

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VII. Comments

Interested persons may, on or before July 25, 2000, submit to the Dockets Management Branch (address above) written comments regarding this direct final rule. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comment 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

## VIII. Report to Congress

For purposes of congressional review requirements under 5 U.S.C. 801–808, the report to Congress for this direct final rule will be issued when FDA confirms the effective date of this rule. Thus, no report is due at this time. If, however, a significant adverse comment is received, the agency will withdraw this direct final rule and no report will be issued to Congress.

### List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 25 is amended as follows:

### PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

2. Section 25.20 is amended by revising paragraph (i) to read as follows:

### § 25.20 Actions requiring preparation of an environmental assessment.

\* \* \* \* \*

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under § 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

\* \* \* \* \*

3. Section 25.32 is amended by revising paragraphs (i), (j), (k), (q), and (r) to read as follows:

### § 25.32 Foods, food additives, and color additives.

\* \* \* \* \*

(i) Approval of a food additive petition or GRAS affirmation petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food additive petition or GRAS affirmation petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive petition, color additive petition, or GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

\* \* \* \* \*

(q) Approval of a food additive petition, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance registered by the Environmental Protection Agency

under FIFRA for the same use requested in the petition, request for exemption, or notification.

(r) Approval of a food additive petition, color additive, GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

Dated: January 24, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–11749 Filed 5–10–00; 8:45 am]

BILLING CODE 4160–01–F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[CA 154–0236; FRL–6587–1]

### Revisions to the California State Implementation Plan, Mojave Desert Air Quality Management District

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing a limited approval and limited disapproval of revisions to the Mojave Desert Air Quality Management District portion of the California State Implementation Plan (SIP). This action was proposed in the **Federal Register** on March 2, 2000 and concerns oxide of nitrogen (NO<sub>x</sub>) emissions from cement kilns. Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), this action simultaneously approves local rules that regulate these emission sources and directs California to correct rule deficiencies.

**EFFECTIVE DATE:** This rule is effective on June 12, 2000.

**ADDRESSES:** You can inspect copies of the administrative record for this action at EPA's Region IX office during normal business hours. You can inspect copies of the submitted rule revisions at the following locations:

Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.  
Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington D.C. 20460.  
California Air Resources Board, Stationary Source Division, Rule

Evaluation Section, 2020 "L" Street, Sacramento, CA 95812.  
 Mojave Desert Air Quality Management District, 15428 Civic Drive, Suite 200, Victorville, CA 92392-2383  
**FOR FURTHER INFORMATION CONTACT:** Max Fantillo, Rulemaking Office (AIR-4),

U.S. Environmental Protection Agency, Region IX, (415) 744-1183.

**SUPPLEMENTARY INFORMATION:**  
 Throughout this document, "we," "us" and "our" refer to EPA.

**I. Proposed Action**

On March 2, 2000 (42 FR 11275), EPA proposed a limited approval and limited disapproval of the following rule that was submitted for incorporation into the California SIP.

Local agency	Rule #	Rule title	Adopted	Submitted
MDAQMD .....	1161	Portland Cement Kilns .....	06/28/95	06/29/95

We proposed a limited approval because we determined that this rule improves the SIP and is largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act. These provisions include the following:

1. Alternative Compliance Strategy in Section (D).
2. Exemption during start-up and shutdown in Section (G)(1)(a).
3. Referencing a rule not approved in State Implementation Plan in Section (G)(1)(c).

Our proposed action contains more information on the rule and our evaluation.

**II. Public Comments and EPA Responses**

EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

**III. EPA Action**

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a limited approval of the submitted rule. This action incorporates the submitted rule into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3), EPA is simultaneously finalizing a limited disapproval of the rule. As a result, sanctions will be imposed unless EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the effective date of this action. These sanctions will be imposed under section 179 of the Act as described in 59 FR 39832 (August 4, 1994). In addition, EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months. Note that the submitted rule has been adopted by the MDAQMD, and EPA's final limited disapproval does not

prevent the local agency from enforcing it.

**IV. Administrative Requirements**

*A. Executive Order 12866*

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

*B. Executive Order 13045*

Executive Order 13045, entitled 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 Executive Order 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 Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

*C. Executive Order 13084*

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, 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 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. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

*D. Executive Order 13132*

Executive Order 13121, entitled Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that 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." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism

implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will 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), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order 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 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

#### H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to

perform activities conducive to the use of VCS.

#### I. 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 July 10, 2000. 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, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, volatile organic compounds.

Dated: April 16, 2000.

**Felicia Marcus,**

*Regional Administrator, Region IX.*

Part 52, Chapter I, Title 40 of the Code of Federal Regulations 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 F—California

2. Section 52.220 is amended by adding paragraphs (c)(274) to read as follows:

#### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(274) New and amended regulations for the following APCD were submitted on June 29, 1995, by the Governor's designee.

(i) Incorporation by reference.

(A) Mojave Desert Air Quality Management District.

(1) Rule 1161, adopted on June 28, 1995.

