<sup>10</sup> See *id.* at 10657. The Index is representative of the LTC trading activity on selected trading platforms and is calculated by Compass Financial Technologies. See *id.*

<sup>11</sup> See *id.* at 10656.

<sup>12</sup> See *id.* at 10657.

<sup>13</sup> 15 U.S.C. 78s(b)(2)(B).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b–4.

<sup>3</sup> See Securities Exchange Act Release No. 102444 (Feb. 19, 2025), 90 FR 10656 (“Notice”). Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-013/srnasdaq2025013.htm>.

<sup>4</sup> 15 U.S.C. 78s(b)(2).

<sup>5</sup> See Securities Exchange Act Release No. 102606, 90 FR 12425 (Mar. 17, 2025). The Commission designated May 26, 2025, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,<sup>14</sup> the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be "designed to prevent fraudulent and manipulative acts and practices" and "to protect investors and the public interest."<sup>15</sup>

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on whether the proposal to list and trade Shares of the Trust, which would hold LTC, is designed to prevent fraudulent and manipulative acts and practices or raises any new or novel concerns not previously contemplated by the Commission.

#### IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.<sup>16</sup>

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be

approved or disapproved by June 20, 2025. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by July 3, 2025.

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](mailto:rule-comments@sec.gov). Please include file number SR-NASDAQ-2025-013 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-2025-013. 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-2025-013 and should be submitted on or before June 20, 2025. Rebuttal comments should be submitted by July 3, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>17</sup>

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2025-09628 Filed 5-28-25; 8:45 am]

BILLING CODE 8011-01-P

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration #21090 and #21091; PENNSYLVANIA Disaster Number PA-20019]**

### Administrative Declaration of a Disaster for the Commonwealth of Pennsylvania

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Administrative declaration of a disaster for the Commonwealth of Pennsylvania dated May 22, 2025.

*Incident:* Severe Storms and Flooding.

**DATES:** Issued on May 22, 2025.

*Incident Period:* May 13, 2025.

*Physical Loan Application Deadline*

*Date:* July 21, 2025.

*Economic Injury (EIDL) Loan*

*Application Deadline Date:* February 23, 2026.

**ADDRESSES:** Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

**FOR FURTHER INFORMATION CONTACT:** Sharon Henderson, 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 as a result of the Administrator's disaster declaration, 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](mailto: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 County:* Somerset.

*Contiguous Counties:*

Pennsylvania: Bedford, Cambria,

Fayette, Westmoreland.

Maryland: Allegany, Garrett.

The Interest Rates are:

<sup>17</sup> 17 CFR 200.30-3(a)(57).

<sup>14</sup> *Id.*

<sup>15</sup> 15 U.S.C. 78f(b)(5).

<sup>16</sup> Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere .....	5.625
Homeowners without Credit Available Elsewhere .....	2.813
Businesses with Credit Available Elsewhere .....	8.000
Businesses without Credit Available Elsewhere .....	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	3.625
Non-Profit Organizations without Credit Available Elsewhere .....	3.625
<i>For Economic Injury:</i>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere .....	4.000
Non-Profit Organizations without Credit Available Elsewhere .....	3.625

The number assigned to this disaster for physical damage is 210906 and for economic injury is 210910.

The Commonwealth and State which received an EIDL Declaration are Pennsylvania and Maryland.

(Catalog of Federal Domestic Assistance Number 59008)

**James Stallings,**

*Associate Administrator, Office of Disaster Recovery and Resilience.*

[FR Doc. 2025-09654 Filed 5-28-25; 8:45 am]

**BILLING CODE 8026-09-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**Notice of Meeting on Section 1115 of the FAA Reauthorization Act of 2024**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of meeting.

**SUMMARY:** The Federal Aviation Administration (FAA) announces a virtual meeting regarding the identification of potential scheduling conflicts pursuant to section 1115 of the FAA Reauthorization Act of 2024. This meeting is open to all representatives of FAA-approved air shows, the general aviation community, stadiums and other large outdoor events and venues or organizations that run such events, the Department of Homeland Security, and the Department of Justice. The goal of this meeting is to identify potential scheduling conflicts so the FAA can develop appropriate operational and communication procedures to ensure the safety and security of both events.

**DATES:** The FAA will hold this virtual meeting on Tuesday, June 24, 2025,

beginning at 1 p.m. (Eastern Time), and the meeting will continue until adjourned by FAA’s Rules and Regulations Group. The FAA must receive requests to attend no later than Tuesday, June 17, 2025.

**FOR FURTHER INFORMATION CONTACT:** Brian Konie, Acting Manager, Airspace Rules and Regulations, email: *9-ajo-airspaceandrules@faa.gov*; mail: Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; or telephone: (202) 267-8783.

**SUPPLEMENTARY INFORMATION:**  
*Format:* The meeting will be held virtually on Zoom.

*Background:* Section 1115 of the FAA Reauthorization Act of 2024 (Pub. L. 118-63, May 16, 2024) requires the Administrator to conduct an annual meeting to identify scheduling conflicts between FAA-approved airshows and large outdoor events and venues where flight restrictions will be imposed pursuant to section 521 of division F of the Consolidated Appropriations Act, 2004 (49 U.S.C. 40103 note) or any other restriction will be imposed pursuant to FAA Flight Data Center Notice to Airmen 4/3621 (or any successor notice to airmen). The purpose of the meeting is to bring together representatives of FAA-approved air shows, the general aviation community, stadiums and other large outdoor events and venues or organizations that run such events, the Department of Homeland Security, and the Department of Justice. If a scheduling conflict is identified, the FAA plans to use that information to develop appropriate operational and communication procedures to ensure the safety and security of both events.

*Meeting Procedures:*

(a) *Registration:* To attend the meeting, send requests to Brian Konie, Acting Manager, Airspace Rules and Regulations via email (preferred) at *9-ajo-airspaceandrules@faa.gov* no later than Tuesday, June 17, 2025.

