

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.

VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

IX. Other Issues for Consideration

This proposed rule would only delay the effective date of the portions of a final rule amending the “intended use” regulations for medical products (§§ 201.128 and 801.4), published in the **Federal Register** of January 9, 2017. Therefore, comments to this proposed rule should pertain to this delay of the effective date only with respect to such provisions.

X. Request for Comments

FDA is proposing to delay, until further notice, the effective date of the amendments to §§ 201.128 and 801.4 that were published at 82 FR 2193 on January 9, 2017. FDA had previously delayed the effective date on February 7, 2017 (82 FR 9501), and on March 20, 2017 (82 FR 14319). FDA requests comment on this proposal to further delay the effective date of the amendments to §§ 201.128 and 801.4.

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-00555 Filed 1-12-18; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2017-0697; FRL-9972-98-Region 1]

Air Plan Approval; Connecticut; Revision of the Low Emission Vehicles Program

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 Connecticut on December 14, 2015. This SIP revision includes Connecticut’s revised regulation for new motor vehicle emission standards. Connecticut has updated its rule to be consistent with various updates made to California’s low emission vehicle (LEV) program. The Connecticut LEV regulations also include updates to the zero emission vehicle (ZEV) provision. Connecticut has adopted these revisions to reduce emissions of volatile organic compounds (VOC), particulate matter (PM), and nitrogen oxides (NO_x) in accordance with the requirements of the Clean Air Act (CAA), as well as to reduce greenhouse gases. The intended effect of this action is to propose approval of Connecticut’s December 14, 2015 SIP revision. This action is being taken under the CAA.

DATES: Written comments must be received on or before February 15, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R01-OAR-2017-0697 at www.regulations.gov, or via email to rackauskas.eric@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 www.epa.gov/dockets/commenting-epa-dockets. Publicly available docket materials are available at www.regulations.gov or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact 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 legal holidays.

FOR FURTHER INFORMATION CONTACT: Eric Rackauskas, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05-2), Boston, MA 02109-3912, telephone number (617) 918-1628, fax number (617) 918-0628, email rackauskas.eric@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

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I. Background and Purpose

On December 14, 2015, the Connecticut Department of Energy and Environmental Protection (DEEP) submitted a revision to its SIP consisting of the amended Section 22a-174-36b “Low Emission Vehicle II Program” (LEV II) and the newly adopted Section 22a-174-36c “Low Emission Vehicle III Program” (LEV III) of the Regulations of Connecticut State Agencies (RCSA). This SIP revision proposes to adopt regulations to mirror the California Air Resources Board (CARB) emission limits for new passenger cars, light-duty trucks, and medium-duty passenger vehicles sold, leased, imported, delivered, purchased, rented, acquired, or received in the State of Connecticut. Connecticut’s amended LEV II and adopted LEV III programs were submitted as part of an overall revision to their “infrastructure SIP” for the 2012 Fine Particle (PM_{2.5}) National

Ambient Air Quality Standards (NAAQS), as required by section 110(a)(1) and (2) of the CAA.

EPA previously approved RCSA Section 22a–174–36b (LEV II) into the Connecticut SIP on March 17, 2015 (80 FR 13768). The SIP revision approved on March 17, 2015, adopted the California LEV II program, which was effective in Connecticut on December 4, 2004, and subsequently amended on December 22, 2005, August 4, 2009, and September 10, 2012. The previously SIP-approved LEV II program also included all elements of the ZEV program, commencing with 2008 model year vehicles. The current version of Connecticut's LEV II program regulation, which is being proposed for approval, was amended with an effective date of August 1, 2013. The revised Connecticut LEV II program, submitted as part of Connecticut's December 14, 2015 SIP revision, contains minor updates that place an end date to LEV II program standards of model year 2014, for vehicles bought in Connecticut. Any 2015 and subsequent model year vehicle is regulated by the more stringent RCSA Section 22(a)–174–36c (LEV III), also effective in CT on August 1, 2013.

Connecticut's revised regulations also include updates to the California ZEV program. In 2003, CARB finalized modifications to the ZEV program that better aligned the requirements with the status of then-available technology development. The updated CARB regulations require that 10% of vehicles be ZEVs starting in 2005, and allow manufacturers to earn and bank credits for those types of vehicles produced before 2005. The program also includes an "alternative compliance path" that allowed advanced technology partial ZEVs (AT PZEVs) (e.g. gasoline electric hybrids) to be used to meet ZEV program requirements, provided that manufacturers meet a requirement that a portion of the motor vehicle fleet be fueled by hydrogen fuel cells. The modifications to the ZEV program also broadened the scope of vehicles that qualified for meeting a portion of the ZEV sales requirement.

