

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.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from the Office of Device Evaluation, CDRH, FDA, to the Energy Basin Clinic regarding substantially equivalent determination for the Barrier Condom, August 3, 1987.
2. Beadle, E. L., "A New Method for the Profession: Outline of Successful Prophylactic Program," The Hemingway Press, Waterbury, CN, 1934.
3. Affidavit from Richard Beadle to FDA regarding the Gee Bee Ring, its labeling, and its distribution, July 17, 1989.
4. Letter from the Office of Device Evaluation, CDRH, FDA, to the Wisconsin Pharmacal Co. regarding the not substantially equivalent determination for the WPC-333 Vaginal or Female Condom, April 14, 1989.
5. Letter from the Office of Device Evaluation, CDRH, FDA, to the Energy Basin Clinic regarding the not substantially equivalent determination for the Barrier Condom, April 26, 1989.
6. CDRH, FDA guidance document entitled "Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases," April 4, 1990.
7. Letter from the Office of Device Evaluation, CDRH, FDA, to MD Personal Products, Inc., regarding the not substantially equivalent determination for the Women's Choice Brand Condom," August 29, 1990.
8. Letter from the Office of Device Evaluation, CDRH, FDA, to the Wisconsin Pharmacal Co. regarding PMA approval for the "Reality" Female Condom, May 7, 1993.
9. Bounds, W., J. Guillebaud, L. Stewart, and S. Steele, "A Female Condom (Femshield™): A Study of its User-Acceptability," *British Journal of Family Planning*, 14:83, 1988.
10. Bounds, W., "Male and Female Condoms," *British Journal of Family Planning*, 15:14, 1989.
11. Connell, E. B., "Barrier Contraceptives," *Clinical Obstetrics and Gynecology*, 32:377, 1989.
12. Harris, J. R., L. W. Kanagas, and J. D. Shelton, "Role of Condoms in Preventing HIV Transmission in Developing Countries," *Heterosexual Transmission of AIDS*, ch. 32, p. 399, Alan R. Liss, Inc., 1990.
13. Gregersen, E., and B. Gregersen, "The Female Condom—A Pilot Study of the Acceptability of a New Female Barrier Method," *Acta Obstetrica ET Gynecologica Scan*, 69:73, 1990.

14. Obstetrics-Gynecology Devices Panel, transcript and meeting minutes, March 7, 1989.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 884 be amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.5330 is added to subpart F to read as follows:

§ 884.5330 Female condom.

(a) *Identification.* A female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for contraceptive and prophylactic (preventing the transmission of sexually transmitted diseases) purposes.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* No effective date has been established of the requirement for premarket approval for the devices described in paragraph (b) of this section. See § 884.3 for effective dates of requirement for premarket approval.

Dated: May 28, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99-14653 Filed 6-9-99; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI72-01-7280; FRL-6357-2]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to disapprove a revision to Michigan's State Implementation Plan (SIP) which would change the State's definition of

volatile organic compound (VOC). The Michigan Department of Environmental Quality (MDEQ) submitted this revision on August 20, 1998 and supplemented it with a November 3, 1998, letter.

DATES: Comments on this proposed action must be received by July 12, 1999.

ADDRESSES: You may send written comments to: Carlton T. Nash, Chief, Regulation Development Section, Air Programs Branch (AR-18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the proposed SIP revision and EPA's analysis are available for inspection at the following location: United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Kathleen D'Agostino at (312)886-1767 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Regulation Development Section (AR-18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-1767.

SUPPLEMENTARY INFORMATION:

- A. Background Information
- B. Contents of State Submittal and EPA's Evaluation
- C. EPA's Proposed Action

A. Background

On August 20, 1998, the MDEQ submitted to EPA a proposed revision to the Michigan SIP. MDEQ supplemented the proposed revision with a November 3, 1998, letter from Robert Irvine. The submittal included a revision to the State's definition of VOC, as well as other rule revisions and rescissions. In this document EPA is proposing action only on the revision to the definition of VOC, R 336.1122(f). We will address the remaining rule revisions and rescissions in separate rulemaking actions.

