use in the treatment and/or prevention of malaria. Therefore, quinine or quinine salts cannot be safely and effectively used for the treatment and/or prevention of malaria except under the care and supervision of a doctor.

(b) Any OTC drug product containing quinine or quinine salts that is labeled, represented, or promoted for the treatment and/or prevention of malaria is regarded as a new drug within the meaning of section 201(p) of the act, for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use for the treatment and/or prevention of malaria is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After April 20, 1998, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

Dated: March 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7186 Filed 3–19–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA–169–0065; FRL–5974–6]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan. This action is an administrative change which revises the definitions in South Coast Air Quality Management District (SCAQMD or District) Rule 102, Definition of Terms. The intended effect of approving this action is to incorporate changes to the definitions for clarity and consistency with revised Federal and state definitions.

DATES: This action is effective on May 19, 1998 unless adverse or critical comments are received by April 20, 1998. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments must be submitted to Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule revisions and EPA's evaluation report are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 M Street, SW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 L Street, Sacramento, CA 95814

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765.

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone (415–744–1189).

SUPPLEMENTARY INFORMATION:

I. Applicability

The rule being approved into the California SIP is: SCAQMD Rule 102, Definition of Terms, submitted on March 26, 1996, by the California Air Resources Board.

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included South Coast, see 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the South Coast AQMD portion of the California SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). In response to the SIP call and other requirements, the SCAQMD submitted many rules which EPA approved into the SIP.

This document addresses EPA's direct-final action for the following SCAQMD rule: Rule 102, Definition of Terms. This rule was adopted by SCAQMD on November 17, 1995, and submitted by the State of California for incorporation into its SIP on March 26, 1996. This rule was found to be complete on August 6, 1997, pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V [1] and is being finalized for approval into the SIP. This rule was originally adopted as part of SCAQMD's efforts to achieve the National Ambient Air Quality Standards (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement.

The following is EPA's evaluation and final action for this rule.

III. EPA Evaluation and Action

In determining the approvability of a rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements appears in various EPA policy guidance documents. [2]

EPA previously reviewed many rules from the SCAQMD and its predecessor agencies and incorporated them into the federally approved SIP pursuant to section 110(k)(3) of the CAA. Those rules that are being superseded by today's action are as follows:

- Los Angeles County Rule 2, Definitions (submitted 6/30/72)
- Orange County Rule 2, Definitions (submitted 6/30/72)
- Riverside County Rule 2, Definitions (submitted 2/21/72 and 6/30/72)
- San Bernardino County Rule 2, Definitions (submitted 2/21/72)
- South Coast Air Quality Management District Rule 102, Definition of Terms (submitted 2/10/77, 10/13/77, and 6/22/78)

[1] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section (110)(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

[2] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviation, Clarification to Appendix D of November 24, 1987 Federal Register Notice'' (Blue Book)(notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

EPA has evaluated the submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, SCAQMD Rule 102, Definition of Terms, is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective May 19, 1998 without further notice unless the Agency receives relevant adverse comments by April 20, 1998.

If the EPA received such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule did not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. Any parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on May 19, 1998 and no further action will be taken on the proposed rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

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 impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, 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).

C. 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 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 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 Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

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).

E. 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 May 19, 1998. 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, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the **Federal Register** on July 1, 1982.

Dated: February 13, 1998.

Laura Yoshii,

Acting Regional Administrator, EPA, Region IX.

Part 52, chapter I, title of 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 paragraph (c)(230)(i)(B)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(230) * * *

(i) * * *

(B) * * *

(*2*) Rule 102 amended on November 17, 1995.

* * * * *

[FR Doc. 98–7004 Filed 3–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[KS 044–1044a; FRL–5979–7]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Kansas; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving the Kansas plan for implementing the Municipal Solid Waste (MSW) Landfill Emission Guideline (EG) at 40 CFR part 60, subpart Cc, which was required pursuant to section 111(d) of the Clean Air Act (Act). The state's plan was submitted to the EPA on December 1, 1997, in accordance with the requirements for adoption and submittal of state plans for designated facilities in 40 CFR part 60, subpart B. The plan establishes emission limits for existing MSW landfills, and provides for the implementation and enforcement of those limits.

