

questions and answers on coverage; definitions; *Salmonella* Enteritidis (SE) prevention measures; and environmental sampling for SE. 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.

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued the egg rule requiring shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the egg rule and to register with FDA. The egg rule became effective September 8, 2009, with a compliance date of July 9, 2010, for producers with 50,000 or more laying hens. For producers with fewer than 50,000, but at least 3,000 laying hens, the compliance date was July 9, 2012. Producers with fewer than 3,000 laying hens and those that sell all of their eggs directly to consumers are exempt from requirements in the egg rule. The egg rule is codified at part 118 (21 CFR part 118).

In the **Federal Register** of July 24, 2013 (78 FR 44483), we made available a draft guidance entitled “Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)” and gave interested parties an opportunity to submit comments by September 23, 2013, for us to consider before beginning work on the final version of the guidance. We received more than 3,000 comments on the draft guidance and have modified the content, where appropriate, for this final guidance. In the draft guidance, we indicated that we consider porches to be part of the poultry house because we considered them to be part of a structure used to house poultry. However, comments to the draft guidance indicated that, from a structural perspective, the difference between a porch and an outdoor run (whether an outdoor run-row style or an outdoor run-attached run style) was the presence of a roof, in some cases concrete flooring, and the height of the fence. We considered these comments and upon further analysis determined those differences do not warrant considering one of these systems different from the other two. We have concluded that our initial interpretation did not fully consider how the term “structure” is used within the context of 21 CFR 118.3, particularly with respect to the

goal of housing poultry and considering factors such as protection from the elements and from predation and control of temperature, humidity, and lighting. Accordingly, in this final guidance, we consider a porch to be an area outside the poultry house rather than part of the poultry house. Other changes to the guidance include listing additional guidance documents that egg producers should be aware of, and adding additional references to support the statement that wild birds are common vectors of SE. In addition, we made editorial changes to improve clarity and removed certain recommendations based on practicality. The guidance announced in this notice finalizes the draft guidance dated July 2013.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in part 118 have been approved under OMB control number 0910–0660.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <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: August 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0645]

Special Local Regulation; Olympia Harbor Days Tug Boat Races, Budd Inlet, WA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Olympia Harbor Days Tug Boat Races, Budd Inlet, WA, from 11 a.m. until 4 p.m. on September 3, 2022. This action is necessary to limit vessel movement within the specified race area immediately prior to, during, and immediately after racing activity in order to ensure the safety of participants, spectators, and the maritime public. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.1309 will be enforced from 11 a.m. until 4 p.m. on September 3, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Peter McAndrew, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6051, email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations for the Olympia Harbor Days Tug Boat Races, Budd Inlet, WA regulated area detailed in 33 CFR 100.1309(a), which encompasses approximately 2 nautical miles of the navigable waters in Budd Inlet south of Big Tykle Cove to west of Priest Point.

Under the provisions of 33 CFR 100.1309, the regulated area shall be closed immediately prior to, during, and immediately after the event to all persons and vessels not participating in the event and authorized by the event sponsor. This action is necessary to ensure the safety of participants, spectators, and the maritime public. During the enforcement periods, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign. All persons or vessels who desire to enter the race area while it is enforced must obtain permission from the on-scene patrol craft on VHF–FM channel 13.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to

grant general permission to enter the regulated area.

Dated: August 5, 2022.

P.M. Hilbert,

Captain, U.S. Coast Guard, Captain of the Port, Sector Puget Sound.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0673]

RIN 1625-AA00

Safety Zone; Grosse Pointe Farms Fireworks, Lake St. Clair, Grosse Pointe Farms, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters within Lake St. Clair in Grosse Pointe Farms, MI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards during a fireworks event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Detroit.

DATES: This rule is effective from 9:30 p.m. on September 3, 2022, through 10:30 p.m. on September 4, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0673 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 Ms. Tracy Girard, U.S. Coast Guard; (313) 475-7475, Tracy.M.Girard@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 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 is impracticable. The Coast Guard did not receive notice of the fireworks with sufficient time to undergo notice and comment. We must establish this safety zone by September 3, 2022 in order to protect the public from the hazards associated with a fireworks event.

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 because immediate action is needed to respond to the potential safety hazards associated with a fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Detroit (COTP) has determined that potential hazards associated with fireworks starting September 3, 2022, will be a safety concern for anyone within a 250-yard radius of the fireworks location. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while fireworks show is being displayed.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:30 p.m. through 10:30 p.m. on September 3, 2022. In the case of inclement weather on September 3, 2022, this safety zone will be enforced from 10 p.m. to 10:30 p.m. on September 4, 2022. The safety zone will cover all navigable waters within a 250 yard radius of location 42° 24.51' N 082°52.97' W (WGS 84). The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the fireworks show is being displayed. 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, 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 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, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Lake St. Clair for less than an hour during the night when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter 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