

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 117 and 507**

[Docket Nos. FDA–2011–N–0920 and FDA–2011–N–0922]

**Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Supply-Chain Programs and Onsite Audits; Announcement of Effective Date****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the effective date for requirements related to establishing and implementing supply-chain programs, records documenting supply-chain programs, and onsite audits in two final rules, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, that appeared in the **Federal Register** of September 17, 2015.

**DATES:** The effective date for the amendments to 21 CFR 117.405(a)(2), 117.435(d), and 117.475(c)(2), which published in the **Federal Register** of September 17, 2015 (80 FR 55908), is October 31, 2022. The effective date for the amendments to 21 CFR 507.105(a)(2), 507.135(d), and 507.175(c)(2), which published in the **Federal Register** of September 17, 2015 (80 FR 56170), is October 31, 2022.

**FOR FURTHER INFORMATION CONTACT:** For questions relating to *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

For questions relating to *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals*: Jennifer Erickson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7382.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 17, 2015

(80 FR 55908), we published a final rule that established “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” in part 117 (21 CFR part 117). Section 117.405(a)(2) specifies circumstances in which a receiving facility that is an importer need not conduct certain supplier verification activities. Section 117.475(c)(2) provides for documentation related to its supply-chain program that a receiving facility that is an importer is required to maintain. Section 117.435(d) specifies that if an onsite audit is solely conducted to meet the supply-chain program requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M (21 CFR part 1, subpart M), the audit is not subject to the requirements in those regulations.

At the time the final rule published, §§ 117.405(a)(2) and 117.475(c)(2) referred to provisions in a future final rule, “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (FSVP rule) (80 FR 74226; November 27, 2015), whereas § 117.435(d) referred to a provision in a future final rule, “Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications” (third-party certification rule) (80 FR 74570; November 27, 2015). In the final rule establishing part 117, we stated that we would publish a document in the **Federal Register** announcing the effective dates of §§ 117.405(a)(2), 117.475(c)(2), and 117.435(d) (80 FR 55908 at 56131).

In the **Federal Register** of September 17, 2015 (80 FR 56170), we published a final rule that established “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” in part 507 (21 CFR part 507). Section 507.105(a)(2) specifies circumstances in which a receiving facility that is an importer need not conduct certain supplier verification activities. Section 507.175(c)(2) provides for documentation related to its supply-chain program that a receiving facility that is an importer is required to maintain. Section 507.135(d) specifies that if an onsite audit is solely conducted to meet the supply-chain program requirements of part 507 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations.

At the time the final rule published, §§ 507.105(a)(2) and 507.175(c)(2) referred to provisions in a future final FSVP rule, whereas § 507.135(d) referred to a provision in a future final third-party certification rule. In the final rule establishing part 507, we stated that we would publish a document in the **Federal Register** announcing the effective dates of §§ 507.105(a)(2), 507.175(c)(2), and 507.135(d) (80 FR 56170 at 56330).

The final FSVP rule and the final third-party certification rule published in the **Federal Register** on November 27, 2015, with effective dates of January 26, 2016.

This document announces that the effective date for §§ 117.405(a)(2), 117.475(c)(2), 117.435(d), 507.105(a)(2), 507.175(c)(2), and 507.135(d) is October 31, 2022.

Dated: October 21, 2022.

**Robert M. Califf,***Commissioner of Food and Drugs.*

[FR Doc. 2022–23534 Filed 10–28–22; 8:45 am]

BILLING CODE 4164–01–P

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket Number USCG–2022–0789]

RIN 1625–AA00

**Safety Zone; Upper Mississippi River Mile Marker 485.3–485.9 Davenport, IA****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all navigable waters in the Upper Mississippi River at Mile Marker (MM) 485.3 through 485.9. The safety zone is needed to protect personnel, vessels, and the marine environment from all potential hazards associated with electrical line work. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

**DATES:** This rule is effective from October 31, 2022 through November 23, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0789 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 Lieutenant Commander Richard Cherkauer, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email [Richard.G.Cherkauer@uscg.mil](mailto:Richard.G.Cherkauer@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
 COTP Captain of The Port Sector Upper Mississippi River  
 DHS Department of Homeland Security  
 FR Federal Register  
 MM Mile marker  
 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 temporary safety zone immediately and lack sufficient time to provide a reasonable comment period and then 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 this rule would be contrary to public safety due to ongoing construction work.

##### 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 Sector Upper Mississippi River (COTP) has determined that potential hazards associated with electrical line work will be a safety concern for anyone operating or transiting within the Upper Mississippi River from MM 485.3 through 485.9. This rule is needed to protect personnel, vessels, and the marine environment in the navigable

waters within the safety zone while electrical line work is being conducted.

##### IV. Discussion of the Rule

Electrical line work will be occurring near Mile Marker (MM) 485.6 beginning October 31, 2022. The safety zone is designed to protect waterway users until work is complete.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. 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, as well as reductions in the size of the safety zone as conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), 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 the 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 a safety zone located on the Upper Mississippi River at MM 485.3–485.9, near Davenport, IA. The Safety Zone is expected to be active only during the hours of 9 a.m. through 4 p.m., or when work is being conducted, until November 23, 2022.

###### 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 because the zone will be enforced only when work is being conducted.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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 encompassing the width of the Upper Mississippi River at MM 485.3–485.9. 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.T08–0789 to read as follows:

#### § 165.T08 –0789 Safety Zone; Upper Mississippi River, Mile Markers 485.3–485.9, Davenport, IA.

(a) *Location.* The following area is a safety zone: all navigable waters within the Upper Mississippi River, Mile Markers (MM) 485.3–485.9.

(b) *Effective period.* This section is effective from October 31, 2022 through November 23, 2022.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* 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, as well as reductions in size or scope of the safety zone as ice or flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: October 25, 2022.

**A.R. Bender,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.*

[FR Doc. 2022–23717 Filed 10–27–22; 4:15 pm]

**BILLING CODE 9110–04–P**

#### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2022–0883]

RIN 1625–AA00

#### Safety Zone; Upper Mississippi River Mile Markers 125–126, Sainte Genevieve, MO

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all navigable waters of the Upper Mississippi River extending from mile marker (MM) 125 to MM 126 near Sainte Genevieve, MO. The safety zone is needed to protect personnel and vessels from potential hazards due to shoaling in the area. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative.

**DATES:** This rule is effective without actual notice from October 31, 2022 through November 3, 2022. For the purposes of enforcement, actual notice will be used from October 20, 2022, until October 31, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0883 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 Chief Nathaniel Dibley, Waterways Management, Sector Upper Mississippi River, U.S. Coast Guard; telephone 314–269–2550, email [Nathaniel.D.Dibley@uscg.mil](mailto:Nathaniel.D.Dibley@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

#### I. Table of Abbreviations

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
FR Federal Register  
MM Mile marker  
NPRM Notice of proposed rulemaking