

(ii) A description of any normative database that includes the following:

(A) The clinical definition used to establish a “normal” population and the specific selection criteria;

(B) The format for reporting normal values;

(C) Examples of screen displays and reports generated to provide the user results and normative data;

(D) Statistical methods and model assumptions; and

(E) Any adjustments for age and gender.

(iii) A warning that the device should only be used by trained healthcare professionals;

(iv) A warning that the device does not identify the presence or absence of traumatic brain injury or other clinical diagnoses;

(v) A warning that the device is not a standalone diagnostic; and

(vi) Any instructions to convey to patients regarding the administration of the test and collection of test data.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-27227 Filed 12-15-21; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[EPA-HQ-OAR-2021-0868; FRL-9251-01-OAR]

Findings of Failure To Submit State Implementation Plan Revisions for the 2016 Oil and Natural Gas Industry Control Techniques Guidelines for the 2015 Ozone National Ambient Air Quality Standards (NAAQS) and for States in the Ozone Transport Region

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to find that the states of New York and Pennsylvania failed to submit State Implementation Plan (SIP) revisions required by the Clean Air Act (CAA) in a timely manner to address reasonably available control technology (RACT) requirements associated with the 2016 Oil and Natural Gas Industry Control Techniques Guidelines (CTG) for reducing volatile organic compounds (VOC). The RACT requirements associated with the CTG apply in

certain nonattainment areas for the 2015 ozone National Ambient Air Quality Standards (NAAQS) and in states in the Ozone Transport Region (OTR). Both New York and Pennsylvania are in the OTR. This action triggers certain CAA deadlines for the EPA to impose sanctions if a state does not submit a complete SIP addressing the outstanding requirements and for the EPA to promulgate a Federal Implementation Plan (FIP) if the EPA does not approve the state’s SIP revision.

DATES: This action is effective on January 18, 2022.

FOR FURTHER INFORMATION CONTACT: General questions concerning this notice should be addressed to Bob Lingard, Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail Code: C539-01, 109 T.W. Alexander Drive, Research Triangle Park, NC 27709; by telephone (919) 541-5272; or by email at lingard.robort@epa.gov.

SUPPLEMENTARY INFORMATION:

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B. Notice and Comment Under the Administrative Procedure Act (APA)

Section 553 of the APA, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this final agency action without prior proposal and opportunity for comment because no significant EPA judgment is involved in making findings of failure to submit SIPs, or elements of SIPs, required by the CAA, where states have made no submissions to meet the requirement. Thus, notice and public procedures are unnecessary to take this action. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

C. How can I get copies of this document and other related information?

The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2021-0868. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the EPA Docket Center, EPA/DC, William Jefferson Clinton Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID-19. Docket Center staff will continue to provide remote customer service via email, phone, and webform. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Office of Air and Radiation Docket and Information Center is (202) 566-1742. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

D. Where do I go if I have specific state questions?

For questions related to specific states mentioned in this notice, please contact the appropriate EPA Regional office:

Regional offices	States
<i>EPA Region 2:</i> Mr. Kirk Wieber, Chief, Air Program Branch, EPA Region 2, 290 Broadway, New York, New York 10007. wieber.kirk@epa.gov .	New York.
<i>EPA Region 3:</i> Mike Gordon, Chief, Planning and Implementation Branch, EPA Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103. gordon.mike@epa.gov .	Pennsylvania.

II. Background

On October 26, 2015, the EPA strengthened the NAAQS for ozone to establish new 8-hour standards.¹ In that action, the EPA promulgated identical revised primary and secondary ozone standards, designed to protect public health and welfare, of 0.070 parts per million (ppm). Those standards are met when the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration (an area's "design value") is less than or equal to 0.070 ppm.²

Promulgation of a revised NAAQS triggers a requirement for the EPA to designate areas of the country as nonattainment, attainment, or unclassifiable for the standards, as well as, for the ozone NAAQS, a requirement for the EPA, at the same time, to classify any nonattainment areas.³ Ozone nonattainment areas are classified upon designation based on the severity of their ambient ozone levels, as determined based on an area's design value for the most recent 3 years. The possible classifications for ozone nonattainment areas are Marginal, Moderate, Serious, Severe, and Extreme.⁴ Nonattainment areas with a "lower" classification (e.g., Marginal) have ozone levels that are closer to the standards than areas with a "higher" classification (e.g., Severe).⁵

