

processing of the received ultrasonic signal.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers." See § 892.1(e) for the availability of this guidance document.

Dated: July 2, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8-16354 Filed 7-16-08; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2007-1000; FRL-8691-6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendments to the Control of Volatile Organic Compound Emissions From Portable Fuel Containers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Maryland. This revision establishes and requires the control of emissions of volatile organic compounds (VOCs) portable fuel containers. EPA is approving this SIP revision in accordance with the Clean Air Act (CAA).

DATES: *Effective Date:* This final rule is effective on August 18, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2007-1000. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are

available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT:

Gobeail McKinley, (215) 814-2033, or by e-mail at mckinley.gobeail@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 3, 2007 (72 FR 67878), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. The NPR proposed approval of the control of VOC emissions from portable fuel containers. The formal SIP revision was submitted by the Maryland Department of the Environment (MDE) on June 18, 2007.

II. Summary of SIP Revision

Maryland's amendments to the portable fuel containers rule incorporate the changes to the 2007 Ozone Transport Commission (OTC) Model Rule for portable fuel containers that was based on the changes adopted by California Air Resources Board (CARB) in July 2006. The amendments address the fact that the original rule did not apply to kerosene containers which were offered for sale in place of compliant portable fuel containers. Other amended incorporations include: Modifying the existing spout regulations in order to improve spillage control; elimination of the fuel flow rate and fill level performance standards; elimination of the automatic shutoff performance standard; new containers must be certified for use and sale by the manufacturer through CARB; and, new portable fuel container testing procedures to streamline testing. The amendments, which includes a one-year sell-through period, apply to any person who sells, supplies, advertises or offers for sale, or manufactures for sale portable fuel containers and/or spouts. Owners of portable fuel containers and/or spouts purchased prior to the July 1, 2007 implementation date are not required to purchase or replace the containers and/or spouts with newer, compliant fuel containers. There are no manufacturers of portable fuel containers in Maryland.

The rationale for EPA's proposed action are explained in the NPR and will not be restated here. On December 6, 2007, EPA received a comment on its December 3, 2007 NPR. A summary of the comment submitted and EPA's response is provided in section III of this document.

III. Summary of Public Comments and EPA Response

Comment: The commenter expressed a concern that in New Jersey, the container designs are not easy to use, especially for those who use these containers only occasionally, and some people might defeat the designs thereby eliminating any air quality benefits. The commenter asks if EPA would investigate whether the containers will really bring a significant clean air benefit.

Response: These amendments, submitted by the State of Maryland concerning the control of VOCs from portable fuel containers, are being considered by EPA, on the basis that they strengthen the existing Maryland SIP. There is no comparable Federal rule to reduce VOC emissions from portable fuel containers. The State of Maryland has estimated that these amendments will result in an emission reduction potential of 1.6 tons per day of VOC in the Baltimore nonattainment area, and 6 tons per day of VOC statewide beginning in 2009.¹ The commenter does not dispute that the Maryland portable fuel container rule will reduce VOC emissions, but rather speculates that the emissions reduction features of the fuel containers might be defeated by end-users and asks EPA to investigate whether the rule will achieve "significant clean air benefits." For purposes of approving this regulation as a SIP-strengthening measure, EPA does not have to determine if the emissions reductions from this regulation are or are not "significant." EPA merely needs to determine if the rule will generate some additional reductions that would not be achieved by the current Maryland SIP. The commenter does not challenge that at least some amount of reductions will occur due to the implementation of the fuel container rule.

