

annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

Accordingly, for the reasons stated in the preamble, part 1303 of title 21 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1303—QUOTAS

- 1. The authority citation for part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

- 2. In § 1303.11:
- a. Remove the word “and” at the end of paragraph (b)(4).
- b. Redesignate paragraph (b)(5) as paragraph (b)(7).
- c. Add new paragraphs (b)(5) and (6).
- d. In paragraph (c), add the phrase “and transmitted to each state attorney general” before the period in the second sentence, add the phrase “except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States need” before the period in the fourth sentence, remove the word “such” in the fifth sentence, add the phrase “, the Administrator” before “shall issue” in the sixth sentence, and add the phrase “and transmitted to each state attorney general” before the period in the final sentence.

The additions read as follows:

§ 1303.11 Aggregate production quotas.

* * * * *

(b) * * *

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states; and

* * * * *

- 3. In § 1303.12(b), add after the fifth sentence a new sentence to read as follows:

§ 1303.12 Procurement quotas.

* * * * *

(b) * * * The Administrator may require additional information from an applicant which, in the Administrator’s judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer. * * *

* * * * *

- 4. In § 1303.13:

- a. Revise paragraph (b)(1).
- b. In paragraph (c), add the phrase “and transmitted to each state attorney general” before the period in the second sentence, add the phrase “, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed adjusted quota as excessive for legitimate United States need” before the period in the fourth sentence, remove the word “such” in the fifth sentence, and add the phrase “and transmitted to each state attorney general” before the period in the final sentence.

The revision reads as follows:

§ 1303.13 Adjustments of aggregate production quotas.

* * * * *

(b) * * *

(1) Changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class;

* * * * *

§ 1303.21 [Amended]

- 5. In § 1303.21(a), remove “§§” in the second sentence and add in its place “§”.

- 6. In § 1303.22:

■ a. In paragraph (c)(2), remove the word “econolic” and add in its place the word “economic”.

■ b. Add paragraph (d).

The addition reads as follows:

§ 1303.22 Procedure for applying for individual manufacturing quotas.

* * * * *

(d) The Administrator may require additional information from an applicant which, in the Administrator’s judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.

§ 1303.23 [Amended]

- 7. In § 1303.23, add the phrase “the extent of any diversion of the controlled

substance,” after “strikes),” in paragraph (a)(2), and add the phrase “any risk of diversion of the controlled substance,” after “strikes),” in paragraph (b)(2).

§ 1303.32 [Amended]

- 8. In § 1303.32(a), add the phrase “and shall, if determined by the Administrator to be necessary under § 1303.11(c) or 1303.13(c) based on objection by a state,” before “hold a hearing”.

Dated: April 13, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018-08111 Filed 4-18-18; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2018-0224]

RIN 1625-AA08

Special Local Regulation; Monongahela, Allegheny, and Ohio Rivers, Pittsburgh PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation for parts of the navigable waters of the Allegheny, Monongahela, and Ohio Rivers. This action is necessary to provide for the safety of life on these navigable waters during the weekend of the Kenny Chesney concert at Heinz Field. This proposed rulemaking would prohibit persons and vessels from loitering, anchoring, stopping, mooring, remaining, or drifting in any manner that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative. In addition, this proposed rulemaking would prohibit persons and vessels from loitering, anchoring, stopping, or drifting more than 100 feet from any riverbank unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh 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 May 4, 2018.

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

2018–0224 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 MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email Jennifer.L.Haggins@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 COTP Captain of the Port Marine Safety Unit Pittsburgh
 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

Heinz Field notified the Coast Guard that it would be holding a concert from 4 p.m. to 11 p.m. on June 2, 2018. Heinz Field is located in close proximity to the banks of the Ohio and Allegheny Rivers, which is a high vessel traffic area used by both commercial and recreational vessels. Due to the proximity of Heinz Field to these waterways, it will be a destination for many recreational vessels to anchor and loiter throughout the concert weekend from June 1, 2018 through June 3, 2018. The Coast Guard is concerned about possible collisions that could occur in this area and the impact of vessel congestion on maritime commerce due to transit delays. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that this special local regulation is necessary to maintain an open navigation channel and ensure the safety of vessels and these navigable waters during the concert weekend.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters adjacent to Heinz Field on the Allegheny, Monongahela, and Ohio Rivers before, during, and after the Kenny Chesney concert weekend. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233.

The Coast Guard is issuing this notice of proposed rulemaking (NPRM) with a 15-day prior notice and opportunity to comment pursuant to section (b)(3) of the Administrative Procedure Act (APA) (5 U.S.C. 553). This provision authorizes an agency to publish a rule in less than 30 days before its effective date for

“good cause found and published with the rule.” Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for publishing this NPRM with a 15-day comment period because it is impractical to provide a 30-day comment period. This proposed special local regulation is necessary to ensure the safety of vessels and persons during the concert weekend. It is impracticable to publish an NPRM with a 30-day comment period because we must establish this special local regulation by June 1, 2018. A 15-day comment period would allow the Coast Guard to provide for public notice and comment, but also publish a rule, if adopted, soon enough that the length of the notice and comment period does not compromise public safety.

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary special local regulation for all navigable waters of the Allegheny, Monongahela, and Ohio Rivers between the Ninth Street Highway Bridge at mile marker (MM) 0.8, Allegheny River, Fort Pitt Highway Bridge at MM 0.22, Monongahela River, and West End-North Side Highway Bridge at MM 0.8, Ohio River. The duration of the temporary special local regulation is intended to ensure the safety of vessels on these navigable waters before, during, and after the concert weekend. This proposed rule would apply to any vessel operating within the area, including a naval or public vessel, except a vessel engaged in law enforcement, servicing aids to navigation, or surveying, maintaining, or improving waters within the regulated area. No vessel would be permitted to loiter, anchor, stop, moor, remain or drift in any manner that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the COTP or a designated representative. In addition, no vessel or person would be permitted to loiter, anchor, stop, remain, or drift more than 100 feet from any riverbank unless authorized by the COTP or a designated representative. Persons and vessels seeking entry into the regulated area must request 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 Marine Safety Unit Pittsburgh. They may be contacted on VHF–FM Channel 16. Persons and vessels permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or

the 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.

