

Conclusion

This notice of intent initiates a temporary scheduling process and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule cyclopropyl fentanyl in Schedule I of the CSA, and finds that placement of this synthetic opioid into Schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of cyclopropyl fentanyl into Schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before December 21, 2017. Because the Administrator hereby finds that it is necessary to temporarily place cyclopropyl fentanyl into Schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling this substance will be effective on the date that order is published in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the temporary order, cyclopropyl fentanyl will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a Schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial

review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action 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. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(22) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(22) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: cyclopropyl fentanyl) . . . (9845)

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Dated: November 13, 2017.

Robert W. Patterson,
Acting Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0994]

RIN 1625-AA00

Safety Zone; Spa Creek, Annapolis, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for certain waters of Spa Creek. This action is necessary to provide for the safety of life on navigable waters during a fireworks display in Anne Arundel County at Annapolis, MD, on December 31, 2017. This proposed rulemaking would prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 28, 2017.

ADDRESSES: You may submit comments identified by docket number USCG-2017-0994 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ronald Houck, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410-576-2674, email Ronald.L.Houck@uscg.mil.

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

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

II. Background, Purpose, and Legal Basis

The City of Annapolis, MD, notified the Coast Guard that it will be conducting an aerial fireworks display at 11:55 p.m. on December 31, 2017. The fireworks display will be conducted by Pyrotecnico of New Castle, PA, and launched from a barge located in Spa Creek, in Anne Arundel County at Annapolis, MD. There is no rain date planned for this fireworks display. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) has determined that these potential hazards would be a

safety concern for anyone within 133 yards of the fireworks discharge barge.

This rule involves the City of Annapolis New Year’s Eve fireworks display, an event that takes place in Annapolis, MD. A permanent safety zone for fireworks in Annapolis on December 31st is at 33 CFR 165.506. However, due to a change in size and location of the regulated area, the event this year is changed to approximately 700 yards west and its size is reduced to 133 yards. The proposed temporary safety zone will include all waters of Spa Creek within 133 yards of the fireworks barge in approximate position latitude 38°58’33.01” N., longitude 076°28’58.00” W.; the event date remains unchanged.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within 133 yards of the barge before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 11 p.m. on December 31, 2017 through 1 a.m. on January 1, 2018. The safety zone would include all navigable waters of Spa Creek, within 133 yards of the fireworks barge in approximate position latitude 38°58’33.01” N., longitude 076°28’58.00” W., located at Annapolis, MD. The duration of the safety zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 11:55 p.m. fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

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 and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive

Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the duration, time-of-year, and time-of-day of the safety zone. Although vessel traffic would not be able to safely transit around this safety zone, the impact would be for only 2 hours during the late evening when vessel traffic in Spa Creek is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone.

B. Impact on Small Entities

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this 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 rule 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 rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact 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 would 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 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 would 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 contact 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 would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, 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 less than 2 hours that would prohibit entry within 133 yards of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.ID. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

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.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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 proposes 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: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0994 to read as follows:

§ 165.T05–0994 Safety Zone; Spa Creek, Annapolis, MD.

(a) *Definitions.* As used in this section:

Captain of the Port means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Maryland-National Capital Region to assist in enforcing the safety zone described in paragraph (b) of this section.

(b) *Location.* The following area is a safety zone: All navigable waters of Spa Creek, within 133 yards of a fireworks barge in approximate position latitude 38°58'33.01" N., longitude 076°28'58.00" W., located at Annapolis, MD. All coordinates refer to North American Datum 83 (NAD 1983).

(c) *Regulations.* The general safety zone regulations found in 33 CFR 165 subpart C apply to the safety zone created by this section.

(1) All persons are required to comply with the general regulations governing safety zones found in 33 CFR 165.23.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Captain of the Port (COTP) or designated representative. All vessels underway within this safety zone at the time it is implemented are to depart the zone.

