

(6) Physician and patient labeling must include:

(i) A detailed summary of the device's technical parameters;

(ii) Instructions for use, including an explanation of all user-interface components and information regarding proper device placement;

(iii) Information related to electromagnetic compatibility classification;

(iv) Instructions on how to clean and maintain the device;

(v) A summary of the clinical performance testing conducted with the device;

(vi) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device; and

(vii) Information on how the device operates and the typical sensations experienced during treatment.

Dated: February 14, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2022-0126]

RIN 1625-AA00

#### Safety Zone; Coast Guard Island, Alameda, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all waters of the Alameda Estuary, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island in support of a munitions transfer on February 20, 2022. The safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with live munitions. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Francisco.

**DATES:** This rule is effective from 8 a.m. through 2 p.m. on February 20, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0126 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 on this rule, call or email LT Anthony Solares, Sector San Francisco Waterways Safety Management, U.S. Coast Guard; telephone 415-399-3585, email [Anthony.I.Solares@uscg.mil](mailto:Anthony.I.Solares@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  
CGC Coast Guard Cutter

##### 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 munitions must be transferred for operational readiness. It is impracticable to publish an NPRM because we must establish this safety zone by February 20, 2022.

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 the munitions transfer near Alameda, CA beginning February 20, 2022.

##### 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 (COTP) San Francisco has determined that potential hazards associated with the munitions transfer starting February 20, 2022 will be a safety concern for anyone within a 250-foot radius of the pier along the southwest side of Coast Guard Island. This rule is needed to protect personnel, vessels, and the marine environment in

the navigable waters within the safety zone during the munitions transfer.

#### IV. Discussion of the Rule

This rule establishes a safety zone from 8 a.m. until 2 p.m. on February 20, 2022. The safety zone will cover all waters of the Alameda Estuary, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island. The safety zone is necessary to ensure the safety of people, vessels, and the marine environment for the duration of the munitions transfer. 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 would impact a small designated area of the Alameda Estuary for only six hours. The Coast Guard will 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 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 six hours that will prohibit entry within 250 feet of the pier along the southwest side of Coast Guard Island. 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

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:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–089 to read as follows:

### § 165.T11–089 Safety Zone; Safety Zone; Coast Guard Island, Alameda, CA.

(a) *Location.* The following area is a safety zone: All waters of the Alameda Estuary, from surface to bottom, within 250 feet of the pier along the southwest side of Coast Guard Island.

(b) *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 phone at 415–399–3547. 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.

(c) *Enforcement period.* This section will be enforced from 8 a.m. to 2 p.m. on February 20, 2022.

Dated: February 14, 2022.

**Taylor Q. Lam,**

*Captain, U.S. Coast Guard, Captain of the Port San Francisco.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2020–0607; FRL–9454–01–OCSPP]

### Fluopyram; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends tolerances for residues of fluopyram in or on cereal grain crop group 15 (except corn and rice), rapeseed subgroup 20A, and multiple animal commodities, which are identified and discussed later in this document. This regulation also establishes an import tolerance for residues of fluopyram in or on coffee. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).