

to remove outdated requirements, accommodate new approaches, and provide flexibility without diminishing public health protections. Because this rulemaking would remove regulations to be consistent with updated practice and does not impose any additional regulatory burdens, this rulemaking is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

- 1. The authority citation for part 600 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 600.21 [Amended]

- 2. Amend § 600.21 by removing the last three sentences.

§ 600.22 [Removed and Reserved]

- 3. Remove and reserve § 600.22.

Dated: March 25, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–06187 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0153; FRL–9990–86–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendment To Control of Emissions of Volatile Organic Compounds From Consumer Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the State of Maryland's state implementation plan (SIP). The State of Maryland's SIP revision pertains to Code of Maryland Regulations (COMAR) 26.11.32—Control of Emissions of Volatile Organic Compounds (VOCs) from Consumer Products. This action is being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on May 2, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2018–0153. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., confidential business information (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 through www.regulations.gov, or please contact the person identified in the For Further Information CONTACT section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Becoat, Office of Air Program Planning (3AP30), Air Protection Division, U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2036. Mr. Becoat can also be reached via electronic mail at becoat.gregory@epa.gov.

SUPPLEMENTARY INFORMATION: On November 16, 2017, the Maryland Department of Environment (MDE) submitted a revision to its SIP for COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products. The amendment is part of Maryland's strategy to achieve and maintain the 8-hour ozone national ambient air quality standards (NAAQS) throughout the State.

I. Background

EPA has designated certain areas within Maryland as nonattainment for the 2008 ozone NAAQS. See 40 CFR 81.321. Also, all of Maryland is included in the Ozone Transport Region (OTR) and is therefore treated as a moderate nonattainment area for ozone. See CAA section 184(a), (b)(2), 42 U.S.C. 7511c(a), (b)(2). Therefore, Maryland must continue to enact regulations to gain further reductions of the emissions of VOCs, a class of compounds that are precursors to ground-level ozone. Ozone is formed in the atmosphere by photochemical reactions between VOCs and oxides of nitrogen (NO_x) in the presence of sunlight. In order to reduce ozone concentrations, the CAA requires control of VOC and NO_x emission sources to achieve VOC and/or NO_x emission reductions in nonattainment areas.

In December 1999, EPA identified emission reduction shortfalls in several severe 1-hour ozone nonattainment areas, including those located in the OTR. The Ozone Transport Commission (OTC) developed model rules for a number of source categories. One of the model rules was to reduce VOC emissions from consumer products. The OTC model rules are based on existing rules developed by the California Air Resources Board (CARB). The OTC

Model Rule for Consumer Products was first issued in March 28, 2001, revised November 29, 2001, and April 23, 2002. Additional amendments followed in 2006, 2010, and 2014. Maryland adopted the 2001 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on August 18, 2003. EPA approved Maryland's adopted regulation COMAR 26.11.32 as part of the SIP on December 8, 2004 (69 FR 70895). Maryland adopted the amended 2006 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on June 8, 2007. EPA approved Maryland's amended regulation into the SIP on December 10, 2007 (72 FR 69621). Maryland again amended its consumer products regulation and on October 18, 2010 (75 FR 63717), EPA approved Maryland's SIP revision to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products.

II. Summary of SIP Revision and EPA Analysis

On November 16, 2017, Maryland submitted a SIP revision to amend COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, in order to institute the requirements of the 2010 and 2014 OTC model rules for consumer products. The 2010 and 2014 model rules were developed as part of a regional effort to attain and maintain the 8-hour ozone NAAQS and reduce 8-hour ozone levels. The 2010 OTC model rule reflected changes made by the 2006 CARB rule. The 2014 OTC model rule reflected changes made by the 2009 CARB rule. The OTC model rules further enhance VOC standards for specific consumer products and introduces VOC standards for new products. Generally, the amendments to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products regulations, established or amended VOC content limits and standards for a variety of consumer product categories, including personal care products, household products, automotive cleaners, and adhesives, in order to be consistent with the CARB and OTC model rules. More detailed information on these provisions, as well as a detailed summary of EPA's review and rationale for approving these SIP revisions, can be found in the notice of proposed rulemaking (NPR) for this action which is available on line at

www.regulations.gov, Docket number EPA-R03-OAR-2018-0153.

After evaluating the SIP revision submittal, EPA concluded that the revisions made to COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, meet the SIP revision requirements of the CAA. The revision will continue to help Maryland attain and maintain the eight-hour ozone standard for the 2008 NAAQS. On August 8, 2018 (83 FR 39009), EPA published a NPR for the State of Maryland SIP revision. EPA received two comments, one which was a relevant adverse comment on the NPR, noting that the CARB and the OTC model rules referenced in the NPR were not in the docket on www.regulations.gov. As a result, EPA placed the missing CARB and OTC model rules into the docket for this action on August 16, 2018, and then published a supplemental NPR on November 26, 2018 (83 FR 57704), reopening the comment period for this action for thirty days. EPA received two additional comments during the supplemental NPR comment period. All comments received during the initial public comment period and the supplemental NPR comment period are addressed in Section III. Response to Comments of this rulemaking action.

III. Response to Comments

During the two comment periods, EPA received four anonymous comments on the proposed rulemaking action. One comment generally discussed air quality in China and India. EPA believes this comment is not germane to this rulemaking and therefore no further response is provided. Two comments were supportive of EPA's approval of the State of Maryland's SIP revision and noted the air quality benefits of approving the CARB and OTC model rules into Maryland's SIP. EPA thanks those commenters and agrees that this SIP revision will have air quality benefits in Maryland. The fourth comment, received during the first public comment period, pointed out that the CARB and OTC regulations were not in the docket for the rule, which EPA corrected by issuing the supplemental NPR and, also, raised the comment discussed below.

