

(j) *Medical device component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

**§ 1.79 Tobacco products.**

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE.

(a) *Brand name* of the article that is a tobacco product being imported or offered for import.

(b) *Name and address* of the ACE filer for any entry that includes an article that is a tobacco product.

**§ 1.80 Cosmetics.**

An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE.

■ 3. In § 1.83, revise paragraph (a) to read as follows:

**§ 1.83 Definitions.**

\* \* \* \* \*

(a) The term *owner* or *consignee* means the person eligible to make entry under the provisions of sections 484 and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1484 and 1485), namely, the “importer of record.”

\* \* \* \* \*

■ 4. Revise § 1.90 to read as follows:

**§ 1.90 Notice of sampling.**

When a sample of an article offered for import has been requested by the district director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or U.S. Customs and Border Protection of the results of examination of the sample.

■ 5. In § 1.94, revise the first sentence of paragraphs (a) and (c) to read as follows:

**§ 1.94 Hearing on refusal of admission or destruction.**

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. \* \* \*

\* \* \* \* \*

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may

give the owner or consignee a single written or electronic notice that provides the notice on refusal of admission and the notice on destruction of an article described in paragraph (a) of this section. \* \* \*

**PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS**

■ 6. The authority citation for part 1005 continues to read as follows:

*Authority:* 21 U.S.C. 360ii, 360mm.

■ 7. Revise § 1005.2 to read as follows:

**§ 1005.2 Definitions.**

As used in this part:

The term *owner* or *consignee* means the person eligible to make entry under the provisions of sections 484 and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1484 and 1485), namely, the “importer of record.”

**PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS**

■ 8. The authority citation for part 1271 continues to read as follows:

*Authority:* 42 U.S.C. 216, 243, 263a, 264, 271.

■ 9. In § 1271.420, revise paragraph (a) to read as follows:

**§ 1271.420 HCT/Ps offered for import.**

(a) Except as provided in paragraphs (c) and (d) of this section, when an HCT/P is offered for import, the importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part, and must provide sufficient information, including information submitted in the Automated Commercial Environment (ACE) system or any other Electronic Data Interchange system authorized by the United States Customs and Border Protection Agency as required in part 1, subpart D of this chapter, for FDA to make an admissibility decision.

\* \* \* \* \*

Dated: June 28, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy, Food and Drug Administration.*

**In concurrence with FDA:**

Dated: June 28, 2016.

**Timothy E. Skud,**

*Deputy Assistant Secretary (Tax, Trade, and Tariff Policy), Department of the Treasury.*

[FR Doc. 2016-15684 Filed 6-30-16; 8:45 am]

BILLING CODE 4164-01-P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket No. USCG-2016-0451]

RIN 1625-AA00

**Safety Zone; South Branch of the Chicago River and Chicago Sanitary and Ship Canal, Chicago, IL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a temporary safety zone on the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal, Chicago, IL. This action is necessary to protect spectators, participants, and vessels from the hazards associated with the Tough Cup event. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Lake Michigan.

**DATES:** Comments and related material must be received by the Coast Guard on or before August 1, 2016.

**ADDRESSES:** You may submit comments identified by docket number USCG-2016-0451 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 Lindsay Cook, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986-2155, email [Lindsay.N.Cook@uscg.mil](mailto:Lindsay.N.Cook@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
- Pub. L. Public Law
- § Section
- U.S.C. United States Code

## II. Background, Purpose, and Legal Basis

On December 27, 2015, the Coast Guard received an Application for Marine Event for the Tough Cup event to be held on the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal between the Illinois Northern Bridge and the Loomis Street Highway Bridge. This event involves high performance rowing shells and sculls that range in size from 27 feet to 65 feet in length and oars out to 25 feet in width to race on a course along the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal. The Captain of the Port Lake Michigan (COTP) has determined that the potential hazards associated with this event would be a safety concern for participants as well as recreational and commercial traffic in or around the course where the event will take place.

The purpose of this rulemaking is to ensure the safety of vessels, persons and the navigable waters immediately before, during, and immediately after the scheduled event. The specific hazards include collisions among event participants, recreational traffic, and commercial traffic that may cause injury or marine casualties. 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.

## III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone on all waters of the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal between the Illinois Northern Bridge and the Loomis Street Highway Bridge. This safety zone will be enforced from 6:30 a.m. to 1:00 p.m. on September 24, 2016. The safety zone enforcement times are intended to ensure the safety of persons and vessels immediately before, during and immediately after the event.

The Captain of the Port Lake Michigan has determined that the safety zone in this proposed rule is necessary to ensure the safety of vessels and people during this event. The safety zone in this proposed rule will be enforced for six and a half hours on September 24, 2016.

The Captain of the Port Lake Michigan will notify the public that the zone in this proposal 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 Lake Michigan or his or her designated representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port or his or her designated representative. The Captain of the Port or his or her designated representative may be contacted via VHF Channel 16.

## IV. Regulatory Analysis

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 the 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. 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.

We conclude that this proposed rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a short duration on the one day this rule will be in effect to ensure safety of spectators and participants at this scheduled event. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety 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 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 E.O. 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 above.

#### 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 the establishment of a safety zone for the Tough Cup event scheduled to take place on September 24, 2016. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.ID. An 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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

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 Web site'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 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes 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:** 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.T09–0451 to read as follows:

#### § 165.929 T09–0451 Safety Zone; South Branch of the Chicago River and the Chicago Sanitary and Ship Canal, Chicago, IL.

(a) *Location.* All waters of the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal between the Illinois Northern Bridge and the Loomis Street Highway Bridge.

(b) *Effective and Enforcement Period.* This rule will be effective from 6:30 a.m. to 1:00 p.m. on September 24, 2016 and will be enforced from 6:30 a.m. to 1:00 p.m. on September 24, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Lake Michigan or a designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Lake Michigan is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Lake Michigan to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Lake Michigan or an on-scene representative to obtain permission to do so. The Captain of the Port Lake Michigan or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Lake Michigan, or an on-scene representative.

Dated: June 20, 2016.

**A.B. Cocanour,**

*Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.*

[FR Doc. 2016–15695 Filed 6–30–16; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 51 and 52

[EPA–HQ–OAR–2015–0531; FRL–9948–53–OAR]

#### Protection of Visibility: Amendments to Requirements for State Plans

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; extension of comment period.