

within the zone without prior approval by the Captain of the Port or his designated representatives. Vessels or persons desiring to enter or transit the areas encompassed by any of the security zones may contact the Coast Guard Captain of the Port or his designated representatives on VHF Channel Marine 12 to seek permission to enter or transit the zone. If permission is granted, all persons and vessels must comply with the instructions of the COTP or that officer's designated representatives.

(d) *Effective period.* This section is effective from 6 a.m. on February 2, 2004, until 11:59 p.m. on February 7, 2005.

Dated: November 26, 2004.

David B. Peterman,

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

[FR Doc. 04-27100 Filed 12-9-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. R02-OAR-2004-NJ-0004, FRL-7847-1]

Approval and Promulgation of Implementation Plans; New Jersey Consumer Product Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the New Jersey State Implementation Plan (SIP) for ozone concerning the control of volatile organic compounds. The SIP revision consists of amendments to Subchapter 24 "Prevention of Air Pollution From Consumer Products" of 7:27 of the New Jersey Administrative Codes. This SIP revision consists of two control measures, consumer products and portable fuel containers, needed to meet the shortfall emissions reduction identified by EPA in New Jersey's 1-hour ozone attainment demonstration SIP. The intended effect of this action is to approve control strategies required by the Clean Air Act which will result in emission reductions that will help achieve attainment of the national ambient air quality standard for ozone.

DATES: Comments must be received on or before January 10, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R02-OAR-

2004-NJ-0004 by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

1. Agency Web site: <http://docket.epa.gov/rmepub/> Regional Material in EDocket (RME), EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select "quick search," then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

2. E-mail: Werner.Raymond@epa.gov.

3. Fax: (212) 637-3901.

4. Mail: "RME ID Number R02-OAR-2004-NJ-0004", Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007-1866.

5. Hand Delivery or Courier. Deliver your comments to: Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007-1866. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

A copy of the New Jersey submittal is available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007-1866.

New Jersey Department of Environmental Protection, Office of Air Quality Management, Bureau of Air Quality Planning, 401 East State Street, CN418, Trenton, New Jersey 08625.

FOR FURTHER INFORMATION CONTACT: Paul R. Truchan, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007-1866, (212) 637-3711.

SUPPLEMENTARY INFORMATION:

I. What Is Required by the Clean Air Act and How Does It Apply to New Jersey?

Section 182 of the Clean Air Act (Act) specifies the required State Implementation Plan (SIP) submissions and requirements for areas classified as nonattainment for ozone and when these submissions and requirements are to be submitted to EPA by the states. The specific requirements vary

depending upon the severity of the ozone problem. The New York-Northern New Jersey-Long Island and Philadelphia-Trenton nonattainment areas are nonattainment areas classified as a severe. Under section 182, severe ozone nonattainment areas were required to submit demonstrations of how they would attain the 1-hour ozone standard. On December 16, 1999 (64 FR 70380), EPA proposed approval of New Jersey's 1-hour ozone attainment demonstration SIP for the New Jersey portion of the New York-Northern New Jersey-Long Island nonattainment area and the New Jersey portion of the Philadelphia-Trenton nonattainment area. In that rulemaking, EPA identified an emission reduction shortfall associated with New Jersey's 1-hour ozone attainment demonstration SIPs, and required New Jersey to address the shortfalls. In a related matter, the Ozone Transport Commission (OTC) developed control measures into model rules for a number of source categories and estimated emission reduction benefits from implementing these model rules. These model rules were designed for use by states in developing their own regulations to achieve additional emission reductions to close emission shortfalls.

On February 4, 2002 (67 FR 5152), EPA approved New Jersey's 1-hour ozone attainment demonstration SIPs. This approval included an enforceable commitment submitted by New Jersey to adopt additional control measures to close the shortfalls identified by EPA for attainment of the 1-hour ozone standard.

II. What Was Included in New Jersey's Submittal?

On June 22, 2004, Bradley M. Campbell, Commissioner, New Jersey Department of Environmental Protection (NJDEP), submitted to EPA a revision to the SIP which included an adopted revision to subchapter 24, "Prevention of Air Pollution From Consumer Products," which contained two control programs. The two control programs are consumer products and portable fuel container spillage control. This SIP revision will provide volatile organic compound (VOC) emission reductions to address, in part, the shortfall identified by EPA when New Jersey's one-hour ozone attainment demonstrations were approved. New Jersey used the OTC model rules as guidelines to develop its rules.

III. Was Subchapter 24 Previously Approved by EPA?

On May 2, 1997 as part of the New Jersey SIP EPA previously approved subchapter 24 (62 FR 24036) which included the innovative product exemption as a method of compliance and the option of variances. The innovative product exemption and variance provision was fully discussed in the proposed approval (January 21, 1997, 62 FR 2984). As part of the SIP revision, New Jersey committed to forwarding all innovative product exemptions and variances that the State accepts to EPA, Region 2, in order for EPA to be able to determine compliance with the New Jersey SIP.

IV. What Are the Requirements for "Consumer Products" ?

The revised Subchapter 24 now regulates 45 separate consumer product categories and applies statewide. It requires that, on or after January 1, 2005, no person shall sell, supply, offer for sale, or manufacture consumer products which contain VOCs in excess of the VOC content limits specified by New Jersey for those products. Subchapter 24 includes specific exemptions, as well as registration and product labeling requirements, recordkeeping and reporting requirements, and test methods and procedures.

