

§ 610.48 (21 CFR 610.48) of the final rule, FDA established HCV “lookback” requirements based on review of historical testing records. The requirements under § 610.48 were to remain in effect for 8 years after the date of publication of the final rule in the **Federal Register** (§ 610.48(e)). Section 610.48(e) specifically provides that the section expired on August 24, 2015; therefore, FDA is removing this regulation from Title 21 of the Code of Federal Regulations.

FDA is also making conforming changes to other biologics regulations where § 610.48 is referenced.

FDA is revising the biologics regulations as follows:

- Removing and reserving § 610.48.
- Revising § 606.100(b)(19) (21 CFR 606.100(b)(19)) by removing the reference to § 610.48.
- Revising § 606.160(b)(1)(viii) by removing the reference to § 610.48.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comments are unnecessary because the amendments to the regulations provide only technical changes to remove and update information and are nonsubstantive.

List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606 and 610 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

■ 1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

§ 606.100 [Amended]

■ 2. Amend § 606.100(b)(19) introductory text by removing “§§ 610.46, 610.47, and 610.48” and adding in its place “§§ 610.46 and 610.47”.

§ 606.160 [Amended]

■ 3. Amend § 606.160(b)(1)(viii) by removing “§§ 610.46, 610.47, and, 610.48” and adding in its place “§§ 610.46 and 610.47”.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.48 [Removed and Reserved]

■ 5. Remove and reserve § 610.48.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32477 Filed 12–24–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–1074]

RIN 1625–AA00

Safety Zone; New Year’s Eve Firework Displays, Chicago River, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone that encompasses all waters of the Main Branch of the Chicago River between the Michigan Avenue Highway Bridge and the west entrance to the Chicago Harbor Lock. The safety zone is intended to restrict vessels from a portion of the Main Branch of the Chicago River from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with multiple barge based firework displays for Chicago’s New Year’s Eve Celebration.

DATES: This rule will be effective from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2015–1074 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Lindsay Cook, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986–2155, email Lindsay.N.Cook@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary 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 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. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish a NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard’s ability to protect the public and vessels from the hazards associated with multiple barge based firework displays on the Main Branch of the Chicago River.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary 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.

III. Legal Authority and Need for Rule

The legal basis for the 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.

December 31, 2015 and January 1, 2016 Chicago’s New Year’s Eve firework displays will take place from multiple barge based launch sites on the Main

Branch of the Chicago River. The Captain of the Port, Lake Michigan has determined that the firework displays will pose a significant risk to public safety and property. Such hazards include falling debris, flaming debris, and collisions among spectator vessels. The safety zone is necessary to protect spectators from hazards associated with aerial firework displays.

IV. Discussion of the Rule

With the aforementioned hazards in mind, the Captain of the Port, Lake Michigan has determined that a temporary safety zone is necessary to ensure the safety of the public and the participants during Chicago's New Year's Eve Fireworks Display on the Main Branch of the Chicago River. This safety zone will be effective from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016. The safety zone will encompass all waters of the Main Branch of the Chicago River between the Michigan Avenue Highway Bridge and west entrance of the Chicago Harbor Lock. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan, or a designated on-scene representative. The Captain of the Port or a designated on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

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 created by this rule will be

relatively small and effective for less than a one hour period on December 31, 2015 and January 1, 2016. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

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 rule will not have a significant economic impact on a substantial number of small entities.

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this temporary rule on 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 on a portion of the Main Branch of the Chicago River on December 31, 2015 and January 1, 2016.

The safety zone will not have a significant economic impact on a substantial number of small entities for the reasons cited in the *Regulatory Planning and Review* section. Additionally, before the enforcement of the zone, we will issue local Broadcast Notice to Mariners and Public Notice of Safety Zone so vessel owners and operators can plan accordingly.

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** section.

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.

C. 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).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 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 have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this rule does not have tribal implications under E.O. 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. If you believe this 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. 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 (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 safety zone for the New Year's Eve firework displays on the Main Branch of the Chicago River. It 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.

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.

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; 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.T09-1074 to read as follows:

§ 165.T09-1074 Safety Zone; New Year's Eve Fireworks Display, Chicago River, Chicago, IL.

(a) *Location*. All waters of the the Main Branch of the Chicago River between the Michigan Avenue Highway Bridge and the west entrance of the Chicago Harbor Lock.

(b) *Enforcement Period*. This rule will be enforced from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 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: December 11, 2015.

A.B. Cocanour,

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

[FR Doc. 2015-32642 Filed 12-24-15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA-HQ-OPP-2010-0305; FRL-9934-44]

RIN 2070-AJ79

Pesticides; Revisions to Minimum Risk Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revising its regulations to more clearly describe the active and inert ingredients that are permitted in products eligible for the minimum risk pesticide exemption. EPA is improving the clarity and transparency of the minimum risk exemption by codifying the inert ingredients list and by adding specific chemical identifiers, where available, for all eligible active and inert ingredients. These specific identifiers will make it easier for manufacturers, the public, and Federal, state, and tribal inspectors to determine the specific chemical substances that are permitted in minimum risk pesticide products. EPA is also modifying the labeling requirements in the exemption to require products to list ingredients on the label with a designated label display name and to provide the producer's

contact information on the product's label. These changes will provide more consistent information for consumers and clearer regulations for producers, and will simplify compliance determination by states, tribes, and EPA.

DATES: This final rule is effective February 26, 2016. The compliance date for the requirements to label ingredients with a label display name and to provide company contact information on the label is February 26, 2019.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0305, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Ryne Yarger, Field and External Affairs Divisions (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 605-1193; fax number: (703) 305-5884; email address: yarger.ryne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. Minimum risk pesticide products are exempt from registration and other requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and are described in 40 CFR 152.25(f). The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers of these products, which includes pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (NAICS