

FDA or between FDA and regulated industry on a specified therapeutic nicotine product policy topic); (2) the rationale for doing so, including why direct engagement by the NSC would be appropriate/helpful; (3) recommendations on how the nicotine policy issue could be addressed; and (4) existing policy documents (*e.g.*, final guidance) relevant to the nicotine product policy issue. Note that policy issues concerning any draft guidance or proposed rule should be submitted to the docket for that draft guidance or rulemaking.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment. In general, policy decisions reached by the NSC are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

Dated: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2017-0637; FRL-9974-62—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Emissions Statement Requirement for the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Maryland. This revision fulfills Maryland's emissions statement requirement for the 2008 ozone national ambient air quality standard (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before March 22, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R03-OAR-2017-0637 at <http://www.regulations.gov>, or via email to spielberger.susan@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, 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. 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:

Gavin Huang, (215) 814-2042, or by email at huang.gavin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On March 27, 2008, EPA strengthened the ozone standard from 0.08 to 0.075 parts per million (ppm). 73 FR 16436. On May 21, 2012, EPA designated areas as nonattainment for the 2008 ozone NAAQS, including the Baltimore and Washington, DC-MD-VA areas, which include the following counties in Maryland: Anne Arundel, Baltimore, Baltimore City, Carroll, Harford, Howard, Cecil, Calvert, Charles, Frederick, Montgomery, and Prince George's Counties. See 40 CFR 81.321.

Additionally, Maryland is located in the ozone transport region (OTR) established by Congress in section 184 of the CAA. Pursuant to section 184(b)(2), any stationary source that emits or has the potential to emit at least 50 tons per year (tpy) of volatile organic compounds (VOC) shall be considered a major stationary source and subject to the requirements which would be applicable to major stationary sources if the area were classified as a moderate nonattainment area. See CAA section 184. Thus, states within the OTR are subject to plan (or SIP) requirements in CAA section 182(b) applicable to moderate nonattainment areas. Also, section 182(f)(1) of the CAA requires that the plan provisions required for major stationary sources of VOC also apply to major stationary sources of

oxides of nitrogen (NO_x) for states with moderate (or worse) ozone nonattainment areas. A major stationary source of NO_x is defined as stationary facility or source of air pollutants which directly emits, or has the potential to emit 100 tpy or more of NO_x. See CAA section 302(j).

Section 182 of the CAA identifies additional plan submissions and requirements for ozone nonattainment areas. Specifically, section 182(a)(3)(B) of the CAA requires that states develop and submit rules which establish annual reporting requirements for certain stationary sources. Sources that are within marginal (or worse) ozone nonattainment areas must annually report the actual emissions of NO_x and VOC to the state. However, states may waive sources that emit under 25 tpy of NO_x and VOC if the state provides an inventory of emissions from such class or category of sources. See CAA section 182(a)(3)(B)(ii).

In summary, because Maryland is located in the OTR, sources that are located in ozone attainment areas and emit above 50 tpy of VOC or 100 tpy of NO_x are considered major sources and subject to the requirements of major stationary sources in moderate (or worse) nonattainment area, such as an emissions statement submission as required by CAA section 182(a)(3)(B). See CAA sections 182(f) and 184(b)(2). Sources that are located in designated marginal (or worse) nonattainment areas must submit an emissions statement as required by CAA section 182(a)(3)(B). As stated previously, states may waive sources under that emit 25 tpy of NO_x and 25 tpy of VOC threshold if the state provides an inventory of emissions from such class or category of sources as required by CAA sections 172 and 182.¹ See section 182(a)(3)(B)(ii).

On September 25, 2017, the State of Maryland, through the Maryland Department of the Environment (MDE), submitted a SIP revision to satisfy the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2008 ozone NAAQS.

II. Summary of SIP Revision and EPA Analysis

On October 12, 1994 (59 FR 51517), EPA approved Maryland's SIP submittal that satisfies CAA section 182(a)(3)(B). Maryland's emissions reporting requirements are codified in Maryland regulation COMAR 26.11.01.05-1

¹ For further information on the emissions statement reporting requirements, see "Guidance on the Implementation of an Emission Statement Program (July 1992)" https://www.epa.gov/sites/production/files/2015-09/documents/emission_statement_program_zypdf.pdf, pp. 5-9.

“Emissions Statements.” COMAR 26.11.01.05–1 requires installations or sources that emit above a particular threshold of NO_x or VOC and are within certain geographic areas to submit an emissions statement to the State. The statement must be submitted by a certified individual who can verify the source’s actual emissions.

COMAR 26.11.01.05–1 requires that sources that emit 25 tons or more of NO_x or VOC during a calendar year in the following counties (which include nonattainment areas for the 2008 ozone NAAQS) submit an emissions statement: Anne Arundel, Baltimore, Baltimore City, Calvert, Carroll, Cecil, Charles, Frederick, Harford, Howard, Kent, Montgomery, Prince George’s, and Queen Anne’s counties. As previously mentioned, per CAA section 182(a)(3)(B)(ii), states may waive sources under 25 tpy of NO_x and VOC if the state provides an inventory of emissions from such class or category of sources as required by CAA sections 172 and 182. Maryland does provide emissions inventories for nonattainment areas as required by CAA section 172(c)(3). *See e.g.* 82 FR 44544 (September 25, 2017).

Finally, COMAR 26.11.01.05–1 also requires that sources that emit 50 tons or more of VOC or 100 tons or more of NO_x during a calendar year in the following counties (which are in ozone attainment for the 2008 ozone NAAQS but still located within the OTR) submit an emissions statement: Allegany, Caroline, Dorchester, Garrett, St. Mary’s, Somerset, Talbot, Washington, Wicomico, and Worcester counties. Because Maryland is located in the OTR, sources that are located in attainment areas for the 2008 ozone NAAQS and emit above 50 tpy of VOC and 100 tpy of NO_x are considered major sources and subject to the requirements of major stationary sources in moderate (or worse) nonattainment area, such as an emissions statement submission as required by CAA section 182(a)(3)(B). *See* CAA sections 182(f) and 184(b)(2).

In Maryland’s September 25, 2017 SIP submittal, Maryland states that the existing COMAR 26.11.01.05–1 “Emissions Statements” continues to satisfy section 182(a)(3)(B) for the 2008 ozone NAAQS because Maryland has not made any changes since EPA’s prior approval and COMAR 26.11.01.05–1 meets the CAA requirements for emission statements. *See* 59 FR 51517 (October 12, 1994). EPA finds that COMAR 26.11.01.05–1 continues to satisfy section 182(a)(3)(B) because the existing rule is applicable to the entire State of Maryland and requires

stationary sources that emit NO_x or VOC to submit an emissions statement to the State detailing the sources’ emissions. EPA finds Maryland’s emissions’ thresholds for sources that are required to submit an emissions statement meet CAA requirements in sections 182 (plan submissions and requirements for ozone nonattainment areas) and 184 (OTR requirements). *See also* “Guidance on the Implementation of an Emission Statement Program (July 1992).” Therefore, EPA has determined that COMAR 26.11.01.05–1, which is currently in the Maryland SIP, is appropriate to address the emissions statement requirement in section 182(a)(3)(B) and is proposing to approve this SIP revision. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

III. Proposed Action

EPA is proposing to approve the September 25, 2017 Maryland SIP revision certifying that Maryland’s existing SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2008 ozone NAAQS.

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 CAA 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 proposed 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- 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 (Public Law 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, this proposed rule, which proposes to approve Maryland’s certification that Maryland’s SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: February 9, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

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