

will continue to make information concerning the implementation of the MRA and part 26 available to the public on FDA's web site at <http://www.fda.gov/oia/homepage.htm> (International section).

II. The Public Meeting

The December 8, 1999, meeting is the first public meeting FDA has held on the Pharmaceutical GMP's Annex to the MRA since the final rule published. The purpose of the meeting is to provide information concerning FDA activities related to the implementation of the MRA Pharmaceutical GMP's Annex (covering human and animal drug and human biological products) and to provide an opportunity to hear comments and address concerns from interested members of the public.

The meeting agenda will include: (1) FDA presentations with a summary of the progress made in the implementation of the Pharmaceutical GMP's Annex; discussion of the two-way alert system; public access to information; the process used to determine the equivalence of the regulatory systems for pharmaceutical GMP's and work plan, (2) outside presentations, and (3) panel discussion; question and answer session.

When submitting a request for time for an oral presentation at the meeting, please indicate your topic, provide a presentation outline, and identify any presentation needs (an overhead projector, slide projector, etc.). Time allowed for accepted presenters will depend on the number of presentation requests. Registration information (including name, title, firm name, address, telephone, and fax number) and requests for presentation (including topic and outline) should be submitted to the listed contact person by November 22, 1999. Space is limited, therefore, interested parties are encouraged to register early. Special accommodations due to disability should be submitted at least 7 days in advance.

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-27973 Filed 10-26-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[DC-2012a; FRL-6457-1]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Stage II Gasoline Vapor Recovery and RACT Requirements for Major Sources of VOC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the District of Columbia State Implementation Plan (SIP). These revisions amend the requirements for all major volatile organic compounds (VOC) sources to implement reasonably available control technology (RACT) in the District of Columbia. These revisions also revise Stage II gasoline vapor recovery requirements. The intended effect of this action is to approve the revisions to the District's VOC regulations because they strengthen the SIP. This action is being taken in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on December 13, 1999 without further notice, unless EPA receives adverse comment by November 26, 1999. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to David L. Arnold, Chief, Ozone and Mobile Sources Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available 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 and the District of Columbia Department of Public Health, Air Quality Division, 51 N Street, N.E., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Cristina Fernandez, (215) 814-2178, or by e-mail at fernandez.cristina@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Summary of the SIP Revisions

On June 21, 1985, the Mayor of the District of Columbia submitted a formal revision of the District of Columbia SIP. This 1985 submittal consisted of D.C. Law 5-165, "The District of Columbia

Air Pollution Control Act of 1984". This law covered a variety of air pollution control programs including RACT requirements for major sources of VOC and Stage II gasoline vapor recovery requirements.

On October 22, 1993, the District of Columbia submitted a revision to its SIP for VOC RACT to comply with the RACT fix-up and catch-up requirements of the Clean Air Act (the Act). This 1993 submittal consisted of D.C. Law 10-24, "Air Pollution Control Act of 1984 National Ambient Air Quality Standards Attainment Amendment Act of 1993". The revision consists of new regulations which require sources that emit or have the potential to emit 50 tons per year (tpy) or more of VOC in the District ozone nonattainment area to comply with the RACT requirements, as well as amendments to Title 20 District of Columbia Municipal Regulations (DCMR) Chapter 7—Volatile Organic Compounds.

On April 8, 1993, the District of Columbia Department of Consumer and Regulatory Affairs (DCRA), Environmental Regulation Administration submitted a negative declaration for 25 source categories of VOC covered by control technique guideline documents (CTG) issued prior to November 15, 1990. A negative declaration is a certification that no sources exist in the District for specified source categories.

On September 4, 1997, the District of Columbia submitted a supplement to its October 22, 1993, VOC RACT SIP revision. This supplement included a negative declaration for additional categories of VOC sources covered by CTGs prior to November 15, 1990 and non-CTG major sources, to certify that no such sources are located in the District.

On December 16, 1998, the District of Columbia Department of Health submitted a revision to its SIP regarding RACT for solvent cleaning (degreasing) activities and offset lithography printing operations. Amendments to Appendix 5-1, *Test Methods for Sources of Volatile Organic Compounds* and to the definitions and abbreviations were also included in this submittal.

Portions of the June 21, 1985 and October 22, 1993 submittal have already been approved into the District's SIP. These include most of the definitions in Section 199 of Title 20 of the DCMR, the monitoring, reporting and record keeping requirements in Sections 500, 501, and 502 applicable to the VOC sources covered under *Chapter 7—Volatile Organic Compounds, and Section 710—Engraving and Plate Printing*. The deficiencies previously

identified by EPA in the District's VOC RACT regulations have either been rendered moot by the submittal of a negative declaration or corrected by the District of Columbia in its October 22, 1993 submittal.

For *Section 701—Storage of Petroleum Products*, *Section 702—Control of VOC Leaks from Petroleum Refinery Sources* and *Section 709—Cutback Asphalt of Title 20 of the DCMR, Chapter 7—Volatile Organic Compounds*, the District decided to take no action on the deficiencies identified by EPA because the District has determined that there are no sources located in the District subject to these regulations. A negative declaration has been submitted by the District of Columbia that covers these sources categories. If new major sources in these source categories were to locate in the District, they would be subject to the SIP's more stringent provisions for New Source Review (NSR).

Chapter 5—Source Monitoring and Testing of Title 20 of the DCMR has been amended by the District of Columbia in its October 22, 1993 and December 16, 1998 submittals. The District has amended *Section 500—Records and Reports* by adding subsections 500.6 and 500.7 to address EPA's requirement that owners and operators of stationary sources must maintain written records for at least two years. The District of Columbia has also amended *Section 502—Sampling Test and Monitoring* by adding subsections 503.13, 502.17 and appendix No. 5 to address the federal requirement for specifying the applicable test methods for sources of VOC.

Title 20 of the DCMR, *Chapter 7—Volatile Organic Compounds* has been amended by the District of Columbia in their October 22, 1993 submittal. The District of Columbia amended *Section 703—Terminal Vapor Recovery—Gasoline or Volatile Organic Compounds* regarding bulk gasoline plants and bulk gasoline terminals by adding subsection 703.7 and by modifying subsections 703.1 and 703.4. The District also added subsection 703.6 regarding leaks from gasoline tank trucks and vapor collection systems.

The October 22, 1993 submittal amended requirements in *Section 705—Stage II Gasoline Vapor Recovery* that established Stage II gasoline vapor controls to be applied to any facility that dispenses more than 10,000 gallons per month or 50,000 gallons per month in the case of independent small businesses marketers. Language was also incorporated to indicate that applicability will be based upon the average monthly throughput determined

for the two year period prior to November 15, 1992 and that any periods of facility inactivity would not be included. The regulation stated the average monthly throughput shall be calculated using a thirty day rolling average. Also, the term "selling" was replaced in the regulation with the term "dispensing". EPA has determined that the District of Columbia has complied with section 182 (b)(3) of the Act and is approving the revised *Section 705—Stage II Gasoline Vapor Recovery* as a revision to the District of Columbia's SIP.

The December 16, 1998 submittal amended Chapter 1 by adding and revising definitions; Chapter 5 by adding test methods for degreasing and offset lithography to Appendix 5-1, and Chapter 7 by adding new sections 708.9 through 708.12 and 716 to regulate solvent cleaning (degreasing) activities and offset lithography printing operations.

II. Final Action

EPA is approving revisions to the District of Columbia SIP submitted on June 21, 1985, October 22, 1993, and December 16, 1998. The revisions to Title 20 DCMR, *Chapter 7—Volatile Organic Compounds* consist of the District's revised Stage II gasoline vapor recovery requirements and RACT requirements for major sources of VOC.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipate no adverse comment. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on December 13, 1999 without further notice unless EPA receives adverse comment by November 26, 1999. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled "Regulatory Planning and Review."

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates." Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule. On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 [64 FR 43255 (August 10, 1999)] which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 [52 FR 41685 (October 30, 1987)] on federalism still applies. This rule will not have a substantial direct effect on 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 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

E.O. 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines (1) is "economically significant," as defined under E.O. 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is

preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve

requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. 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 rule 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**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action to approve amendments to the District of Columbia's VOC RACT rules and its Stage II Vapor Recovery Program must be filed in the United States Court of Appeals for the appropriate circuit by December 27, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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 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, Hydrocarbons, Incorporation by reference, Ozone.

Dated: October 5, 1999.

Thomas Voltaggio,

Acting 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 J—District of Columbia

2. In § 52.470, the entries for Chapter 1, Section 199; Chapter 5, Section 599; all of Chapter 7; and all of Chapter 9 in the "EPA Approved Regulations for the District of Columbia" table in paragraph (c) are revised. The entry for Chapter 5, Sections 500.6 is added to this table after the existing entry for Chapter 5, Sections 500.4 and 500.5. The entry for Chapter 5, Sections 502.17 is added to this table after the existing entry for Chapter 5, Sections 502.1 through 502.15. The entry for Appendices is added to this table after the revised entry for Chapter 9. The amendments read as follows:

§ 52.470 Identification of plan.

* * * * *

(c) EPA approved regulations.

