

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-0763 for "Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Crystal Rivers, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1444.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 31, 2017, FDA published a proposed rule to revoke our regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. We proposed this action based on our review of the totality of publicly available scientific evidence currently available and our tentative conclusion that such evidence does not support our previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. We provided a 75-day comment period for the proposed rule.

We have received requests for a 60-day extension of the comment period for the proposed rule. Each request conveyed concern that the current comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule until March 19, 2018. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: January 11, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2017-1058]

RIN 1625-AA00

### Safety Zone; Lower Mississippi River, New Orleans, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish two temporary safety zones for multiple locations and dates within the Captain of the Port Sector New Orleans Zone. These safety zones are necessary to protect persons and vessels from potential safety hazards associated with fireworks displays on or over navigable waterways. Entry into these zones is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) 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 19, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2017-1058 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 Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, US Coast Guard; telephone 504-365-2281, email [Howard.K.Vacco@uscg.mil](mailto:Howard.K.Vacco@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port Sector New Orleans  
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 Coast Guard proposes to establish temporary safety zones for the following fireworks displays:

(1) On November 7, 2017, the New Orleans Tourism & Marketing Corporation notified the Coast Guard that it would be conducting a fireworks display from 7:45 p.m. through 8:45 p.m. on May 25, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate mile marker (MM) 95.9, above Head of Passes, New Orleans, LA.

(2) On March 14, 2017, the NOLA 2018 Foundation notified the Coast Guard that it would be conducting a fireworks display from 8 p.m. through 8:20 p.m. on May 6, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate MM 95.4, above Head of Passes, New Orleans, LA.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within a one-mile range 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 two temporary safety zones within the Captain of the Port Sector New Orleans (COTP) Zone on two different dates and locations. Both safety zones will encompass a one-mile stretch of river with a duration lasting no more than one hour. The duration of the zones is intended to ensure the safety of vessels on these navigable waters before, during, and after the scheduled fireworks displays. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The proposed zones are as follows:

(1) Bayou Country Music Fest: a safety zone from 7:45 p.m. through 8:45 p.m. on May 25, 2018. The safety zone would cover all navigable waters of the Lower Mississippi River between MM 95.4 and MM 96.4, above Head of Passes.

(2) NOLA Tricentennial 2018 Jazz and Heritage Fest: A safety zone from 8 p.m. through 9 p.m. on May 6, 2018. This safety zone would cover all navigable waters of the Lower Mississippi River between MM 95 and MM 96, above Head of Passes.

## 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 short duration of the waterway closure, which would remain in effect for one hour on a one-mile section of the waterway. In addition, vessel traffic seeking to transit the areas would be able to seek permission from the COTP or his designated representative to do so.

### 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 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, which guides 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 two safety zones lasting one hour that would prohibit entry within a one-mile section of the Lower Mississippi River. They are categorically excluded from further review under paragraph L60(a) 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 <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 165

Harbors, 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 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.T08-1058 to read as follows:

##### § 165.T08-1058 Safety Zones; Lower Mississippi River, New Orleans, LA

(a) *Safety Zones.* The following areas are a safety zone:

(1) Bayou Country Music Fest, New Orleans, LA.

(i) *Location:* All navigable waters of the Lower Mississippi River between mile marker (MM) 95.4 and MM 96.4, above Head of Passes.

(ii) *Effective Period:* This rule is effective from 7:45 p.m. through 8:45 p.m. on May 25, 2018.

(2) NOLA Tricentennial 2018 Jazz and Heritage Fest.

(i) *Location:* All navigable waters of the Lower Mississippi River between mile marker (MM) 94 and MM 95, above Head of Passes.

(ii) *Effective Period:* This rule is effective from 8 p.m. through 9 p.m. on May 6, 2018.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into these zones is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (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 Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF-FM Channel 16 or 67.

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

(c) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: January 11, 2018.

**Wayne R. Arguin,**

*Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.*

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**BILLING CODE 9110-04-P**

#### DEPARTMENT OF VETERANS AFFAIRS

#### 38 CFR Part 17

**RIN 2900-AP02**

#### Civilian Health and Medical Program of the Department of Veterans Affairs

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulations governing the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). The proposed revisions would clarify and update these regulations to conform to changes in law and policy that control the administration of CHAMPVA and would include details concerning the administration of CHAMPVA that are not reflected in current regulations. The proposed revisions would also expand covered services and supplies to include certain preventive services and eliminate cost-share amounts and deductibles for certain covered services.

**DATES:** Written comments must be received on or before March 19, 2018.

**ADDRESSES:** Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to the Director, Regulation and Policy Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in