

Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm>. For electronic submission go to FDA's Industry Systems Web site at [www.access.fda.gov](http://www.access.fda.gov). Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: *Provided*, That such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.

(2) *Process filing*. A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (Fo), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size: *Provided*, That the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method), Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method), or Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems). These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch

Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm>. For electronic submission, go to FDA's Industry Systems Web site at [www.access.fda.gov](http://www.access.fda.gov).

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(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if that modification is thereafter to be regularly scheduled, the modified process shall be promptly filed as a scheduled process, accompanied by full information on the specified forms as provided in this paragraph.

\* \* \* \* \*

(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Food Safety Inspection Service of the Department of

Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 *et seq.*)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 *et seq.*)).

\* \* \* \* \*

Dated: September 15, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-23614 Filed 9-21-15; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R04-OAR-2015-0444; FRL-9934-42-Region 4]

### Air Plan Approval; KY; Emissions Statements for the 2008 8-Hour Ozone NAAQS

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve the portion of a draft state implementation plan (SIP) revision submitted by the Commonwealth of Kentucky, through the Kentucky Division of Air Quality (DAQ) on April 15, 2015, for parallel processing, that addresses the emissions statement requirements for Kentucky's portion of the Cincinnati, Ohio-Kentucky-Indiana (Cincinnati, OH-KY-IN) 2008 8-hour ozone national ambient air quality standards (NAAQS) nonattainment area (hereinafter referred to as the "Cincinnati, OH-KY-IN Area" or "Area"). Annual emissions reporting (*i.e.*, emissions statements) is required for all ozone nonattainment areas. The Area is comprised of Butler, Clermont, Clinton, Hamilton and Warren Counties in Ohio; portions of Boone, Campbell, and Kenton Counties in Kentucky; and a portion of Dearborn County in Indiana. EPA will consider and take action on the Ohio and Indiana submissions addressing the emissions statements requirements for their portions of this Area in separate actions. This action is being taken pursuant to the Clean Air Act (CAA or Act) and its implementing regulations.

**DATES:** Written comments must be received on or before October 22, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2015-0444, by one of the following methods:

1. [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.

2. *Email*: R4-ARMS@epa.gov.

3. *Fax*: (404) 562-9019.

4. *Mail*: "EPA-R04-OAR-2015-0444," Air Regulatory Management Section, (formerly the Regulatory Development Section), Air Planning and Implementation Branch (formerly the Air Planning Branch), Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.

5. *Hand Delivery or Courier*: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

*Instructions*: Direct your comments to Docket ID No. EPA-R04-OAR-2015-0444. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through [www.regulations.gov](http://www.regulations.gov) or email, information that you consider to be CBI or otherwise protected. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or

viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket*: All documents in the electronic docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information may not be 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 either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

#### **FOR FURTHER INFORMATION CONTACT:**

Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Ms. Bell can be reached at (404) 562-9088 and via electronic mail at [bell.tiereny@epa.gov](mailto:bell.tiereny@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. What is parallel processing?**

Consistent with EPA regulations found at 40 CFR part 51, Appendix V, section 2.3.1, for purposes of expediting review of a SIP submittal, parallel processing allows a state to submit a plan to EPA prior to actual adoption by the state. Generally, the state submits a copy of the proposed regulation or other revisions to EPA before conducting its public hearing. EPA reviews this proposed state action and prepares a notice of proposed rulemaking. EPA's notice of proposed rulemaking is published in the **Federal Register** during the same time frame that the state is holding its public process. The state and EPA then provide for concurrent public comment periods on both the state action and federal action.

If the revision that is finally adopted and submitted by the state is changed in aspects other than those identified in the proposed rulemaking on the parallel

process submission, EPA will evaluate those changes and if necessary and appropriate, issue another notice of proposed rulemaking. The final rulemaking action by EPA will occur only after the SIP revision has been adopted by the state and submitted formally to EPA for incorporation into the SIP.

On April 15, 2015, the State of Kentucky, through Kentucky DAQ, submitted a formal letter request for parallel processing of a draft SIP revision that the Commonwealth was already taking through public comment. Kentucky DAQ requested parallel processing so that EPA could begin to take action on its draft SIP revision in advance of the Commonwealth's submission of the final SIP revision, should that be necessary. As stated above, the final rulemaking action by EPA will occur only after the SIP revision has been: (1) Adopted by Kentucky; (2) submitted formally to EPA for incorporation into the SIP; and (3) evaluated by EPA, including any changes made by the State after the April 15, 2015, draft was submitted to EPA.

##### **II. Background**

On March 12, 2008, EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm). *See* 73 FR 16436 (March 27, 2008). Under EPA's regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm. *See* 40 CFR 50.15. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined in Appendix I of part 50.

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS, based on the three most recent years of ambient air quality data at the conclusion of the designation process. The Cincinnati, OH-KY-IN Area was designated nonattainment for the 2008 8-hour ozone NAAQS on April 30, 2012 (effective July 20, 2012) using 2008–2010 ambient air quality data. *See* 77 FR 30088. At the time of designation, the Cincinnati, OH-KY-IN Area was classified as a marginal nonattainment area for the 2008 8-hour ozone NAAQS.

On March 6, 2015, EPA finalized a rule entitled “Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements” (SIP Requirements Rule) that establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2008 8-hour ozone NAAQS.<sup>1</sup> See 80 FR 12264. This rule establishes nonattainment area attainment dates based on Table 1 of section 181(a) of the CAA, including an attainment date three years after the July 20, 2012, effective date, for areas classified as marginal for the 2008 8-hour ozone NAAQS. Therefore, the attainment date for the Cincinnati, OH-KY-IN Area is July 20, 2015.

Based on the nonattainment designation, Kentucky is required to develop a nonattainment SIP revision addressing certain CAA requirements. Specifically, pursuant to CAA section 182(a)(3)(B), Kentucky is required to submit a SIP revision addressing emissions statements requirements.

Ground level ozone is not emitted directly into the air, but is created by chemical reactions between oxides of nitrogen (NO<sub>x</sub>) and volatile organic compounds (VOC) in the presence of sunlight. Emissions from industrial facilities and electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO<sub>x</sub> and VOC. Section 182(a)(3)(B) of the CAA requires each state with ozone nonattainment areas to submit a SIP revision requiring annual emissions statements to be submitted to the state by the owner or operator of each NO<sub>x</sub> or VOC stationary source<sup>2</sup> located within a nonattainment area showing the actual emissions of NO<sub>x</sub> and VOC from that source. The first statement is due three years from the area's nonattainment designation, and subsequent statements are due at least annually thereafter.

On April 15, 2015, Kentucky submitted a draft SIP revision, for parallel processing, containing emissions statements requirements

related to its portion of the Cincinnati, OH-KY-IN Area. EPA is now taking action to propose approval of this SIP revision as meeting the requirements of section 182(a)(3)(B) of the CAA. More information on EPA's analysis of Kentucky's SIP revision is provided below.

### III. Analysis of the Commonwealth's Submittal

Kentucky's April 15, 2015, draft submission seeks to include the specific sections of 401 Kentucky Administrative Regulations (KAR) 52.020—*Title V permits*, 401 KAR 52.030 *Federally-enforceable permits for non-major sources*, 401 KAR 52:040—*State-Origin Permits*, and 401 KAR 52:070—*Registration of designated sources* identified on pages 8 and 9 of its submittal into the SIP to meet the emissions statements requirements of CAA section 182(a)(3)(B). EPA has preliminarily determined that the specific regulatory sections identified on pages 8 and 9 of the SIP submission, collectively, meet the emissions statement requirements of section 182(a)(3)(B) because they require sources that emit 25 tons per year or more of VOCs or NO<sub>x</sub> within the Kentucky portion of the Area to submit annual certified statements showing actual VOC and NO<sub>x</sub> emissions.<sup>3</sup> Consequently, EPA is proposing to approve the portion of Kentucky's April 15, 2015, draft SIP submission that addresses the emissions statements requirements for the Kentucky portion of the Area.

### IV. Incorporation By Reference

In this proposed rule, EPA is proposing to finalize regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to finalize the incorporate by reference of 401 KAR 52:020—*Title V permits*, Section 22 entitled “Annual Emissions Certification”, first sentence only and Section 23 entitled “Certification by Responsible Official”, introductory paragraph text and subsection (4) only; 401 KAR 52:030—*Federally-enforceable permits for nonmajor sources*, Section 3 entitled “General Provisions”, subsection (4) only, Section 22 entitled “Certification by Responsible Official”, introductory text and subsection (4) only, and Section 25 entitled “Sources Subject to Title V”, subsection (1) introductory text, subsection (1)(c), and

subsection (2) introductory text only; 401 KAR 52:040—*State-Origin Permits*, Section 3 entitled “General Provisions”, subsection (2) introductory text, subsection (2)(c), and subsection (3) only, Section 20 entitled “Annual Emissions Certification for Specified Sources”, subsection (1) only, and Section 21 entitled “Certification by Responsible Official”, introductory text and subsection (4) only; and 401 KAR 52:070—*Registration of designated sources*, Section 3 entitled “General Provisions”, subsection (2) introductory text, subsection (2)(a)(1), and subsection (2)(a)(2) first sentence only. EPA has made, and will continue to make, these documents generally available electronically through [www.regulations.gov](http://www.regulations.gov) and/or in hard copy at the Region 4 EPA office (see the ADDRESSES section of this preamble for more information).

### V. Proposed Action

EPA is proposing to approve the portion of a draft SIP revision submitted by Kentucky on April 15, 2015, that addresses the CAA section 182(a)(3)(B) emissions statements requirements for the Kentucky portion of the Cincinnati, OH-KY-IN Area. EPA has preliminarily concluded that this portion of the Commonwealth's draft submission meets the requirements of sections 110 and 182 of the CAA.

### VI. 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. See 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.*);

<sup>1</sup> The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. The rule also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.

<sup>2</sup> A state may waive the emissions statements requirement for any class or category of stationary sources which emit less than 25 tons per year of VOCs or NO<sub>x</sub> if the state meets the requirements of section 182(a)(3)(B)(ii).

<sup>3</sup> Kentucky's requirement for an emissions statement program is listed within its permitting regulations. Kentucky does not have a stand-alone regulation addressing the emissions statement requirements of section 182(a)(3)(B).

- 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).

In addition, 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 as specified by Executive Order 13175 (65 FR 67249,

November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### **List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: September 10, 2015.

**Heather McTeer Toney,**

*Regional Administrator, Region 4.*

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