

- c.12. Clostridium perfringens, epsilon toxin producing types;
  - c.13. Coxiella burnetii;
  - c.14. Francisella tularensis;
  - c.15. Mycoplasma capricolum subspecies capripneumoniae (“strain F38”);
  - c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);
  - c.17. Rickettsia prowazekii;
  - c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);
  - c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;
  - Note:** Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).
  - c.20. Shigella dysenteriae;
  - c.21. Vibrio cholerae; or
  - c.22. Yersinia pestis.
  - d. “Toxins,” as follows, or their subunits:
    - d.1. Abrin;
    - d.2. Aflatoxins;
    - d.3. Botulinum toxins;
    - d.4. Brevetoxin;
    - d.5. Cholera toxin;
    - d.6. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
    - d.7. Conotoxins;
    - d.8. Diacetoxyscirpenol;
    - d.9. Gonyautoxin;
    - d.10. HT–2 toxin;
    - d.11. Microcystins (Cyanginosins);
    - d.12. Modeccin;
    - d.13. Nodularin;
    - d.14. Palytoxin;
    - d.15. Ricin;
    - d.16. Saxitoxin;
    - d.17. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
    - d.18. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
    - d.19. T–2 toxin;
    - d.20. Tetrodotoxin;
    - d.21. Viscumin (Viscum album lectin 1); or
    - d.22. Volkensin.
  - e. “Fungi”, as follows:
    - e.1. Coccidioides immitis; or
    - e.2. Coccidioides posadasii.
- \* \* \* \* \*
- 1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).**

**License Requirements**

*Reason for Control:* CB, AT

<i>Control(s)</i>	<i>Country chart (see Supp. No. 1 to part 738)</i>
CB applies to 1C991.c.	CB Column 3
AT applies to entire entry.	AT Column 1

**List Based License Exceptions (See Part 740 for a Description of All License Exceptions)**

*LVS:* N/A

*GBS:* N/A

**List of Items Controlled**

*Related Controls:* (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

- (a) Ricinus communis AgglutininII (RCA<sub>II</sub>), also known as ricin D, or Ricinus Communis LectinIII (RCL<sub>III</sub>);
  - (b) Ricinus communis LectinIV (RCL<sub>IV</sub>), also known as ricin E; or
  - (c) Saxitoxin identified by C.A.S. #35523–89–8.
- (2) The export of a “medical product” that is an “Investigational New Drug” (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.
- (3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

*Related Definitions:* For the purpose of this entry, ‘immunotoxins’ are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, ‘medical products’ are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions; (2) prepackaged for distribution as clinical or medical products; and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an “Investigational New Drug” (IND) (see 21 CFR part 312). For the purpose of this entry, ‘diagnostic and food testing kits’ are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, ‘vaccine’ is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

*Items:*

**Technical Note:** For purposes of the controls described in this ECCN, ‘toxins’ refers to those toxins, or their subunits, controlled under ECCN 1C351.d.

- a. Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.
- b. Immunotoxins containing toxins controlled by 1C351.d;
- c. Medical products that contain any of the following:
  - c.1. Toxins controlled by ECCN 1C351.d (except for botulinum toxins controlled by

ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.7, or items controlled for CW reasons under ECCN 1C351.d.15 or .d.16); or

- c.2. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 (except for those that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7);
- d. Medical products not controlled by 1C991.c that contain any of the following:
  - d.1. Botulinum toxins controlled by ECCN 1C351.d.3;
  - d.2. Conotoxins controlled by ECCN 1C351.d.7; or
  - d.3. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7;
- e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (except for items controlled for CW reasons under ECCN 1C351.d.15 or .d.16).

\* \* \* \* \*

**Thea D. Rozman Kendler,**  
*Assistant Secretary for Export Administration.*

[FR Doc. 2022–10907 Filed 5–20–22; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG–2022–0355]

**RIN 1625–AA00**

**Safety Zone; Lake Erie, Cleveland, OH**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary safety zone for certain waters of Lake Erie. This action is necessary to provide for the safety of life on these navigable waters near Cleveland, OH, during the Tall Ships Cleveland event fireworks display tri-annually in July. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Buffalo 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 June 22, 2022.