B. Contents of State Submittal and EPA's Evaluation

The State's definition of the term "volatile organic compound" is "any compound of carbon, or mixture of compounds of carbon that participates in photochemical reactions, excluding the following materials, all of which do not contribute appreciably to the formation of ozone: * * * *". The definition goes on to list the exempt compounds. The wording of the State definition is ambiguous, in that it could

imply that there are compounds, other than those listed, which arguably do not "participate in photochemical reactions," and therefore may be excluded from the definition of VOC. Instead, the State should define the term VOC as all organic compounds except those that EPA has listed as negligibly photochemically reactive. (See 40 CFR 51.100(s).) As worded, the definition is unacceptable.

The State has added the following substances as materials excluded from the State definition of VOC: acetone; cyclic, branched, or linear completely-methylated siloxanes; parachlorobenzotrifluoride; trichlorofluoromethane (CFC-11); dichlorodifluoromethane (CFC-12); 1,1,2-trichloro-1,2,2-trifluoroethane (CFC-113); 1,2-dichloro 1,1,2,2-tetrafluoroethane (CFC-114); chloropentafluoroethane (CFC-115); 1,1-dichloro 1-fluoroethane (HCFC-141b); 1-chloro 1,1-difluoroethane (HCFC-142b); chlorodifluoromethane (HCFC-22); 1,1,1-trifluoro 2,2-dichloroethane (HCFC-123); 2-chloro-1,1,1,2-tetrafluoroethane (HCFC-124); trifluoromethane (HFC-23); pentafluoroethane (HFC-125); 1,1,2,2-tetrafluoroethane (HFC-134); 1,1,1,2-tetrafluoroethane (HFC-134a); 1,1,1-trifluoroethane (HFC-143a); 1,1-difluoroethane (HFC-152a); and perfluorocarbon compounds which fall into these classes: cyclic, branched, or linear, completely fluorinated alkanes; cyclic, branched, or linear, completely fluorinated ethers with no unsaturations; cyclic, branched, or linear, completely fluorinated tertiary amines with no unsaturations; and sulfur containing perfluorocarbons with no unsaturations and with sulfur bonds only to carbon and fluorine. These compounds are on the list of compounds exempted from the Federal definition of VOC in 40 CFR 51.100(s), and their exclusion is acceptable.

In addition to the compounds listed above, however, the State has included as an exempt compound, "ingredient compounds in materials other than surface coatings that have a vapor pressure less than or equal to 0.1 millimeters of mercury at the temperature at which they are used." This is unacceptable because it contradicts established EPA policy and is inconsistent with the Federal definition of VOC found in 40 CFR 51.100(s).

In the past, MDEQ has cited EPA's similar treatment of certain VOCs in our Consumer Products rule to justify its proposed change. However, we noted in our proposed Consumer Products rule (61 FR 14531) that the we adopted the

volatility threshold specifically for consumer products, to differentiate between products containing ingredients with higher volatility. Many consumer products would contain 100 percent VOC by definition, making all of them subject to rules designed to reduce VOCs from consumer products, unless we devised a means to distinguish them. To address this problem, we examined the possibility of targeting only those consumer products with relatively higher volatility. We also noted in the proposed rule for Consumer Products that it did not alter our overall VOC policy, which does not allow vapor pressure cutoffs, such as 0.1 mm Hg, to exempt compounds from the definition of VOC. Thus, the proposed Consumer Products rule did not redefine VOC, it proposed to adopt an applicability threshold based on pressure for that specific source category only.

Michigan has proposed a change to the definition of VOC which would allow the State to use "other methods and procedures acceptable to the department" to determine compliance with emission limits if the methods listed in rules 336.2004 and 336.2040 do not result in accurate or reliable results. This represents unacceptable State discretion. The State must submit any change in test methods to EPA for our approval as a SIP revision.

