

compliance dates (Ref. 1). If a contract prevents a co-manufacturer from being able to review a brand owner's documentation of supplier verification activities, the co-manufacturer would not be able to verify suppliers based on its review of that documentation. Consequently, the co-manufacturer would need to conduct supplier verification activities (e.g., on-site audits) that might otherwise not be required.

To provide time for contracts to be revised to allow co-manufacturers to review all necessary documentation from the brand owner, FDA is announcing that, under certain circumstances and on a temporary basis, we do not intend to take enforcement action against a receiving facility that is a co-manufacturer, and that is not in compliance with certain supply-chain program requirements (§§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3)) for food manufactured for the brand owner until November 6, 2019. Furthermore, we do not intend to take enforcement action under the FSVP regulation against an importer who is relying on § 1.502(c)(3) but whose supply-chain program is subject to enforcement discretion regarding §§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3).

The guidance represents 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.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789.

## III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>, <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/default.htm>, or <https://www.regulations.gov>. Use the FDA Web sites listed in the previous sentence to

find the most current version of the guidance.

## IV. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>.

1. Letter from Grocery Manufacturers Association to Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs, February 7, 2017.

Dated: October 31, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[Docket Number USCG–2017–1011]

**RIN 1625–AA00**

### Safety Zone, Delaware River; Pipeline Removal

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety zones in the Mifflin Range on the Delaware River to facilitate pipeline removal in preparation for the deepening of the Delaware River. The safety zones will be established for the waters in the vicinity of the dredge, dredge equipment, dive operations, and pipe removal operations. This regulation is necessary to provide for the safety of life on navigable waters of the Delaware River in the vicinity of pipeline removal operations and to protect mariners from the hazards associated with dredging and pipeline removal operations. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Delaware Bay.

**DATES:** This rule is effective from November 6, 2017, through December 4, 2017.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–1011 in the “SEARCH” box and click “SEARCH.” Click on Open Docket

Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Petty Officer Edmund Ofalt, Waterways Management Branch, U.S. Coast Guard Sector Delaware Bay; telephone (215) 271–4814, email [Edmund.J.Ofalt@uscg.mil](mailto:Edmund.J.Ofalt@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 Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This 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.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule due to the short time period between when Sector Delaware Bay received complete details of this project, October 20, 2017, and the date when these safety zones needed to go into effect by. It is impracticable and contrary to the public interest to publish an NPRM to provide a notice and opportunity for comment period because the safety zones must be established by November 6, 2017 to ensure safety of life on navigable waters in the vicinity of dredging operations, underwater cutting operations, and pipeline removal operations and to protect mariners from hazards associated with the same.

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 impracticable and contrary to the public interest because immediate action is needed to mitigate the hazards presented to safety of life on the Delaware River by the presence of dredge equipment, dredging operations, dive operations, and pipeline removal operations.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port (COTP) Delaware Bay has determined that potential hazards associated with dredging, dive operations, and pipeline removal operations starting November 6, 2017, will be a safety concern for vessels attempting to transit the Delaware River along the Mifflin Range. This rule is needed to protect personnel, vessels, and the marine environment on the navigable waters within the safety zone while dredging, dive operations, and pipeline removal operations are being conducted.

### IV. Discussion of the Rule

This rule establishes two safety zones on a portion of the Mifflin Range, just upriver of the green 63 buoy, in the Delaware River from November 6, 2017, through December 4, 2017, unless cancelled earlier by the COTP, to facilitate dredging, dive operations, and pipeline removal. Dredging operations to expose the pipeline will commence on November 6, 2017. The hopper dredge 549 will be conducting the dredging operations and will be attended by the towing vessel SHELBY. Dive operations will commence approximately one week after the completion of dredging operations and will continue through completion of removal of the pipeline.

Safety zone one includes all navigable waters within 250 yards of the dredge barge 549 and associated pipeline removal equipment, to include any equipment located within Anchorage 9 near the entrance to Mantua Creek found in 33 CFR 110.157(a)(10).

Safety zone two includes all navigable waters within 250 yards of the dive barge 543 and all associated pipeline removal equipment, to include any equipment located within Anchorage 9 near the entrance to Mantua Creek Found in 33 CFR 110.157 (a)(10).

Vessels requesting to transit either safety zone must contact the towing vessel SHELBY on VHF-FM channel 13 or 65, at least 1 hour, as well as 30 minutes prior to arrival to arrange safe passage. Vessels may also contact the COTP for permission to enter or transit either safety zone on VHF-FM channel 16.