(b) The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend or participate. One or more representatives of the FAA’s Rules and Regulations Group will conduct the meeting.

(c) The FAA will email registrants the meeting access information in a timely manner prior to the start of the meetings.

(d) Each participant will be given an opportunity to deliver comments in support of identifying potential scheduling conflicts, although a time limit may be imposed to accommodate all participants during the meeting. As the development of appropriate

operational and communication procedures to ensure for the safety and security of both events will occur as a follow-on action at a local level, the FAA will limit comments to only those that support the identification of potential scheduling conflicts.

(e) Each person wishing to make a presentation will be asked to note their intent when registering for the meeting so those time frames can be established. This meeting will not be adjourned until everyone registered to speak has had an opportunity to address the panel. This meeting may be adjourned at any time if all persons present have had an opportunity to speak.

(f) The FAA will accept material relating to the substance of the meeting. Participants submitting materials should send them to the email (preferred) or mailing addresses noted in the **FOR FURTHER INFORMATION CONTACT** section no later than Tuesday, June 17, 2025.

Issued in Washington, DC, on May 21, 2025.

**Brian Eric Konie,**

*Manager (A), Airspace Rules and Regulations.*

[FR Doc. 2025-09450 Filed 5-28-25; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Railroad Administration**

[Docket No. FRA-2025-0010]

**Proposed Agency Information Collection Activities; Comment Request**

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) summarized below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On March 25, 2025, FRA published a notice providing a 60-day period for public comment on the ICR. FRA received no comments in response to the notice.

**DATES:** Interested persons are invited to submit comments on or before June 30, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to

[www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find the particular ICR by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Ms. Arlette Mussington, Information Collection Clearance Officer, at email: [arlette.mussington@dot.gov](mailto:arlette.mussington@dot.gov) or telephone: (571) 609–1285 or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: [joanne.swafford@dot.gov](mailto:joanne.swafford@dot.gov) or telephone: (757) 897–9908.

**SUPPLEMENTARY INFORMATION:** The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. See 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On March 25, 2025, FRA published a 60-day notice in the **Federal Register** soliciting public comment on the ICR for which it is now seeking OMB approval. See 90 FR 13656. FRA has received no comments related to the proposed collection of information.

Before OMB decides whether to approve this proposed collection of information, it must provide 30 days’ notice for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); See also 60 FR 44978, 44983, Aug. 29, 1995. The 30-day notice informs the regulated community of their opportunity to file relevant comments and affords the agency adequate time to consider public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA’s estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques

or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

*Title:* Railroad Workplace Safety.

*OMB Control Number:* 2130–0539.

*Abstract:* FRA collects a variety of information associated with 49 CFR part 214, Railroad Workplace Safety. To ensure compliance with part 214, FRA collects data on affected railroads’ on-track safety programs to determine that railroads have policies, procedures, and practices in place that protect roadway workers from dangers in their work environment. Railroads are required to provide all roadway workers with on-track safety manuals that they can readily consult to determine what on-track safety procedures are required for their work assignment. Under the regulation, railroads are required to provide initial and recurrent training to roadway workers on their on-track safety program. This includes training for roadway workers who work where on-track safety for adjacent controlled tracks is required, and the appropriate practices and procedures they must follow.

FRA collects data from railroads on training through the records that they are required to keep. Additionally, FRA collects information on violations of workplace safety regulations on Form FRA F 6180.119. FRA uses violation information to support actions that will reduce or eliminate hazards to railroad workers. Specifically, FRA uses the information that it collects, under this regulation, to monitor and enforce requirements relating to the safety of roadway workers and ensure that railroads fulfill their responsibilities to keep roadway workers secure and free from unnecessary and avoidable hazards.

*Type of Request:* Extension without change (with changes in estimates) of a currently approved collection.

*Affected Public:* Businesses, Roadway Workers, State Safety Inspectors.

*Form(s):* FRA F 6180.119.

*Respondent Universe:* 800 Railroads, 200 Contractors, 43,000 Roadway Workers, and 350 Inspectors.

*Frequency of Submission:* On occasion.

*Total Estimated Annual Responses:* 290,698.

*Total Estimated Annual Burden:* 13,604 hours.

*Total Estimated Annual Dollar Cost Equivalent:* 966,583.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does

not display a currently valid OMB control number.

*Authority:* 44 U.S.C. 3501–3520.

**Christopher S. Van Nostrand,**

*Deputy Chief Counsel.*

[FR Doc. 2025–09647 Filed 5–28–25; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD–2025–0085]

#### Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, S/V GOOD KARMA

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor’s vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

**DATES:** Submit comments on or before June 30, 2025.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2025–0085 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search MARAD–2025–0085 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2025–0085, 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.

*Note:* If you mail or hand-deliver your comments, we recommend that you

include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at [www.regulations.gov](http://www.regulations.gov), including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR-620, Washington, DC 20590. Telephone: (202) 366-5400. Email: [smallvessels@dot.gov](mailto:smallvessels@dot.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if the Maritime Administration (MARAD), after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.<sup>1</sup>

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT docket as MARAD-2025-0085 at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

<sup>1</sup> The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

## Public Participation

### *How do I submit comments?*

Please submit comments, including the attachments, following the instructions provided under the above heading entitled ADDRESSES. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

### *Where do I go to read public comments, and find supporting information?*

The docket online is located at <https://www.regulations.gov>, keyword search MARAD-2025-0085 or visit the Docket Management Facility (see ADDRESSES for hours of operation). Please periodically check the Docket for new submissions and supporting material.

### *Will my comments be made available to the public?*

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

### *May I submit comments confidentially?*

You may request that MARAD treat your comments as commercially confidential by submitting them to [SmallVessels@dot.gov](mailto:SmallVessels@dot.gov). Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

## Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 12121)

By Order of the Maritime Administration.  
**T. Mitchell Hudson, Jr.**,  
 Secretary, Maritime Administration.  
 [FR Doc. 2025-09684 Filed 5-28-25; 8:45 am]  
 BILLING CODE 4910-81-P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD-2025-0083]

### Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, S/V NORTHERN LIGHT

**AGENCY:** Maritime Administration, DOT.  
**ACTION:** Notice and request for comments.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

**DATES:** Submit comments on or before June 30, 2025.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD-2025-0083 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search MARAD-2025-0083 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD-2025-0083, 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.

**Note:** If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body

of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at [www.regulations.gov](http://www.regulations.gov), including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR-620, Washington, DC 20590. Telephone: (202) 366-5400. Email: [smallvessels@dot.gov](mailto:smallvessels@dot.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if the Maritime Administration (MARAD), after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.<sup>1</sup>

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT docket as MARAD-2025-0083 at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

### Public Participation

#### *How do I submit comments?*

Please submit comments, including the attachments, following the instructions provided under the above

heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

The docket online is located at <https://www.regulations.gov>, keyword search MARAD-2025-0083 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

You may request that MARAD treat your comments as commercially confidential by submitting them to [SmallVessels@dot.gov](mailto:SmallVessels@dot.gov). Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

### Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 12121)

By Order of the Maritime Administration.

**T. Mitchell Hudson, Jr.,**  
Secretary, Maritime Administration.

[FR Doc. 2025-09685 Filed 5-28-25; 8:45 am]

**BILLING CODE 4910-81-P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

[Docket No. MARAD-2025-0086]

### Request for Comments on the Renewal of a Previously Approved Collection: U.S. Merchant Marine Academy Candidate Application for Admission

**AGENCY:** Maritime Administration, DOT.  
**ACTION:** Notice.

**SUMMARY:** The Maritime Administration (MARAD) invites public comments on our intention to request approval from the Office of Management and Budget (OMB) to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133-0010 (U.S. Merchant Marine Academy (USMMA) Candidate Application for Admission) is being updated to reflect the new Student Information System (SIS) and online application and admissions portal, as an alternate to the paper-based application and admissions process. 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 July 28, 2025.

**ADDRESSES:** You may submit comments identified by Docket No. MARAD-2025-0086 through one of the following methods:

- *Federal eRulemaking Portal:* [www.regulations.gov](http://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](http://www.regulations.gov) including any personal information provided.

*Comments are invited on:* (a) whether the proposed collection of information is reasonable 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 lessened without reducing the quality of the collected information. The agency will summarize and/or include

<sup>1</sup> The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

your comments in the request for OMB's clearance of this information collection.

**FOR FURTHER INFORMATION CONTACT:** CDR Mike Bedryk, 516-726-5641, Director, Office of Admissions, U.S. Merchant Marine Academy, 300 Steamboat Rd., Kings Point, NY 11024, Email: [admissions@usmma.edu](mailto:admissions@usmma.edu).

**SUPPLEMENTARY INFORMATION:**

*Title:* U.S. Merchant Marine Academy Candidate Application for Admission.

*OMB Control Number:* 2133-0010.

*Type of Request:* Extension with change of a previously approved collection.

*Abstract:* The Candidate Application for Admission is administered through the USMMA Student Information System (SIS), PeopleSoft Campus Solutions (UCAS). Candidates must create an applicant account and log into the SIS via [login.gov](http://login.gov). The application system will be used by the Office of Admissions and the Candidate Evaluation Board (CEB) to select the best qualified candidates for admission. Candidates will also provide contact information for guidance counselors, teachers and physical fitness evaluations, who are asked to provide information on the applicant's behalf that is also used in the admission process.

*Respondents:* Respondents consist of citizens seeking to apply for admission to the U.S. Merchant Marine Academy, school officials and other evaluators submitting supplemental information required to determine the most qualified applicants for offers of admission.

*Affected Public:* Individuals.

*Estimated Number of Respondents:* 2,000.

*Estimated Number of Responses:* 2,000.

*Estimated Hours per Response:* 3.

*Annual Estimated Total Annual Burden Hours:* 6,000.

*Frequency of Response:* One time in any given admission cycle.

(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 Administration.

**T. Mitchell Hudson, Jr.,**

Secretary, Maritime Administration.

[FR Doc. 2025-09597 Filed 5-28-25; 8:45 am]

**BILLING CODE 4910-81-P**

**DEPARTMENT OF TRANSPORTATION**

**Maritime Administration**

[Docket No. MARAD-2025-0084]

**Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V OSPREY**

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

**DATES:** Submit comments on or before June 30, 2025.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD-2025-0084 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov>. Search MARAD-2025-0084 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD-2025-0084, 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.

**Note:** If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

**Instructions:** All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at [www.regulations.gov](http://www.regulations.gov),

including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR-620, Washington, DC 20590. Telephone: (202) 366-5400. Email: [smallvessels@dot.gov](mailto:smallvessels@dot.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if the Maritime Administration (MARAD), after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.<sup>1</sup>

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT docket as MARAD-2025-0084 at <https://www.regulations.gov>. Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

**Public Participation**

*How do I submit comments?*

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

<sup>1</sup> The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

*Where do I go to read public comments, and find supporting information?*

The docket online is located at <https://www.regulations.gov>, keyword search MARAD–2025–0084 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

You may request that MARAD treat your comments as commercially confidential by submitting them to [SmallVessels@dot.gov](mailto:SmallVessels@dot.gov). Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

#### Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT’s compliance with the Privacy Act, please visit <https://www.transportation.gov/privacy>.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 12121)

By Order of the Maritime Administration.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2025–09683 Filed 5–28–25; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### Agency Information Collection Activities: Revision of an Approved Information Collection; Comment Request; Interagency Policy Statement on Funding and Liquidity Risk Management

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

**ACTION:** Notice and request for comment.

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a revision to its information collection titled “Interagency Policy Statement on Funding and Liquidity Risk Management.”

**DATES:** Comments must be received by July 28, 2025.

**ADDRESSES:** Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* [prainfo@occ.treas.gov](mailto:prainfo@occ.treas.gov).
- *Mail:* Chief Counsel’s Office,

Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0244, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

- *Fax:* (571) 293–4835.

**Instructions:** You must include “OCC” as the agency name and “1557–0244” in your comment. In general, the OCC will publish comments on [www.reginfo.gov](http://www.reginfo.gov) without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice’s 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to [www.reginfo.gov](http://www.reginfo.gov). Hover over the “Information Collection Review” tab and click on “Information Collection Review” from the drop-down menu. From the “Currently under Review” drop-down menu, select “Department of Treasury” and then click “submit.” This information collection can be located by searching OMB control number “1557–0244” or “Interagency Policy Statement on Funding and Liquidity Risk Management.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating [www.reginfo.gov](http://www.reginfo.gov), please contact the Regulatory Information Service Center at (202) 482–7340.

#### FOR FURTHER INFORMATION CONTACT:

Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include 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 title 44 generally requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the revision of this collection.

*Title:* Interagency Policy Statement on Funding and Liquidity Risk

Management. *OMB Control No.*: 1557–0244.

*Type of Review*: Regular.

*Affected Public*: Businesses or other for-profit.

*Description*: On March 22, 2010, the OCC, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the National Credit Union Administration (the agencies), in conjunction with the Conference of State Bank Supervisors, issued a policy statement on funding and liquidity risk management (Policy Statement).<sup>1</sup> The Policy Statement sets forth guidance and principles for sound liquidity risk management that apply to OCC-supervised national banks, Federal savings associations, and Federal branches and agencies of foreign banking organizations (together, banks). The Policy Statement summarizes and builds on previously issued guidance.<sup>2</sup> In 2023, the agencies supplemented their liquidity risk management guidance with an Addendum to the Policy Statement.<sup>3</sup>

The OCC is proposing to revise this information collection to account for all the recordkeeping provisions set forth in the Policy Statement related to liquidity risk management policies, procedures, and assumptions, and Contingency Funding Plans (CFPs). The information collection currently does not account for the recordkeeping provisions related to CFPs and does not fully account for the recordkeeping provisions related to liquidity risk management policies, procedures, and assumptions. In addition, the OCC is proposing to revise the information collection to account for the guidance in the Addendum to the Policy Statement.

### Section-by-Section Analysis

Section 3 of the Policy Statement provides that banks should use liquidity risk management processes and systems that are commensurate with the bank's complexity, risk profile, and scope of operations. In addition, banks' processes and plans should be well documented and available for supervisory review.

Section 6 of the Policy Statement provides that a bank's liquidity management process should be sufficient to meet its daily funding

needs and cover both expected and unexpected deviations from normal operations. Accordingly, banks should have a comprehensive management process for identifying, measuring, monitoring, and controlling liquidity risk, which should be fully integrated into the bank's risk management processes. Section 6 of the Policy Statement also describes the following critical elements of sound liquidity risk management:

- Effective corporate governance consisting of oversight by the board of directors and active involvement by management in a bank's control of liquidity risk.
- Appropriate strategies, policies, procedures, and limits used to manage and mitigate liquidity risk.
- Comprehensive liquidity risk measurement and monitoring systems (including assessments of the current and prospective cash flows or sources and uses of funds) that are commensurate with the complexity and business activities of the bank.
- Active management of intraday liquidity and collateral.
- An appropriately diverse mix of existing and potential future funding sources.
- Adequate levels of highly liquid marketable securities free of legal, regulatory, or operational impediments, that can be used to meet liquidity needs in stressful situations.
- CFPs that sufficiently address potential adverse liquidity events and emergency cash flow requirements.
- Internal controls and internal audit processes sufficient to determine the adequacy of the bank's liquidity risk management process.

Section 7 of the Policy Statement provides that a bank's board of directors or its delegated committee should oversee the establishment and approval of liquidity management strategies, policies and procedures, and review them at least annually. In addition, the board should ensure that it understands and periodically reviews the bank's CFPs for handling potential adverse liquidity events.

Section 9 of the Policy Statement provides that a bank's senior management should determine the structure, responsibilities, and controls for managing liquidity risk and for overseeing the liquidity positions of the bank. These elements should be clearly documented in liquidity risk policies and procedures. For institutions comprised of multiple entities, such elements should be fully specified and documented in policies for each material legal entity and subsidiary. Senior management should be able to

monitor liquidity risks for each entity across the institution on an ongoing basis. Processes should be in place to ensure that the group's senior management is actively monitoring and quickly responding to all material developments and reporting to the boards of directors as appropriate.

Section 11 of the Policy Statement provides that banks should have documented strategies for managing liquidity risk and clear policies and procedures for limiting and controlling risk exposures that appropriately reflect the bank's risk tolerances. The strategies should identify primary sources of funding for meeting daily operating cash outflows, as well as seasonal and cyclical cash flow fluctuations. Strategies should also address alternative responses to various adverse business scenarios. Policies and procedures should provide for the formulation of plans and courses of actions for dealing with potential temporary, intermediate-term, and long-term liquidity disruptions. Policies, procedures, and limits also should address liquidity separately for individual currencies, legal entities, and business lines, when appropriate and material, and should allow for legal, regulatory, and operational limits for the transferability of liquidity as well.

Section 12 of the Policy Statement states that a bank's policies should clearly articulate a liquidity risk tolerance that is appropriate for the business strategy of the bank considering its complexity, business mix, liquidity risk profile, and its role in the financial system. Policies should also contain provisions for documenting and periodically reviewing assumptions used in liquidity projections. Policy guidelines should employ both quantitative targets and qualitative guidelines.

