

D&C Yellow No. 8 continues to be necessary to protect the public health.

#### V. Public Disclosure

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **ADDRESSES**). As provided in § 71.15(b), we will delete from the documents any materials that are not available for public disclosure.

#### VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the May 31, 2017, **Federal Register** notice of filing for CAP 7C0311 (82 FR 24912). We stated that we had determined, under 21 CFR 25.32(I), that this action “is of a type that does not individually or cumulatively have a significant effect on the human environment” such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

#### VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VIII. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file electronic objections to this docket at <https://www.regulations.gov>, or written objections with the Dockets Management Staff (see **ADDRESSES**). You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a

description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

#### IX. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Memorandum from H. Lee, Chemistry Review Team, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 3, 2018.
2. Memorandum from A. Khan, Toxicology Team, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 12, 2018.

#### List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 74 is amended as follows:

#### PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

- 1. The authority citation for part 74 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

- 2. Add § 74.3708 to subpart D to read as follows:

#### § 74.3708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* (1) D&C Yellow No. 8 may be safely used for coloring contact lens solution for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses at a level not to exceed 0.044 percent in the contact lens solution. Following excitation by ultraviolet light, the colored contact

lenses fluoresce a yellow-green color. The contact lens solution colored with D&C Yellow No. 8 is distributed by prescription only and used in accordance with the supplied directions for use. Contact lens solutions containing D&C Yellow No. 8 are intended for use only for coloring contact lenses that are worn for infrequent, celebratory occasions, and not for regular or daily use.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens solution in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–20767 Filed 9–24–18; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2018–0619]

RIN 1625-AA00

#### Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters near New Orleans, LA, during a fireworks display on October 6, 2018. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative.

**DATES:** This rule is effective from 9 p.m. through 10 p.m. on October 6, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>

[www.regulations.gov](http://www.regulations.gov), type USCG–2018–0619 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 about this rulemaking, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email [Benjamin.P.Morgan@uscg.mil](mailto:Benjamin.P.Morgan@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  
 MM Mile marker  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code

##### II. Background, Purpose, and Legal Basis

The Coast Guard was notified that Zito Company, LLC would be conducting a fireworks display from 9 p.m. through 10 p.m. on October 6, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate mile marker (MM) 94.5, above Head of Passes, off Algiers Point, New Orleans, LA. Hazards from firework displays include discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks display will be a safety concern for anyone within a one-mile stretch of the river.

In response, on July 19, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled *Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA* (83 FR 34092). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended August 20, 2018 we received no comments.

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**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the fireworks display.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector New Orleans (COTP) is establishing a temporary safety zone from 9 p.m. through 10 p.m. on October 6, 2018. The safety zone covers all navigable waters of the Lower Mississippi River between MM 94 and MM 95, above Head of Passes. The duration of the zone is intended to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the scheduled fireworks display.

##### IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on July 19, 2018. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 9 p.m. to 10 p.m. on October 6, 2018. The safety zone covers all navigable waters of the Lower Mississippi River between MM 94 and MM 95, above Head of Passes. The duration of the zone is intended to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the scheduled fireworks display.

No vessel or person is permitted to enter the safety zone without obtaining permission from the 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. 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. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The COTP or a designated representative would inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

##### V. Regulatory Analyses

We developed this 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 13563 (“Improving Regulation and Regulatory Review”) and 12866 (“Regulatory Planning and Review”) 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (“Reducing Regulation and Controlling Regulatory Costs”) directs agencies to reduce regulation and control regulatory costs and provides that “for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.”

The Office of Management and Budget (OMB) has not designated this rule a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB’s Memorandum “Guidance Implementing Executive Order 13771, Titled ‘Reducing Regulation and Controlling Regulatory Costs’” (April 5, 2017). This regulatory action determination is based on the size and short duration of the safety zone, which would impact a one-mile stretch of the Lower Mississippi River for one hour on one evening. In addition, vessel traffic seeking to transit the area may seek permission from the COTP or a 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 received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this 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 temporary safety zone may be small entities, for the reasons stated in section V.A above, this 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 (Public Law 104–121), we want to assist small entities in understanding this rule 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 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 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 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 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 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 rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, 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 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 rule involves a safety zone lasting one hour that would prohibit entry on one-mile stretch of the Lower Mississippi River. Normally such actions 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 Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

#### 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.T08–0619 to read as follows:

#### § 165.T08–0619 Safety Zone; Lower Mississippi River, Mile Markers 94 to 95, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River between mile marker (MM) 94 and MM 95 above Head of Passes, New Orleans, LA.

(b) *Effective period.* This section is effective from 9 p.m. through 10 p.m. on October 6, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or 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 this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

Dated: September 19, 2018.

**K.M. Luttrell,**

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

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