Interested persons were originally given until April 11, 2022, to comment on this hearing. The Agency has received a request to allow interested persons additional time to comment. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop comprehensive comments. We have concluded that it is reasonable to extend the comment period for 60 days. The Agency believes that this extension allows adequate time for interested persons to submit comments.

Dated: March 25, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

[FR Doc. 2022–06762 Filed 3–30–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0336]

RIN 1625–AA09

Drawbridge Operation Regulation; Fox River, Oshkosh, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the Tayco Street Bridge, mile 37.52, the Main Street Bridge, mile 55.97, the Jackson Street Bridge, mile 56.22, the Wisconsin Street Bridge, mile 56.72, and the Congress Avenue Bridge, mile 58.01, all over the Fox River near Oshkosh, Wisconsin. This proposed rule will allow the bridges to operate remotely. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must reach the Coast Guard on or before May 31, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0336 using Federal Decision Making Portal at *https://www.regulations.gov*.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
WisDOT Wisconsin Department of Transportation

II. Background, Purpose and Legal Basis

On July 6, 2021, we published a temporary deviation in the **Federal Register** (86 FR 35402) to test the effectiveness of the remote bridge operations and to solicit public comments; public commenting closed on November 1, 2021. The Main Street Bridge, mile 55.97, provides a horizontal clearance of 89 feet and a vertical clearance 11 feet in the closed position, the Jackson Street Bridge, mile 56.22, provides a horizontal clearance of 97 feet and a vertical clearance of 11 feet in the closed position, the Wisconsin Street Bridge, mile 56.72, provides a horizontal clearance of 75 feet and a vertical clearance of 12 feet in the closed position, the Congress Avenue Bridge, mile 58.01, provides a horizontal clearance of 75 feet and a vertical clearance of 13 feet in the closed position, and the Tayco Street Bridge provides a horizontal clearance of 63 feet and a vertical clearance of 3 feet in the closed position. All of these bridges are over the Fox River and provide an unlimited clearance in the open position, and are governed by the regulations found in 33 CFR 117.1087.

WisDOT has tested the capabilities of the remote operating system with live operators in the bridges and allowed the public to comment on the bridge operations before this proposed rule was published.

This proposed rule will not change the operation of the bridges. WisDOT will provide weekly bridge opening data and approximate vehicle and pedestrian crossings at the end of the comment period. If the proposed rule is finalized, remote bridge operators will have the ability to communicate by visual or audio (two-way radio, loudspeaker, and telephone) means with vessels, including enough cameras to see above and below the bridge, including night vision cameras to monitor approaching river traffic in adverse weather conditions.

The Coast Guard will also inform the users of the waterways through our Local Notice to Mariners when the comment period opens and how to leave comments.

III. Discussion of Proposed Rule

The remote operations of the bridges will not affect the operations of the current regulations. During the test deviation, we received nine comments. In addition to the responses to the comments below, WisDOT took the opportunity to answer each comment, and we have added those responses to the docket.

Most of the commenters described increased wait times for a remote bridge opening and indicated wait times were at least 30 minutes per bridge. Most of these delays were the result of challenges associated with training certain drawtenders on the new remote system. Moving forward, said drawtenders will be retrained to prevent delays beyond what users experience with live drawtenders. Further, WisDOT agreed that on certain weekends and holidays, when vessel and vehicle traffic will be the greatest, extra drawtenders will be provide to maintain a reliable level of safety for the public. Despite the comments discussed above, the data collected by WisDOT show that there were limited delays to boaters.

In response to the safety concern, there is audio and video equipment to monitor the bridge, with cameras above and below the bridge to provide sufficient visualization of the areas surrounding the bridge. Further, we would like to note that from January to December 2020 there were five reported boating accidents while the bridges were operated by independent drawtenders. Out of the five accidents, one required advanced first aid. During the 2021 test deviation, there were no reported boating accidents. The test deviation covered June 30 to October 7, 2021, when the waterways are the busiest. During 2021, during the period before and after the test deviation, no accidents were reported.

We did not address the incident of the bicyclist accident on the Racine Street Bridge because it occurred during the July 4th celebrations in 2018, on a bridge not included in the NPRM, and the cause of the incident, according to police records, was the result of human negligence and wholly unrelated to bridge operations.

The Tayco Street Bridge, mile 37.52 was not included in the test deviation because its remote operations were not discovered until after the conclusion of the test deviation. WisDOT has been remotely operating this bridge since 1984, after the U.S. Army Corps of Engineers abandoned the lock system

and the U.S. Coast Guard stopped regulating bridges as the waterway could not engage in interstate commerce. Because the bridge has been operated remotely for 37 years we find no reason to repeat the test deviation to include this bridge for comments.

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 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 NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This proposed rule is not a significant regulatory action, as the bridges will open normally.

B. 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 proposed 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 bridge may be small entities, for the reasons stated in section IV.A above, this proposed 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 (Pub. L. 104–121), we want to assist small entities in understanding this proposed 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. 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 would call for no 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 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 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 proposed 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 proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has 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 promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

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.

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–2021–0336 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 your material cannot be submitted using *https://www.regulations.gov,* contact the person

in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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. 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.

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 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 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 117.1087 by adding paragraph (b)(3) to read as follows:

§ 117.1087 Fox River.

* * * * *

(b) * * *

(3) All drawbridges between mile 37.52 and 58.01, are authorized to be operated remotely, and are required to operate and maintain a VHF–FM Marine Radio.

* * * * *

M.J. Johnston,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2022–06803 Filed 3–30–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0062]

RIN 1625–AA00

Safety Zone, Saint Simons Sound, GA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to remove an existing temporary safety zone which was put in place in response to the grounding of the M/V GOLDEN RAY. Salvage operations pertaining to the M/V GOLDEN RAY have concluded, therefore a safety zone is no longer required. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 2, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0062 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.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST1 Ashley Schad, Marine Safety Unit Savannah Office of Waterways Management, Coast Guard, 912–652–4188 extension 242, or email *Ashley.M.Schad@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On September 19, 2019, an emergency safety zone was put into place to protect vessels using the waterway from response and salvage operations pertaining to the capsizing of the M/V GOLDEN RAY.[1] On January 25, 2022 the Unified Command in charge of the M/V GOLDEN RAY response and salvage operations notified the COTP, Marine Safety Unit Savannah that salvage operations have concluded, therefore the safety zone in Saint Simons Sound is no longer required.

The purpose of this rulemaking is to remove the safety zone previously established in response to the capsizing of the M/V GOLDEN RAY. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP is proposing to remove the temporary safety zone which was put into place on September 19, 2019, in response to the grounding of the M/V GOLDEN RAY (located at 31°07′39.66 North, 081°24′10.58 West, between Saint Simons Lighthouse and the north end of Jekyll Island, in the vicinity of green buoy #19). By removing the safety zone, all waterway users, including commercial, private, and recreational vessels would have unrestricted access to the waterway. The temporary zone was originally established with the intention that it would be removed once all response and salvage resources were demobilized and removed from the waterway pertaining to the capsizing of the M/V GOLDEN RAY. On January 25, 2022, it was determined that all response and salvage resources and assests were no longer in the vicinity of the safety zone and removal of the M/V GOLDEN RAY was complete. Removal of environmental protective barriers including cofferdams and precautionary containment boom were also completed.

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, 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 NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on waterway usage and the temporary nature of the previously established safety zone. While the temporary safety zone that we are proposing for removal was in place for

[1] 84 FR 51413.