Additionally, Connecticut's LEV III regulation includes the California updates to the State's greenhouse gas (GHG) program. This update applies to all passenger cars, light-duty trucks, and medium-duty vehicles for 2017 and subsequent model years. Connecticut previously adopted a GHG provision as part of its LEV II regulation, which applies to model year 2009–2016 vehicles. The updated Connecticut GHG language mirrors the California GHG regulation.

II. The California LEV Program

CARB adopted the first generation of LEV regulations (LEV I) in 1990, which impacted vehicles through the 2003 model year. CARB adopted California's second generation LEV regulation (LEV II) following a November 1998 hearing. Subsequent to the adoption of the California LEV II program in February 2000, EPA adopted separate Federal standards known as the Tier 2 regulations (February 10, 2000; 65 FR 6698). In December 2000, CARB modified the California LEV II program to take advantage of some elements of the Federal Tier 2 regulations to ensure that only the cleanest vehicle models would continue to be sold in California. EPA granted California a waiver for its LEV II program on April 22, 2003 (68 FR 19811). In 2012, CARB "packaged" the third generation LEV program (LEV III) with updated GHG emission standards and ZEV requirements as part of California's Advanced Clean Cars (ACC) program. EPA granted California a waiver for the ACC program on January 9, 2013 (78 FR 2112).

The LEV II and LEV III regulations expanded the scope of LEV I regulations by setting strict fleet-average emission standards for light-duty, medium-duty (including sport utility vehicles) and heavy-duty vehicles. The standards for LEV II began with the 2004 model year and increased in stringency with each vehicle model year. The LEV III standards began in 2015 and continue to increase emission stringency with each progressive vehicle model year through 2025 and beyond.

An automobile manufacturer must show that the overall vehicle fleet for a given model year meets the specified phase-in requirements according to the fleet average non-methane hydrocarbon requirement for that year. The fleet average non-methane hydrocarbon emission limits are progressively lower with each model year. The program also requires auto manufacturers to include a "smog index" label on each vehicle sold, which is intended to inform consumers about the amount of pollution produced by that vehicle relative to other vehicles.

In addition to meeting the LEV II and LEV III requirements, large or intermediate volume manufacturers must ensure that a certain percentage of the passenger cars and light-duty trucks that they market in California are ZEVs. This is referred to as the ZEV mandate. California has modified the ZEV mandate several times since it took effect. One modification allowed an alternative compliance program (ACP) to provide auto manufacturers with

several options to meet the ZEV mandate. The ACP established ZEV credit multipliers to allow auto manufacturers to take credit for meeting the ZEV mandate by selling more partial ZEVs (PZEVs) and AT PZEVs than they are otherwise required to sell. On December 28, 2006, EPA granted California's request for a waiver of Federal preemption to enforce provisions of the ZEV regulations through the 2011 vehicle model year. In a letter dated June 27, 2012, CARB requested that EPA grant a waiver of preemption that allowed updated ZEV regulations as part of the ACC program. These updated ZEV regulations will require manufacturers to produce increasing numbers of ZEVs and plug-in hybrid electric vehicles in 2018 and subsequent years. EPA granted this waiver on January 9, 2013 (78 FR 2112).

On October 15, 2005, California amended its LEV II program to include GHG emission standards for passenger cars, light-duty trucks, and medium-duty passenger vehicles. On December 21, 2005, California requested that EPA grant a waiver of preemption under CAA section 209(b) for its GHG regulations. On June 30, 2009, EPA granted CARB's request for a waiver of CAA preemption to enforce its GHG emission standards for new model year 2009 and subsequent model year motor vehicles (July 8, 2009; 74 FR 32744–32784). Approval for updated and extended GHG emissions standards was granted by EPA as part of the January 9, 2013 ACC waiver (78 FR 2112), which includes regulations that incrementally reduce GHG emissions through 2025 and beyond.

III. Relevant EPA and CAA Requirements

Section 209(a) of the CAA prohibits states from adopting or enforcing standards relating to the control of emissions from new motor vehicles or new motor vehicle engines. However, under section 209(b) of the CAA, EPA shall grant a waiver of the section 209(a) prohibition to the State of California if EPA makes specified findings, thereby allowing California to adopt its own motor vehicle emission standards. Furthermore, other states may adopt California's motor vehicle emission standards under section 177 of the CAA.

