

## V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VI. Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 500.84 have been approved under OMB control number 0910–0032.

### List of Subjects in 21 CFR Part 500

Animal drugs, animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 500 is amended as follows:

### PART 500—GENERAL

■ 1. The authority citation for 21 CFR part 500 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 500.82(b), revise the definitions of “ $S_m$ ” and “ $S_o$ ” to read as follows:

#### § 500.82 Definitions.

\* \* \* \* \*

(b) \* \* \*

$S_m$  means the concentration of a residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of cancer to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this  $S_m$  will correspond to the concentration of residue in a specific edible tissue that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

$S_o$  means the concentration of a residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer

to the human consumer. For the purpose of § 500.84(c)(1), FDA will assume that this  $S_o$  will correspond to the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.

\* \* \* \* \*

■ 3. In § 500.84, revise paragraph (c) introductory text to read as follows:

#### § 500.84 Conditions for approval of the sponsored compound.

\* \* \* \* \*

(c) For each sponsored compound that FDA decides should be regulated as a carcinogen, FDA will either analyze the data from the bioassays using a statistical extrapolation procedure as outlined in paragraph (c)(1) of this section or evaluate an alternate procedure proposed by the sponsor as provided in § 500.90. In either case, paragraphs (c)(2) and (3) of this section apply.

\* \* \* \* \*

Dated: August 17, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2012–0765]

RIN 1625–AA00

#### Safety Zone; Seafood Festival Fireworks Display, Marquette, MI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone near Marquette, Michigan. This safety zone is intended to restrict vessels from a portion of Lake Superior due to a fireworks display. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with a fireworks display.

**DATES:** This rule is effective from 9:30 p.m. until 11:00 p.m. on August 25, 2012.

**ADDRESSES:** Documents mentioned in this preamble are part of docket [USCG–2012–0765]. To view documents in this preamble as being available in the

docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box, and click “Search.” You may visit the Docket Management Facility, Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or email MST2 Kevin Moe, U.S. Coast Guard, Sector Sault Sainte Marie, telephone 906–253–2429, email at [Kevin.D.Moe@uscg.mil](mailto:Kevin.D.Moe@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

#### SUPPLEMENTARY INFORMATION:

##### Table of Acronyms

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

##### A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not received by the Coast Guard with sufficient time for a comment period to run before the start of the event. Thus, delaying this rule to wait for a notice and comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect the public from the hazards associated with maritime fireworks displays.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

## B. Basis and Purpose

On the evening of August 25, 2012, fireworks will be launched from a point on Marquette Bay to celebrate the Annual Marquette Seafood Festival. The Captain of the Port, Sector Sault Sainte Marie, has determined that the Marquette Seafood Festival Fireworks Display will pose significant risks to the public. The likely congested waterways in the vicinity of a fireworks display could easily result in serious injuries or fatalities.

## C. Discussion of Rule

To mitigate the risks associated with the Seafood Festival Fireworks Display, the Captain of the Port, Sector Sault Sainte Marie will enforce a temporary safety zone in the vicinity of the launch site. This safety zone will encompass all waters of Lake Superior in Marquette Harbor, within the arc of a circle with a 1,000 ft radius from the fireworks launch site located in position 46°32'21.7" N, 087°23'07.60" W [DATUM: NAD 83]. The safety zone will be effective and enforced from 9:30 p.m. until 11:30 p.m. on August 25, 2012.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Sector Sault Sainte Marie, or his or her on-scene representative. The Captain of the Port, Sector Sault Sainte Marie, or his or her on-scene representative may be contacted via VHF channel 16.

## D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

### 1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under these Orders. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this 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 will exist for only a minimal time. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by proper authority.

### 2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portion of Lake Superior between 9:30 p.m. and 11:00 p.m. on August 25, 2012.

This safety zone will not have significant economic impact on a substantial number of small entities for the following reasons: This rule will only be enforced for a short period of time. Vessels may safely pass outside the safety zone during the event. In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port, Sector Sault Sainte Marie, to transit through the safety zone. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

### 3. Assistance for Small Entities

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 the 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 above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain

about this rule or any policy or action of the Coast Guard.

### 4. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### 5. Federalism

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 rule under that Order and determined that this rule does not have implications for federalism.

### 6. 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.

### 7. 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### 8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### 9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### 10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and

does not create an environmental risk to health or risk to safety that may disproportionately affect children.

#### 11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

#### 12. Energy Effects

This action is not a "significant energy action" under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

#### 13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### 14. Environment

We have analyzed this 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 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction because it involves the establishment of a safety zone. A final environmental analysis checklist and a 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 rule.

#### 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 amends 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; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09-0765 to read as follows:

#### § 165.T09-0765 Safety Zone; Seafood Festival Fireworks Display, Marquette, Michigan.

(a) *Location.* All U.S. navigable waters of Marquette Harbor within a 1000-foot radius of the fireworks launch site, centered approximately 1250 feet south of the Mattson Park Bulkhead Dock and 450 feet east of Ripley Rock, at position 46°32'21.7" N, 087°23'07.60" W [DATUM: NAD 83].

(b) *Effective and enforcement period.* This rule is effective and will be enforced from 9:30 p.m. until 11:00 p.m. on August 25, 2012.

#### (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, Sector Sault Sainte Marie, or his or her on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port, Sector Sault Sainte Marie, or his or her on-scene representative.

(3) The "on-scene representative" of the Captain of the Port, Sector Sault Sainte Marie, is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Sector Sault Sainte Marie, to act on his or her behalf. The on-scene representative of the Captain of the Port, Sector Sault Sainte Marie, will be aboard either a Coast Guard or Coast Guard Auxiliary vessel.

(4) Vessel operators desiring to enter the safety zone or operate within the safety zone shall contact the Captain of the Port, Sector Sault Sainte Marie, or his or her on-scene representative to obtain permission to do so. The Captain of the Port, Sector Sault Sainte Marie, or his or her 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, Sector Sault Sainte Marie, or his or her on-scene representative.

Dated: August 13, 2012.

**J.C. McGuiness,**

*Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.*

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-RO1-OAR-2008-0117; EPA-RO1-OAR-2008-0107; EPA-RO1-OAR-2008-0445; FRL-9672-5]

#### Approval and Promulgation of Air Quality Implementation Plans; Connecticut, Massachusetts, and Rhode Island; Reasonable Further Progress Plans and 2002 Base Year Emission Inventories

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

**ACTION:** Final rule.

**SUMMARY:** EPA is approving State Implementation Plan revisions submitted by the States of Connecticut, Massachusetts, and Rhode Island. These revisions establish 2002 base year emission inventories and reasonable further progress emission reduction plans for areas within these states designated as nonattainment of EPA's 1997 8-hour ozone standard. The intended effect of this action is to approve these states' 2002 Base Year Inventories and reasonable further progress (RFP) emission reduction plans, and to approve the 2008 motor vehicle transportation budgets and contingency measures associated with the RFP plans. EPA also is approving three rules adopted by Connecticut that will reduce volatile organic compound emissions in the state. This action is being taken in accordance with the Clean Air Act.

**DATES:** *Effective Date:* This rule is effective on September 21, 2012.

**ADDRESSES:** EPA has established dockets for these actions under Docket Identification Numbers EPA-RO1-OAR-2008-0117 for our action for Connecticut, EPA-RO1-OAR-2008-0107 for our action for Massachusetts, and EPA-RO1-OAR-2008-0445 for our action for Rhode Island. All documents in the dockets are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality