

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-2013-N-1425 for “What You Need To Know About the FDA Regulation: Mitigation Strategies to Protect Food Against Intentional Adulteration—Small Entity Compliance Guide.” 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 office between 9 a.m. and 4 p.m., Monday through Friday.

- *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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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 office, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the SECG to the Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-3712.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 27, 2016 (81 FR 34166), we issued a final rule titled “Mitigation Strategies to Protect Food Against Intentional Adulteration” (the final rule) in which we require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. The final rule, which is codified at part 121 (21 CFR part 121), became effective July 26, 2016, but has compliance dates staggered starting 3 years after publication of the final rule.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions

that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG 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. This is not a significant regulatory action subject to Executive Order 12866 and does not impose any additional burden on regulated entities.

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 121 have been approved under OMB control number 0910-0812.

III. Electronic Access

Persons with access to the Internet may obtain the SECG at either <https://www.fda.gov/FoodGuidances>, or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 21, 2017.

Anna K. Abram,

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

[FR Doc. 2017-18028 Filed 8-24-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2017-0317]

Safety Zones; Recurring Annual Events Held in Coast Guard Sector Boston Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce two safety zones within the Captain of the Port Boston zone on August 31, 2017. This action is necessary to ensure the safety of vessels, spectators, and participants from hazards associated with fireworks displays. During the

enforcement period, no person or vessel, except for the safety vessels assisting with the events, may enter the safety zones without permission of the Captain of the Port (COTP) or his designated on-scene representative.

DATES: The regulation in 33 CFR 165.119(a)(2) and (4) will be enforced

during the dates and times in the table displayed in **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Mark Cutter, Sector Boston Waterways Management Division, U.S. Coast Guard; telephone

617-223-4000, email Mark.E.Cutter@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones listed in 33 CFR 165.119(a)(2) and (4) on the specified dates and times as indicated in the following table:

33 CFR 165.119

Name	Location	Date	Time
Long Wharf Safety Zone	All U.S. navigable waters of Boston inner Harbor within a 700-foot radius of the fireworks barge in approximate position 42°21'41.2" N. 071°02'36.5" W. (NAD 1983), located off of Long Wharf, Boston, MA.	August 31, 2017 ...	8 p.m. to 10 p.m.
Pier 6 Safety Zone	All U.S. navigable waters of Boston inner Harbor within a 700-foot radius of the fireworks barge in approximate position 42°21'11.9" N. 071°02'1.3" W. (NAD 1983), located off of Pier 6, South Boston, MA.	August 31, 2017 ...	8 p.m. to 10 p.m.

The final rule establishing these safety zones was published in the **Federal Register** on May 12, 2014 (79 FR 26846).

This notice of enforcement is issued under authority of 33 CFR 165.119 and 5 U.S.C. 552 (a). During the enforcement period, persons and vessels are prohibited from entering into, transiting through, mooring, or anchoring within the safety zone unless they receive permission from the COTP or designated representative. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide mariners with advanced notification of this enforcement period via the Local Notice to Mariners.

Dated: August 21, 2017.

C.C. Gelzer,

Captain, U.S. Coast Guard, Captain of the Port Boston.

[FR Doc. 2017-18030 Filed 8-24-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0811]

RIN 1625-AA00

Safety Zone, Delaware River; Dredging

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; with request for comments.

SUMMARY: The Coast Guard is establishing temporary safety zones in portions of Bellevue Range, Marcus Hook Range, Anchorage 7 off Marcus Hook Range, Chester Range, and Eddystone Range, on the Delaware River, in Philadelphia, PA. The safety zone will temporarily restrict vessel

traffic from transiting or anchoring in a portion of the Delaware River while dredging operations are being conducted to facilitate the Delaware River Main Channel Deepening project for the main navigational channel of the Delaware River. This regulation is necessary to provide for the safety of life on navigable waters of the Delaware River, in the vicinity of dredging activity and is intended to protect mariners from the hazards associated with pipe-laying and dredging operations.

DATES: This rule is effective from August 30, 2017, through March 15, 2018.

ADDRESSES: You may submit comments identified by docket number USCG-2017-0811 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 rulemaking, call or email Petty Officer Amanda Boone, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, telephone (215) 271-4814, email Amanda.N.Boone@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
Pub. L. Public Law
§ Section
U.S.C. United States Code
COTP Captain of the Port

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 because doing so would be impractical and contrary to the public interest. Final details for the dredging operation were not received by the Coast Guard until August 10, 2017. Vessels transiting through Bellevue Range, Chester Range, Eddystone Range, and Marcus Hook Range or attempting to enter the waters of Anchorage 7 off Marcus Hook Range during dredging operations may be at risk. We are taking immediate action to help protect the safety of the project personnel, vessels, and the marine environment on the navigable waters within the safety zones while dredging is being conducted. It is important to have these regulations in effect during dredging operations and it is impracticable to delay the regulations.

We are issuing this rule and, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register** because doing so would be contrary to the public interest. Allowing this dredging operation to go forward without safety zones in place would expose mariners and the public to unnecessary dangers.