

comment is significant and warrants withdrawing a direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment also states why this rule would be ineffective without the additional change.

If FDA does not receive significant adverse comment, the Agency will publish a document in the **Federal Register** confirming the effective date of the final rule. The Agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the Federal Register.

A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance document may be accessed at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

III. Analysis of Impacts

HHS/FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule imposes no duties or obligations on small entities, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that

includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 21

Privacy.

45 CFR Part 5b

Privacy.

Therefore, the Department of Health and Human Services is amending 21 CFR part 21 and 45 CFR part 5b to read as follows:

Title 21

PART 21—PROTECTION OF PRIVACY

■ 1. The authority citation for 21 CFR part 21 continues to read as follows:

Authority: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

■ 2. Section 21.61 is amended by adding paragraph (d) to read as follows:

§ 21.61 Exempt systems.

* * * * *

(d) Records in the following Food and Drug Administration Privacy Act Records Systems are exempt under 5 U.S.C. 552a(k)(2) and (k)(5) from the provisions enumerated in paragraph (a)(1) through paragraph (3) of this section: FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09–10–0020.

Title 45

PART 5b—PRIVACY ACT REGULATIONS

■ 3. The authority citation for 45 CFR part 5b continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

■ 4. Section 5b.11 is amended by adding paragraph (b)(2)(vii)(C) to read as follows:

§ 5b.11 Exempt systems.

* * * * *

(b) * * *

(2) * * *

(vii) * * *

(C) FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC.

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Dated: July 20, 2012.

Kathleen Sebelius,

Secretary of Health and Human Services.

[FR Doc. 2012–20889 Filed 8–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0618]

RIN 1625–AA00

Safety Zone; Tom Lyons Productions Fireworks, Long Island Sound, Sands Point, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of Long Island Sound, in the vicinity of Sands Point, NY. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays. This rule is intended to restrict all vessels from a portion of Long Island Sound before, during, and immediately after the fireworks event.

DATES: This rule will be effective from 10:30 p.m. on October 6, 2012 until 11:45 p.m. on October 7, 2012. This rule will be enforced from 10:30 p.m. to 11:45 p.m. on October 6, 2012, and from 10:30 p.m. to 11:45 p.m. on October 7, 2012.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2012–0618. To view documents mentioned 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.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 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 rule, call or email Lieutenant Junior Grade Kristopher Kesting, Sector NY Waterways Management, U.S. Coast Guard; Telephone (718) 354-4154, E-Mail Kristopher.R.Kesting@uscg.mil. If you have questions on viewing or submitting material to 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
COTP—Captain of the Port

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 sufficient information about the event was not received in time to publish a NPRM followed by a final rule before the effective date, thus making the publication of a NPRM impractical. The Coast Guard received the information about the event on June 25, 2012. Any delay encountered in this regulation’s effective date by publishing a NPRM would be contrary to public interest, since immediate action is needed to provide for the safety of life and property on navigable waters from the hazards associated with fireworks including unexpected detonation and burning debris.

The rule must become effective on the date specified in order to provide for the safety of spectators and vessels operating in the area near this event. Delaying this rule would be impracticable and contrary to the public interest, and would expose spectators and vessels to the hazards associated with the fireworks event.

B. Basis and Purpose

The legal basis for this rule is 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, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

This temporary safety zone is necessary to ensure the safety of spectators and vessels from hazards associated with the fireworks display.

C. Discussion of the Final Rule

This rule establishes a temporary safety zone on the navigable waters of Long Island Sound, in the vicinity of Sands Point, NY. All persons and vessels shall comply with the instructions of the Captain of the Port (COTP) New York or the designated representative during the enforcement of the temporary safety zone. Entering into, transiting through, or anchoring within the temporary safety zone is prohibited unless authorized by the COTP New York, or the designated representative.

Based on the inherent hazards associated with fireworks, the COTP New York has determined that fireworks launches in close proximity to water crafts pose a significant risk to public safety and property. The combination of increased number of recreational vessels, congested waterways, darkness punctuated by bright flashes of light, and debris, especially burning debris falling on passing or spectator vessels has the potential to result in serious injuries or fatalities. This temporary safety zone will restrict vessels from a portion of Long Island Sound around the location of the fireworks launch platform before, during, and immediately after the fireworks display.

The Coast Guard has determined that this regulated area will not have a significant impact on vessel traffic due to its temporary nature and limited size and the fact that vessels are allowed to transit the navigable waters outside of the regulated area.

Advance public notifications will also be made to the local mariners through appropriate means, which will include, but are not limited to, the Local Notice to Mariners as well as Broadcast Notice to Mariners.

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 Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard’s implementation of this temporary safety zone will be of short duration and is designed to minimize the impact to vessel traffic on the navigable waters. This temporary safety zone will only be enforced for approximately 75 minutes, in the late evening. Due to the location, vessels will be able to transit around the zone in a safe manner.

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.

(1) This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in a portion of the navigable waters in the vicinity of the marine event during the effective period.

(2) This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: this rule will be in effect for 75 minutes; late at night when vessel traffic is low, vessel traffic could pass safely around the safety zone, and the Coast Guard will notify mariners before activating the zone by appropriate means including but not limited to Local Notice to Mariners and Broadcast Notice to Mariners.

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 this 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**, 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 will not call for a 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 determined 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 rule involves the establishment of a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. An environmental analysis checklist supporting this determination 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 AREA

■ 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, 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01-0618 to read as follows:

§ 165.T01-0618 Safety Zone; Tom Lyons Productions Fireworks, Long Island Sound, Sands Point, NY.

