

Chemical	Threshold by weight
(2) Distributions by persons required to report under § 1310.03(c) of this part .....	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section) .....	1 kilogram.
(4) Imports and Exports .....	1 kilogram
(C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors .....	24 grams.
(2) Distributions by persons required to report under §1310.03(c) of this part .....	24 grams.
(3) All other domestic distributions, (other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section) .....	1 kilogram.
(4) Imports and Exports .....	1 kilogram.
(D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors .....	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part .....	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section) .....	1 kilogram.
(4) Imports and Exports .....	1 kilogram.
(E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors .....	24 grams.
(2) Distributions by persons required to report under § 1310.03(c) of this part .....	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section) .....	2.5 kilograms.
(4) Imports and Exports .....	2.5 kilograms.
(F) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors .....	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part .....	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(F) (1) and (2) of this section) .....	2.5 kilograms.
(4) Imports and Exports .....	2.5 kilograms.

4. Section 1310.05 is amended by adding a new paragraph (e) to read as follows:

**§ 1310.05 Reports.**

\* \* \* \* \*

(e) Each regulated person required to report pursuant to § 1310.03(c) of this part shall either:

(1) Submit a written report, containing the information set forth in § 1310.06(i) of this part, on or before the 15th day of each month following the month in which the distributions took place. The report shall be submitted under company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant, to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, ATTN: Electronic Reporting.

5. Section 1310.06 is amended by adding new paragraphs (i) and (j) to read as follows:

**§ 1310.06 Content of records and reports.**

\* \* \* \* \*

(i) Each monthly report required by § 1310.05(e) of this part shall provide the following information for each distribution:

- (1) Supplier name and registration number.
- (2) Purchaser's name and address.
- (3) Name/address shipped to (if different from purchaser's name/address).
- (4) Name of the chemical and total amount shipped (i.e. Pseudoephedrine, 250 grams).
- (5) Date of shipment.
- (6) Product name (if drug product).
- (7) Dosage form (if drug product) (i.e., pill, tablet, liquid).
- (8) Dosage strength (if drug product) (i.e., 30mg, 60mg, per dose etc.).
- (9) Number of dosage units (if drug product) (100 doses per package).
- (10) Package type (if drug product) (bottle, blister pack, etc.).
- (11) Number of packages (if drug product) (10 bottles).
- (12) Lot number (if drug product).

(j) Information provided in reports required by § 1310.05(e) of this part which is exempt from disclosure under section 552(a) of Title 5, by reason of section 552(b)(6) of Title 5, will be provided the same protections from disclosure as are provided in section 310(c) of the Act (21 U.S.C. 830(c)) for confidential business information.

6. Section 1310.10 is amended by revising the introductory text of paragraph (d) to read as follows:

**§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug, and Cosmetic Act.**

\* \* \* \* \*

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

\* \* \* \* \*

Dated: March 18, 2002.  
**Asa Hutchinson,**  
*Administrator.*  
 [FR Doc. 02-7258 Filed 3-27-02; 8:45 am]  
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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 117**

**[CGD08-02-006]**

**RIN 2115-AE47**

**Drawbridge Operation Regulation; Mississippi River, Iowa and Illinois**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary rule; request for comments.

**SUMMARY:** The Commander, Eighth Coast Guard District is temporarily changing the regulation governing the Rock Island Railroad and Highway

Drawbridge, Mile 482.9, Upper Mississippi River due to imminent failure of the upper tread plates if the drawbridge continues to operate in accordance with the existing regulation. The drawbridge will remain in the closed-to-navigation position on weekdays from 5:30 a.m. to 7 a.m. and from 2:45 p.m. to 4:15 p.m. All other times including weekends and Federal Holidays the drawbridge will remain in the open-to-navigation position. Allowing the drawbridge to remain in the open-to-navigation position most of the time will reduce the number of turns of the swing span and extend the life of the deteriorated upper tread plates until they can be replaced.

**DATES:** This temporary rule is effective from 8 a.m. on March 13, 2002, to 8 a.m. on December 31, 2002. Comments must be received by May 28, 2002.

**ADDRESSES:** Material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD08-02-006 and are available for inspection or copying at room 2.107f in the Robert A. Young Federal Building at the Eighth Coast Guard District, Bridge Branch, 1222 Spruce Street, St. Louis, MO 63103-2832, between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Roger K. Wiebusch, Bridge Administrator, Eighth Coast Guard District, Bridge Branch, 1222 Spruce Street, St. Louis, MO 63103-2832, at (314) 539-3900, extension 378.

#### **SUPPLEMENTARY INFORMATION:**

##### **Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. This rule is being promulgated without an NPRM due to the short time frame allowed between the submission of the request by the Department of the Army, Rock Island Arsenal and the date of requested closure. The Coast Guard received the request from the Department of the Army, Rock Island Arsenal, on March 5, 2002.

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**. If the drawbridge continues to operate at its normal frequency, the failure of the upper tread plates is imminent. Failure of the upper tread plates will result in total loss of operation of the drawbridge with catastrophic consequences to traffic on

the Mississippi River. This temporary drawbridge operation amendment has been coordinated with the commercial waterway operators. No objections were raised.

##### **Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for the rulemaking [CGD08-02-006], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8 1/2 by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received. We may change this rule in view of them.

##### **Public Meeting**

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the address under **ADDRESSES**, explaining why one would be beneficial. If the Coast Guard determines that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

##### **Background and Purpose**

On March 5, 2002, the Department of the Army, Rock Island Arsenal requested a temporary change to the operation of the Rock Island Railroad and Highway Drawbridge across the Upper Mississippi River, Mile 482.9 at Rock Island, Illinois. Department of the Army, Rock Island Arsenal requested that the drawbridge remain closed to navigation from 5:30 a.m. to 7 a.m. and from 2:45 p.m. to 4:15 p.m. All other times including weekends and Federal Holidays the drawbridge will remain in the open-to-navigation position. The deteriorated upper tread plates make it necessary to reduce the number of turns of the swing span.

The Rock Island Railroad and Highway Drawbridge has a vertical clearance of 23.8 feet above normal pool in the closed-to-navigation position. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. Presently, the draw opens on signal for passage of river traffic. The Department of the Army, Rock Island Arsenal requested the drawbridge be permitted to remain closed-to-navigation from 5:30 a.m. to 7 a.m. and from 2:45 p.m. to 4:15 p.m. All other times including weekends and

Federal Holidays the drawbridge will remain in the open-to-navigation position. Limiting the operation of the swing span will extend the life of the worn tread plates until they can be replaced during the 2002 winter maintenance season. If this regulatory action is not taken, catastrophic consequences to traffic on the Mississippi River are imminent. This temporary drawbridge operation amendment has been coordinated with the commercial waterway operators. No objections were raised.

##### **Regulatory Evaluation**

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

The Coast Guard expects the economic impact of the temporary rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

##### **Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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.

Since the proposed regulation change will have little effect on present operating conditions for rail or river traffic, 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.

##### **Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we offered to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. Any individual that qualifies

or, believes he or she qualifies as a small entity and requires assistance with the provisions of this rule, may contact Mr. Roger K. Wiebusch, Bridge Administrator, Eighth Coast Guard District, Bridge Branch, at (314) 539-3900, extension 378.

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).

#### Collection of Information

This rule contains no new collection-of-information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

#### Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that this rule does not have implications for federalism.

#### 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 regulation 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 or \$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.

#### Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### 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.

#### 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 concern an environmental risk to health or risk to safety that may disproportionately affect children.

#### 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.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### Environment

We have considered the environmental impact of this rule and concluded that under figure 2-1, paragraph (32)(e), of Commandant Instruction M16475.1 (series), this rule is categorically excluded from further environmental documentation. Promulgation of changes to drawbridge regulations has been found not to have significant effect on the human environment. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES**.

#### 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. Sec. 499; 49 CFR 1.46; 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. From 8 a.m., March 13, 2002, through 8 a.m., December 31, 2002, § 117.T-408 is added to read as follows:

#### § 117.T-408 Upper Mississippi River.

From 8 a.m., March 13, 2002, through 8 a.m., December 31, 2002, the Rock Island Railroad Drawbridge, mile 482.9, may be maintained in the closed-to-navigation position on weekdays from 5:30 a.m. to 7 a.m. and from 2:45 p.m. to 4:15 p.m. All other times, including weekends and Federal Holidays, the drawbridge will remain in the open-to-navigation position.

Dated: March 13, 2002.

**J.R. Whitehead,**

*Captain, U.S. Coast Guard, Commander, 8th Coast Guard District, Acting.*

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#### POSTAL SERVICE

#### 39 CFR Part 111

#### Domestic Mail Manual Changes to Announce the Periodicals Accuracy, Grading, and Evaluation (PAGE) Program

**AGENCY:** Postal Service.

**ACTION:** Final rule.

**SUMMARY:** This final rule provides a change to certain sections applicable to Periodicals mail in the *Domestic Mail Manual* (DMM). It adds a new optional method a publisher may use to determine per-copy weights and to substantiate the advertising percentage in each edition of each issue of a periodical. The new option is called the Periodicals Accuracy, Grading, and Evaluation (PAGE) Program.

**EFFECTIVE DATE:** March 11, 2002.

**FOR FURTHER INFORMATION CONTACT:** Charles Tricamo, New York Rates and Classification Service Center, at (212) 613-8754.

**SUPPLEMENTARY INFORMATION:** In this rulemaking, the Postal Service announces the adoption of an optional method that will eliminate a publisher's need to submit a manually marked copy showing the percentage of advertising for each edition of each issue at the time of mailing. It also eliminates the requirement for Postal Service acceptance employees to determine per-copy weights by weighing 10 copies of each edition at the time of mailing.

Because of technology innovations made in the publishing industry, the