

CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

**FOR FURTHER INFORMATION CONTACT:** Benjamin Warren, Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-645-7004, [Benjamin.Warren@fda.hhs.gov](mailto:Benjamin.Warren@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 7, 2025 (90 FR 1052), we published a document announcing the availability of a draft guidance entitled “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” The notice of availability opened a docket with a 120-day comment period, that closed on May 7, 2025.

We have received requests to extend the comment period for the draft guidance. The requests conveyed concern that a 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance. We have considered the requests and have concluded that an extension of the

comment period by 60 days is appropriate. The extension will allow adequate time for interested persons to submit comments without significantly delaying the final guidance.

Dated: May 22, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09653 Filed 5-28-25; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2025-0355]

RIN 1625-AA00

#### Safety Zone; Ohio River MM 469.5–470.5 and Licking River MM 0.0 to 0.3, Cincinnati, OH

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary safety zone from Mile Marker 469.5–Mile Marker 470.5 of the Ohio River and from Mile Marker 0.0–Mile Marker 0.3 of the Licking River. This action is necessary to provide for the safety of life on these navigable waters near Cincinnati, OH, during the Red Bull Flugtag sporting event occurring on August 9, 2025. This safety zone prohibits persons and vessels from transiting through the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 30, 2025.

**ADDRESSES:** You may submit comments identified by docket number USCG-2025-0355 using the Federal Decision-Making Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rule, call or email MST2 William Quinby, Marine Safety Detachment Cincinnati, U.S. Coast Guard; telephone

(513) 921-9033, email [William.E.Quinby@uscg.mil](mailto:William.E.Quinby@uscg.mil).

## SUPPLEMENTARY INFORMATION:

### I. Table of Abbreviations

CFR Code of Federal Regulations  
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 Red Bull Flugtag event will be held in Cincinnati, Ohio, at Sawyer Point Park and Yeatman’s Cove, near the Ohio River and Licking River, on August 9, 2025. During this event, teams launch homemade, human-powered flying machines from a ramp into the water. The purpose of this rulemaking is to ensure the safety of vessels, participants, and the navigable waters in the vicinity of this event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

### III. Discussion of Proposed Rule

This proposed rule would establish a safety zone from 7 a.m. through 6 p.m. on August 9, 2025. The safety zone will cover all navigable waters from Mile Marker 469.5–Mile Marker 470.5 of the Ohio River and Mile Marker 0.0–Mile Marker 0.3 of the Licking River. The duration of the zone is intended to protect waterway users, vessels, event participants, and the marine environment in these navigable waters while the sporting event is occurring. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

### 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. 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 proposed rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, this proposed rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the duration of the safety zone. The duration of the safety zone is eleven hours, and vessels will be able to contact the COTP for directions on how to transit around or seek permission to enter.

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

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 rulemaking would economically affect it.

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 proposed rule. If the proposed rule will 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

#### *C. 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).

#### *D. Federalism and Indian Tribal Governments*

A rulemaking 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 proposed 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 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. If you believe this proposed 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 proposed rule will not result in such an expenditure, we do discuss the effects of this rulemaking elsewhere in this preamble.

#### *F. 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. 4321–4370f), and have made a preliminary 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 proposed rule involves a safety zone lasting 11 hours that would prohibit any vessel or person from entering the safety zone without obtaining permission from the Captain of the Port (COTP) of Sector Ohio Valley or a designated representative. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### **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 through the Federal Decision-Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2025–0355 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 docket.** To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a “Subscribe” option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

**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. 01.3.

- 2. Add § 100.T08–0355 to read as follows:

**§ 165.T08–0355 Safety Zone; Ohio River MM 469.5–470.5 and Licking River MM 0.0 to 0.3, Cincinnati, OH.**

(a) *Regulated area.* This section applies to the following area: Ohio River Mile Marker 469.5–Miler Marker 470.5,

extending the entire river and the Licking River from Mile Marker 0.0–Mile Marker 0.3, extending the entire river.

(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 Sector Ohio Valley (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) This section establishes a safety zone from 7 a.m. through 6 p.m. on August 9, 2025. The safety zone will cover all navigable waters designated in paragraph (a) of this section. No vessel or person will be permitted to enter the safety zone

without obtaining permission from the COTP or a designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by contacting the Patrol Commander via VHF–FM radio channel 16 or phone at 1–800–253–7465. 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 7 a.m. through 6 p.m. on August 9, 2025.

Dated: May 19, 2025.

**H.R. Mattern,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.*

[FR Doc. 2025–09663 Filed 5–28–25; 8:45 am]

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