Section 13 of the Policy Statement provides that a bank's policies should specify the nature and frequency of management reporting. Senior managers should receive liquidity risk reports at least monthly, while the board of directors should receive liquidity risk reports at least quarterly. Management reporting may need to be more frequent, depending on the complexity of the bank's business mix and liquidity risk profile. Regardless of an institution's complexity, it should have the ability to increase the frequency of reporting on short notice, if the need arises. Liquidity risk reports should impart to senior management and the board a clear understanding of the bank's liquidity risk exposure, compliance with risk limits, consistency between management's strategies and tactics, and

<sup>1</sup> 75 FR 13656 (March 22, 2010). The former Office of Thrift Supervision, which merged with the OCC on July 21, 2011, was also involved in issuing the Policy Statement.

<sup>2</sup> For national banks and Federal savings associations, refer to the *Comptroller's Handbook on Liquidity*.

<sup>3</sup> See OCC Bulletin 2023–25, "Liquidity: Addendum to the Interagency Policy Statement on Funding and Liquidity Risk Management" (July 28, 2023), <https://www.occ.gov/news-issuances/bulletins/2023/bulletin-2023-25.html>.

consistency between these strategies and the board's expressed risk tolerance.

Section 14 of the Policy Statement provides that banks should consider liquidity costs, benefits, and risks in strategic planning and budgeting processes. Significant business activities should be evaluated for liquidity risk exposure as well as profitability. More complex and sophisticated banks should incorporate liquidity costs, benefits, and risks in the internal product pricing, performance measurement, and new product approval process for all material business lines, products, and activities. Incorporating the cost of liquidity into these functions should align the risk-taking incentives of individual business lines with the liquidity risk exposure their activities create for the bank as a whole. The quantification and attribution of liquidity risks should be explicit and transparent at the line management level and should include consideration of how liquidity would be affected under stressed conditions.

Section 15 of the Policy Statement provides that the process for measuring liquidity risk should include robust methods for comprehensively projecting cash flows arising from assets, liabilities, and off-balance-sheet items over an appropriate set of time horizons. Banks should ensure that the assumptions used are reasonable, appropriate, and adequately documented. Banks should periodically review and formally approve these assumptions.

Section 18 of the Policy Statement provides that banks should conduct stress tests regularly for a variety of bank-specific and market-wide events across multiple time horizons. The magnitude and frequency of stress testing should be commensurate with the complexity of the bank and the level of its risk exposures. Stress test outcomes should be used to identify and quantify sources of potential liquidity strain and to analyze possible impacts on the bank's cash flows, liquidity position, profitability, and solvency. Stress tests should also be used to ensure that current exposures are consistent with the bank's established liquidity risk tolerance. The results of stress tests should also play a key role in shaping the bank's contingency planning.

Section 20 of the Policy Statement states that liquidity risk reports should provide aggregate information with sufficient supporting detail to enable management to assess the sensitivity of the bank to changes in market conditions, its own financial performance, and other important risk

factors. Banks also should report on the use and availability of government support, such as lending and guarantee programs, and implications on liquidity positions, particularly since these programs are generally temporary or reserved as a source for contingent funding.

Section 23 of the Policy Statement provides that liquidity risk management plans should describe assumptions regarding the transferability of funds and collateral.

Section 24 of the Policy Statement provides that senior management should develop and adopt an intraday liquidity strategy that allows the bank to:

- Monitor and measure expected daily gross liquidity inflows and outflows;
- Manage and mobilize collateral when necessary to obtain intraday credit;
- Identify and prioritize time-specific and other critical obligations in order to meet them when expected;
- Settle other less critical obligations as soon as possible;
- Control credit to customers when necessary; and
- Ensure that liquidity planners understand the amounts of collateral and liquidity needed to perform payment-system obligations when assessing the organization's overall liquidity needs.

Section 25 of the Policy Statement provides that a bank should establish a funding strategy that provides effective diversification in the sources and tenor of funding.

Section 31 of the Policy Statement provides additional guidance concerning the CFP, as described in section 6. The section provides that all banks, regardless of size and complexity, should have a formal CFP that clearly sets out the strategies for addressing liquidity shortfalls in emergency situations. A CFP should delineate policies to manage a range of stress environments, establish clear lines of responsibility, and articulate clear implementation and escalation procedures. It should be regularly tested and updated to ensure that it is operationally sound. Sections 34, 35, and 37 of the Policy Statement include additional guidance concerning CFPs.

Section 34 of the Policy Statement provides that CFPs should be revised to reflect macroeconomic and bank-specific conditions.

Section 35 of the Policy Statement provides that the CFP should identify stress events, assess levels of severity and timing, assess funding sources and needs, identify potential funding

sources, establish liquidity event management processes, and establish a monitoring framework for contingent events.

Section 36 of the Policy Statement provides that smaller banks should have plans in place for managing press inquiries that may arise during a liquidity event.

Section 41 of the Policy Statement provides that a bank's internal controls should address relevant elements of the risk management process, including adherence to policies and procedures, the adequacy of risk identification, risk measurement, reporting, and compliance with applicable rules and regulations.

Section 42 of the Policy Statement provides that management should ensure that an independent party regularly reviews and evaluates the various components of the bank's liquidity risk management process. These reviews should assess the extent to which the bank's liquidity risk management complies with both supervisory guidance and industry sound practices, taking into account the level of sophistication and complexity of the bank's liquidity risk profile. Smaller, less-complex banks may achieve independence by assigning this responsibility to the audit function or other qualified individuals independent of the risk management process.

The Addendum to the Policy Statement provides that banks should be aware of the operational steps required to obtain funding from contingency funding sources, including potential counterparties, contact details, and availability of collateral. In addition, banks should:

- Regularly test any contingency borrowing lines to ensure the bank's staff are well versed in how to access them and that they function as envisioned;
- Engage in planning that recognizes the operational challenges involved in moving and posting collateral to access critical funding in a timely fashion;
- Ensure that the CFPs recognize that during times of stress, contingency lines may become unavailable and include a range of contingency funding sources;
- Review and revise the CFPs periodically and more frequently as market conditions and strategic initiatives change in order to address evolving liquidity risks; and
- Incorporate the discount window as part of their contingency funding arrangements. If the discount window is included in the bank's CFP, establish and maintain operational readiness to borrow from the discount window.

