

TABLE 1—NON-EEG PHYSIOLOGICAL SIGNAL BASED SEIZURE MONITORING SYSTEM RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
<p>Incorrect alerts, including:</p> <ul style="list-style-type: none"> Missing a seizure—device fails to identify physiological signal that is associated with a seizure; or. False alarm—device mistakenly identifies a physiological signal as being associated with a seizure. 	<p>Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Labeling; and Training.</p>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, non-EEG physiological signal based seizure monitoring systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.1580 to subpart B to read as follows:

§ 882.1580 Non-electroencephalogram (EEG) physiological signal based seizure monitoring system.

(a) *Identification.* A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to achieve its intended use, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical, thermal, and mechanical safety and electromagnetic compatibility (EMC).

(4) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for

monitoring for seizure-related activity in the intended population and for the intended use setting. Performance measurements must include positive percent agreement and false alarm rate.

(5) Training must be provided for intended users that includes information regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(6) The labeling must include health care professional labeling and patient-caregiver labeling. The health care professional and the patient-caregiver labeling must include the following information:

(i) A detailed summary of the clinical performance testing, including any adverse events and complications.

(ii) Any instructions technicians and clinicians should convey to patients and caregivers regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(iii) Instructions to technicians and clinicians regarding how to set the device threshold to achieve the intended performance of the device.

Dated: October 24, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23516 Filed 10–27–17; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG 2017–0162]

RIN 1625–AA09

Drawbridge Operation Regulation; Nanticoke River, Seaford, DE

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the SR 13 Bridge across the Nanticoke River, mile 39.6, in Seaford, Delaware (DE). This modification will require the

bridge to open on signal every Saturday and Sunday during the winter season, if at least 24 hours notice is given. This action is necessary to balance bridge operations and maintenance with the existing needs of navigation.

DATES: This rule is effective November 29, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>. Type USCG–2017–0162 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Martin A. Bridges, Fifth Coast Guard District (dpb), at (757) 398–6422, email Martin.A.Bridges@uscg.mil.

SUPPLEMENTARY INFORMATION section below for instructions on submitting comments.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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 Information and Regulatory History

On July 5, 2017, we published a notice of proposed rulemaking entitled, “Drawbridge Regulation; Nanticoke River, Seaford, DE” in the **Federal Register** (see 82 FR 127). We did not receive any comments on the proposed rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The US 13 Bridge across the Nanticoke River, Mile 39.6, in Seaford, DE, owned and operated by the Delaware Department of Transportation, has a vertical clearance of 3 feet above mean high water in the closed-to-navigation position. There is a

monthly average of three bridge openings on Saturdays and Sundays, from 7:30 a.m. to 3:30 p.m., from November 1 through March 31, which allow one or more vessels to transit through the bridge during each opening. The bridge is normally maintained in the closed position, due to the volume of vehicular traffic crossing the bridge. The current operating schedule is published in 33 CFR 117.243(b). The Coast Guard’s authority to make a permanent change to a drawbridge operating schedule is contained in 33 CFR 117.8.

The Nanticoke River is used predominately by recreational vessels and pleasure craft. The three-year average number of bridge openings, maximum number of bridge openings, and weekend bridge openings between 7:30 a.m. and 3:30 p.m., by month and overall for 2014 through 2016, as drawn from the data contained in the bridge tender logs provided by the Delaware Department of Transportation, is presented below.

Month	Average openings	Maximum openings	Proposed weekends—average openings 7:30 a.m.–3:30 p.m.
January	11	31	3
February	1	3	1
March	21	53	4
April	72	91	N/A
May	138	192	N/A
June	150	168	N/A
July	280	175	N/A
August	198	223	N/A
September	144	214	N/A
October	51	66	N/A
November	8	13	5
December	1	4	1
Monthly	89	223	3
Daily	3	7	<1

IV. Discussion of Comments, Changes and the Final Rule

The Delaware Department of Transportation has requested to modify the operating regulation for the bridge, due to the limited number of requested openings of the bridge on Saturday and Sunday, from 7:30 a.m. to 3:30 p.m., from November 1 through March 31, over a period of approximately the past three years. The data presented in the table above demonstrate that the requested modification may be implemented with minimal impact to navigation. The modification requested will require the bridge to open on signal on Saturday and Sunday; from 7:31 a.m. to 3:29 p.m., from November 1 through March 31, if at least 24 hours notice is given. All other provisions of 33 CFR 117.243 (b) will remain the same.

The Coast Guard provided a comment period of 60 days and received zero comments on the proposed rule.

V. Regulatory Analysis

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 protesters.

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. Executive Order 13771 directs agencies to control regulatory costs through a

budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This is not considered a significant regulatory action. This determination is based on the findings that: (1) The potential impact is small, given the limited number of vessels requiring a bridge opening during the time frame of the proposed modification, and (2) vessels will be able to transit through the bridge during the time frame of the proposed modification, given the bridge will open on signal, if at least 24 hours notice is given.

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 received zero comments from the Small Business Administration on this rule. 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 bridge 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 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.

C. 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).

D. Federalism and Indian Tribal Government

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. We received zero comments on this rule.

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. We received zero comments on this rule.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this 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.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 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; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.243(b) to read as follows:

§ 117.243 Nanticoke River.

* * * * *

(b) The draw of the SR 13 Bridge, mile 39.6, in Seaford shall:

(1) Open on signal, except from 6 p.m. to 8 a.m., from April 1 through October 31; from November 1 through March 31, Monday to Friday and on Saturday and Sunday from 3:30 p.m. to 7:30 a.m., if at least four hours notice is given.

(2) Open on signal, on Saturday and Sunday, from 7:31 a.m. through 3:29 p.m., from November 1 through March 31, if at least 24 hours notice is given.

Dated: October 10, 2017.

M.L. Austin,

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

[FR Doc. 2017–23559 Filed 10–27–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0155; FRL–9968–12]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing tolerance for residues of the ovicide/miticide hexythiazox in/on hop, dried cones, by increasing the current tolerance from 2.0 parts per million (ppm) to 20 ppm. Gowan Company requested modification of this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 30, 2017. Objections and requests for hearings must be received