

on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

Dated: July 14, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: July 22, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021-15980 Filed 7-30-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0480]

RIN 1625-AA00

Safety Zone; Lake of the Ozarks, Mile Markers 7, 10.5, 13, 16, 22, 26, 34, and 42, Lake of the Ozarks, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones in all navigable waters extending 420 feet in all directions around fireworks barges at eight different locations on the Lake of the Ozarks. These safety zones are needed to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks displays. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative.

DATES: This rule is effective on August 10, 2021 at 10 p.m. to 10:30 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0480 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 Stephanie Moore, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314-269-2560, email Stephanie.R.Moore@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 by August 10, 2021 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 contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the fireworks displays on August 10, 2021.

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 the fireworks displays on August 10, 2021 will be a safety concern for anyone on the Lake of the Ozarks at the designated launch locations. This rule resulted from a marine event notification stating that there will be fireworks displays to celebrate a bicentennial birthday on the Lake of the Ozarks. This rule is needed to protect personnel, vessels, and the marine environment in the navigable

waters within the safety zone before, during, and after the fireworks display.

IV. Discussion of the Rule

This rule establishes safety zones on August 10, 2021 from 10 p.m. until 10:30 p.m. The safety zones will be located on all navigable waters extending 420 feet in all directions around fireworks barges at the following locations on the Lake of the Ozarks at (1) mile marker 7 (38 12'35.20" N 92 45'02.57" W), (2) mile marker 10.5 (38 01'21.93" N 92 47'38.93" W), (3) mile marker 13 (38 11'01.86" N 92 41'19.32" W), (4) mile marker 16 (38 08'54.89" N 92 38'29.53" W), (5) mile marker 22 (38 08'54.89" N 92 41'18.95" W), (6) mile marker 26 (38 07'25.22" N 92 42'58.65" W), (7) mile marker 34 (38 07'25.22" N 92 47'34.59" W) and (8) mile marker 42 (38 08'55" N 92 52'23.30" W). The duration of these zones is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the fireworks displays. No vessel or person will be permitted to enter the safety zones 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 Upper Mississippi River. The COTP or a designated representative will inform the public of the enforcement date and times for these safety zones, as well as any emergent safety concerns that may delay the enforcement of the zones.

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 size, location, and duration of the temporary safety zones. This action involves fireworks displays at multiple designated locations on the

Lake of the Ozarks accruing simultaneously on August 10, 2021 and lasting 30 minutes. Vessels will be able to transit around the safety zones. Moreover, the Coast Guard will publish a Local Notice to Mariners and mariners may seek permission to enter the zones.

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 zones 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 safety zones lasting thirty minutes that will prohibit entry on the Lake of the Ozarks at (1) mile marker 7 (38 12°35.20′ N 92 45°02.57′ W), (2) mile marker 10.5 (38 01°21.93′ N 92 47°38.93′ W), (3) mile marker 13 (38 11°01.86′ N 92 41°19.32′ W), (4) mile marker 16 (38 08°54.89′ N 92 38°29.53′ W), (5) mile marker 22 (38 08°54.89′ N 92 41°18.95′ W), (6) mile marker 26 (38 07°25.22′ N 92 42°58.65′ W), (7) mile marker 34 (38 07°25.22′ N

92 47°34.59′ W) and (8) mile marker 42 (38 08°55′ N 92 52°23.30′ W). It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. It is categorically excluded from further review under paragraph L60, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 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. 0170.1.

- 2. Add § 165.T08–0707 to read as follows:

§ 165.T08–0707 Safety Zones; Lake of the Ozarks, Mile Markers 7, 10.5, 13, 16, 22, 26, 34, 42, Lake of the Ozarks, MO

(a) *Location.* All navigable waters extending 420 feet in all directions around fireworks barges at the following locations on the Lake of the Ozarks at:

- (1) Mile marker 7 (38 12°35.20′ N 92 45°02.57′ W);
- (2) Mile marker 10.5 (38 01°21.93′ N 92 47°38.93′ W);
- (3) Mile marker 13 (38 11°01.86′ N 92 41°19.32′ W);
- (4) Mile marker 16 (38 08°54.89′ N 92 38°29.53′ W);
- (5) Mile marker 22 (38 08°54.89′ N 92 41°18.95′ W);
- (6) Mile marker 26 (38 07°25.22′ N 92 42°58.65′ W);
- (7) Mile marker 34 (38 07°25.22′ N 92 47°34.59′ W); and

(8) Mile marker 42 (38 08'55" N 92 52'23.30" W).

(b) *Period of enforcement.* August 10, 2021 from 10 p.m. until 10:30 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, persons and vessels are prohibited from entering the safety zone unless authorized by the Captain of the Port Sector Upper Mississippi River (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 Upper Mississippi River.

(2) Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF radio Channel 16 or by telephone at 314-269-2332.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative while navigating in the regulated area.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement date and times for this safety zone, as well as any emergent safety concerns that may delay the enforcement of the zone through either A Safety Marine Information Broadcast (SMIB), Broadcast Notice to Mariners (BNM) and or Local Notices to Mariners (LNMs).

R.M. Scott,

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

[FR Doc. 2021-16197 Filed 7-30-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0584]

RIN 1625-AA00

Temporary Safety Zone; Loveless Wedding Fireworks, Omena, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a fireworks display off the shore of the Omena Traverse Yacht Club in Omena, MI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks display. Entry of

vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or a designated representative.

DATES: This rule is effective from 6 p.m. through 11:59 p.m. on August 21, 2021. It will be enforced from 9 p.m. through 11 p.m. on that day.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0584 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 on this rule, call or email LT Deaven Palenzuela, U.S. Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906-635-3223, email ssmprevention@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 doing so would be impracticable. The event sponsor did not submit notice to the Coast Guard with sufficient time to publish an NPRM and receive public comments prior to the event. Delaying the effective date of this rule to wait for a comment period to run would be contrary to the public interest and impractical by inhibiting the Coast Guard's ability to protect the public from the dangers associated with a fireworks display with a potential blast zone and expected fall-out area occurring over the water.

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 action is needed to establish a safety zone in order to protect the public from the hazards associated with the fireworks display.

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 Sault Sainte Marie (COTP) has determined that potential hazards associated with a fireworks display on August 21, 2021, will be a safety concern for anything within a 250-foot radius of the navigable waters surrounding the fireworks launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced from 9 p.m. through 11 p.m. on August 21, 2021. The safety zone will cover all navigable waters within 250 feet of a fireworks display off shore Omena Traverse Yacht Club in Omena, MI in position 45°6'6.36" N 85°34'48.22" W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in the safety zone proceeding, during and immediately after the fireworks display.

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 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 off shore of Omena Traverse Yacht Club.