DATES: This action is effective May 19, 1998, unless by April 20, 1998, relevant adverse comments are received. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the: Environmental Protection Agency, Air Planning and Development Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 111(d) of the Act, the EPA has established procedures whereby states submit plans to control certain existing sources of ''designated pollutants.'' Designated pollutants are defined as pollutants for which a standard of performance for new sources applies under section 111, but which are not ''criteria pollutants'' (i.e., pollutants for which National Ambient Air Quality Standards are set pursuant to sections 108 and 109 of the Act). As required by section 111(d) of the Act, the EPA established a process at 40 CFR part 60, subpart B, similar to the process required by section 110 of the Act (regarding State Implementation Plan (SIP) approval) which states must follow in adopting and submitting a section 111(d) plan. Whenever the EPA promulgates a new source performance standard (NSPS) that controls a designated pollutant, the EPA establishes emissions guidelines (EG) in accordance with 40 CFR 60.22 which contain information pertinent to the control of the designated pollutant from that NSPS source category (i.e., the ''designated facility'' as defined at 40 CFR 60.21(b)). Thus, a state's section 111(d) plan for a designated facility must comply with the EG for that source category as well as 40 CFR part 60, subpart B.

On March 12, 1996, the EPA published an EG for existing MSW landfills at 40 CFR part 60, subpart Cc (40 CFR 60.30c through 60.36c) and NSPS for new MSW landfills at 40 CFR part 60 subpart WWW (40 CFR 60.750 through 60.759). The pollutant regulated by the NSPS and EG is MSW landfill emissions, which contain a mixture of volatile organic compounds, other organic compounds, methane, and hazardous air pollutants. To determine whether control is required, nonmethane organic compounds (NMOC) are measured as a surrogate for MSW landfill emissions. Thus, NMOC is considered the designated pollutant. The designated facility which is subject to the EG is each existing MSW landfill (as defined in 40 CFR 60.31c) for which construction, reconstruction or modification was commenced before May 30, 1991.

Pursuant to 40 CFR 60.23(a), states were required to submit a plan for the control of the designated pollutant to which the EG applies within nine months after publication of the EG, or by December 12, 1996. If there were no designated facilities in the state, then the state was required to submit a negative declaration by December 12, 1996.

II. Analysis of State Submittal

The official procedures for adoption and submittal of state plans are codified in 40 CFR part 60, subpart B, §§ 60.23 through 60.26. Subpart B addresses public participation, legal authority, emission standards and other emission limitations, compliance schedules, emission inventories, source surveillance, compliance assurance and enforcement requirements, and cross references to the MSW landfill EG.

On December 1, 1997, the state of Kansas submitted its section 111(d) plan for MSW landfills for implementing the EPA's MSW landfill EG.

The Kansas plan includes documentation that all applicable subpart B requirements have been met. More detailed information on the requirements for an approvable plan and Kansas' submittal can be found in the Technical Support Document (TSD) accompanying this action, which is available on request.

The Kansas plan cross-referenced both the NSPS subpart WWW and EG subpart Cc to adopt the requirements of the Federal rule. The state has ensured, through this cross-reference process, that all the applicable requirements of the Federal rule have been adopted into the state plan. The emission limits, testing, monitoring, reporting and recordkeeping requirements, and other aspects of the Federal rule have been adopted. Kansas rules K.A.R. 28–19–721 through K.A.R. 28–19–727 contain the applicable requirements.

Kansas demonstrated that it has the legal authority to implement and enforce the applicable requirements. The state provided evidence that it complied with the public notice and comment requirements of 40 CFR part 60, subpart B.

III. Final Action

Based on the rationale discussed above and in further detail in the TSD associated with this action, the EPA is approving Kansas' December 1, 1997, submittal of its section 111(d) plan for the control of landfill gas from existing MSW landfills, except those located in Indian Country.

The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, the EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective May 19, 1998 without further notice unless the Agency receives relevant adverse comments by April 20, 1998.

If the EPA receives such comments, then the EPA will publish a document withdrawing the final rule and informing the public that the rule did not take effect. All public comments received will then be addressed in a