On June 4, 2018, and July 25, 2018, respectively, the EPA issued two separate rules that cumulatively designated areas throughout the country as nonattainment for the 2015 ozone NAAQS, effective August 3, 2018, and September 24, 2018, and established classifications for the designated nonattainment areas.⁶ Areas designated nonattainment for the ozone NAAQS are subject to the general nonattainment

area planning requirements of CAA section 172 and also to the ozone-specific planning requirements of CAA section 182. States in the OTR are subject to the requirements outlined in CAA section 184.⁷ CAA section 172(c)(1) provides that SIPs for nonattainment areas must include reasonably available control technology (RACT), including RACT for existing sources of emissions. CAA section 182(b)(2)(A) requires states in which a nonattainment area classified as Moderate is located to amend their SIP "to include provisions to require the implementation of [RACT] . . . with respect to . . . [e]ach category of VOC sources in the area covered by a CTG document . . ." CAA sections 182(c) through (e) apply this requirement to states with designated ozone nonattainment areas classified as Serious, Severe, or Extreme. CAA section 184(b) provides that states in the OTR must submit a SIP revision addressing RACT with respect to all sources of VOCs in the OTR covered by a CTG document. The states of New York and Pennsylvania are both included in the OTR and thus are subject to the CTG RACT requirements of CAA section 184(b). In addition to being included in the OTR, the state of New York contains portions of a multi-state nonattainment area classified as Moderate for the 2015 ozone NAAQS and is thus independently subject to the CTG RACT requirement due to CAA section 182(b)(2)(A). The relevant nonattainment area is called the New York-Northern New Jersey-Long Island, NY-NJ-CT ozone nonattainment area.

On October 27, 2016, the EPA issued a final CTG document for reducing VOC emissions from existing oil and natural gas industry equipment and processes.⁸ On March 9, 2018, for reasons explained

in the **Federal Register** (83 FR 10478), the EPA proposed to withdraw the CTG. However, the EPA did not finalize the proposal to withdraw the CTG. The EPA announced in the U.S. Office of Management and Budget's Spring 2020 Unified Agenda and Regulatory Plan that "the CTG will remain in place as published on October 27, 2016."⁹

The RACT SIP revisions addressing the 2016 oil and natural gas industry CTG, among other things, were due for EPA review from states with nonattainment areas classified as Moderate or higher for the 2015 ozone NAAQS, as well as the 12 states and the District of Columbia that comprise the OTR, by August 3, 2020.¹⁰ For nonattainment areas and/or states subject to this RACT SIP requirement without any oil and natural gas sources covered by the CTG in their jurisdictions, states were required to make a SIP submission that could be comprised of a "negative declaration" stating as much.

Pursuant to CAA section 110(k)(1)(B), the EPA must determine no later than 6 months after the date by which a state is required to submit a SIP whether a state has made a submission that meets the minimum completeness criteria established pursuant to CAA section 110(k)(1)(A). These criteria are set forth at 40 CFR part 51, appendix V. The EPA refers to the determination that a state has not submitted a SIP submission that meets the minimum completeness criteria as a "finding of failure to submit."

The following Table 1 provides the names of states with nonattainment areas and/or OTR states that this action finds failed to submit the SIP revision required for the CTG for the 2015 ozone NAAQS for reducing VOC emissions from existing oil and natural gas industry equipment and processes as of the date of this action.

⁹ See <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202004&RIN=2060-AT76> (last accessed October 14, 2020).

¹⁰ 83 FR 62998 (December 6, 2018), see also 40 CFR 51.1312 and 51.1316.

¹ 80 FR 65292 (October 26, 2015).

² 40 CFR 50.15.

³ CAA sections 107(d)(1) and 181(a)(1).

⁴ CAA section 181(a)(1).

⁵ See 40 CFR 51.1303 for the design value thresholds for each classification for the 2015 ozone NAAQS.

⁶ 83 FR 25776 (June 4, 2018) and 83 FR 35316 (July 25, 2018).

⁷ CAA section 184(a) establishes a single OTR comprised of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and the Consolidated Metropolitan Statistical Area that includes the District of Columbia.

⁸ 81 FR 74798 (October 27, 2016).

TABLE 1—STATES AND/OR NONATTAINMENT AREAS INCLUDED IN FINDINGS OF FAILURE TO SUBMIT REQUIRED SIP REVISIONS TO ADDRESS THE 2016 OIL AND NATURAL GAS INDUSTRY CTG FOR THE 2015 OZONE NAAQS

State	Nonattainment area/OTR state	Classification	EPA Region
NY	NY portion of New York-N New Jersey-Long Island non-attainment area.	Serious	2
NY	NY—OTR state	OTR	2
PA	PA—OTR state	OTR	3

III. Consequences of Findings of Failure To Submit

If the EPA finds that a state has failed to make the required SIP submittal or that a submitted SIP is incomplete, then CAA section 179(a) establishes specific consequences, after a period of time, including the imposition of mandatory sanctions for the affected area or state (as appropriate in the case of the OTR). Additionally, such a finding triggers an obligation under CAA section 110(c) for the EPA to promulgate a FIP no later than 2 years after issuance of the finding of failure to submit if the affected state has not submitted, and the EPA has not approved, the required SIP submittal.

If the EPA has not affirmatively determined that a state has made the required complete SIP submittal for an area or OTR state within 18 months of the effective date of this rulemaking, then, pursuant to CAA section 179(a) and (b) and 40 CFR 52.31, the offset sanction identified in CAA section 179(b)(2) will apply in the affected nonattainment area or OTR state. If the EPA has not affirmatively determined that the state has made the required complete SIP submittal within 6 months after the offset sanction is imposed, then the highway funding sanction will apply in the affected nonattainment area, in accordance with CAA section 179(b)(1) and 40 CFR 52.31.¹¹ The sanctions will not take effect if, within 18 months after the effective date of these findings, the EPA affirmatively determines that the state has made a complete SIP submittal addressing the deficiency for which the finding was made. Additionally, if the state makes the required SIP submittal and the EPA takes final action to approve the submittal within 2 years of the effective date of these findings, the EPA is not required to promulgate a FIP for the affected nonattainment area or OTR state.