### V. Regulatory Analyses

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

#### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule 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 size, location, and duration of the safety zones. Although this regulation will restrict access to regulated areas, the effect of this rule will not be significant because there are a number of alternate anchorages available. Furthermore, vessels may be permitted to transit through the safety zone with the permission of the COTP or make satisfactory passing arrangements with the towing vessel SHELBY in accordance with this rule and the Rules of the Road (33 CFR subchapter E). Extensive notification of the safety zones to the maritime public will be made via maritime advisories allowing mariners to alter their plans accordingly.

#### B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental

jurisdiction and you have questions concerning its provisions or options for compliance, please contact 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

#### 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 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 determined that this action is 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 encompasses all navigable waters within 250 yards of a dredge, diving operations, pipeline removal operations and all associated equipment. It is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

#### 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.

#### 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:** 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.T05-1011, to read as follows:

#### § 165.T05-1011 Safety Zone, Delaware River; Pipeline Removal.

(a) *Location*. The following areas are safety zones:

(1) Safety zone one includes all navigable waters within 250 yards of the dredge barge 549 and associated equipment operating in Mifflin Range and Anchorage 9 near the entrance to Mantua Creek, upriver of green buoy 63, on the Delaware River.

(2) Safety zone two includes all navigable waters within 250 yards of the dive barge 543 and associated equipment operating in Mifflin range and Anchorage 9 near the entrance to Mantua Creek, upriver of green buoy 63, on the Delaware River.

(b) *Definitions*. (1) Captain of the Port means the Commander Sector Delaware Bay or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) Designated representative means any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Delaware Bay, to assist with the enforcement of safety zones described in paragraph (a) of this section.

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

(1) Entry into or transiting within either safety zone is prohibited unless vessels obtain permission from the Captain of the Port via VHF-FM channel 16, or make satisfactory passing arrangements via VHF-FM channels 13 or 65, with the towing vessel SHELBY per this section and the rules of the Road (33 CFR subchapter E). Vessels requesting to transit shall contact the towing vessel SHELBY on channel 13 or 65, at least 1 hour, as well as 30 minutes, prior to arrival.

(2) Vessels granted permission to enter and transit the safety zone must do so in accordance with any directions or orders of the Captain of the Port, his designated representative, or the towing vessel SHELBY. No person or vessel may enter or remain in a safety zone without permission from the Captain of the Port or the towing vessel SHELBY.

(3) At least one side of the main navigational channel will be kept clear for safe passage of vessels.

(4) This section applies to all vessels that intend to transit through the safety zone except vessels that are engaged in the following operations: Enforcement of laws; service of aids to navigation, and emergency response.

(d) *Enforcement periods*. This section will be enforced from November 6, 2017, through December, 4 2017.

Dated: November 1, 2017.

**Scott E. Anderson,**

*Captain, U.S. Coast Guard, Captain of the Port, Delaware Bay.*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R01-OAR-2017-0138; FRL-9970-41-Region 1]

#### Air Plan Approval; New Hampshire; Rules for Open Burning and Incinerators; Withdrawal of Direct Final Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Withdrawal of direct final rule.

**SUMMARY:** Due to the receipt of an adverse comment, the Environmental Protection Agency (EPA) is withdrawing the September 6, 2017 direct final rule approving a State Implementation Plan (SIP) revision submitted by the State of New Hampshire. New Hampshire's SIP revision establishes emission standards and operating practices for incinerators and wood waste burners that are not regulated pursuant to federal incinerator standards. This action is being taken in accordance with the Clean Air Act.

**DATES:** The direct final rule was published on September 6, 2017 (82 FR 42037), and is withdrawn effective November 6, 2017.

**FOR FURTHER INFORMATION CONTACT:** Alison Simcox, Air Quality Planning Unit, U.S. Environmental Protection Agency, New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05-2), Boston, MA 02109—3912, telephone (617) 918-1684, facsimile (617) 918-0684, email [simcox.alison@epa.gov](mailto:simcox.alison@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the direct final rule, EPA stated that if adverse comments were submitted by October 6, 2017, the rule would be withdrawn and not take effect. EPA received an adverse comment prior to the close of the comment period and, therefore, is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed rule also published on September 6, 2017 (82 FR 42054). EPA will not institute a second comment period on this action.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide,