

organizational information for the Office of Regulatory Policy, CDER, Office of Medical Products and Tobacco.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—ORGANIZATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

§ 5.1100 [Amended]

■ 2. In § 5.1100, under the heading “OFFICE OF MEDICAL PRODUCTS AND TOBACCO”, under “Office of Regulatory Policy.”, under “Division of Regulatory Policy III.”, add the words “Division of Regulatory Policy IV.”.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06065 Filed 3–26–18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0929]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters on the Lower Mississippi River from mile marker (MM) 94 to MM 95, above Head of Passes. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or a designated representative.

DATES: This rule is effective from 7:30 p.m. through 8:30 p.m. on April 21, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–0929 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 about this rulemaking, call or email Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email Howard.K.Vacco@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AHP	Above Head of Passes
COTP	Captain of the Port Sector New Orleans
CFR	Code of Federal Regulations
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

On September 14, 2017, the New Orleans Convention Company, Inc. notified the Coast Guard that it would be conducting a fireworks display from 7:30 p.m. through 8:30 p.m. on April 21, 2018 to for the fireworks to be launched from a barge on the Lower Mississippi River at mile marker (MM) 94.5, above Head of Passes (AHP), New Orleans, LA. In response, on December 11, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) Safety Zone; Lower Mississippi River, New Orleans, LA in 82 FR 58147. There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended on February 9, 2018, we received 0 comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in this April 21, 2018 display will be a safety concern for anyone within a one mile stretch of the Lower Mississippi River. The purpose of this rule is to ensure safety of persons and vessels on the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on December 11, 2017. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 7:30 p.m. through 8:30 p.m. on April 21, 2018. The safety zone will cover all navigable waters of the Lower Mississippi River between MMs 94 and 95 AHP in New Orleans, LA. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks display. No vessel or person would 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 assigned to units under the operational control of USCG Sector New Orleans. Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on this rule only encompassing a one mile stretch of the Lower Mississippi River for one hour in the evening.

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 received no comments from the Small Business Administration on this rulemaking. 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 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.

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, which guides 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 one hour that will prohibit entry within a one mile stretch of the Lower Mississippi River, between MMs 94 and 95. 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. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

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: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T08–0929 to read as follows:

§ 165.T08–0929 Safety Zone; Lower Mississippi River, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River, New Orleans, LA between Mile Marker (MM) 94 and MM 95 above Head of Passes.

(b) *Effective period.* This section is effective from 7:30 p.m. through 8:30 p.m. on April 21, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast

Notices to Mariners of any changes in the planned schedule.

Wayne R. Arguin,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2018-0104]

RIN 1625-AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River from Mile Marker (MM) 94.5 to MM 95.5, above Head of Passes. The safety zone is needed to protect persons and vessels from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or a designated representative.

DATES: This rule is effective from 7:30 p.m. through 8:30 p.m. on April 15, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0104 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 about this rulemaking, call or email Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, U.S. Coast Guard; telephone 504-365-2281, email Howard.K.Vacco@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port Sector New Orleans
 CFR Code of Federal Regulations
 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) because it is impracticable. It is impracticable to publish an NPRM because we must establish this safety zone on April 15, 2018 to prevent injury to persons and vessels 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 the effective date of this rule would be impracticable because urgent action is necessary to protect the public and vessels from the hazards associated with a fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with a fireworks display on April 15, 2018, will be a safety concern for anyone within a one-mile range of the Lower Mississippi River above Head of Passes. This rule is needed to protect persons and vessels in the navigable waters within the safety zone from the hazards associated with a fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 7:30 p.m. through 8:30 p.m. on April 15, 2018. The safety zone will cover all navigable waters between Mile Markers (MMs) 94.5 and 95.5 on the Lower Mississippi River above Head of Passes. The duration of the zone is intended to protect persons and vessels in these navigable waters from the hazards associated with a fireworks display. 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 assigned to units under the operational control of USCG Sector New Orleans.

The COTP or a designated representative may be contacted on VHF-FM Channel 16 or 67. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the 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.

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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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on this rule only encompassing a one-mile stretch of river for one hour in the evening.

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