Section 110 of the CAA provides the statutory framework for approval/disapproval of SIP revisions. Under the CAA, EPA establishes NAAQS for certain pollutants. The CAA establishes a joint Federal and State program to control air pollution and protect the public health. States are required to prepare SIPs for each designated "air quality region" within their borders. The SIP must specify emission limits

¹ Maryland is not at this time requesting EPA to approve a quantified amount of VOC emission reduction from the enactment of its regulation. Rather, this regulation has been submitted by Maryland, and is being considered by EPA, on the basis that it strengthens the existing Maryland SIP. EPA will only review and approve a specific amount of emissions reductions after receiving a proper request to do so from the State of Maryland.

and other measures necessary for that area to meet and maintain the required NAAQS. Each SIP must be submitted to the EPA for its review and approval. EPA will review and must approve the SIP revision if it is found to meet the minimum requirements of the CAA. *See* section 110(k)(3) of the CAA, 42 U.S.C. 7410(k)(3); *see also*, *Union Elec. Co. v. EPA*, 427 U.S. 246, 265, 96 S.Ct. 2518, 49 L.Ed.2d 474 (1976).

EPA has concluded that Maryland's amendments concerning the control of VOCs from portable fuel containers meet the minimum criteria for approvability. Furthermore, to the extent that the fuel containers achieve any emissions reductions at all, even reductions that are not "significant," this SIP revision will be more stringent than the current Maryland SIP.

III. Final Action

EPA is approving the control of VOC emissions from portable fuel containers (COMAR 26.11.13.07) as a revision to the Maryland SIP which was submitted on June 18, 2007. This regulation will result in the reduction of VOC emissions from the affected sources.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- 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);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit 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. EPA will submit a report containing this action and other required information to the U.S. Senate,

the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 15, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action pertaining to Maryland's amendments to the portable fuel containers rule may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: July 1, 2008.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart V—Maryland

■ 2. In § 52.1070, the table in paragraph (c) is amended by revising the entries for COMAR 26.11.13 [title] and 26.11.13.07 to read as follows:

§ 52.1070 Identification of plan.

*	*	*	*	*
(c)	*	*	*	

EPA-APPROVED REGULATIONS IN THE MARYLAND SIP

Code of Maryland administrative regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
* COMAR 26.11.13	* Control of Gasoline and Volatile Organic Compound Storage and Handling	* 	* 	*

EPA-APPROVED REGULATIONS IN THE MARYLAND SIP—Continued

Code of Maryland administrative regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
26.11.13.07	Control of VOC Emissions from Portable Fuel Containers.	6/18/07	7/17/08 [Insert page number where the document begins].	

* * * * *

[FR Doc. E8-16021 Filed 7-16-08; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2006-1029; FRL-8689-7]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Control of Air Pollution from Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Texas. This revision, adopted by Texas on November 15, 2006, and submitted to EPA on December 13, 2006, extends requirements to reduce volatile organic compound (VOC) emissions in the Dallas-Fort Worth (DFW) area. Specifically, this revision extends requirements for control of VOC emissions to the five counties that were added to the DFW nonattainment area under the 1997 8-hour ozone standard designation: Ellis, Johnson, Kaufman, Parker, and Rockwall, and the affected VOC sources will be subject to the same emission limitation, control, monitoring, testing, recordkeeping, and recording requirements already in effect in Collin, Dallas, Denton, and Tarrant counties. As a result of this action, these new VOC control requirements will be consistent for all nine counties in the DFW ozone nonattainment area. This revision meets statutory and regulatory requirements, and is consistent with EPA's guidance. EPA is approving this revision pursuant to section 110, 116 and part D of the Federal Clean Air Act (CAA).

DATES: This direct final rule will be effective September 15, 2008 without

further notice, unless EPA receives relevant adverse comments by August 18, 2008. If EPA receives such comment, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA-R06-OAR-2006-1029, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *EPA Region 6 "Contact Us" Web site:* <http://epa.gov/region6/r6comment.htm>. Please click on "6PD" (Multimedia) and select "Air" before submitting comments.
- *E-mail:* Mr. Guy Donaldson at donaldson.guy@epa.gov. Please also send a copy by email to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

- *Fax:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD-L), at fax number 214-665-7263.

- *Mail:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733.

- *Hand or Courier Delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R06-OAR-2006-1029. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov> your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT**