

3), in a manner that provides for effective monitoring of devices and is beneficial for FDA, industry, and the public. An important part of this voluntary program is providing clarification to manufacturers regarding the product codes eligible for the program.

Consistent with the MDUFA IV Commitment Letter (Ref. 3), FDA has identified eligible product codes for the Voluntary Malfunction Summary Reporting Program in FDA's Product Classification Database, available on FDA's website <https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/voluntary-malfunction-summary-reporting-program>.

Manufacturers that choose to participate in quarterly summary reporting through this program will remain responsible for complying with applicable MDR requirements under part 803 (e.g., requirements to establish and maintain MDR event files under § 803.18) and quality system requirements under part 820 (21 CFR part 820) (e.g., the requirement to evaluate, review, and investigate any complaint that represents an MDR reportable event under § 820.198).

If FDA determines that individual malfunction reports are necessary from a specific manufacturer or for specific devices, FDA will notify relevant manufacturers that they must submit individual reports and provide an explanation for that decision and, as appropriate, the steps necessary to return to summary, quarterly reporting. The Agency also notes that, under § 803.19(d), it may revoke or modify in writing an exemption, variance, or alternative reporting requirement if it determines that revocation or modification is necessary to protect the public health.

V. Updating Product Codes for Inclusion Into the Program

FDA recognizes that new product codes will be created in the future. In general, as explained in the document published in 2018 (83 FR 40973, August 17, 2018), FDA does not intend to consider devices under product codes in existence for fewer than 2 years to be eligible for the program, unless the new product code was issued solely for administrative reasons. However, FDA will periodically evaluate new product codes after they have been in existence for 2 years to determine whether they should be added to the list of product codes eligible for the Voluntary Malfunction Summary Reporting Program. If FDA determines that a new product code should be added, then it

will grant manufacturers of devices within that product code the same alternative under § 803.19 for malfunction events associated with those devices and update FDA's Product Classification database accordingly to reflect the changes.

Manufacturers can send a request for a product code to be added to the list of eligible product codes and for manufacturers of devices within that product code to be granted the same alternative for malfunction events associated with those devices to the MDRPolicy@fda.hhs.gov mailbox.

VI. Conclusion

In accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19(d), FDA is modifying the alternative granted to manufacturers of devices in eligible product codes, as identified in the FDA's Product Classification Database, available on FDA's website <https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/voluntary-malfunction-summary-reporting-program>, for the Voluntary Malfunction Summary Reporting Program. Specifically, we are modifying the malfunction summary reporting format to enhance consistency with the revised Form FDA 3500A and to update FDA references to MDR adverse event codes, as well as to make a few editorial changes for additional clarity. This modification will help ensure the accuracy and consistency of summary malfunction reporting information submitted to FDA and thus help protect the public health.

VII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website

address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA. MedWatch Form FDA 3500A. Available at: <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>.
2. FDA. Electronic Medical Device Reporting (eMDR) website. Available at: <https://www.fda.gov/industry/fda-esubmitter/electronic-medical-device-reporting-emdr>.
3. * FDA. Medical Device User Fee Agreement IV Commitment Letter. Available at: <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>.

Dated: August 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-19414 Filed 8-28-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2024-0559]

RIN 1625-AA00

Safety Zone; West Passage Narragansett Bay, Jamestown, RI

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 250-yard radius of the MARMAC 306 cable laying barge, and a J.F. Brennan construction barge #4132. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by cable laying operations being conducted in the vicinity of the West Passage Narragansett Bay, Jamestown, RI, between the Jamestown Verrazzano Bridge and south to Dutch Island. When enforced, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Southeastern New England.

DATES:

Effective date: This temporary interim rule is effective from 12:01 a.m. on September 1, 2024, through 11:59 p.m. on December 31, 2024. The rule will

only be subject to enforcement while the MARMAC 306 cable laying barge and J.F. Brennan construction barge #4132 are engaged in operations.

Comment date: Comments and related material must be received by the Coast Guard on or before September 30, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0559 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 MST2 Nicholas Easley, Sector Southeastern New England, U.S. Coast Guard; telephone 206–827–4160, email Nicholas.S.Easley@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 COTP Captain of the Port Sector
 Southeastern New England
 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

On May 31, 2024, Orsted, an offshore wind energy developer, made the Coast Guard aware of their plans for cable laying operations associated with the Revolution Wind Farm project in vicinity of West Passage Narragansett Bay, Jamestown, RI, between Jamestown Verrazzano Bridge, and south to Dutch Island. The cable laying operation involves the use of a MARMAC 306 barge and J.F. Brennan construction barge #4132 that will utilize a thruster system and five high tension anchors extending out from each barge to maintain its position. At times the anchor lines may lie just below the surface of the water.

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 doing so would be impracticable and contrary to the public interest. The details of the project were not known to the Coast Guard in sufficient time to publish an

NPRM. Delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect the public and vessels from the hazards associated with the cable laying process. The expeditious implementation of this rule is in the public interest because it will help ensure the safety of personnel, waterway users, and the marine environment.

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 because prompt action is needed to respond to the potential safety hazards associated with the cable installation being conducted by the MARMAC 306 barge and J.F. Brennan construction barge #4132.

We are soliciting comments on this rulemaking. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 46 U.S.C. 70034. The Captain of the Port Sector Southeastern New England (COTP) has determined that potential hazards associated with the cable installation starting on September 1, 2024, will be a safety concern for anyone within a 250-yard radius of the MARMAC 306 barge and J.F. Brennan construction barge #4132. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the cable installation is being conducted.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 12:01 a.m. on September 1, 2024, until 11:59 p.m. on December 31, 2024. While the safety zone will be effective through this period, it will only be enforced during active submerged cable laying operations or other instances which may create a hazard to navigation. The safety zone will cover all navigable waters within 250 yards of the barge MARMAC 306 and J.F. Brennan construction barge #4132 while they are operating in the vicinity of the West Passage Narragansett Bay, Jamestown, RI, between the Jamestown Verrazzano Bridge (41°31’43.7” N 71°24’18.2” W) and south to Dutch Island (41°29’47.3” N, 71°24’16.5” W). During times of

enforcement, all persons or vessels would be prohibited from entering the safety zone without permission from the COTP or a designated representative. If cable laying operations and associated operations are completed before 11:59 p.m. on December 31, 2024, enforcement of the safety zone will be suspended, and notice given via Broadcast Notice to Mariners.

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 the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around the safety zone which would impact a 250-yard radius around the MARMAC 306 and J.F. Brennan construction barge #4132 while engaged in cable laying operations. 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 during the hours of operation of the MARMAC 306 J.F. Brennan construction barge #4132, that will prohibit entry within 250 yards of vessels and machinery being used by personnel to install the cable. It is categorically excluded from further review under paragraph L60a 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.

VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. If we determine that changes to the temporary interim rule are necessary, the Coast Guard will publish a temporary final rule or other appropriate document. If you submit a comment, please include the docket

number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2024–0559 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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, 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.T01–0559 to read as follows:

§ 165.T01–0559 Safety Zone; West Passage Narragansett Bay, Jamestown, RI.

(a) *Location.* The following area is a safety zone: All waters within a 250-yard radius of the MARMAC 306 cable laying barge and J.F. Brennan construction barge #4132 while operating in West Passage Narragansett Bay, Jamestown, RI, between Jamestown Verrazzano Bridge (41°31'43.7" N 71°24'18.2" W) and Dutch Island (41°29'47.3" N, 71°24'16.5" W).

(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 Sector Southeastern New England (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 VHF–FM radio channel 16 or phone at 866–819–9128. 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 is effective from 12:01 a.m. on Sunday, September 1, 2024, through 11:59 p.m. on Tuesday, December 31, 2024. The safety zone described in paragraph (a) of this section will only be subject to enforcement while the MARMAC 306 cable laying barge and J.F. Brennan construction barge #4132 are engaged in cable laying operations.

Y. Moon,

Captain, U.S. Coast Guard, Captain of the Port Sector Southeastern New England.

[FR Doc. 2024–19576 Filed 8–28–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0208; FRL–12187–01–OCSPPI]

Tetraacetylenediamine (TAED), and Its Metabolite Diacetylenediamine (DAED); Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of tetraacetylenediamine (TAED), including its metabolites and degradates, on or applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. This tolerance exemption is established on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), in order to implement the tolerance actions EPA identified during its review of this chemical as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: This regulation is effective August 29, 2024. Objections and requests for hearings must be received on or before October 28, 2024 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0208, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Anita Pease, Antimicrobials Division (7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC

20460–0001; telephone number: (202) 566–0736; email address: pease.anita@epa.gov or ADFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).
- Restaurant kitchen cleaning services (NAICS code 561720).
- Milk production, dairy cattle (NAICS code 112120).
- Food processing machinery and equipment merchant wholesalers (NAICS code 423830).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2023–0208 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk in the Office of the Administrative Law Judges on or before October 28, 2024. Notwithstanding the procedural requirements of 40 CFR 178.25(b), the Office of the Administrative Law Judges has issued an order urging parties to file and serve documents with the Tribunal by electronic means only. See *Revised Order Urging Electronic Filing and Service* (dated June 22, 2023), <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>.