*Estimated Burden:*

*Estimated Frequency of Response:* On occasion.

*Estimated Number of Respondents:* Liquidity Risk Management Policies, Procedures, Assumptions, and Contingency Funding Plans-Implementation of recordkeeping 8; Liquidity Risk Management Policies, Procedures, Assumptions, and Contingency Funding Plans-Ongoing recordkeeping 979.

*Estimated Total Annual Burden:* 31,648 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

**Patrick T. Tierney,**

*Assistant Director, Office of the Comptroller of the Currency.*

[FR Doc. 2025-09619 Filed 5-28-25; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Interagency Statement on Complex Structured Finance Transactions

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

**ACTION:** Notice and request for comment.

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or

sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, "Interagency Statement on Complex Structured Finance Transactions." The OCC also is giving notice that it has sent the collection to OMB for review.

**DATES:** Comments must be received by June 30, 2025.

**ADDRESSES:** Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email:* [prainfo@occ.treas.gov](mailto:prainfo@occ.treas.gov).
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557-0229, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.
- *Fax:* (571) 293-4835.

*Instructions:* You must include "OCC" as the agency name and "1557-0229" in your comment. In general, the OCC will publish comments on [www.reginfo.gov](http://www.reginfo.gov) without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). You can find this information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to [www.reginfo.gov](http://www.reginfo.gov). Hover over the "Information Collection Review" tab and click on "Information Collection Review" from the drop-down menu. From the "Currently under Review"

drop-down menu, select "Department of Treasury" and then click "submit." This information collection can be located by searching OMB control number "1557-0229" or "Interagency Statement on Complex Structured Finance Transactions." Upon finding the appropriate information collection, click on the related "ICR Reference Number." On the next screen, select "View Supporting Statement and Other Documents" and then click on the link to any comment listed at the bottom of the screen.

- For assistance in navigating [www.reginfo.gov](http://www.reginfo.gov), please contact the Regulatory Information Service Center at (202) 482-7340.

**FOR FURTHER INFORMATION CONTACT:** Shaquita Merritt, Clearance Officer, (202) 649-5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks the OMB to extend its approval of the collection in this notice.

*Title:* Interagency Statement on Complex Structured Finance Transactions.

*OMB Control No.:* 1557-0229.

*Type of Review:* Regular.

*Affected Public:* Businesses or other for-profit.

*Description:* The Interagency Statement on Complex Structured Finance Transactions<sup>1</sup> describes the types of internal controls and risk management procedures that the agencies (OCC, Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, and the Securities and Exchange Commission) consider particularly effective in helping financial institutions identify and address certain risks associated with complex structured finance transactions. Those internal controls and risk management procedures form the basis of this information collection.

*Estimated Burden:*

*Estimated Frequency of Response:* On occasion.

<sup>1</sup> 72 FR 1372 (January 11, 2007).

*Estimated Number of Respondents:* 9.  
*Estimated Total Annual Burden:* 225 hours.

*Comments:* On March 13, 2025, the OCC published a 60-day notice for this information collection, 90 FR 12032. No comments were received.

Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

**Patrick T. Tierney,**

*Assistant Director, Office of the Comptroller of the Currency.*

[FR Doc. 2025-09691 Filed 5-28-25; 8:45 am]

**BILLING CODE 4810-33-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Agency Collection Activities; Requesting Comments on Form 1099-CAP

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

**DATES:** Written comments should be received on or before July 28, 2025 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to [pra.comments@irs.gov](mailto:pra.comments@irs.gov). Include OMB Control No. 1545-1814 in the subject line of the message.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620-2128.

**SUPPLEMENTARY INFORMATION:** The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. 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: (a) 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; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) 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 (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

*Title:* Changes in Corporate Control and Capital Structure.

*OMB Number:* 1545-1814.

*Form Number:* 1099-CAP.

*Abstract:* A corporation whose control was acquired or who underwent a substantial change in capital structure uses Form 1099-CAP if it determines the shareholders may have to recognize gain from the cash, stock, or other property they received in exchange for the corporation's stock.

*Current Actions:* There are no changes being made to the form at this time. However, the agency is updating the estimated number of responses based on the most recent filing data.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations, and individuals.

*Estimated Number of Responses:* 300.

*Estimated Time per Respondent:* 11 minutes.

*Estimated Total Annual Burden Hours:* 54.

Dated: May 22, 2025.

**Jason M. Schoonmaker,**  
*Tax Analyst.*

[FR Doc. 2025-09668 Filed 5-28-25; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Agency Collection Activities; Requesting Comments on Form 911

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

**DATES:** Written comments should be received on or before July 28, 2025 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to [pra.comments@irs.gov](mailto:pra.comments@irs.gov). Include OMB Control No. 1545-1504 in the subject line of the message.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620-2128.

**SUPPLEMENTARY INFORMATION:** The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. 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: (a) 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; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) 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 (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

*Title:* Request for Taxpayer Advocate Service Assistance (And Application for Taxpayer Assistance Order).

OMB Number: 1545–1504.

Form Number: 911.

**Abstract:** Form 911 is used by taxpayers to apply for relief from a significant hardship which may have already occurred or is about to occur if the IRS takes or fails to take certain actions. This form is submitted to the IRS Taxpayer Advocate Office in the state or city where the taxpayer resides.

**Current Actions:** There is no change to the existing collection.

**Type of Review:** Extension of a currently approved collection.

**Affected Public:** Individuals or households, business or other for-profit organizations, not-for-profit institutions, farms, and state, local or tribal governments.

