

is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(2) In addition to the tamper-evident packaging feature described in paragraph (b)(1) of this section, any two-piece, hard gelatin capsule covered by this section must be sealed using an acceptable tamper-evident technology.

(c) *Labeling.* (1) In order to alert consumers to the specific tamper-evident feature(s) used, each retail package of an OTC drug product covered by this section (except ammonia inhalant in crushable glass ampules, containers of compressed medical oxygen, or aerosol products that depend upon the power of a liquefied or compressed gas to expel the contents from the container) is required to bear a statement that:

- (i) Identifies all tamper-evident feature(s) and any capsule sealing technologies used to comply with paragraph (b) of this section;
- (ii) Is prominently placed on the package; and
- (iii) Is so placed that it will be unaffected if the tamper-evident feature of the package is breached or missing.

(2) If the tamper-evident feature chosen to meet the requirements in paragraph (b) of this section uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

(d) \* \* \* A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this

chapter and should be clearly identified on the envelope as a "Request for Exemption from the Tamper-Evident Packaging Rule." \* \* \*

\* \* \* \* \*

Dated: October 28, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[FRL-6182-9]

#### Technical Amendments to Approval and Promulgation of Air Quality State Implementation Plans, Texas; Recodification of, and Revisions to the State Implementation Plan; Chapter 114; Correction of Effective Date Under the Congressional Review Act (CRA)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correction of effective date under CRA.

**SUMMARY:** On July 1, 1998 (63 FR 35839), EPA published in the **Federal Register** a direct final rule concerning the Approval and Promulgation of Air Quality Implementation Plans, Texas; Recodification of, and Revisions to the State Implementation Plan, Chapter 114, which established an effective date of August 31, 1998. This document corrects the effective date of the rule to November 4, 1998 to be consistent with sections 801 and 808 of the Congressional Review Act (CRA), enacted as part of the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 801 and 808.

**EFFECTIVE DATE:** November 4, 1998.

**FOR FURTHER INFORMATION CONTACT:** Bill Deese, Air Planning Section (6PD-L), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, telephone (214) 665-7253.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 801 of the CRA precludes a rule from taking effect until the agency promulgating the rule submits a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States, head of the General Accounting Office (GAO). EPA recently discovered that it had inadvertently failed to submit the above rule as required; thus, although the rule was promulgated on

July 1, 1998, by operation of law, the rule did not take effect on August 31, 1998 as stated. Now that EPA has discovered its error, the rule is being submitted to both Houses of Congress and the GAO. This document amends the effective date of the rule consistent with the provisions of the CRA.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since July 1, 1998, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

#### II. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), establish any technical standards subject to the section 12(d) of the National Technology Transfer and Advancement Act, or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or with officials of Indian tribal governments as specified by Executive Orders 12875 and 13084 (63 FR 27655, involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994), or involve special consideration of children's health and safety risks under Executive Order 13045 (62 FR 19885, April 23, 1997). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to

the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). EPA's compliance with these statutes and Executive Orders, as applicable, for the underlying rule is discussed in the July 1, 1998 **Federal Register** document.

Pursuant to 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States; however, in accordance with 5 U.S.C. 808(2), this rule is effective on November 4, 1998. This action is not a "major rule" as defined in 5 U.S.C. 804(2).

This final rule only amends the effective date of the underlying rule; it does not amend any substantive requirements contained in the rule. Accordingly, to the extent it is available, judicial review is limited to the amended effective date. Pursuant to section 307(b)(1) of the Clean Air Act, challenges to this amendment must be brought by January 4, 1999.

Dated: October 26, 1998.

**Carol M. Browner,**  
Administrator.

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 46 CFR Part 2

[CGD 96-067]

RIN 2115-AF40

#### Vessel Inspection User Fees

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

**SUMMARY:** The Coast Guard is adopting as final, with changes, the interim rule it published on April 21, 1997. The interim rule reduced annual vessel inspection user fees for small passenger vessels and exempted publicly owned ferries from payment of vessel inspection user fees as required by the Coast Guard Authorization Act of 1996. The rule also revised the discretionary exemption criteria for vessels owned or operated by non-profit organizations.

