

through 15, 1998; the International Symposium and Workshop on Measurements of Optical Radiation Hazards, at the National Institute for Standards and Technology, Gaithersburg, MD, September 1 through 3, 1998; and (3) the Research Workshop on Risks and Benefits of Exposure to Ultraviolet Radiation and Tanning, at the National Institutes of Health, Bethesda, MD, September 16 through 18, 1998. The proceedings of these meetings describe current research findings that show a stronger correlation between UV exposure and skin cancer, photoaging, and photoimmunological effects.

2. FDA is considering revising and updating its August 21, 1986, guidance on the determination of the maximum timer interval and recommended exposure schedule for sunlamp products entitled, "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products." FDA is concerned that inadequate attention is being paid to current recommended exposure schedules and that current guidance may allow higher exposures than are necessary to produce and maintain a tan, and it does not incorporate the differences in individual human sensitivity to UV exposure. FDA intends to update this guidance after reviewing and evaluating material presented at the meetings listed previously and other available information. FDA is further considering incorporating the previous guidance into the sunlamp product performance standard because it believes such incorporation would result in a more comprehensive regulatory standard with all relevant information for compliance in the standard.

3. FDA is considering adding a provision clarifying that manufacturing includes the modification of a sunlamp product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling or modifying sunlamp products if the modification affects any aspect of the product's performance, information or intended function for which § 1040.20 has an applicable requirement. This addition would clarify that sunlamp products are being regulated like other products regulated under § 1010.2. FDA is also considering requiring the manufacturer who performs such modification to recertify and re-identify the product in accordance with the provisions of §§ 1010.2 and 1010.3. This potential amendment is intended to clarify the responsibilities of firms and individuals who are in the business of installing ultraviolet lamps and new timers with different performance

characteristics than the original lamps and timers in previously certified products.

4. FDA is concerned that the current warning label is not read by many tanning salon patrons because it is too long and detailed. Therefore, FDA is considering updating the warning statement required by § 1040.20(d)(1)(i) to simplify the wording and to highlight the risk of skin cancers. In order to update the warning statements, FDA intends to review and evaluate epidemiological and mechanistic information on UV exposure-related skin cancers, including possibly fatal cutaneous malignant melanoma. In developing its specific proposal for this item, FDA will be reviewing the material presented at the meetings cited previously and other available information.

5. FDA is considering requiring the reproduction of the text of the warning statement specified in § 1040.20(d)(1)(i) in catalogs, specification sheets, and brochures pertaining to sunlamp products. FDA is concerned that consumers who purchase sunlamp products through catalog mail order or through catalogs on electronic media may not receive information about the associated hazards and risks until the products are delivered to their homes and unpacked.

6. To simplify appropriate lamp replacement, FDA is considering the development of a biological efficacy rating scale for ultraviolet lamps intended for use in sunlamp products. Lamp technology continues to evolve, affecting the levels of UV exposure, the spectral characteristics and, therefore, the biological efficacy of ultraviolet lamp radiation. At present, a label that specifies the type of lamps suitable for replacement in the product is required on sunlamp products and in the user instructions. As new lamps and new lamp manufacturers enter the marketplace, while other manufacturers abandon the marketplace, it is increasingly cumbersome to keep track of individual lamp designations which are compatible with the product and compliant with the standard. In order to simplify the process, especially for industry and State regulators, FDA is considering a uniform grading/rating system.

III. Comments

Interested persons may, on or before May 10, 1999, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This ANPRM is issued under section 531 *et seq.* of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh *et seq.*) and under authority of the Commissioner of Food and Drugs.

Dated: February 2, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-3109 Filed 2-8-99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07-98-048]

RIN 2115-AE47

Drawbridge Regulations: Grand Canal, FL

AGENCY: Coast Guard, DOT.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the Tortoise Island drawbridge across the Grand Canal at Tortoise Island, Brevard County, Florida. The Coast Guard has reconsidered its original proposal in the NPRM published on August 28, 1998, extending the 2 hours advance notice for opening on signal to include Friday and Saturday nights and evenings preceding federal holidays, and now is proposing only 30 minutes advance notice for opening the bridge on Friday and Saturday nights and evenings preceding federal holidays. This rule is intended to reduce the requirement to maintain bridgetender service on the bridge during evening hours while still meeting the reasonable needs of navigation on Grand Canal.

DATES: Comments must be received on or before April 12, 1999.

ADDRESSES: Comments may be mailed to Commander (oan) Seventh Coast Guard District, 909 SE 1st Avenue, Miami, Florida 33131-3050, or may be delivered to room 406 at the above address between 7:30 a.m. and 4:00 p.m. Monday through Friday, except federal holidays. The telephone number is (305) 536-6546. The Commander, Seventh Coast Guard District, maintains the

public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at the above address.

FOR FURTHER INFORMATION CONTACT: Miss Evelyn Smart, Project Manager, Bridge Section, (305) 536-6546.

SUPPLEMENTARY INFORMATION:

Requests for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views or arguments. Persons submitting comments should include their names and addresses, identify the rulemaking [CGD07-98-048] and the specific section of this revised proposal to which each comment applies, and give the reason for each comment. The Coast Guard requests that all comments and attachments be submitted in an unbound format suitable for copying. If not practical, a second copy of any bound material is requested. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope. The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments received.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Ms. Evelyn Smart at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Regulatory History

On August 28, 1998, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (63 FR 45978). The NPRM proposed to change the regulations governing the operation of the Tortoise Island drawbridge. In response to the NPRM, the Coast Guard received objections from local waterway users stating that Grand Canal provides a well lit, deep water alternative to the shallow main channel of the Banana River. The Banana River is not regularly maintained and has unlighted day marks that are far apart. The local waterway users expressed their concerns about weekend night openings being delayed 2 hours vice opening on signal.

