

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. The action does not have substantial direct effects 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs

that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as compared to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute "rule making" under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 5 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States because it is being done pursuant to 21 U.S.C. 811(d)(1), which requires that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in 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 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting the required reports to the Government Accountability Office, the House, and the Senate under the CRA.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(46) through (90) as paragraphs (b)(47) through (91);

■ b. Add new paragraph (b)(46); and

■ c. Remove and reserve paragraph (h)(48).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(46) Isotonitazene (*N,N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine) 9614

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2021–23848 Filed 11–3–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0582]

RIN 1625–AA08

Special Local Regulation; Atlantic Ocean, Key West, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for power boat races. This action is necessary to ensure safety of life on navigable waters on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. This regulation prohibits persons and vessels from entering, transiting through, anchoring in, or remaining within the regulated area without permission from the Captain of the Port Key West or a designated representative.

DATES: This rule is effective from 9:30 a.m. on November 10, 2021, until 4:30 p.m. on November 14, 2021. This rule will only be subject to enforcement from the hours of 9:30 a.m. to 4:30 p.m., on November 10, 12, and 14, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2021–0582 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 Lieutenant Junior Grade Vera Max, Sector Key West Waterways Management Division, Coast Guard; telephone (305) 292–8768, email SKWWaterways@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 Information and Regulatory History

On May 7, 2021, Race World Offshore notified the Coast Guard that it would be conducting high-speed boat races from 9:30 a.m. until 4:30 p.m. each day on November 10, 12, and 14, 2021. Approximately 50 participants and 200 spectator craft are expected to attend the event, which will take place in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance in Key West, FL. In response, on October 5, 2021, the Coast Guard published a notice of proposed rulemaking (NPRM) titled, “Special Local Regulation; Atlantic Ocean, Key West, FL” (86 FR 54879). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this power boat race event.

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 impracticable because the event is taking place on November 10, 12, and 14, 2021, and immediate action is needed to respond to the potential safety hazards associated with this event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Key West (COTP) has determined that the potential hazards associated with the high-speed boat race would be a safety concern for the participants, participant vessels, and the general public. The purpose of this rule is to protect event participants, spectators, and vessels on the navigable waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received six comments on our NPRM published October 5, 2021. Four comments were in support of the rule, citing the need for safety around this large event. One comment was in support of the rule, but pointed out the possible effects on small entities and their options for working with the Coast Guard to mitigate those effects, as discussed in section V.B of this rule. We received one comment that raised concerns about the West Indian Manatee, calling for measures to be in place to account for injuries to manatees and other species that could be harmed by the high-speed boat races. The Coast Guard has conducted outreach with several state and federal agencies, including the Florida Keys National Marine Sanctuary and U.S. Department of Fish and Wildlife, through the Environmental Analysis discussed in Section V.F. The sponsor has provided a safety plan, including measures for protection of manatees. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a temporary special local regulation that will be subject to enforcement from 9:30 a.m. until 4:30 p.m. on November 10, 12, and 14, 2021. The temporary special local regulation consists of two regulated areas: (1) Race and safety buffer area, and (2) spectator area. These areas prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within the race area or buffer zone and prohibit vessels from transiting at speeds that cause wake within the spectator area, unless authorized by the COTP Key West or a designated representative. The temporary special local regulation covers all navigable waters in the Atlantic Ocean, off the tip of Key West, Florida, on the waters of the Key West Main Ship Channel, Key West Turning Basin, and Key West Harbor Entrance.

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 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. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the location, duration, and time-of-day of the regulated area. Although persons and vessels may not enter, transit through, anchor in, or remain within the area without authorization from the COTP or a designated representative, they will be able to safely transit around the area. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the area, and the rule will allow vessels to seek permission to enter the area between race heats.

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

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 call or email 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 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 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 call or email 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 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 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. 4321-4370f), 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. Additionally, the event sponsor has provided a marine protection plan that includes aerial and on-water monitoring and provisions for halting the race should any manatees or turtles be observed in or near the race area. This rule involves a temporary special local regulation lasting 7 hours on 3 days that will prohibit entry into the race area or buffer zone, and prohibit vessels from transiting at speeds that cause wake within the spectator area. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. 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 call or email 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 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05-1.

■ 2. Add temporary § 100.T799-0582 to read as follows:

§ 100.T799-0582 Special Local Regulation; Power Boat Races, Key West, FL.