C. EPA's Proposed Action

To determine a rule's approvability, we must evaluate the rule for consistency with the requirements of the Clean Air Act, EPA regulations and the our interpretation of these requirements as expressed in EPA policy guidance documents. We have found Michigan's proposed SIP revision to be inconsistent with the Federal definition of VOC in 40 CFR 51.100(s). The proposed revision is also inconsistent with EPA policy guidance documents, including: "Issues Relating to VOC Regulation Cutpoints, Deficiencies and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice" dated May 25, 1988; EPA's policy memorandum dated June 8, 1989, from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, entitled "Definition of VOC: Rationale;" EPA's policy memorandum dated April 17, 1987, from G. T. Helms, Chief, Control Programs Operations Branch, entitled "Definition of VOC;" and EPA's policy memorandum dated April 17, 1987, from G. T. Helms, Chief, Control Programs Operations Branch, entitled "Definition of Volatile Organic Compounds (VOC's)." Therefore, we are

proposing to disapprove Michigan's SIP revision request.

II. Administrative Requirements

A. Executive Order 12866

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

B. Executive Order 12875

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 the mandate is unfunded, EPA must provide to the OMB 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 any 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 elective 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." This 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.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have 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 rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

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 the mandate is unfunded, EPA must provide to the OMB, 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, E.O. 13084 requires EPA to develop an effective process permitting elected officials and other representatives of tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." This rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility

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. EPA's disapproval of the State request under Section 110 and subchapter I, part D of the Clean Air Act does not affect any existing requirements applicable to small entities. Any pre-existing Federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

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.

The EPA has determined that the disapproval action proposed 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 disapproval action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, and Volatile organic compounds.

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

Dated: May 28, 1999.

Francis X. Lyons,

Regional Administrator, Region 5.

[FR Doc. 99-14763 Filed 6-9-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL-6358-2]

Report to Congress on Fossil Fuel Combustion Wastes; Response to Requests for Extension of Public Comment Period

AGENCY: Environmental Protection Agency.

ACTION: Response to requests for extension of public comment period.

SUMMARY: The Environmental Protection Agency published a notice of availability on April 28, 1999 (64 FR 22820) for the Agency's Report to Congress on Fossil Fuel Combustion Wastes that is required by section 8002(n) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C.

6982(n). That notice also announced a 45-day public comment period on the report. The Agency has received numerous requests to extend the public comment period by up to six months. Because the Agency is currently subject to a court-approved consent decree to issue its regulatory determination by October 1, 1999, EPA is not able, at this time, to grant an extension of the comment period, since any extension would leave insufficient time for EPA to complete a regulatory determination by that date. However, the Agency is currently discussing the possibility of an extension of this deadline with the parties to the consent decree. Such an extension would allow the Agency to grant an extension of the public comment period. Pending the conclusion of those discussions and any extension of the consent decree deadline, the closing date for the comment period on the Report remains June 14, 1999.

DATES: The comment period on the Report to Congress on Fossil Fuel Combustion Wastes closes June 14, 1999.

ADDRESSES: Those persons wishing to submit public comments must send an original and two copies of their comments referencing EPA docket number F-1999-FF2P-FFFFF to: RCRA Docket Information Center (5305G), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, SW., Washington, DC, 20460. Hand deliveries of comments should be made to the Arlington, VA address below.

Comments may also be submitted electronically through the Internet to: rcra-docket@epa.gov. Comments in electronic format should also identify the docket number F-1999-FF2P-FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Commenters should not submit electronically any confidential business information (CBI). An original and two copies of CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, SW, Washington, DC 20460.

Public comments and supporting materials are available for viewing in the RCRA Docket Information Center (RIC), located at Crystal Gateway I Building, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, we recommend that the public make an appointment by calling (703) 603-9230.