¹¹ For the OTR states, such highway sanctions would only apply in nonattainment areas. If the OTR state does not contain any nonattainment areas, then the highway sanctions would not apply in that state.

IV. Findings of Failure To Submit for States That Failed To Make a Nonattainment Area and/or Ozone Transport Region SIP Submittal

Based on a review of SIP submittals received and deemed complete as of the date of signature of this action, the EPA finds that the states listed in Table 1 above failed to submit the 2016 Oil and Gas CTG RACT SIP revisions required under subpart 2 of part D of Title I of the CAA and that were due no later than August 3, 2020, for the listed nonattainment areas and OTR states.

V. Environmental Justice Considerations

The EPA believes that the human health or environmental risks addressed by this action will not have disproportionately high or adverse human health or environmental effects on minority, low-income, or indigenous populations because it does not directly affect the level of protection provided to human health or the environment under the 2015 ozone NAAQS. The purpose of this action is to make findings that the named states failed to provide the identified SIP submissions to the EPA that are required per the CAA. As such, this action does not directly affect the level of protection provided for human health or the environment. Moreover, it is intended that the actions and deadlines resulting from this notice will in fact lead to greater protection for U.S. citizens, including minority, low-income, or indigenous populations, by ensuring that states meet their statutory obligation to develop and submit SIPs to ensure that areas make progress toward reducing ozone pollution.

VI. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA. This final rule does not establish any new information collection requirement apart from what is already required by law. This rule relates to the requirement in the CAA for states to submit SIPs under sections 172, 182, and 184 which address the statutory requirements that apply to areas designated as nonattainment for the ozone NAAQS and to states within the Ozone Transport Region, respectively.

C. Regulatory Flexibility Act (RFA)

I certify that this rule will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The rule is a finding that the named states have not made the necessary SIP submission for certain nonattainment areas and/or states in the OTR to meet the requirements of part D of Title I of the CAA.

D. Unfunded Mandates Reform Act of 1995 (UMRA)

This action does not contain any unfunded mandate as described in UMRA 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This rule finds that two states have failed to submit SIP revisions that satisfy the nonattainment area planning requirements under

sections 172 and 182 of the CAA, and/or the OTR requirements under section 184 of the CAA. No tribe is subject to the requirement to submit an implementation plan under section 172 or under subpart 2 of part D of Title I of the CAA. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it is a finding that several states failed to submit SIP revisions that satisfy the nonattainment area planning requirements under sections 172 and 182 of the CAA, and/or the OTR requirements under Section 184, and does not directly or disproportionately affect children.

HI. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

IJ. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. In finding that two states have failed to submit SIP revisions that satisfy the nonattainment area planning requirements under sections 172 and 182 of the CAA, and/or the OTR requirements under section 184 of the CAA, this action does not directly affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United

States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

L. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by the EPA under the CAA. This section provides, in part, that petitions for review must be filed in the United States Court of Appeals for the District of Columbia Circuit if (i) the agency action consists of “nationally applicable regulations promulgated, or final actions taken, by the Administrator,” or (ii) such action is locally or regionally applicable, but “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.”

This final action is nationally applicable. To the extent a court finds this final action to be locally or regionally applicable, the EPA finds that this action is based on a determination of “nationwide scope or effect” within the meaning of CAA section 307(b)(1). This final action consists of findings of failure to submit required SIPs from two states in the OTR, one with a Moderate nonattainment area, located in two of the ten EPA Regions, and in two different federal judicial circuits. This final action is also based on a common core of factual findings concerning the receipt and completeness of the relevant SIP submittals. For these reasons, this final action is nationally applicable or, alternatively, to the extent a court finds this action to be locally or regionally applicable, the Administrator has determined that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1).

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 District of Columbia Circuit within 60 days from the date this final action is published in the **Federal Register**. Filing a petition for reconsideration by the Administrator of this final action does not affect the finality of the action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedures, Air pollution control, Approval and promulgation of implementation plans, Intergovernmental relations, and

Reporting and recordkeeping requirements.

Michael S. Regan,
Administrator.

[FR Doc. 2021–27213 Filed 12–15–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0659; FRL–9322–01–OCSPP]

α-Terpineol (CAS No. 98–55–5); Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of α-terpineol (CAS No. 98–55–5) when used as a solvent inert ingredient in pesticide formulations at rates of 5% of the formulation in pre-harvest applications to crops. Landis International, Inc., on behalf of Morse Enterprises Limited, Inc. d/b/a KeyPlex submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of α-terpineol (CAS No. 98–55–5) on food or feed commodities when used in accordance with this exemption.

DATES: This regulation is effective December 16, 2021. Objections and requests for hearings must be received on or before February 14, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0659, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC