

“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 Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857. 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:**

Stacie Hammack, Food and Feed Laboratory Operations, Office of Regulatory Affairs, Food and Drug Administration, 60 8th Street NE, Atlanta, GA 30309, 301-796-5817.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of December 3, 2021 (86 FR 68728), we issued a final rule establishing a program for the testing of food in certain circumstances by accredited laboratories, as required under the Federal Food, Drug, and Cosmetic Act (the final rule). Establishing this program will help FDA improve the safety of the U.S. food supply and protect U.S. consumers by helping to ensure that certain food testing of importance to public health is conducted subject to appropriate oversight and in accordance with appropriate model standards to produce reliable and valid test results. The final rule, which is codified at 21 CFR part 1, subpart R (21 CFR 1.1101 through 1.1201), became effective February 1, 2022.

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 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (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 21 CFR part 1, subpart R have been approved under OMB control number 0910-0898.

**III. Electronic Access**

Persons with access to the internet may obtain the SECG at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry>, <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: October 14, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-22706 Filed 10-19-22; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG-2022-0867]

RIN 1625-AA00

**Safety Zone; Corpus Christi Shipping Channel, Corpus Christi, TX**

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all navigable waters of the Corpus Christi Shipping Channel in a zone defined by the following coordinates; 27°50′31.28″ N, 97°04′17.23″ W; 27°50′31.73″ N, 97°04′15.44″ W; 27°50′29.06″ N, 97°04′16.61″ W; 27°50′29.32″ N, 97°04′14.82″ W. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by pipelines that will be removed from the floor of the Corpus Christi Shipping Channel. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi or a designated representative.

**DATES:** This rule is effective from 7 p.m. on October 19, 2022, through 5 a.m. on October 22, 2022. For the purposes of enforcement, actual notice will be used from 7 p.m. on October 19, 2022, through October 20, 2022.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Commander Anthony Garofalo, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361-939-5130, email [CCWaterways@uscg.mil](mailto:CCWaterways@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 it is impracticable. We must establish this safety zone immediately to protect personnel, vessels, and the marine environment from potential hazards created by pipeline removal operations and lack sufficient time to provide a reasonable comment period and then to consider those comments before issuing the rule.

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 contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with pipeline removal operations in the Corpus Christi Shipping Channel.

### 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 Sector Corpus Christi (COTP) has determined that potential hazards associated with pipeline removal operations occurring from 7 p.m. on October 19, 2022, through 5 a.m. on October 22, 2022, will be a safety concern for anyone within the Corpus Christi Shipping Channel in a zone defined by the following coordinates; 27°50′31.28″ N, 97°04′17.23″ W; 27°50′31.73″ N, 97°04′15.44″ W; 27°50′29.06″ N, 97°04′16.61″ W; 27°50′29.32″ N, 97°04′14.82″ W. The purpose of this rule is to ensure safety of vessels and persons on these navigable waters in the safety zone while pipelines are removed from the floor of the Corpus Christi Shipping Channel.

### IV. Discussion of the Rule

This rule establishes a temporary safety zone from 7 p.m. on October 19, 2022, through 5 a.m. on October 22, 2022, and will be subject to enforcement from 7 p.m. to 5 a.m. of the next day, each day. The safety zone will encompass all navigable waters of the Corpus Christi Shipping Channel in a zone defined by the following coordinates; 27°50′31.28″ N, 97°04′17.23″ W; 27°50′31.73″ N, 97°04′15.44″ W; 27°50′29.06″ N, 97°04′16.61″ W; 27°50′29.32″ N, 97°04′14.82″ W. The pipeline will be removed along the floor of the Corpus

Christi Shipping Channel. No vessel or person is permitted to enter the temporary safety zone during the effective period without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF-FM (156.8 MHz) or by telephone at 361-939-0450. The Coast Guard will issue Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts 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 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, and duration of the safety zone. The temporary safety zone will be enforced for a short period of only 9 hours each day. The rule does not completely restrict the traffic within a waterway and allows mariners to request 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 temporary 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 contact 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

*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, 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 establishment of a temporary safety zone for navigable waters of the Corpus Christi Shipping Channel in a zone defined by the following coordinates; 27°50'31.28" N, 97°04'17.23" W; 27°50'31.73" N, 97°04'15.44" W; 27°50'29.06" N, 97°04'16.61" W; 27°50'29.32" N, 97°04'14.82" W. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by pipeline that will be removed from the floor of the Corpus Christi Shipping Channel. It is categorically excluded from further review under paragraph L60(c) Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

*G. Protest Activities*

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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.T08–0867 to read as follows:

**§ 165.T08–0867 Safety Zone; Corpus Christi Shipping Channel, Corpus Christi, TX.**

(a) *Location.* The following area is a safety zone: all navigable waters of the Corpus Christi Shipping Channel in a zone defined by the following coordinates; 27°50'31.28" N, 97°04'17.23" W; 27°50'31.73" N, 97°04'15.44" W; 27°50'29.06" N, 97°04'16.61" W; 27°50'29.32" N, 97°04'14.82" W.

(b) *Effective period.* This section is effective from 7 p.m. on October 19, 2022, through 5 a.m. on October 22, 2022. This section is subject to enforcement from 7 p.m. to 5 a.m. of the next day, each day.

(c) *Regulations.* (1) According to the general regulations in § 165.23, entry into this temporary safety zone is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. They may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450.

(2) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

Dated: October 14, 2022.

**M.A. Cintron,**

*Captain, U.S. Coast Guard, Acting Captain of the Port Sector Corpus Christi.*

[FR Doc. 2022–22872 Filed 10–18–22; 11:15 am]

**BILLING CODE 9110–04–P**

**DEPARTMENT OF EDUCATION****34 CFR Parts 668, 600, and 602**

[Docket ID ED–2018–OPE–0076, ED–2018–OPE–0027]

RIN 1840–AD26, 1840–AD36, 1840–AD37, 1840–AD38

**Student Assistance General Provisions, Federal Family Education Loan Program, and William D. Ford Federal Direct Loan Program; Student Assistance General Provisions, The Secretary's Recognition of Accrediting Agencies, The Secretary's Recognition Procedures for State Agencies; Distance Education and Innovation; Corrections**

**AGENCY:** Office of Postsecondary Education, Department of Education.

**ACTION:** Final rule; technical corrections.

**SUMMARY:** The Department of Education (Department or we) corrects the text in regulations issued under the Higher Education Act of 1965, as amended (HEA) and published in the **Federal Register** on: September 23, 2019, for provisions relating to Borrower Defense to Repayment and Financial Responsibility; November 1, 2019, for provisions relating to Accreditation, State Authorization, and the Student Assistance General Provisions; and September 2, 2020, for provisions relating to Distance Education and Innovation, Institutional Eligibility, and the Student Assistance General Provisions.

**DATES:** These corrections are effective October 20, 2022. The incorporation by reference of certain publications listed in this document is approved by the Director of the **Federal Register** as of October 20, 2022.

**FOR FURTHER INFORMATION CONTACT:** Gregory Martin, 400 Maryland Avenue SW, Room 2C–136, Washington DC 20202. Telephone: (202) 453–7535. Email: [Gregory.Martin@ed.gov](mailto:Gregory.Martin@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:**

*Incorporation by Reference.* In § 668.172(c)(1) of this correction, we reference the following accounting standard: Accounting Standards Codification (ASC) 205. ASC 205 provides standards on the presentation of financial statements. In § 668.23(d)(1), we reference the following accounting standard: Accounting Standards Codification