EPA-APPROVED DISTRICT OF COLUMBIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
Chapter 1—General				
* Section 199	* Definitions and Abbreviations	* 10/02/98	* 10/27/99 [Insert Federal Register cite] ...	* Added/revised definitions, effective 03/15/85: condensate, dry cleaning facility, external floating roof, petroleum refinery complex, solvent recovery dryer, vapor mounted seal, waxy heavy pour crude oil effective 10/02/98; Director, volatile organic compounds
Chapter 5—Source Monitoring and Testing				
* Section 500.6	* Records and Reports	* 09/30/93	* 10/27/99 [Insert Federal Register cite] ...	*
* Section 502.17	* Sampling Tests, and Measurements.	* 09/30/93	* 10/27/99 [Insert Federal Register cite] ...	*
* Section 599	* Definitions and Abbreviations	* 09/30/93	* 10/27/99 [Insert Federal Register cite] ...	*
Chapter 7—Volatile Organic Compounds				
Section 700	Organic Solvents	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 701.1 through 701.3	Storage of Petroleum Products	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 702	Control of VOC leaks from Petroleum Refinery Equipment.	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 703.2, 703.3	Terminal Vapor Recovery—Gasoline or VOCs.	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 703.1, 703.4 through 703.7.	Terminal Vapor Recovery—Gasoline or VOCs.	09/30/93	10/27/99 [Insert Federal Register cite].	
Section 704	Stage I—Vapor Recovery	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 705.4 through 705.14	Stage II—Gasoline Vapor Recovery.	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 705.1 through 705.3	Stage II—Gasoline Vapor Recovery.	09/30/93	10/27/99 [Insert Federal Register cite].	
Section 706	Petroleum dry Cleaners	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 707	Perchloroethylene Dry Cleaning.	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 708.1 through 708.8	Solvent Cleaning	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 708.9 through 708.12	Solvent Cleaning	10/02/98	10/27/99 [Insert Federal Register cite].	
Section 709	Asphalt Operations	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 710	Engraving and Plate Printing	03/15/85	8/4/92 57 FR 34249.	
Section 711	Pumps and Compressors	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 712	Waste Gas Disposal from Ethylene Producing Plant.	03/15/85	10/27/99 [Insert Federal Register cite].	
Section 713	Waste Gas Disposal from Blow-down Systems.	03/15/85	10/27/99 [Insert Federal Register cite].	

EPA-APPROVED DISTRICT OF COLUMBIA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
Section 715	Reasonably Available Control Technology.	09/30/93	10/27/99	[Insert Federal Register cite].
Section 716	Offset Lithography	10/02/98	10/27/99	[Insert Federal Register cite].
Section 799	Definitions and Abbreviations	10/02/98	10/27/99	[Insert Federal Register cite].
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Chapter 9—Motor Vehicle Pollutants, Lead, Odors, and Nuisance Pollutants

Section 904	Oxygenated Fuels	09/30/93	1/26/95	60 FR 5134.
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Appendices

Appendix 1	Emission Limits for Nitrogen Oxide.	03/15/85	8/28/95	60 FR 44431.
Appendix 2	Table of Allowable Particulate Emissions from Process Sources.	03/15/85	8/28/95	60 FR 44431.
Appendix 3	Allowable VOC Emissions Under Section 710.	03/15/85	8/28/95	60 FR 44431.
Appendix 5	Test Methods for Sources of Volatile Organic Compounds.	10/02/98	10/27/99	[Insert Federal Register cite].
*	*	*	*	*

3. Section 52.478 is added to read as follows:

§ 52.478 Rules and Regulations.

(a) On April 8, 1993, the District of Columbia submitted a letter to EPA declaring that there are no sources located in the District belonging to the following VOC categories:

- (1) Automobile and light-duty truck manufacturing;
- (2) Coating of cans, coils, paper, fabric and vinyl, metal furniture, large appliances, magnet wire, miscellaneous metal parts and products, and flatwood paneling;
- (3) Storage of petroleum liquids in fixed-roof tanks and external floating-roof tanks;
- (4) Bulk gasoline plants and terminals;
- (5) Petroleum refinery sources;
- (6) Petroleum refinery equipment leaks;
- (7) Manufacture of synthesized pharmaceutical products, pneumatic rubber tires, vegetable oil, synthetic organic chemicals (fugitive VOCs and air oxidation), and high density polyethylene, polypropylene and polystyrene resins;
- (8) Graphic arts systems;
- (9) Storage, transportation and marketing of VOCs (fugitive VOCs from oil and gas production and natural gas and gasoline processing).

(b) On September 4, 1997, the District of Columbia submitted a letter to EPA declaring that there are no sources located in the District which belong to the following VOC categories:

- (1) Coating of plastic parts (business machines and other);
- (2) Aerospace;
- (3) Shipbuilding and repair;
- (4) Automobile refinishing;
- (5) Industrial wastewater;
- (6) Distillation or reactor or batch processes in the synthetic organic chemical manufacturing industry;
- (7) Volatile organic storage;
- (8) Wood furniture coatings;
- (9) Offset lithography;
- (10) Clean-up solvents.

[FR Doc. 99-26849 Filed 10-26-99; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[PA022-4089a; FRL-6456-4]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Pennsylvania; Control of Total Reduced Sulfur Emissions From Existing Kraft Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves the section 111(d) plan submitted by the Commonwealth of Pennsylvania for the purpose of controlling total reduced sulfur (TRS) emissions from existing kraft pulp mills. The plan was submitted to fulfill requirements of the Clean Air Act (the Act). The Pennsylvania plan establishes emission limits for existing Kraft Pulp Mills, and provides for the implementation and enforcement of those limits.

DATES: This final rule is effective December 27, 1999 unless by November 26, 1999 adverse or critical comments are received. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the Federal Register informing the public the rule will not take effect.

ADDRESSES: Comments may be mailed to Harold A. Frankford, Office of Air Programs, Mail Code 3AP20, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations: Air Protection Division, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Pennsylvania