

machines, or who voluntarily register with FDA to be covered, to declare calories for those vending machine foods for which the Nutrition Facts label cannot be examined before purchase or for which visible nutrition information is not otherwise provided at the point of purchase. Covered vending machine operators must comply with the rule by December 1, 2016. However, in the **Federal Register** of August 1, 2016 (81 FR 50303), we issued a final rule entitled “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date.” This rule provides that the compliance date for type size front-of-pack labeling requirements (§ 101.8(b)(2) (21 CFR 101.8(b)(2))) and calorie disclosure requirements (§ 101.8(c)(2)) for certain gums, mints, and roll candy products in glass-front machines in the final rule published December 1, 2014 (79 FR 71259) is extended to July 26, 2018. The compliance date for all other requirements in the final rule (79 FR 71259) remains December 1, 2016.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 101.8 have been approved under OMB Control No. 0910–0782.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 11, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2016–19493 Filed 8–15–16; 8:45 am]

**BILLING CODE 4164–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R07–OAR–2014–0213; FRL–9950–65–Region 7]

#### Approval and Promulgation of Implementation Plans; State of Iowa; Infrastructure State Implementation Plan (SIP) Requirements for the 1997 and 2006 Fine Particulate Matter (PM<sub>2.5</sub>) National Ambient Air Quality Standards (NAAQS), and the Adoption of the 1997 PM<sub>2.5</sub> Standard

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving elements of two State Implementation Plan (SIP) submissions from the State of Iowa for the Infrastructure SIP Requirements for the 1997 and 2006 Fine Particulate Matter (PM<sub>2.5</sub>) National Ambient Air Quality Standards (NAAQS). Infrastructure SIPs address the applicable requirements of Clean Air Act (CAA) section 110, which requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by the EPA. The infrastructure requirements are designed to ensure that the structural components of each state’s air quality management program are adequate to meet the state’s responsibilities under the CAA. This action also approves the adoption of the 1997 PM<sub>2.5</sub> standard.

On September 8, 2011, EPA issued a Finding of Failure to Submit a Complete State Implementation Plan for several states, including Iowa. With respect to Iowa, the Finding of Failure to Submit included the following 2006 PM<sub>2.5</sub> NAAQS infrastructure requirements: 110(a)(2)(A)–(C), (D)(i)(II) (prong 3 only), (E)–(H) and (J)–(M). This approval of Iowa’s infrastructure SIP for the 2006 PM<sub>2.5</sub> NAAQS addresses the September 8, 2011 finding.

**DATES:** This final rule is effective on September 15, 2016.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2014–0213. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

Publicly available docket materials are available electronically at [www.regulations.gov](http://www.regulations.gov) and at EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219. Please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7039, or by email at [Hamilton.heather@epa.gov](mailto:Hamilton.heather@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document “we,” “us,” or “our” refer to EPA. This section provides additional information by addressing the following:

- I. What is being addressed in this document?
- II. EPA’s Response to Comments
- III. Final Action
- IV. Statutory and Executive Order Reviews

### I. What is being addressed in this document?

The EPA is approving two submissions from the State of Iowa: The infrastructure SIP submissions for the 1997 and 2006 PM<sub>2.5</sub> NAAQS received on March 31, 2008 and July 29, 2013. The SIP submissions from Iowa addressed the requirements of CAA sections 110(a)(1) and (2) as applicable to the 1997 and 2006 PM<sub>2.5</sub> NAAQS. The March 31, 2008 SIP submission also included the state adoption of the 1997 PM<sub>2.5</sub> standard. The EPA is also approving the 1997 PM<sub>2.5</sub> standard in today’s action.

For the 1997 PM<sub>2.5</sub> NAAQS, the EPA took previous action to address section 110(a)(2)(D)(i)(I)—prongs 1 and 2 for Iowa. (72 FR 10380, March 8, 2007, as revised in 76 FR 48208, August 8, 2011). Therefore, in this final action, we are not acting on these portions since they have already been acted upon by the EPA.

A Technical Support Document is included as part of the docket to discuss the details of this final action.

### II. EPA’s Response to Comment

The public comment period on EPA’s proposed regulation opened June 23, 2016, the date of its publication in the **Federal Register**, and closed on July 25, 2016. 81 FR 40825. During this period, EPA received one comment that is addressed as follows:

*Comment:* The commenter stated that EPA must disapprove the Prevention of Significant Deterioration (PSD) portions of the infrastructure SIP, 110(a)(2)(C), (D)(i)(II) (prong 3) and (J), because the local air agencies in Iowa with their

own PSD programs lack the PM<sub>2.5</sub> increment or do not treat NO<sub>x</sub> as a precursor for ozone.

*Response to comment:* Iowa has a delegated PSD program (see 72 FR 27056) that is not delegated to local air agencies. PSD permits are only issued by the Iowa Department of Natural Resources. 81 FR 44795, 44796. Therefore, no changes will be made in response to this comment.