\* \* \* \* \*

[FR Doc. 00-11674 Filed 5-10-00; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[AL-53-200019(a); FRL-6605-8]

#### Approval and Promulgation of Implementation Plans—Alabama: Approval of Revisions to the Alabama State Implementation Plan: Transportation Conformity Interagency Memorandum of Agreement

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is approving a revision to the Alabama State Implementation Plan (SIP) that contains the transportation conformity rule pursuant to sections 110(k) and 176 of the Clean Air Act as amended in 1990 (Act). The transportation conformity rule assures that projected emissions from transportation plans and projects in air quality nonattainment or maintenance areas stay within the motor vehicle emissions ceiling contained in the SIP. The transportation conformity SIP revision enables the State to implement and enforce the Federal transportation conformity requirements at the State level per regulations on Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. of the Federal Transit Laws. This EPA approval action streamlines the conformity process and allows direct consultation among agencies at the local level. This final approval action is limited to certain regulations on Transportation Conformity. Rationale for approving this SIP revision is provided in the **SUPPLEMENTARY INFORMATION** Section of this action.

**DATES:** This direct final rule is effective on July 10, 2000, without further notice, unless EPA receives adverse comment by June 12, 2000. If adverse comment is received, 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:** All comments should be addressed to Kelly Sheckler at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303.

Copies of the state submittal are available at the following addresses for inspection during normal business hours:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection

Agency, Ariel Rios Building, N.W., Washington, DC 20460.

Environmental Protection Agency, Atlanta Federal Center, Region 4 Air Planning Branch, 61 Forsyth Street S.W., Atlanta, Georgia 30303-3104. Attn: Kelly Sheckler, (404) 562-9042. Alabama Department of Environmental Management, Post Office Box 301463, 1400 Coliseum Boulevard, Montgomery, Alabama 36130-1463.

#### FOR FURTHER INFORMATION CONTACT:

Kelly Sheckler, at 404/562-9042, E-mail: Sheckler.Kelly@epa.gov.

**SUPPLEMENTARY INFORMATION:** Outlined below are the contents of this document:

- I. Background
  - A. What is a SIP?
  - B. What is the Federal approval process for a SIP?
  - C. What is transportation conformity?
  - D. Why must the State submit a transportation conformity SIP?
  - E. How does transportation conformity work?
- II. Approval of the State Transportation Conformity Rule
  - A. What did the State submit?
  - B. What is EPA approving today and why?
  - C. How did the State satisfy the interagency consultation process (40 CFR 93.105)?
  - D. How does the State's submittal address the United States Court of Appeals for the District of Columbia Circuit ruling overturning the grace period for new nonattainment areas (40 CFR 93.102(d)) in the *Sierra Club v. Environmental Protection Agency* lawsuit?
  - E. What other parts of the rule are excluded?
- III. Opportunity for Public Comments
- IV. Administrative Requirements

#### I. Background

##### A. What Is a SIP?

The states, under section 110 of the Act, must develop air pollution regulations and control strategies to ensure that state air quality meets the National Ambient Air Quality Standards (NAAQS) established by EPA. The Act, under section 109, established these NAAQS which currently address six criteria pollutants. These pollutants are: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must send these regulations and control strategies to EPA for approval and incorporation into the Federally enforceable SIP, which protects air quality and contains emission control plans for NAAQS nonattainment areas. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring

networks, and modeling demonstrations.

##### B. What Is the Federal Approval Process for a SIP?

The states must formally adopt the regulations and control strategies consistent with state and Federal laws for incorporating the state regulations into the Federally enforceable SIP. This process generally includes a public notice, public comment period, public hearing, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state will send these provisions to EPA for inclusion in the Federally enforceable SIP. EPA must then determine the appropriate Federal action, provide public notice, and request additional public comment on the action. The possible Federal actions include: approval, disapproval, conditional approval and limited approval/disapproval. If adverse comments are received, EPA must consider and address the comments before taking final action.

EPA incorporates state regulations and supporting information (sent under section 110 of the Act) into the Federally approved SIP through the approval action. EPA maintains records of all such SIP actions in the CFR at Title 40, Part 52, entitled "Approval and Promulgation of Implementation Plans." The EPA does not reproduce the text of the Federally approved state regulations in the CFR. They are "incorporated by reference," which means that the specific state regulation is cited in the CFR and is considered a part of the CFR the same as if the text were fully printed in the CFR.

##### C. What Is Transportation Conformity?

Conformity first appeared as a requirement in the Act's 1977 amendments (Pub. L. 95-95). Although the Act did not define conformity, it stated that no Federal department could engage in, support in any way or provide financial assistance for, license or permit, or approve any activity which did not conform to a SIP which has been approved or promulgated.

The 1990 Amendments to the Act expanded the scope and content of the conformity concept by defining conformity to a SIP. Section 176(c) of the Act defines conformity as conformity to the SIP's purpose of eliminating or reducing the severity and number of violations of the NAAQS and achieving expeditious attainment of