Background and Purpose

The Coast Guard's original proposal included extension of the 2 hours advance notice for opening on signal now authorized during evening hours Sunday through Thursday, to include Friday and Saturday nights and evenings preceding federal holidays. This rule was intended to reduce the requirement to maintain bridgetender service on the bridge during weekend evening hours due to the low volume of boat traffic analyzed over an extended period of time.

Discussion of Comments

Four objections were received to the original NPRM stating that the proposed weekend opening restriction would place an undue burden on the boating public. They were in opposition of the proposed rule because they felt that the bridge owner is not abiding by their original agreement that boaters would have access to the waterway at all times. The National Marine Fisheries Service stated in their letter that the proposal would not affect resources for which the NMFS is responsible and offered neither support nor objection.

Discussion of the Revised Proposal

The Coast Guard reviewed its original proposal and continues to believe that the lack of boat use during the evening hours on weekends justifies placing additional restrictions on bridge openings. However, in order to minimize the impact on navigation, the Coast Guard has decreased the proposed restriction to require only 30 minutes advance notice for a bridge opening on Friday and Saturday nights and evenings preceding federal holidays.

This revised regulation proposal would maintain the existing 2 hours advance notice for openings during evening hours Sunday through Thursday and would add the 30 minute advance notice for bridge openings on Friday and Saturday nights and evenings preceding federal holidays. This change is intended to reduce the requirement to maintain bridgetender service while still meeting the reasonable needs of navigation.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under Section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget 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 this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their field, and governmental jurisdictions with populations of less than 50,000.

Because it expects the impact of this rule to be minimal, 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.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act. (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612, and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this rule and has determined pursuant to Figure 2-1, paragraph 32(e) of Commandant Instruction M16475.1C, that this action is categorically excluded from further environmental documentation. A categorical exclusion determination for this rulemaking is available in the public docket for inspection and copying.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend 33 CFR part 117, as follows:

PART 117—[AMENDED]

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

Authority: 33 U.S.C. 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. Revise § 117.285 paragraph (b) to read as follows:

§ 117.285 Grand Canal.

* * * * *

(b) The draw of the Tortoise Island bridge, mile 2.6, shall open on signal; except that during the evening hours from 10 p.m. to 6 a.m. from Sunday evening until Friday morning, the draw shall open on signal if at least 2 hours advance notice is given. On Friday and Saturday evening hours and evenings preceding federal holidays, from 10 p.m. to 6 a.m., the draw shall open on signal if at least 30 minutes advance notice is given.

Dated: January 21, 1999.

Norman T. Saunders,

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

[FR Doc. 99-3133 Filed 2-8-99; 8:45 am]

BILLING CODE 4910-15-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA-011-0071b; FRL-6229-6]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, North Coast Unified Air Quality Management District and Northern Sonoma County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP). This action is an administrative change which revises definitions in North Coast Unified Air Quality Management District (NCUAQMD) and Northern Sonoma County Air Pollution Control District (NSAPCD) Rule 130, Definitions.

The intended effect of proposing approval of these rule is to incorporate changes to the definitions for clarity and consistency with revised federal and state definitions. EPA is proposing approval of these rules to be incorporated into the California SIP for the attainment and maintenance of the national ambient air quality standards (NAAQS) under title I of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this **Federal Register**, the EPA is approving these rules as a direct final rule without

prior proposal because the Agency views this as noncontroversial amendment and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this proposed rule. If EPA receives relevant adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by March 11, 1999.

ADDRESSES: Written comments on this action should be addressed to: Andrew Steckel, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Copies of the rule revisions and EPA's approval of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95812.

North Coast Unified Air Quality Management District, 2300 Myrtle Avenue, Eureka, CA 95501.

Northern Sonoma County Air Pollution Control District, 150 Matheson, Healdsburg, CA 95448.

FOR FURTHER INFORMATION CONTACT:

Cynthia G. Allen, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901, Telephone: (415) 744-1189.

SUPPLEMENTARY INFORMATION: This document concerns North Coast Unified Air Quality Management District and Northern Sonoma County Air Pollution Control District Rules 130, Definitions, submitted on EPA on December 31, 1990 (NCUAQMD) and June 23, 1998 (NCUAQMD) and March 10, 1998 (NSCAPCD), by the California Air Resources Board. For further information, please see the information provided in the Direct Final action that is located in the Final Rules section of this **Federal Register**.

Authority: 42 U.S.C. 7401 et seq.

Dated: January 4, 1999.

Laura Yoshii,

Acting Regional Administrator, Region IX.

[FR Doc. 99-2794 Filed 2-8-99; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 194-0125b; FRL-6226-6]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, Monterey Bay Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the California State Implementation Plan (SIP) which concerns the control of volatile organic compounds (VOC) emissions from leather processing operations within the Monterey Bay Unified Air Pollution Control District (MBUAPCD) area.

The intended effect of proposing approval of this rule is to regulate emissions of VOC in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules section of this **Federal Register**, the EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this rule. Any parties interested in commenting on this rule should do so at this time.

DATES: Written comments must be received in writing by March 11, 1999.

ADDRESSES: Written comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Copies of the rule revisions and EPA's evaluation report of the rule are available for public inspection at EPA's Region IX office during normal business