

about a change of information for the United States agent, but only a registrant is permitted to designate a new United States agent.

(4)(i) For a distributed manufacturing unit that is capable of moving or being moved to a new physical location, prior to changing the location of such distributed manufacturing unit the registrant must update their registration by providing advance notice as follows:

(1) For a location change within or to the United States, registrants must provide notice at least 30 calendar days prior to the relocation; or

(2) For a location change within or to a foreign country, registrants must provide notice at least 120 calendar days prior to the relocation.

(ii) The notification must include the unit identifier; the location from which the unit is departing (physical address or GPS coordinates); anticipated departure date; the destination location (physical address or GPS coordinates); anticipated arrival date; anticipated date to begin manufacturing operations at the new location.

(iii) The registrant must update the registration to confirm that the distributed manufacturing unit has arrived at the location specified in § 207.29(b)(4)(ii) and that manufacturing has commenced. The registrant must provide this update no later than 5 calendar days after a domestic distributed manufacturing unit begins to manufacture a drug or an animal feed bearing or containing a new drug for commercial distribution, or before a drug or an animal feed bearing or containing a new animal drug manufactured at a foreign distributed manufacturing unit is imported or offered for import into the United States.

(c) *Annual review and update of registration information.* Registrants must review and update all registration information required under § 207.25 for each establishment.

(1) The first review and update must occur during the period beginning on October 1 and ending December 31 of the year of initial registration, if the initial registration occurs prior to October 1. Subsequent reviews and updates must occur annually, during the period beginning on October 1 and ending December 31 of each calendar year.

(2) The updates must reflect all changes that have occurred since the last annual review and update.

(3) If no changes have occurred since the last registration, registrants must certify that no changes have occurred.

§ 207.41 [Amended]

■ 7. In § 207.41, add new paragraph (d) to read as follows:

Subpart D—Listing

§ 207.41 Who must list drugs and what drugs must they list?

* * * * *

(d) Each registrant must comply with the requirements set forth in subsections (a), (b), and (c) of this section with respect to any drug that it manufactures, repacks, relabels, or salvages for commercial distribution at a foreign establishment regardless of whether such drug undergoes further manufacture, preparation, propagation, compounding, or processing at a separate foreign establishment prior to being imported or offered for import into the United States.

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Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–0766]

RIN 1625–AA00

Safety Zone; Fireworks Display, Columbia River, Cascade Locks, OR

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain navigable waters of the Columbia River. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks displays on the Columbia River on September 19, 2026. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless specifically authorized by the Captain of the Port, Sector Columbia River. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 12, 2026.

ADDRESSES: To submit comments and view available documents, go to <https://www.regulations.gov> and search for USCG–2026–0766.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rule, contact LCDR Jesse Wallace, Sector Columbia River Waterways Management Division, U.S. Coast Guard; telephone 503–572–3524, or email SCRWWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

On April 8, 2026, an event organizer notified the Coast Guard that they will be launching fireworks over the Columbia River near Cascade Locks, OR on September 19, 2026. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) Sector Columbia River has determined that potential hazards associated with fireworks are a safety concern for anyone within 1,200 feet of the fireworks display. Therefore, the COTP is proposing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

III. Discussion of the Rule

This proposed rule would establish a safety zone from 8 p.m. until 10:30 p.m. on September 19, 2026. The safety zone would cover all navigable waters within a 1,200 foot radius of the fireworks launch site. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative. The regulatory text we are proposing appears at the end of this document.

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.

A. 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. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. 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 for the following reasons.

Vessel traffic will be able to safely transit around this regulated area. This regulation will only impact a small area for a few hours. The enforcement period is during a time when vessel traffic is normally low. In addition, the Coast Guard will issue a Broadcast Notice to Mariners via VHF FM marine channel 16, which will allow small entities to adjust their transit plans, and the rule allows vessels to request permission to enter the regulated area from the COTP.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed 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 proposed rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this proposed rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247).

B. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

C. Federalism and Indian Tribal Governments

We have analyzed this proposed rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

Also, this proposed 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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this proposed rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–*et seq.*), 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 proposed rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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.

Submitting comments. We encourage you to submit comments at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2026–0766 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in the docket. To view available documents, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. We will post public comments in our online docket. Additional information is on the <https://www.regulations.gov> Frequently Asked Questions webpage.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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 is proposing 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: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T13–0766 to read as follows:

§ 165.T130766 Safety Zone; Fireworks Display, Columbia River, Cascade Locks, OR.

(a) **Location.** The following area is a safety zone: All navigable waters within a 1,200-foot radius of a fireworks launch site in Cascade Locks, OR. The fireworks launch site will be at the approximate point of 45°40′15″ N, 121°53′43″ W.

(b) **Definitions.** As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Columbia River in the enforcement of the safety zone.

(c) **Regulations.** (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative.