**ADDRESSES:** You may submit comments identified by docket number USCG–2022–0355 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 LT Jared Stevens, Waterways Management Division, MSU Cleveland, U.S. Coast Guard; telephone 216–937–0124, email [Jared.M.Stevens@uscg.mil](mailto:Jared.M.Stevens@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 January 28, 2022, Tall Ships America notified the Coast Guard that it will be conducting a Tall Ships fireworks display tri-annually in July. Hazards from the fireworks display may include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The event fireworks are to be launched from the Cleveland Port Authority Terminal adjacent to Lake Erie, Cleveland, Ohio. The Captain of the Port Buffalo (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 420-foot radius of the Cleveland Port Authority during the fireworks display.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 420 foot radius of the fireworks, before, during, and after the scheduled event.

The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

**III. Discussion of Proposed Rule**

The COTP is proposing to establish a safety zone tri-annually in July. This safety zone will cover all navigable waters within a 420-foot radius of the fireworks display, before, during, and after the scheduled event. The duration of the zone is intended to ensure the safety of vessels and these navigable waters during the scheduled Tall Ships fireworks display.

No vessel or person would be permitted to enter 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.

*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 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).

This regulatory action determination is based on the size, location, and duration of the proposed rule. This safety zone would restrict navigation around the Tall Ships fireworks display triannually with a limited radius from the fireworks launch point for a period not likely to exceed 6 hours. Vessel traffic will be able to safely transit around the safety zone. Moreover, 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 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 proposed 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 proposed 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. 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 call or email 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 potential effects of this proposed rule elsewhere in this preamble.

#### F. Environment

We have analyzed this proposed 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 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 triannual safety zone for a fireworks display that would prohibit vessel navigation within 420 feet of the Cleveland Port Authority before, during and after the display.

Normally such actions are 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 preliminary 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. 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 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.

#### 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.

**Submitting comments.** We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov>. To do so,

go to <https://www.regulations.gov>, type USCG–2022–0355 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

**Viewing material in docket.** To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

**Personal information.** We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

#### 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 is proposing to amend 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 § 165.9XX to read as follows:

##### § 165.9XX Safety Zone; Lake Erie, Cleveland, OH

(a) *Location.* All navigable waters of Lake Erie adjacent to Cleveland, OH, within a 420-foot radius from the fireworks launch site located near Port of Cleveland Dock 20.

(b) *Definitions.* *Official Patrol Vessel* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, or local officer designated by or assisting the Captain of the Port Buffalo (COTP) in the enforcement of the regulations in this section. *Participant* means all persons and vessels attending the event.

(c) *Regulations.* (1) The Coast Guard may patrol the event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM.”

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators. The “official patrol vessels” consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels designated or assigned by the Captain of the Port Buffalo to patrol the event.

(3) Spectator vessels desiring to transit the regulated area may do so only with prior approval of the Patrol Commander and when so directed by that officer and will be operated at a no wake speed in a manner which will not endanger participants in the event or any other craft.

(4) No spectator shall anchor, block, loiter, or impede the through transit of official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) The Patrol Commander may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(6) Any spectator vessel may anchor outside the regulated areas specified in this chapter, but may not anchor in, block, or loiter in a navigable channel.

(7) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(8) The Patrol Commander will terminate enforcement of the special regulations at the conclusion of the event.

(d) *Enforcement Period.* This section will be enforced tri-annually in July. The Coast Guard will provide advance notice of the enforcement date and time

of the safety zone by publishing a Notice of Enforcement in the **Federal Register**, as well as issuing a Broadcast Notice to Mariners.

Dated: May 12, 2022.

**M.I. Kuperman,**

*Captain, U.S. Coast Guard, Captain of the Port Buffalo.*

[FR Doc. 2022-10881 Filed 5-20-22; 8:45 am]

**BILLING CODE 9110-04-P**