Consumer products that are sold in New Jersey for shipment and use outside of the State of New Jersey are exempt from the VOC content limits, and administrative and testing requirements of Subchapter 24. This exemption reflects the intent to regulate only the manufacture and distribution of consumer products that actually emit VOCs into New Jersey's air and not to interfere in the transportation of goods that are destined for use outside of the State.

In addition, subchapter 24 contains provisions for accepting innovative products exemptions (IPEs), alternative compliance plans (ACPs), and variances that have been approved by the California Air Resources Board (CARB) or other states with adopted consumer product regulations based on the Ozone Transport Commission (OTC) "Model Rule for Consumer Products" dated November 29, 2001.

The Subchapter 24 IPE and ACP provisions provide alternatives to complying with the VOC content limits specified in the Table 1—VOC Content Limits For Chemically Formulated Consumer Products of Subchapter 24. The IPE provisions require a manufacturer to demonstrate that due to

some characteristics of the formulation, design, delivery system or other factor, VOC emissions resulting from the use of the innovative product would be less than the emissions resulting from the use of a representative product that meets the VOC content standard. The ACP provisions specify a method for averaging the emissions from several consumer products manufactured by the same company such that the total emissions from the products included in the plan will have emissions equal to or less than the sum of emissions from products that actually complied with the individual product emission limitations. The variance provision allows for a temporary exemption based on an extraordinary economic hardship that is beyond the reasonable control of the manufacturer of the regulated consumer product.

The State provisions specify the required documentation that must be submitted and the conditions under which New Jersey will recognize a IPE, ACP or variance that was granted by CARB or another state with equivalent provisions. The IPE, ACP or variance can become effective in New Jersey for the period of time that the approved IPE, ACP or variance remains in effect, provided that all the consumer products within the IPE, ACP or variance are regulated by Subchapter 24.

Paragraph 24.7(b)(2) of subchapter 24 provides for alternate test methods for consumer products provided that the alternate method is at least as accurate, precise, and appropriate as the test methods included in Subchapter 24 and that the alternate test method is first approved by both the NJDEP and the EPA.

V. What Are the Requirements for "Portable Fuel Containers and Spill Proof Spouts"?

Subchapter 24 (sections 24.8–24.12) also reduces refueling emissions from those equipment and engines in the off-road categories that are predominantly refueled with portable fuel containers. Subchapter 24 applies to any person who sells, supplies, offers for sale, or manufactures for sale in New Jersey portable fuel container(s) or spout(s) or both for use in New Jersey. Subchapter 24 includes exemptions; administrative requirements which include date coding and labeling; recordkeeping and reporting requirements; a manufacturer warranty requirement; and test methods and procedures.

Subchapter 24 establishes performance standards applicable on or after January 1, 2005, which are divided into two sections. One standard specifically addresses spill-proof

systems and the other addresses spill-proof spouts for use in portable fuel containers. Included are performance standards for automatic shut off, automatic closure, container openings, fuel flow rates and fill levels. Subchapter 24 also includes a permeation rate for spill-proof systems only.

Portable fuel containers or spouts or both portable fuel containers and spouts manufactured before January 1, 2005 may continue to be sold until January 1, 2006 provided the date of manufacture or a date-code representing the date of manufacture is clearly displayed on the product.

Subchapter 24 also establishes IPE provisions which allow for alternatives to complying with the performance standards specified in subchapter 24 and a variance provision for situations where there is extraordinary economic hardships. Also as in the case for consumer products, the portable fuel container provisions provide for accepting IPE or variances that have been granted by CARB or another state with equivalent provisions. The IPE or variance can become effective in New Jersey for the period of time that the approved IPE or variance remains in effect in the state which originally granted the IPE or variance.

Paragraph 24.11(c) of subchapter 24 provides for alternate test methods for portable fuel containers provided that the alternate method is at least as accurate, precise, and appropriate as the test methods included in subchapter 24 and that the alternate test method is first approved by both the NJDEP and the EPA.

VI. What Is EPA's Conclusion?

EPA has evaluated New Jersey's submittal for consistency with the Act, EPA regulations, and EPA policy. EPA has determined that the revisions made to subchapter 24 "Prevention of Air Pollution From Consumer Products" of title 7, Chapter 27 of the New Jersey Administrative Codes, meet the SIP revision requirements of the Act with the following exception. While the provisions related to variances, IPE and ACP pursuant to subchapter 24, "Consumer Products" are acceptable, each specific application of those provisions will not be recognized as meeting Federal requirements until it is approved by EPA as a SIP revision. Therefore, EPA is proposing to approve the regulation as part of the New Jersey SIP with the exception that any specific application of provisions associated with variances, IPE and ACP, must be submitted as SIP revisions.

VII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

This proposed rule also does not have tribal implications because it will 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act. This proposed rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. In this context, in the absence of a prior existing requirement for the

state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401-7671q.

Dated: November 30, 2004.

George Pavlou,

Acting Regional Administrator, Region 2.

[FR Doc. 04-27170 Filed 12-9-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal and State health care programs' anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 8, 2005.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-91-N, Room

5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-91-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. The OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. The OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), or exclusion from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100-93, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices which, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. The OIG safe harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements"