

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption—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 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)).

Submit written requests for single copies of the SECG to the Office of Food Safety, Division of Produce Safety (HFS–317), 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: Samir Assar, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 2015 (80 FR 74353), we issued a final rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (produce safety rule). The produce safety rule, which is codified at part 112 (21 CFR part 112), established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. On September 6, 2017 (82 FR 42031) we announced the availability of a guidance for industry entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Small Entity Compliance Guide” to help small entities comply with the produce safety rule.

In the **Federal Register** of May 6, 2024 (89 FR 37448), we issued a final rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” (agricultural water final rule) that revised certain requirements in subpart E of part 112 (21 CFR 112.40 through 112.50) of the produce safety rule applicable to pre-harvest agricultural water for covered produce (other than sprouts). The agricultural water final rule is effective July 5, 2024. The final rule establishes compliance dates for the pre-harvest agricultural water provisions for covered produce (other than sprouts) beginning on April 7, 2025, with date staggering based on farm size.

We examined the economic implications of the agricultural water final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule might 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 explain 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no 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 part 112 have been approved under OMB control number 0910–0816.

III. Electronic Access

Persons with access to the internet may obtain the SECG at either <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: September 19, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21840 Filed 9–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0796]

RIN 1625–AA00

Safety Zone; Allegheny River Mile Marker 0.5 to 0.75, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Allegheny River on September 28, 2024, at mile marker 0.5 to mile marker 0.75 from 8 p.m. through 9:30 p.m. This safety zone is necessary to provide for the safety of life on the navigable waters during a drone display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the

Captain of the Port, Pittsburgh, or a designated representative.

DATES: This rule is effective 8 p.m. through 9:30 p.m. on September 28, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0796 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 Marine Science Technician First Class Brett Lanzel, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 206–815–6624, email Brett.J.Lanzel@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. We must establish this safety zone by September 28, 2024, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this 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 impracticable and contrary to the public interest because action is needed by September 28, 2024, to ensure the safety of life on the navigable waters during the drone display.

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 Pittsburgh (COTP)

has determined that potential hazards associated with a drone show on September 28, 2024, will be a safety concern for anyone on the Allegheny River at mile marker 0.5 to mile marker 0.75 from 8 p.m. to 9:30 p.m. This rule is needed to protect participants, vessels, and the navigable waters in the safety zone, before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 p.m. until 9:30 p.m. on September 28, 2024. The safety zone will cover all navigable waters between mile marker 0.5 to 0.75 on the Allegheny River. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during a drone display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. To seek permission to enter, contact the COTP or designated representative via VHF–FM channel 16, or through Marine Safety Unit Pittsburgh at 206–815–6624. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notice to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on size, location, and duration of the temporary safety zone. This safety zone only impacts a 0.25 mile stretch on the Allegheny River for 90 minutes on September 28, 2024. Moreover, the Coast Guard will issue Local Notice to Mariners and/or Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission from the COTP to transit the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 90 minutes that will prohibit entry within mile marker 0.5 through 0.75 on the Allegheny River. 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.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting, Recordkeeping requirements, and 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.T08–0796 to read as follows:

§ 165.T08–0796 Safety Zone; Allegheny River Mile Marker 0.5 to 0.75, Pittsburgh, PA.

(a) *Location.* The following area is a safety zone: All navigable waters on the Allegheny River between mile marker 0.5 and mile marker 0.75.

(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 Pittsburgh (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 VFH Channel 16, or through Marine Safety Unit Pittsburgh at 206–815–6624. 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 8 p.m. to 9:30 p.m. on September 28, 2024.

Dated: September 18, 2024.

Justin R. Jolley,

Commander, U.S. Coast Guard, Captain of the Port, MSU Pittsburgh.

[FR Doc. 2024–21839 Filed 9–23–24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0806]

RIN 1625–AA00

Safety Zone; Ohio River, New Albany, IN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Ohio River, from Mile Markers 606.5–609.6. The safety zone is needed to ensure the safety of spectators during the Fall Break Blast fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Ohio Valley.

DATES: This rule is effective from 8:30 p.m. to 10:30 p.m. on September 27, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0806 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 Petty Officer Second Class Dalton Johnson, U.S. Coast Guard; telephone 502–779–5334, email SECOHV-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5