(2) To seek permission to enter, contact the COTP or the COTP’s

representative on VHF–FM channel 16 or by telephone at 1–(833) 769–8724. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.

(d) *Enforcement period.* This section will be enforced from 8 p.m. to 10:30 p.m. on September 19, 2026.

Anthony R. Migliorini,

Captain, U.S. Coast Guard, Captain of the Port Sector Columbia River.

[FR Doc. 2026–14044 Filed 7–10–26; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 260708–0166]

RIN 0648–BO28

Fisheries of the Caribbean, Gulf of America, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic Region; Abbreviated Framework Amendment 5

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS seeks public comment on proposed regulations to implement Abbreviated Framework Amendment 5 (Abbreviated Framework 5) under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). If implemented by NMFS, this proposed rule would revise catch levels for blueline tilefish in the exclusive economic zone (EEZ) of the South Atlantic. The purposes of these proposed regulatory changes are to ensure the catch levels for blueline tilefish are based on the best scientific information available (BSIA), to achieve and maintain optimum yield (OY), and to prevent overfishing while minimizing adverse social and economic effects to the extent practicable in accordance with NMFS’ statutory mandates.

DATES: Written comments on this proposed rule must be received no later than August 12, 2026.

ADDRESSES: A plain language summary of this proposed rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2026-0727>. You may submit comments on the proposed rule, identified by NOAA-NMFS-2026-0727 by either of the following methods:

- *Electronic Submission:* Submit electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA–NMFS–2026–0727 in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Mary Vara, NMFS Southeast Regional Office (SERO), 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information, confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments. Enter “N/A” in the required fields if you wish to remain anonymous.

An electronic copy of Abbreviated Framework 5, which includes a Regulatory Flexibility Act (RFA) analysis and a regulatory impact review, may be obtained from <https://www.regulations.gov> or the NMFS SERO website at <https://www.fisheries.noaa.gov/action/abbreviated-framework-amendment-5-catch-levels-blueline-tilefish>.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS SERO, telephone: 727–824–5305, email: mary.vara@noaa.gov.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic region is managed under the FMP and includes blueline tilefish, along with other snapper-grouper species. The FMP was prepared by NMFS and the South Atlantic Fishery Management Council (South Atlantic Council) and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Magnuson-Stevens Act requires NMFS and fishery management plans to prevent overfishing and continually achieve the OY from federally managed fish stocks to ensure that fishery resources are managed for the greatest overall benefit to the Nation. This action is proposed under the authority of section 303(a)(1)(A) of the Magnuson-Stevens Act as necessary and appropriate for the conservation and management of the fishery to prevent overfishing and rebuild overfished

stocks and to promote the long-term health and stability of the fishery.

All weights described in this proposed rule are in round weight, unless noted otherwise. The metric conversion for the imperial measurement used in this document is 1 pound (lb) equals approximately 0.45 kilograms.

Background

NMFS and the South Atlantic Council manage blueline tilefish in the EEZ from the North Carolina and Virginia border southward to the South Atlantic Council’s jurisdictional boundary in the Florida Keys. NMFS and the Mid-Atlantic Fishery Management Council (Mid-Atlantic Council) manage blueline tilefish in the EEZ from the North Carolina and Virginia border northward through Maine as part of the Tilefish Fishery Management Plan of the Mid-Atlantic Region. In the South Atlantic region, the South Atlantic and Mid-Atlantic Councils collaborate with NMFS on the management of blueline tilefish from the border of Virginia and North Carolina to Cape Hatteras, North Carolina. NMFS and the Mid-Atlantic Council began managing blueline tilefish in 2017 due to increased fishing activity in the mid-Atlantic. Previously, NMFS and the South Atlantic Council exclusively managed the species off the East Coast.

A Southeast Data, Assessment, and Review (SEDAR) operational stock assessment for blueline tilefish (SEDAR 92) was completed in March 2025, utilizing the newly calibrated Marine Recreational Information Program (MRIP) Fishing Effort Survey (FES) data in place of MRIP Coastal Household Telephone Survey (CHTS) data. Abbreviated Framework 5 would change the overfishing level (OFL) and acceptable biological catch (ABC) for blueline tilefish in the South Atlantic. The South Atlantic Council’s Scientific and Statistical Committee (SSC) updated the total ABC recommendation for the South Atlantic as part of SEDAR 92, in combination with the joint recommendations from the South Atlantic and Mid-Atlantic Council SSCs for the area north of Cape Hatteras to the border with Virginia.

The South Atlantic and Mid-Atlantic Councils’ SSCs recommended use of a data-limited methods model based on average catch rather than the surplus production model for management to establish the ABC for areas north and south of Cape Hatteras in the South Atlantic. The data-limited methods model was used to address deficiencies in the surplus production model and to provide scientifically justifiable catch