(a) *Regulated Area.* The following area is a temporary safety zone: all navigable waters of Long Island Sound within a 240-yard radius of the fireworks barge located in approximate position 40°51'57.09" N, 073°44'04.20" W, in the vicinity of Sands Point, NY, approximately 390 yards west of the tip of Sands Point.

(b) *Effective Dates and Enforcement Periods.* This rule will be effective from 10:30 p.m. on October 6, 2012 until 11:45 p.m. on October 7, 2012. This rule will be enforced from 10:30 p.m. to 11:45 p.m. on October 6, 2012, and from 10:30 p.m. to 11:45 p.m. on October 7, 2012.

(c) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* A "designated representative" is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port Sector New York (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF-FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) *Spectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23, as well as the following regulations, apply.

(2) No vessels, except for fireworks barge and accompanying vessels, will be allowed to transit the safety zone without the permission of the COTP.

(3) All persons and vessels shall comply with the instructions of the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(4) Vessel operators desiring to enter or operate within the regulated area shall contact the COTP or the designated representative via VHF channel 16 or 718–354–4353 (Sector New York command center) to obtain permission to do so.

(5) Spectators or other vessels shall not anchor, block, loiter, or impede the transit of event participants or official patrol vessels in the regulated areas during the effective dates and times, or dates and times as modified through the Local Notice to Mariners, unless authorized by COTP or the designated representative.

(6) Upon being hailed by a U.S. Coast Guard vessel or the designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(7) The COTP or the designated representative may delay or terminate any marine event in this subpart at any time it is deemed necessary to ensure the safety of life or property.

Dated: August 17, 2012.

G. Loeb,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2012–21193 Filed 8–27–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2012–0296; FRL–9720–6]

Approval and Promulgation of Air Quality Implementation Plans; State of New York; Regional Haze State Implementation Plan and Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action on the Regional Haze State Implementation Plan (SIP) submitted by the State of New York. EPA is approving seventeen source-specific SIP revisions containing permits for Best Available Retrofit Technology, revisions for Title 6 of the New York Codes, Rules and Regulations, Part 249, “Best Available Retrofit Technology (BART)” and section 19–0325 of the New York Environmental Conservation Law which regulates the sulfur content of fuel oil. These revisions to the SIP addressing regional haze were submitted by the State of New York on March 15, 2010, and supplemented on August 2, 2010, April 16, 2012 and July 2, 2012. These SIP revisions were submitted to address Clean Air Act requirements and EPA’s rules for states to prevent and remedy future and existing anthropogenic impairment of visibility in mandatory Class I areas through a regional haze program. Although New York State addressed most of the issues identified in EPA’s proposal, EPA is promulgating a Federal Implementation Plan to address two sources where EPA is disapproving New York’s BART determinations.

DATES: This rule is effective on September 27, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R02–OAR–2012–0296. All documents in the docket are listed on the www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., 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 or in hard copy at the Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 212–637–4249.

FOR FURTHER INFORMATION CONTACT: Robert F. Kelly, Air Planning Section, Air Programs Branch, EPA Region 2, 290 Broadway, New York, New York 10007–1866. The telephone number is (212) 637–4249. Mr. Kelly can also be reached via electronic mail at kelly.bob@epa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. What action is EPA taking?
- II. What additional SIP revisions did New York submit consistent with EPA’s proposal?
 - A. SIP Revisions for BART Determinations
 - B. SIP Revision for 6 NYCRR, Part 249, “Best Available Retrofit Technology (BART)”
 - C. SIP Revision for New York’s Low Sulfur Fuel Oil Strategy
- III. What is contained in EPA’s federal implementation plan for New York’s regional haze program?
- IV. What comments did EPA receive on its proposal and what were EPA’s responses?
- V. What are EPA’s conclusions?
- VI. Statutory and Executive Order Reviews

Throughout this document, wherever “Agency,” “we,” “us,” or “our” is used, we mean the EPA.

I. What action is EPA taking?

EPA is approving New York’s State Implementation Plan (SIP) revisions addressing regional haze submitted on March 15, 2010, and supplemented on August 2, 2010, April 16, 2012, and July 2, 2012. EPA is supplementing New York’s SIP with a Federal Implementation Plan (FIP) for three units at two BART sources where EPA is disapproving these BART determinations. The following paragraphs summarize each of EPA’s actions.

EPA is approving aspects of New York’s Regional Haze SIP revision as follows:

- The measures enacted by New York are shown to produce emission reductions that are sufficient to meet New York’s share of the emission reductions needed to meet reasonable progress goals (found at 40 CFR 51.308(d)(1)) at Class I areas affected by New York’s emissions.

- New York’s Long Term Strategy, since New York submitted final approvable permit modifications for all facilities on April 16, 2012 and July 2, 2012 (except for the Roseton and Danskammer Generating Stations), in a timely manner with the level of control in EPA’s April 25, 2012 proposal. EPA’s FIP contains BART determinations and emission limits for the Roseton and Danskammer Generating Stations.

- New York’s SIP revision consisting of Title 6 of the New York Codes, Rules and Regulations (6 NYCRR), Part 249, “Best Available Retrofit Technology (BART).”

- New York’s SIP revision consisting of section 19–0325 of the New York Environmental Conservation Law which regulates the sulfur content of fuel oil.

EPA is approving the following facility BART determinations and