

matter of the withdrawn proposed rules, you may review the Agency's website (<https://www.fda.gov>) for any current information on the matter.

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0883]

RIN 1625–AA08

Special Local Regulation; Manasquan Inlet, Manasquan, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary special local regulation for certain waters of the Manasquan Inlet between Manasquan, NJ, and Point Pleasant Beach, NJ. This action is necessary to protect event participants, spectators, and vessels transiting the area from potential hazards during the Manasquan Inlet Intercoastal Tug marine event. During the enforcement period, unauthorized persons or vessels would be prohibited from entering into, remaining within, transiting through, or anchoring in the regulated area unless authorized by the Captain of the Port Delaware Bay or a designated representative of the Captain of the Port. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before October 5, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0883 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Thomas Welker, U.S. Coast Guard; Sector Delaware Bay, Waterways Management Division; telephone (215) 271–4814, email Thomas.J.Welker@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Manasquan Beach and Recreation Department notified the Coast Guard that it will be conducting a tug of war event from 11 a.m. to 1:30 p.m. on October 20, 2018. The tug of war will consist of teams on opposing sides of the Manasquan Inlet with a rope extended between the sides. The event will span the entire width of the inlet. Vessel operation in the area of the event could be hazardous to both event participants and vessels. The Captain of the Port Delaware Bay (COTP) has determined that a safety concern exists for non-participant vessels within 400 feet of the tug of war rope.

The purpose of this rulemaking is to ensure the safety of participants and vessels transiting the regulated area during the event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary special local regulation to be in effect from 11 a.m. to 1:30 p.m. on October 20, 2018. The regulated area would cover all waters within 400 feet of the event located between approximate locations 40°6'9.22" N, 74°2'7.8" W and 40°6'9.22" N, 74°2'8.2" W. During the event, the inlet would be closed to all non-participant vessel traffic. There is a 30-minute break tentatively planned for midway through the event. If circumstances permit, during the break the rope will be removed from navigable waters and vessels may be allowed to transit through the area at the discretion of the COTP or COTP's designated representative. The regulation is intended to ensure the safety of event participants and vessels during the scheduled 11 a.m. to 1:30 p.m. tug of war event. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative of the Captain of the Port. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM 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 the size, location, and duration of the regulated area. While this regulated area would impact a designated area of the Manasquan River Inlet for 2 and ½ hours, the event sponsor has organized a 30 minute time period during the event where vessels would be able to transit through the inlet. Moreover, the Coast Guard would 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 during the 30 minute time period during the event.

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 proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see

ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 proposed rule involves a regulated area lasting 2 and ½ hours that would prohibit entry within 400 feet of a tug of war event across an inlet. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. 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. Your comment can help shape the outcome of this rulemaking. 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.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION**

CONTACT section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <https://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Maritime safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.T05–0883 to read as follows.

§ 100.T05–0883 Special Local Regulation; Manasquan River; Manasquan, NJ.

(a) *Location.* The following area is a regulated area: All waters of the Manasquan River within the Manasquan Inlet within 400 feet of the event located between approximate locations 40°6'9.22" N, 74°2'7.8" W and 40°6'9.22" N, 74°2'8.2" W. All coordinates are based on World Geodetic System 1984.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port Delaware Bay (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) All non-participant persons and vessels are prohibited from entering into, remaining within, transiting through, or anchoring in the regulated area unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter or remain in the zone, contact the COTP or the COTP's designated representative

via VHF–FM channel 16 or by telephone at 215–271–4807.

(3) If authorization to enter into, remain within, transit through, or anchor in the regulated area is granted, all persons and vessels receiving such authorization shall comply with the instructions of the COTP or the COTP's designated representative.

(4) The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, or by on-scene designated representatives.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by federal, state, and local agencies.

(e) *Enforcement period.* This zone will be enforced from approximately 11 a.m. through 1:30 p.m. on October 20, 2018.

K.A. Clarke,

Captain, U.S. Coast Guard, Acting Captain of the Port Delaware Bay.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0711]

RIN 1625–AA00

Safety Zone; Delaware River; Penn's Landing; Philadelphia, PA; Fireworks Display

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on a portion of the Delaware River in Philadelphia, PA. This action is necessary to protect the surrounding public and vessels on these navigable waters adjacent to Penn's Landing, Philadelphia, PA, during a fireworks display on October 19, 2018. This proposed rulemaking would prohibit persons and vessels from entering, transiting, or remaining within the safety zone unless authorized by the Captain of the Port Delaware Bay or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before October 5, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–

2018–0711 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Thomas Welker, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division; telephone 215–271–4814, email Thomas.j.welker@uscg.mil.

SUPPLEMENTARY INFORMATION:

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II. Background, Purpose, and Legal Basis

On June 18, 2018, a wedding party notified the Coast Guard that it will be conducting a fireworks display from 11:15 p.m. to 11:45 p.m. on October 19, 2018. The fireworks are to be launched from a barge in the Delaware River adjacent to Penn's Landing in Philadelphia, PA. Hazards from firework display include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Delaware Bay (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 500-foot radius of the barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 500-foot radius of the fireworks barge before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 11:00 p.m. through 11:59 p.m. on October 19, 2018. The safety zone would cover all navigable waters within 500 feet of a fireworks barge in the Delaware River adjacent to Penn's Landing in Philadelphia, PA. The barge will be anchored in approximate position 39°57'05.26" N Latitude 075°08'10.85" W Longitude. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 11:15 p.m. to 11:45

p.m. fireworks display. No vessel or person would be permitted to enter, transit, or remain within the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM 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 the size, location, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit around this safety zone which would impact a small designated area of the Delaware River for one hour during the evening when vessel traffic is normally low. Moreover, the Coast Guard would 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 proposed rule would 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