

(b) *Classification.* Class II (special controls). The special control is FDA's guideline entitled "Class II Special Controls Guideline: Trypsin Test System as an Aid in the Diagnosis of Systemic Mastocytosis." For availability of the document, see § 866.1(e).

Dated: September 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-22254 Filed 9-17-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2014-0610]

RIN 1625-AA00

Safety Zone; International Jet Sports Boating Association World Finals; Lake Havasu City, AZ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within the navigable waters of the Colorado River in Lake Havasu, AZ in support of the International Jet Sports Boating Association (IJSBA) World Finals. This safety zone is necessary to ensure the safety of participants, crew, spectators, participating vessels, and other vessels and users of the waterway. Unauthorized persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or their designated representative.

DATES: This rule is effective from 6:30 a.m. to 6:30 p.m. on October 4, 2014 through October 12, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG-2014-0610]. 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 Petty Officer Giacomo Terrizzi, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619-278-7656, email d11marineeventssandiego@uscg.mil. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, 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
TFR Temporary Final Rule
IJSBA International Jet Sports Boating Association

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 an NPRM would be impracticable. Logistical details did not present the Coast Guard enough time to draft, publish, and receive public comment on an NPRM. As such, the event would occur before the rulemaking process was complete. Immediate action is needed to help protect the safety of the participants, crew, spectators, and participating vessels from other vessels during the duration of this event.

Under 5 U.S.C. 553(d)(3), for the same reasons mentioned above, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would be contrary to the public interest, because immediate action is necessary to protect the safety of the participants from the dangers associated with other vessels transiting this area while the race occurs.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 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, and 160.5; Public Law 107-295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to propose, establish, and define regulatory safety zones.

IJSBA is sponsoring the IJSBA World Finals, which will involve approximately 800 personal water craft, 5 to 13 feet in length. The safety zone will encompass an area in the vicinity of the Crazy Horse Campgrounds. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, other vessels, and users of the waterway, specifically in minimizing vessel wakes by transiting vessels in the vicinity of the racing area. Unnecessary wakes can disrupt the personal water craft and could cause injury or damage to the participants.

C. Discussion of the Final Rule

The Coast Guard is establishing a safety zone that will be enforced from 6:30 a.m. to 6:30 p.m. on October 4, 2014 through October 12, 2014. The effect of the temporary safety zone will be to restrict navigation in the vicinity of the race site until the conclusion of the races. The limits of the safety zone will encompass the waters of Lake Havasu, AZ in the area of Crazy Horse Campgrounds encompassed by the following positions:

34°28.32' N, 114°21.71' W
34°28.43' N, 114°21.81' W
34°28.55' N, 114°21.56' W
34°28.49' N, 114°21.33' W

The safety zone is necessary to provide for the safety of the crew, spectators, participants, and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative, during the proposed times. Before the effective period, the Coast Guard will publish a local notice to mariners (LNM). Also, the event sponsor through Lake Havasu City has extensively advertised the marine event with the public.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and 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. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. This determination is based on the size, location, and the limited duration of the safety zone. Additionally, to the maximum extent practicable, the event sponsor will assist with the movement of boaters desiring to transit the racing area during non-racing times.

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 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. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in the impacted portion of Lake Havasu from 6:30 a.m. to 6:30 p.m. on October 4, 2014 through October 12, 2014.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. The safety zone applies to a small area in the vicinity of the Crazy Horse Campground and boating traffic would still be allowed to pass through the safety zone with Captain of the Port approval. The event sponsor will to their maximum extent assist boaters wishing to transit the racing area during non-racing times.

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 calls for no 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 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 establishment of a safety zone on the navigable waters of Lake Havasu. 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 AREAS

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

■ 2. Add § 165.T11–657 to read as follows:

§ 165.T11–657 Safety Zone; International Jet Sports Boating Association World Finals; Lake Havasu City, AZ.

(a) *Location.* The limits of the safety zone will encompass the waters of Lake Havasu, AZ in the area of Crazy Horse Campgrounds encompassed by the following positions: 34°28.32' N, 114°21.71' W; 34°28.43' N, 114°21.81' W; 34°28.55' N, 114°21.56' W; 34°28.49' N, 114°21.33' W.

(b) *Enforcement period.* This section will be enforced on October 4, 2014 through October 12, 2014 from 6:30 a.m. to 6:30 p.m.

(c) *Definitions.* The following definition applies to this section: *Designated representative*, means any commissioned, warrant, or petty officer of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, or local, state, and federal law enforcement vessels who have been authorized to act on the behalf of the Captain of the Port.

(d) *Regulations.* (1) Under the general regulations in subpart C of this part, entry into, transit through or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port of San Diego or his designated representative.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or his designated representative.

(3) Upon being hailed by U.S. Coast Guard or designated patrol personnel by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(4) The Coast Guard may be assisted by other federal, state, or local agencies

in patrol and notification of the regulation.

Dated: August 27, 2014.

J. S. Spaner,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2014–22195 Filed 9–17–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2014–0772]

RIN 1625–AA00

Safety Zone; 2014 Life Time Tri; Oceanside Harbor, Oceanside, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of Oceanside Harbor in Oceanside, CA for the 2014 Life Time Triathlon on October 26, 2014. This temporary safety zone is necessary to provide safety for the swimmers, crew, rescue personnel, and other users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port or his designated representative.

DATES: This rule is effective from 6:30 a.m. to 9:30 a.m. on October 26, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0772]. 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 Petty Officer Giacomo Terrizzi, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619–278–7656, email d11marineeventssandiego@uscg.mil If you have questions on viewing or submitting material to the docket, call

Cheryl Collins, 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
TFR Temporary Final Rule

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 an NPRM would be impracticable. Logistical details did not present the Coast Guard enough time to draft, publish, and receive public comment on an NPRM. As such, the event would occur before the rulemaking process was complete. Immediate action is needed to help protect the safety of the swimmers, crew, spectators, and participating vessels from other vessels during this one day event.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 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, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to propose, establish, and define regulatory safety zones. The event will consist of 2,000 participants swimming a 1.5 KM course within Oceanside Harbor. The course starts at the Oceanside Harbor public boat launch, proceeds to the outer point of the submerged jetty, and back to the boat launch. A safety zone is established to protect the swimmers and assist with vessel traffic management.

C. Discussion of the Final Rule

The Coast Guard is establishing a safety zone that will be enforced from 6:30 a.m. to 9:30 a.m. on October 26, 2014. The safety zone includes the waters of Oceanside Harbor encompassed by drawing a line from