(3) Persons desiring to transit the area of the safety zone must first obtain authorization from the COTP or designated representative. To request permission to transit the area, the COTP and or designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine

Band Radio VHF-FM channel 16 (156.8 MHz). If permission is granted, persons and vessels must comply with the instructions of the COTP or designated representative and proceed as directed while within the zone.

(4) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(d) *Enforcement period.* This section will be enforced from 11 p.m. on December 31, 2017 through 1 a.m. on January 1, 2018.

Dated: November 15, 2017.

L.P. Harrison, Jr.,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2017-25125 Filed 11-20-17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2016-0442; FRL-9971-03-OAR]

RIN 2060-AS92

National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry; Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of data availability.

SUMMARY: The Environmental Protection Agency (EPA) is issuing this notice of data availability (NODA) in support of the proposed rule titled “National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry; Residual Risk and Technology Review,” which was published on September 21, 2017. In this document, the EPA is soliciting public comment on information added to the docket (EPA-HQ-OAR-2016-0442) on November 3, 2017.

DATES: Comments must be received on or before December 4, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2016-0442, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information

you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Mr. Brian Storey, Sector Policies and Programs Division (D243-04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-1103; fax number: (919) 541-4991; and email address: storey.brian@epa.gov.

SUPPLEMENTARY INFORMATION:

Organization of This Document. The information presented in this document is organized as follows:

- I. Background
- II. Purpose of the NODA

I. Background

On September 21, 2017, the EPA proposed amendments to the National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry to address the results of the residual risk and technology review (RTR) in accordance with section 112 of the Clean Air Act (CAA). The proposed rule indicated that the EPA found risks due to emissions of air toxics to be acceptable from this source category, and identified no cost-effective controls under the technology review to achieve further emissions reductions. In addition, the proposed rule included amendments to correct and clarify rule testing and monitoring provisions. In support of the proposed rule, the EPA posted over 160 documents to the docket to allow the public to provide comment on the rule and on documents used to develop the rule, in accordance with section 307(d) of the CAA. The subject matter of these docketed items included various correspondence with stakeholders, summary of meeting minutes, and technical memoranda related to the risk assessment and technology review process.

II. Purpose of the NODA

On November 1, 2017, the EPA became aware that two memoranda prepared to support the September 21, 2017, proposed rule were inadvertently omitted from the docket. The subject of the two memoranda are “Development of the RTR Risk Modeling Dataset for the Portland Cement Manufacturing Source Category,” and “Technology Review for the Portland Cement Production Source Category.”

The purpose of the memorandum with the subject title of “Development of the RTR Risk Modeling Dataset for the Portland Cement Manufacturing Source Category” is to document the technical approach and rationale used to develop the risk modeling input data used to perform the residual risk assessment, pursuant to section 112(f) of the CAA. It includes discussions of the methods used to develop a list of facilities subject to the source category; the development of actual, acute, and allowable emissions datasets; and discussions of how stack parameter data and stack locations were derived. The memorandum was actually included in the docket as Appendix 1 of the document, “Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the September 2017 Risk and Technology Review Proposed Rule.” This document was posted to the docket prior to publication of the proposed rule as Docket Item No. EPA-HQ-OAR-2016-0442-0153. However, we also intended to include this memorandum as a stand-alone document.

The purpose of the memorandum with the subject title of “Technology Review for the Portland Cement Production Source Category” is to provide a summary of the methods used to determine what, if any, new developments in practices, processes, and control technologies exist for the Portland Cement Manufacturing source category to support our proposed determination regarding whether revisions to the rule are warranted under section 112(d)(6) of the CAA. The information provided by this memorandum was summarized in the preamble of the September 21, 2017, proposed rule.

The EPA recognizes the importance of these two documents, and posted both documents to the docket on November 3, 2017. The docket item numbers are EPA-HQ-OAR-2016-0442-0188 for “Development of the RTR Risk Modeling Dataset for the Portland Cement Manufacturing Source Category” and EPA-HQ-OAR-2016-0442-0189 for “Technology Review for