### III. What action is EPA taking?

The EPA is approving two submissions from the State of Iowa: The infrastructure SIP submissions for the 1997 and 2006 PM<sub>2.5</sub> NAAQS received on March 31, 2008 and July 29, 2013. The SIP submissions from Iowa address the requirements of CAA sections 110(a)(1) and (2) as applicable to the 1997 and 2006 PM<sub>2.5</sub> NAAQS. Today's action also approves the adoption of the 1997 PM<sub>2.5</sub> standard.

The EPA's analysis of these submissions is addressed in a TSD as part of the docket.

### IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule

cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 17, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

### Statutory Authority

The statutory authority for this action is provided by section 110 of the CAA, as amended (42 U.S.C. 7410).

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Prevention of significant deterioration, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: August 1, 2016.

**Mike Brincks,**

*Acting Regional Administrator, Region 7.*

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as set forth below:

### PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

#### Subpart Q—Iowa

- 2. Section 52.820 is amended by adding (e)(45) and (46) to read as follows:

#### § 52.820 Identification of plan.

\* \* \* \* \*

(e) \* \* \*

EPA-APPROVED IOWA NONREGULATORY SIP PROVISIONS

Name of non-regulatory SIP revision	Applicable geographic or nonattainment area	State submittal date	EPA Approval date	Explanation
(45) Sections 110(a)(1) and (2) Infrastructure Requirements 1997 PM <sub>2.5</sub> NAAQS.	Statewide	3/21/08	8/16/16 [Insert <b>Federal Register</b> citation].	This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II), prong 3, (E), (F), (G), (H), (J), (K), (L), and (M). 110(a)(2)(I) is not applicable.
(46) Sections 110(a)(1) and (2) Infrastructure Requirements 2006 PM <sub>2.5</sub> NAAQS.	Statewide	7/23/13	8/16/16 [Insert <b>Federal Register</b> citation].	This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II), prong 3, (E), (F), (G), (H), (J), (K), (L), and (M). 110(a)(2)(I) is not applicable.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R03-OAR-2016-0350; FRL-9950-73-Region 3]

**Air Plan Approval; DC; Infrastructure Requirements for the 2012 PM<sub>2.5</sub> NAAQS**

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

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the District of Columbia (the District) state implementation plan (SIP). Whenever new or revised national ambient air quality standards (NAAQS) are promulgated, the Clean Air Act (CAA) requires states to submit a plan for the implementation, maintenance, and enforcement of such NAAQS. The plan is required to address basic program elements including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. The District has made a submittal addressing the infrastructure requirements for the 2012 annual fine particulate matter (PM<sub>2.5</sub>) NAAQS. EPA is approving these revisions addressing the infrastructure requirements for the 2012 PM<sub>2.5</sub> NAAQS in accordance with the requirements of the CAA.

**DATES:** This rule is effective on October 17, 2016 without further notice, unless EPA receives adverse written comment by September 15, 2016. 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:** Submit your comments, identified by Docket ID No. EPA-R03-OAR-2016-0350 at <http://www.regulations.gov>, or via email to [Fernandez.cristina@epa.gov](mailto:Fernandez.cristina@epa.gov). For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Ruth Knapp, (215) 814-2191, or by email at [knapp.ruth@epa.gov](mailto:knapp.ruth@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Summary of SIP Revision**

On December 28, 2015, the District submitted a formal SIP revision to its SIP. The District's SIP revision

submittal addresses the following infrastructure elements for the 2012 annual PM<sub>2.5</sub> NAAQS: section 110(a)(2)(A), (B), (C), (D)(i)(I), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) of the CAA. The infrastructure SIP submittal does not address section 110(a)(2)(I) which pertains to the nonattainment requirements of part D, title I of the CAA, since this element is not required to be submitted by the 3-year submission deadline of CAA section 110(a)(1), and will be addressed in a separate process.

**II. Summary of EPA's Rationale for Proposing Approval**

In accordance with 40 CFR part 51, appendix V, EPA found that the District's December 28, 2015 infrastructure SIP submittal is technically incomplete for the portions addressing the infrastructure elements in section 110(a)(2)(C), (D)(i)(II), (D)(ii), and (J) relating to the permitting program for prevention of significant deterioration (PSD), because the District has not adequately addressed the requirements of part C of title I of the CAA for having a SIP approved PSD permit program. EPA found the remainder of the SIP submittal to be administratively and technically complete. On May 11, 2016, EPA sent a letter to the District Department of Environment and Energy (DDOEE) notifying the District of this determination.

As a result of this incompleteness finding, EPA is not taking rulemaking action on the PSD related portions of section 110(a)(2)(C), (D)(i)(II), (D)(ii), and (J) for the 2012 annual PM<sub>2.5</sub> NAAQS, until the District through DDOEE submits a SIP to address the PSD permit program requirements of part C of title I of the CAA. EPA recognizes, however, that the District is