**DATES:** This final rule is effective December 4, 1998.

**ADDRESSES:** Documents, as indicated in this preamble, are available for inspection or copying at the office of the Executive Secretary, Marine Safety

Council (G-LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593-0001, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is 1-800-842-8740, extension 7-1477 or 202-267-1477.

**FOR FURTHER INFORMATION CONTACT:** CDR Mark McEwen, Office of Planning and Resources, Budget and Resources Division (G-MRP-2), Marine Safety and Environmental Protection at 202-267-1409.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory History

On April 21, 1997, the Coast Guard published an interim rule entitled Vessel Inspection User Fees in the **Federal Register** (62 FR 19229). The rule reduced the annual vessel inspection fees for small passenger vessels to the limits established under the Coast Guard Authorization Act of 1996 (the Act) (Pub. L. 104-324); exempted publicly owned ferries from annual vessel inspection fees, as mandated by Congress; and added definitions for the terms *publicly owned*, *ferry*, *political subdivision*, *State*, *youth*, and *non-profit organization*. The Coast Guard also revised the exemption criteria for vessels owned or operated by a non-profit organization to include some non-profit organizations that did not previously qualify for exemption from payment of fees.

The Coast Guard received 26 letters commenting on the interim rule. Twenty-five comments were from ferry owners or operators (21 "privately owned" ferries, 1 "publicly owned" ferry, and 3 "unspecified ownership" ferries). The remaining comment was from the Passenger Vessel Association (PVA). No public hearing was requested, and none was held.

##### Discussion of Comments and Changes

###### Fee Caps

As required by the Act, the interim rule capped the annual vessel inspection fees for small passenger vessels less than 65 feet in length at \$300 and for small passenger vessels 65 feet or over in length at \$600. The Coast Guard did not receive any comments on this issue and it has not been changed in the final rule.

###### Definitions

The interim rule added several definitions to 46 CFR 2.10-25. Only the definition of *ferry* was mentioned in the comments. The interim rule defined *ferry* as a vessel transporting passengers

or vehicles on a regular run, over the most direct route between a point of embarkation and a point of debarkation on lands separated by a body of water other than an ocean, or between a point of embarkation and an island within the same State.

The Coast Guard received two comments recommending that the rule use the definition of *ferry* in subchapter T, 46 CFR 175.10-9 (now 46 CFR 175.400) and subchapter H, 46 CFR 70.10-15. The Coast Guard agrees that the definition should be consistent with those in subchapters T and H. The definition has been changed in the final rule to conform with those in subchapters T and H.

The Coast Guard has also revised the definition of *youth* by raising the age limit in the definition from 18 to 21 so the exemption could apply to vessels owned by colleges and universities providing courses of marine environmental studies and meeting the other exemption requirements.

###### Exemption Criteria

The interim rule revised the exemption criteria in 46 CFR 2.10-5 to allow some non-profit organizations that did not previously meet the narrowly drawn criteria to qualify for exemption from payment of fees. The Coast Guard received no comments on this revision, but we have changed the language in this section concerning fundraising activities to clearly give owners and operators flexibility in scheduling these activities.

###### Publicly Owned Ferries

Small passenger vessels, passenger ships, and passenger barges operating as ferries pay the annual vessel inspection fee for the vessel category to which they belong, since there is no fee category established specifically for ferries. As required by the Act, the interim rule amended 46 CFR 2.10-25 to exempt publicly owned ferries from the user fee requirements of 46 CFR part 2.

All of the written comments discussed the issue of exempting publicly owned ferries and stated that owners or operators of privately owned ferries should receive the same exemption as publicly owned ferries.

###### Identical Services

Nineteen comments stated that privately owned ferries and publicly owned ferries provide identical services. Several of the comments stated that all ferries provide lifeline services, such as serving as the primary or sole means of transportation for residents and visitors; providing vital transportation services for passengers, autos, trucks, and buses