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 and location of the special local regulation. The special local regulation will impact a small section of the Allegheny, Monongahela, and Ohio Rivers, less than three total miles. Moreover, the special local regulation will not stop vessels from transiting the area, it will only establish certain areas where vessels are prohibited from loitering, anchoring, stopping, or drifting more than 100 feet from any river bank.

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 Management Directive 023–01 and Commandant Instruction M16475.ID, 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 special local regulation that prohibits vessels from loitering, anchoring, stopping, remaining or drifting more than 100 feet from any bank. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of Implementation of the National Environmental Policy Act, Department of Homeland Security Instruction Manual 023–01–001–01. A preliminary environmental analysis checklist and Categorical Exclusion Determination are 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 <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://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 <http://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

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, 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.T08–0224 to read as follows:

§ 100.T08–0224 Allegheny River, Monongahela River, and Ohio Rivers, Pittsburgh, PA

(a) *Location.* The following is a special local regulation for all navigable waters of the Allegheny, Monongahela, and Ohio Rivers between the Ninth Street Highway Bridge at mile marker (MM) 0.8, Allegheny River, Fort Pitt Highway Bridge at MM 0.22, Monongahela River, and West End-North Side Highway Bridge at MM 0.8, Ohio River.

(b) *Applicability.* This section applies to any vessel operating within the area, including a naval or public vessel, except a vessel engaged in:

- (1) Law enforcement;
- (2) Servicing aids to navigation; or

(3) Surveying, maintaining, or improving waters within the regulated area.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801, no vessel shall loiter, anchor, stop, moor, remain or drift in any manner as to impede safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

(2) No vessel shall loiter, anchor, stop, moor, remain or drift at any time more than 100 feet from any riverbank within the regulated area unless authorized by the COTP or a designated representative.

(3) Persons and vessels seeking entry into the regulated area must request 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 Marine Safety Unit Pittsburgh. They may be contacted on VHF-FM Channel 16.

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

(d) *Effective period.* This section will be effective from 4 p.m. on June 1, 2018 through 3 p.m. on June 3, 2018.

(e) *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 through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: April 13, 2018.

F.M. Smith,

Lieutenant Commander, U.S. Coast Guard, Acting Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2018-08192 Filed 4-18-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-1112]

RIN 1625-AA00

Safety Zones; Annual Events in the Captain of the Port Buffalo Zone.

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its safety zones regulation for Annual Events in the Captain of the Port Buffalo Zone. This proposed amendment updates 12 permanent safety zones and adds 12 new permanent safety zones. These amendments and additions are necessary to protect spectators, participants, and vessels from the hazards associated with annual maritime events, including fireworks displays, boat races, and air shows. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 21, 2018.

ADDRESSES: You may submit comments identified by docket number USCG-2017-1112 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 LT Michael Collet, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716-843-9322, email D09-SMB-SECBuffalo-WWM@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, Purpose, and Legal Basis

On June 18, 2008, the Coast Guard published a final rule entitled Safety Zones; Annual Fireworks Events in the Captain of the Port Buffalo Zone in the **Federal Register** (73 FR 28705). This final rule was published after the Coast Guard requested public comments in response to a preceding NPRM in the **Federal Register** (73 FR 18225, April 3, 2008). No public meeting was requested, and none was held.

The legal basis for this proposed rule is the Coast Guard's authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05-1, 160.5; Department of Homeland Security Delegation No. 0170.1.

The purpose of this rulemaking is to update the safety zones in § 165.939 to ensure accuracy of times, dates, and

dimensions for various triggering and marine events that are expected to be conducted within the Captain of the Port Buffalo Zone throughout the year. The purpose of the rulemaking is also to ensure vessels and persons are protected from the specific hazards related to the aforementioned events. These specific hazards include obstructions in the waterway that may cause marine casualties; collisions among vessels maneuvering at a high speed within a channel; the explosive dangers involved in pyrotechnics and hazardous cargo; and flaming/falling debris into the water that may cause injuries. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

This proposed rule amends 12 permanent safety zones found within table 165.939 of 33 CFR 165.939. These 12 amendments involve updating the location, size, and/or enforcement times.

Additionally, this proposed rule adds 12 new safety zones to table 165.939 within § 165.939 for annually-reoccurring events in the Captain of the Port Buffalo Zone. These 12 zones were approved and published in the **Federal Register** as temporary safety zones in 2017 and were added in order to protect the public from the safety hazards previously described. A list of specific changes and additions are available in the attachments within this Docket.

The Captain of the Port Buffalo has determined that the safety zones in this proposed rule are necessary to ensure the safety of vessels and people during annual marine or triggering events in the Captain of the Port Buffalo zone. Although this proposed rule will be effective year-round, the safety zones in this proposed rule will be enforced only immediately before, during, and after events that pose a hazard to the public and only upon notice by the Captain of the Port Buffalo.

The Captain of the Port Buffalo will notify the public that the zones in this proposal are or will be enforced by all appropriate means to the affected segments of the public, including publication in the **Federal Register**, as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include, but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners.

All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port Buffalo or his or her designated representative. Entry into, transiting, or anchoring within the safety zones is prohibited unless authorized by the Captain of the Port or