(a) *Locations.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race and safety buffer area.* Waters of the Atlantic Ocean of Key West, FL that are encompassed within the following points: Starting at Point 1 in position 24°32.506' N, 81°49.984' W; thence southwest to Point 2 in position 24°32.455' N, 81°49.040' W; thence northwest to Point 3 in position 24°32.559' N, 81°49.584' W; thence northwest to Point 4 in position 24°32.608' N, 81°49.628' W; thence northwest to Point 5 in position 24°33.095' N, 81°49.265' W; thence northeast to Point 6 in position 24°33.518' N, 81°48.902' W; thence northeast to Point 7 in position 24°33.908' N, 81°48.448' W; thence east to Point 8 in position 24°33.898' N, 81°48.364' W; thence southeast back to origin.

(2) *Spectator area.* All waters of the Atlantic Ocean in Key West, FL that are encompassed within the following points: starting at Point 1 in position 24°33.123' N, 81°49.290' W; thence northeast to Point 2 in position 24°33.545' N, 81°48.923' W; thence east to Point 3 in position 24°33.518' N, 81°48.902' W thence southwest to point 4 in position 24°33.095' N, 81°49.265' W thence west back to origin.

(b) *Definition.* As used in this section, the term "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 Key West in the enforcement of the safety zone.

(c) *Regulations.* (1) All non-participant persons and vessels, except those persons and vessels participating in the high-speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within the regulated areas described in paragraph (a) of this section unless authorized by the Captain of the Port Key West or their designated representative.

(2) All persons are prohibited from entering the water or swimming in the spectator area described in paragraph (a)(2) of this section.

(3) All vessels are prohibited from transiting at speeds that cause wake within the spectator area described in paragraph (a)(2) of this section.

(4) To seek permission to enter, contact the Captain of the Port Key West or a designated representative by telephone at (305) 433-0954, or via VHF radio on channel 16. If authorization is granted by the Captain of the Port Key West or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or a designated representative.

(5) The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 9:30 a.m. until 4:30 p.m. on November 10, 12, and 14, 2021.

Dated: October 28, 2021.

A. Chamie,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2021-23865 Filed 11-3-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0801]

RIN 1625-AA00

Safety Zone; Munitions Transfer; Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Oakland Estuary in the Brooklyn Basin South Channel near Coast Guard Island in Alameda, CA in support of a munitions transfer on November 14, 2021, and November 21, 2021. This safety zone is necessary to protect personnel, vessels, and the marine environment from the dangers associated with live munitions. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or a designated representative.

DATES: This rule is effective from 8 a.m. on November 14, 2021, until 2 p.m. on November 21, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0801 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade William Harris, U.S. Coast Guard Sector San Francisco; telephone (415) 399-7443, email SFWaterways@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
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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 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 it is impractical and contrary to the public interest. The Coast Guard did not receive final details for this event until October 18, 2021. There was insufficient time to undergo the full rulemaking process, including providing a reasonable comment period and considering those comments because the Coast Guard must establish this temporary safety zone by November 14, 2021.

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 public interest because immediate action is necessary to protect personnel, vessel, and the marine environment from the potential safety hazards associated with the munitions transfer near Alameda, CA beginning November 14, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco (COTP) has determined that potential hazards associated with the munitions transfer on November 14, 2021 and November 21, 2021 will be a safety concern for anyone within a 250-foot radius of the pier. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone around the munitions transfer site during the munitions transfer.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 8 a.m. until 2 p.m. on November 14, 2021 and from 8 a.m. until 2 p.m. on November 21, 2021. The temporary safety zone will cover all navigable waters, from surface to bottom, within 250 feet of the munitions transfer pier located on the southwest side of Coast Guard Island in the Brooklyn Basin South Channel of the Oakland Estuary. The temporary safety zone will be terminated at 2 p.m. on both November 14, 2021 and November 21, 2021 or once announced via broadcast notice to mariners.

This regulation is necessary to keep persons and vessels away from the immediate vicinity of the munitions transfer location to ensure the safety of people, vessels, and the marine environment. Except for persons or vessels authorized by the COTP or the COTP’s designated representative, no person or vessel may enter or remain in the restricted area. A “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

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 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. This rule has not been designated a “significant regulatory action,” under