**Estimated Number of Responses:** 93,000.

**Estimated Time per Respondent:** 30 minutes.

**Estimated Total Annual Burden Hours:** 46,500.

Dated: May 22, 2025.

**Jason M. Schoonmaker,**

*Tax Analyst.*

[FR Doc. 2025–09675 Filed 5–28–25; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0822]

### Agency Information Collection

#### Activity: Camp Lejeune Family Member Program—Reimbursement of Certain Medical Expenses

**AGENCY:** Veterans Health

Administration, Department of Veterans Affairs.

**ACTION:** Notice.

#### SUMMARY:

Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved

collection, and allow 60 days for public comment in response to the notice.

**DATES:** Comments must be received on or before July 28, 2025.

**ADDRESSES:** Comments must be submitted through [www.regulations.gov](http://www.regulations.gov).

#### FOR FURTHER INFORMATION CONTACT:

**Program-specific information:**

Rebecca Mimmall, 202–695–9434, [vhacopra@va.gov](mailto:vhacopra@va.gov).

**VA PRA information:** Dorothy Glasgow, 202–461–1084, [VAPRA@va.gov](mailto:VAPRA@va.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

**Title:** Camp Lejeune Family Member Program—Reimbursement of Certain Medical Expenses (VA Forms 10–10068, 10–10068a, 10–10068b and 10–10068c).

**OMB Control Number:** 2900–0822.  
<https://www.reginfo.gov/public/do/PRAsearch> (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection.)

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

**Abstract:** Pursuant to 38 U.S.C. 1787, VA is required to furnish hospital care and medical services to the family members of certain veterans who were stationed at Camp Lejeune between 1953 and 1987 and have specified medical conditions. The specific

hospital care and medical services that VA must provide are for a number of illnesses and conditions connected to exposure to contaminated drinking water while at Camp Lejeune. In order to furnish such care, VA must collect necessary information from the family members to ensure that they meet the requirements of the law.

The forms in this collection are VA Form 10–10068—Application, VA Form 10–10068a—Claim Form, VA Form 10–10068b—Treating Physician Report, and VA Form 10–10068c—Information Update Form. These forms will be used to determine eligibility and reimbursement for the covered medical care. Some minor changes to the wording in VA Form 10–10068b have been made to clarify the information being collected from the treating physician. There are no changes to the estimated numbers of respondents and burden hours.

**Affected Public:** Individuals or Households.

**Estimated Annual Burden:** Total hours = 5,838 hours.

10–10068—815 hours.

10–10068a—4,480 hours.

10–10068b—407 hours.

10–10068c—136 hours.

**Estimated Average Burden per Respondent:**

10–10068—30 minutes.

10–10068a—15 minutes.

10–10068b—15 minutes.

10–10068c—15 minutes.

**Frequency of Response:**

10–10068—Once annually.

10–10068a—11 times per year.

10–10068b—Once annually.

10–10068c—Once annually.

**Estimated Number of Respondents:**  
Total Respondents = 21,720.

10–10068—1,629.

10–10068a—17,919.

10–10068b—1,629.

10–10068c—543.

**Authority:** 44 U.S.C. 3501 *et seq.*

**Lanea Haynes,**

*Acting, VA PRA Clearance Officer, (Alt.) Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.*

[FR Doc. 2025–09588 Filed 5–28–25; 8:45 am]

**BILLING CODE 8320–01–P**



# FEDERAL REGISTER

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Vol. 90

Thursday,

No. 102

May 29, 2025

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## Part II

### The President

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Presidential Determination No. 2025-04 of May 12, 2025—Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012

Proclamation 10943—National Physical Fitness and Sports Month, 2025

Proclamation 10944—World Trade Week, 2025

Proclamation 10945—Prayer for Peace, Memorial Day, 2025



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**Presidential Documents**

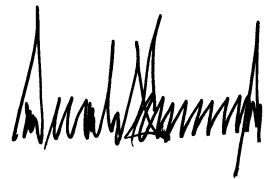
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**Title 3—****Presidential Determination No. 2025–04 of May 12, 2025****The President****Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012****Memorandum for the Secretary of State[,] the Secretary of the Treasury[, and] the Secretary of Energy**

By the authority vested in me as President by the Constitution and the laws of the United States, after carefully considering the reports submitted to the Congress by the Energy Information Administration, including the report submitted in February 2025, and other relevant factors, including global economic conditions, the level of spare capacity, and the availability of strategic reserves, I determine, pursuant to section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112–81, and consistent with prior determinations, that there is a sufficient supply of petroleum and petroleum products from countries other than Iran to permit a significant reduction in the volume of petroleum and petroleum products purchased from Iran by or through foreign financial institutions.

I will continue to monitor this situation closely.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,  
*Washington, May 12, 2025*

## Presidential Documents

Proclamation 10943 of May 24, 2025

### National Physical Fitness and Sports Month, 2025

By the President of the United States of America

#### A Proclamation

During National Physical Fitness and Sports Month, we celebrate the foundational role that physical fitness and sports play in helping us to live longer, healthier, and more fulfilling lives. Through sports, fitness routines, and staying active, we have the opportunity to improve our health, strengthen our communities, and build a brighter future for our country.

For far too long, our Nation has failed to prioritize the health and well-being of the American people. This negligence has come at a devastating cost. As a result, the United States lags behind other developed countries in life expectancy, chronic disease prevention, and overall public health outcomes.

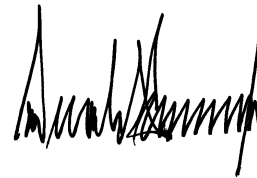
This era of indifference ended when I took office. I was proud to appoint Robert F. Kennedy, Jr. as the Secretary of Health and Human Services to urgently confront and stop this crisis. I also established the Make America Healthy Again Commission, tasked with ensuring Americans have access to nutritious food choices, while addressing the root causes of childhood chronic diseases. With public health as a cornerstone of my Administration, we are forging a future where the American people are healthier and stronger than ever before.

Engagement and active participation in sports, especially among our youth, is vital to fostering a culture of health and physical fitness. My Administration is committed to ensuring that our sports and competitive spaces remain safe, free, and accessible for future generations of Americans. In my first term, I signed an Executive Order to nationally expand children's participation in sports, promoting physical activity, fitness, and the academic and social benefits of healthy lifestyles. I was also proud to recently sign an Executive Order to keep biological men out of women's sports, ensuring our female athletes are free to compete and excel on a level and fair playing field.

Together, we are building a healthier and more flourishing Nation, one that champions physical fitness and well-being, empowering every citizen to reach their full potential and excel in all aspects of life.

NOW, THEREFORE, I, DONALD J. TRUMP, 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 May 2025 as National Physical Fitness and Sports Month. I call upon the people of the United States to incorporate physical fitness and sports participation into their everyday lives.

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

A handwritten signature in black ink, appearing to be a stylized name, possibly "Donald Trump", written in a cursive script.

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## Presidential Documents

**Proclamation 10944 of May 24, 2025**

### **World Trade Week, 2025**

**By the President of the United States of America**

#### **A Proclamation**

This World Trade Week, we reaffirm our commitment to balanced and reciprocal trade with the world. For far too long, globalist elites sold out the American worker and let other countries unfairly take our factories, our jobs, and our dreams. Those days are over. America will not be treated unfairly or disrespected. The United States, and the American worker, will be put first.

While seeking this office, I called for a future that protects the American worker. A future that puts American workers' dreams over corporate profits. A future that raises American wages, strengthens American industry, builds national pride, and defends this country's national interests.

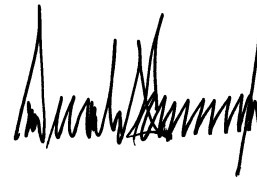
My Administration is delivering that future. Since assuming office, I have taken action to provide a better life for all Americans and especially the millions of Americans left by the wayside as jobs were shipped overseas. I have enacted reciprocal tariffs to stop the hollowing out of American manufacturing and to bring vital jobs back to America. I have enacted tariffs to stop the flow of fentanyl into America, so that our citizens are not poisoned by the hands of foreign countries. And to prepare for the influx of jobs and manufacturing that is returning to America, I have prioritized initiatives for Americans to be trained for the jobs of the future, not the past. These are just a few actions among many meant to benefit the American worker. But the point is simple: The goal of my Administration is for our American workers and their children to have better lives. My Administration is taking action to achieve our goal.

For these reasons, during World Trade Week, we commit to redoubling our efforts to combat unfair trade practices for every American, from farmers and fishermen to entrepreneurs and everyone in between. We commit to bringing jobs back home and advancing opportunities for American businesses to compete abroad through new trade deals like the recent United States-United Kingdom trade agreement.

As President, I will always place the interests of America first. Together, we will build a new Golden Age for America with strong economic growth and America First trade policies that protect our workers, strengthen our industries, and unlock the American Dream for every citizen.

NOW, THEREFORE, I, DONALD J. TRUMP, 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 May 18 through May 24, 2025, as World Trade Week. Let's celebrate the benefits of American trade.

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

A handwritten signature in black ink, appearing to be a stylized name, possibly "Donald Trump", written in a cursive script.

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## Presidential Documents

**Proclamation 10945 of May 24, 2025**

**Prayer for Peace, Memorial Day, 2025**

**By the President of the United States of America**

### **A Proclamation**

Memorial Day is a sacred day of remembrance, reverence, and gratitude for the brave patriots who have laid down their lives in service to our great Nation. Throughout our history, brave men and women have been called to defend the cause of liberty on foreign shores in defense of our homeland. Their noble sacrifices are marked by flag-draped coffins and the silent sorrows of those left behind. We must never forget those who have given everything for our country.

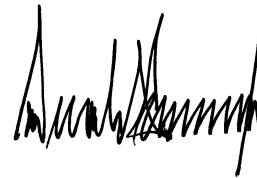
America's Gold Star Families—whose sons, daughters, wives, and husbands are among the honored—endure unfathomable heartache. Their loved ones selflessly gave everything to protect our sovereignty. They have our unwavering support, deepest gratitude, and highest respect. The lives lost in war serve as a solemn reminder of why we must pursue peace through strength.

We are eternally indebted to our Nation's fallen heroes. On this solemn day, as we honor their sacrifice, the First Lady and I ask all citizens to join us in prayer that Almighty God may comfort those who mourn, grant protection to all who serve, and bring blessed peace to the world.

In honor of all of our fallen heroes, the Congress, by a joint resolution approved May 11, 1950, as amended (36 U.S.C. 116), has requested the President issue a proclamation calling on the people of the United States to observe each Memorial Day as a day of prayer for permanent peace and designating a period on that day when the people might unite in prayer. The Congress, by Public Law 106–579, has also designated 3:00 p.m. local time on that day as a time for all Americans to observe, in their own way, the National Moment of Remembrance.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim Memorial Day, May 26, 2025, as a day of prayer for permanent peace, and I designate the hour beginning in each locality at 11:00 a.m. of that day as a time when people might unite in prayer. I ask all Americans to observe the National Moment of Remembrance beginning at 3:00 p.m. local time on Memorial Day. I also request the Governors of the United States and its Territories, and the appropriate officials of all units of government, to direct that on Memorial Day the flag be flown at half-staff until noon on all buildings, grounds, and naval vessels throughout the United States and in all areas under its jurisdiction and control. I also request citizens to display the flag at half-staff from their homes for the customary forenoon period.

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

A handwritten signature in black ink, appearing to be a stylized name with a prominent initial.

# Reader Aids

Federal Register

Vol. 90, No. 102

Thursday, May 29, 2025

## CUSTOMER SERVICE AND INFORMATION

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