

Feingold Association of the United States, Food & Water Watch, Healthy Babies Bright Futures, Life Time Foundation, Momsrising, Prevention Institute, Public Citizen, Public Health Institute, Public Interest Research Group, Real Food for Kids, Lisa Y. Lefferts, Linda S. Birnbaum, and Philip J. Landrigan, c/o Jensen Jose, 1250 I Street NW, Suite 500, Washington, DC 20005. The petition proposes that we repeal the color additive regulations for FD&C Red No. 3 in § 74.303 (21 CFR 74.303), which permits the use of FD&C Red No. 3 in foods (including dietary supplements), and § 74.1303 (21 CFR 74.1303), which permits the use of FD&C Red No. 3 in ingested drugs.

## II. Repeal of §§ 74.303 and 74.1303

In accordance with the procedure in section 721(d) of the FD&C Act for issuance, amendment, or repeal of regulations, the petition asks us to repeal §§ 74.303 and 74.1303 to no longer provide for the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs, respectively. Specifically, the petitioners state that experimental data show that FD&C Red No. 3 induces cancer when fed to rats and that FDA concluded such in 1990. The petitioners also state that subsequent studies and reviews have reinforced FDA's conclusion. The petitioners cite, as evidence, data and information from the National Toxicology Program, the Joint Expert Committee on Food Additives, and the European Commission's Scientific Committee for Food (which was later replaced by the European Food Safety Authority). The petitioners also state that there is widespread exposure to U.S. consumers, particularly children, and that very young children have the highest exposures to the color additive. The petitioners cite the Delaney Clause (section 721(b)(5)(B) of the FD&C Act), which provides that no color additive shall be deemed safe for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary of Health and Human Services (Secretary) to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal. The petitioners state that the Delaney Clause obligates FDA to repeal the regulations for FD&C Red No. 3.

We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justify repealing §§ 74.303

and 74.1303 to no longer provide for the use of FD&C Red No. 3, we will publish our decision in the **Federal Register** in accordance with 21 CFR 71.20.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m) because this action would prohibit or otherwise restrict the use of a substance in food packaging. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: February 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[Docket Number USCG-2023-0081]

**RIN 1625-AA00**

### Safety Zone: Tall Ships America; Tampa Bay, St Petersburg, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is establishing a temporary moving safety zone on the waters of Tampa Bay, around a Tall Ships America Parade of sail in St Petersburg, Florida. The safety zone will extend 100 yards from the beam of the ships as they transit from the muster point in approximate position 27°43.54' N 082°36.38' W to the moorings at Port St Pete, St Petersburg, FL in approximate position 27°45.34' N 082°37.15' W. The safety Zone is necessary to protect the public, wooden sailing vessels and their crews from the hazards associated with transiting the area. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port St. Petersburg 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 March 6, 2023.

**ADDRESSES:** You may submit comments identified by docket number USCG-2023-0081 using the Federal Decision Making 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 Marine Science Technician First Class Regina L Cuevas, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228-2191, email [Regina.L.Cuevas@uscg.mil](mailto:Regina.L.Cuevas@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 March 30, 2023, Tall Ships America will be visiting the Port of St Pete in St Petersburg, FL. The Coast Guard is establishing a temporary moving safety zone on the waters of Tampa Bay, around the Tall Ships America Parade of sail in St Petersburg, Florida on March 30, 2023. The safety zone will extend 100 yards from the beam of the ships as they transit from the muster point in approximate position 27°43.54' N 082°36.38' W to the moorings at Port St Pete, St Petersburg, FL in approximate position 27°45.34' N 082°37.15' W. The safety Zone is necessary to protect the public, wooden sailing vessels and their crews from the hazards associated with transiting the area. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port St. Petersburg or a designated representative.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 100-yard radius of the Tall Ships America vessels. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

### III. Discussion of Proposed Rule

The COTP is proposing to establish a moving safety zone from 1:30 p.m. to 5:30 p.m. on March 30, 2023. The duration of the zone is intended to ensure the safety of vessels and their crews in these navigable waters of

Tampa Bay during this event. 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, 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 Tampa Bay for the Parade route and Port St Pete which is already designated as a restricted area. Vessel traffic is normally low during this time of day, and once moored the Vessels will not be impeding the waterway. 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 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 an initial moving safety zone lasting 4 hours that would prohibit entry within 100 yards of a the Parade of Sail. Normally such actions are categorically excluded from further review under paragraph L[60a] 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–2023–0081 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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

- 2. Add § 165.T07–0081 to read as follows:

#### § 165.T07–0081 Safety Zone: Tall Ships America; Tampa Bay, St Petersburg, FL.

The Coast Guard is establishing a temporary moving safety zone on the waters of Tampa Bay, around a Tall ships America Parade of sail in St Petersburg, Florida on March 30, 2023. The safety zone will extend 100 yards from the beam of the ships as they transit from the muster point in approximate position 27°43.54′ N 082°36.38′ W to the moorings at Port St Pete, St Petersburg, FL in approximate position 27°45.34′ N 082°37.15′ W. The safety Zone is necessary to protect the public, wooden sailing vessels and their crews from the hazards associated with transiting the area. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port St. Petersburg or a designated representative.

Dated: February 14, 2023.

**Micheal P. Kahle,**

*Captain, U.S. Coast Guard, Captain of the Port Saint Petersburg.*

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#### LIBRARY OF CONGRESS

##### Copyright Office

##### 37 CFR Parts 201 and 205

[Docket No. 2023–1]

##### Ex Parte Communications

**AGENCY:** U.S. Copyright Office, Library of Congress.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The U.S. Copyright Office is issuing a notice of proposed rulemaking to establish procedures governing the use of *ex parte* communications in informal rulemakings. The proposed rule defines *ex parte* communications, instructs the public on how to request an *ex parte* meeting with the Office, sets forth the responsibilities of parties after an *ex parte* meeting, and identifies impermissible *ex parte* communications.

**DATES:** Comments on the proposed rule must be made in writing and received by the U.S. Copyright Office no later than 11:59 p.m. Eastern Time on April 3, 2023.

**ADDRESSES:** For reasons of Government efficiency, the Copyright Office is using the [regulations.gov](https://www.regulations.gov) system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through [regulations.gov](https://www.regulations.gov).

Specific instructions for submitting comments are available on the Copyright Office website at <https://copyright.gov/rulemaking/ex-parte-communications>. If electronic submission of comments is not feasible due to lack of access to a computer or the internet, please contact the Office using the contact information below for special instructions.

#### FOR FURTHER INFORMATION CONTACT:

Rhea Efthimiadis, Assistant to the General Counsel, by email at [mefth@copyright.gov](mailto:mefth@copyright.gov), or by telephone at 202–707–8350 or Melinda Kern, Attorney-Advisor, by email at [mkern@copyright.gov](mailto:mkern@copyright.gov), or by telephone at 202–707–8350.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### Statutory Background

The Copyright Office conducts rulemakings consistent with the Administrative Procedure Act (“APA”) rules governing informal rulemakings.<sup>1</sup> An informal rulemaking includes a notice-and-comment period, which gives the public an opportunity to respond to an agency’s proposed regulatory action. Unlike formal rulemakings, informal rulemakings do not require on-the-record hearings or trial-type procedures,<sup>2</sup> such as the presentation of evidence.

While the APA sets forth certain requirements for informal rulemakings,<sup>3</sup> it does not prohibit agencies from engaging in what are commonly referred to as “*ex parte* communications.”<sup>4</sup> The term “*ex parte*” is a bit of a misnomer in this context. In other legal contexts, the term means “[o]n or from one party only, usually without notice to or argument from the adverse party,”<sup>5</sup> and usually refers to communications with a court by one party. In the rulemaking context, an *ex parte* communication is a “[w]ritten or oral communication [] regarding the substance of an

<sup>1</sup> See 5 U.S.C. 553; 17 U.S.C. 701(e).

<sup>2</sup> See 5 U.S.C. 556, 557 (discussing procedural requirements in formal rulemakings).

<sup>3</sup> *Id.* at 553.

<sup>4</sup> See *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 57 (D.C. Cir. 1977) (finding *ex parte* communications in informal rulemakings “completely appropriate” when they “do not frustrate judicial review or raise serious questions of fairness”); *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (noting that under the APA, “[a]gencies are free to grant additional procedural rights in the exercise of their discretion”); see also *Sierra Club v. Costle*, 657 F.2d 298, 401–02 (D.C. Cir. 1981) (noting that Congress declined to extend the *ex parte* prohibition applicable to formal rulemakings to informal rulemakings despite being urged to do so); cf. 5 U.S.C. 557(d) (prohibiting *ex parte* communications in formal rulemaking proceedings).

<sup>5</sup> Black’s Law Dictionary (11th ed. 2019).