Comment #1: The anonymous commenter stated: "Are you or are you not proposing to approve the hair styling gel category? The "Proposed Action" section makes it sound like you are approving everything except the hair styling gel category."

Response #1: EPA is approving the "hair styling product—all other forms"

category—which includes "hair styling gel"—into the Maryland SIP. As noted in the NPR published on August 8, 2018 (83 FR 39009), the 2006 CARB rule eliminated the "hair styling gel" category and now considers gels to fall under "hair styling product—all other forms" category. Considering hair styling gels to be part of the "hair styling product—all other forms" category resulted in a reduction of the hair styling gels VOC limit from 6 to 2 percent VOC by weight. The 2014 OTC model rule did not address the 2006 CARB rule amendment for hair styling gels. However, MDE rectified this omission in the 2014 OTC model rules when amending COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, by moving the "hair styling gel" category into the "hair styling product—all other forms" category. Placing hair styling gels into the "hair styling product—all other forms" category reduces the VOC content to 2 percent VOC by weight and makes the Maryland regulations consistent with the 2006 CARB rules.

IV. Final Action

EPA is approving the State of Maryland's November 16, 2017 SIP revision submittal that adopts the VOC limits established in the 2010 and 2014 OTC model rules for consumer products.

V. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Maryland rule discussed in section II of this preamble. EPA has made, and will continue to make, these materials generally available through <http://www.regulations.gov> and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully Federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.¹

¹ 62 FR 27968 (May 22, 1997).

VI. Statutory and Executive Order Reviews

A. General Requirements

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 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 it is not a significant action 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 (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, this rule 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.

B. 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 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).

C. Petitions for Judicial Review

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 June 3, 2019. 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, which approves the State of Maryland's COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, 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, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: March 4, 2019.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

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 V—Maryland

■ 2. In § 52.1070, the table in paragraph (c) is amended by:

- a. Revising entries for "26.11.32.01", "26.11.32.02", "26.11.32.03", "26.11.32.04", and "26.11.32.05";
- b. Adding an entry in numerical order for "26.11.32.05-1"; and
- c. Revising entries for "26.11.32.06", "26.11.32.08", "26.11.32.12", "26.11.32.14", and "26.11.32.16".

The revisions and addition read as follows:

§ 52.1070 Identification of plan.

* * * * *
(c) * * *

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP

| Code of Maryland Administrative Regulations (COMAR) citation | Title/subject | State effective date | EPA approval date | Additional explanation/citation at 40 CFR 52.1100 |
|---|------------------------------------|----------------------|---|---|
| * | * | * | * | * |
| 26.11.32 Control of Emissions of Volatile Organic Compounds From Consumer Products | | | | |
| 26.11.32.01 | Applicability and Exemptions | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP—Continued

| Code of Maryland Administrative Regulations (COMAR) citation | Title/subject | State effective date | EPA approval date | Additional explanation/citation at 40 CFR 52.1100 |
|--|--|----------------------|---|---|
| 26.11.32.02 | Incorporation by Reference | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| 26.11.32.03 | Definitions | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. Previous Approval dated 12/10/2007. |
| 26.11.32.04 | Standards—General | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| 26.11.32.05 | Standards—Requirements for Charcoal Lighter Materials. | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| 26.11.32.05–1 ... | Requirements for Flammable and Extremely Flammable Multi-Purpose Solvent and Paint Thinner. | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | New Regulation. |
| 26.11.32.06 | Standards—Requirements for Aerosol Adhesives. | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| * * * | * * * | * * * | * * * | * * * |
| 26.11.32.08 | Requirements for Contact Adhesives, Electronic Cleaners, Footwear, or Leather Care Products, and General Purpose Cleaners. | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| * * * | * * * | * * * | * * * | * * * |
| 26.11.32.12 | Innovative Products—Department Exemption. | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| * * * | * * * | * * * | * * * | * * * |
| 26.11.32.14 | Reporting Requirements | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| * * * | * * * | * * * | * * * | * * * |
| 26.11.32.16 | Test Methods | 10/09/2017 | 4/2/2019, Insert Federal Register citation]. | Revised. |
| * * * | * * * | * * * | * * * | * * * |

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 [FR Doc. 2019-04779 Filed 4-1-19; 8:45 am]
 BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R02-OAR-2017-0094; FRL-9991-50-Region 2]

Approval and Promulgation of Implementation Plans: New York Ozone Section 185

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is finalizing approval of the State of New York’s Low Emissions Vehicle program as an alternative program to fulfill the Clean Air Act section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT

nonattainment area for the revoked 1979 1-hour ozone National Ambient Air Quality Standard. Clean Air Act section 185 requires fees to be paid by major sources located in ozone nonattainment areas classified as Severe or Extreme that have failed to attain the National Ambient Air Quality Standard by the required attainment date. The State of New York’s Low Emissions Vehicle program is being approved as an alternate program because the reductions achieved by the program are at least equivalent to the reductions associated with the Clean Air Act section 185 fee program required for the New York portion of the NY-NJ-CT nonattainment area.

DATES: This rule is effective on May 2, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R02-OAR-2017-0094. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available,

e.g., confidential business information 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 through www.regulations.gov, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Gavin Lau, Environmental Protection Agency, Air Programs Branch, 290 Broadway, 25th Floor, New York, NY 10007-1866, (212) 637-3708, or by email at Lau.Gavin@epa.gov.

SUPPLEMENTARY INFORMATION:
 I. What action is the EPA taking?
 II. What comments were received in response to the EPA’s proposed action?
 III. What is the EPA’s conclusion?
 IV. Statutory and Executive Order Reviews