For additional information regarding California's motor vehicle emission standards and adoption by other states, please see EPA's "California Waivers and Authorizations" web page at URL address: www.epa.gov/otaq/cafr.htm. This website also lists relevant **Federal Register** notices that have been issued

by EPA in response to California waiver and authorization requests.

A. Waiver Process

The CAA allows California to seek a waiver of the preemption which prohibits states from enacting emission standards for new motor vehicles. EPA must grant this waiver before California's rules may be enforced. When California files a waiver request, EPA publishes a notice for public hearing and written comment in the **Federal Register**. The written comment period remains open for a period of time after the public hearing. Once the comment period expires, EPA reviews the comments and the Administrator determines whether the requirements for obtaining a waiver have been met.

According to CAA section 209—State Standards, EPA shall grant a waiver unless the Administrator finds that California:

- Was arbitrary and capricious in its finding that its standards are in the aggregate at least as protective of public health and welfare as applicable Federal standards;
- Does not need such standards to meet compelling and extraordinary conditions; or
- Proposes standards and accompanying enforcement procedures that are not consistent with section 202(a) of the CAA.

The most recent EPA waiver relevant to EPA's proposed approval of Connecticut's LEV program is "California State Motor Vehicle Pollution Control Standards; Notice of Decision Granting a Waiver of Clean Air Act Preemption for California's Advanced Clean Car Program and a Within the Scope confirmation for California's Zero Emissions Vehicle Amendments for 2017 and Earlier Model Years" (January 9, 2013; 78 FR 2112–2145). This final rulemaking allows California to strengthen standards for LEV regulations and GHG emissions from passenger cars, light-duty trucks and medium-duty vehicles. It also allows for continuing ZEV regulations by requiring more ZEV manufacturing and sales through 2025 and subsequent years.

B. State Adoption of California Standards

Section 177 of the CAA allows other states to adopt and enforce California's standards for the control of emissions from new motor vehicles, provided that, among other things, such state standards are identical to the California standards for which a waiver has been granted under CAA section 209(b). In addition,

the state must adopt such standards at least two years prior to the commencement of the model year to which the standards will apply. EPA issued guidance (CISD–07–16)¹ regarding its cross-border sales policy for California-certified vehicles. This guidance includes a list and map of states that have adopted California standards, specific to the 2008–2010 model years. All SIP revisions submitted to EPA for approval must also meet the requirements of CAA section 110(l).

The provisions of section 177 of the CAA require Connecticut to amend the Connecticut LEV program at such time as the State of California amends its California LEV program. Connecticut has demonstrated its commitment to maintain a LEV program through the continued adoption of regulatory amendments to Connecticut's initial LEV program.

In addition, Connecticut's December 14, 2015 SIP submittal meets the requirements of section 110(l) of the CAA because the SIP revision would not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the CAA. This SIP revision sets new requirements, the California LEV III standards, that are more stringent than the California LEV I and LEV II standards previously approved into the Connecticut SIP, and expands program coverage to model year vehicles not covered by the California LEV I and LEV II standards, and by extension, not previously included in the Connecticut SIP.

Though the SIP revision places an end date to model year cars covered under the LEV II program, it also adopts the more stringent LEV III program to apply to model years immediately following the LEV II regulated vehicles. Connecticut's SIP revision also includes increasingly stringent GHG emissions and LEV sales requirements that are not currently part of the Connecticut SIP.

IV. Proposed Action

EPA is proposing to approve, and incorporate into the Connecticut SIP, Connecticut's revised RCSA Section 22a–174–36b (LEV II) and adopted RCSA Section 22a–174–36c (LEV III), effective in the State of Connecticut on August 1, 2015, and submitted to EPA on December 14, 2015. The new and revised regulations include: Ending the

California LEV II program with model year 2014 vehicles and adopting the California LEV III program for model year 2015 and subsequent model year vehicles, the updated California GHG provisions, and the updated ZEV provisions. EPA is proposing to approve Connecticut's revised RCSA Section 22a–174–36b and adopted RCSA Section 22a–174–36c into the Connecticut SIP because EPA has found that the requirements are consistent with the CAA.

In addition, EPA is proposing to remove 40 CFR 52.381, which was promulgated on January 24, 1995 (60 FR 4737). This section states that Connecticut must comply with the requirements of 40 CFR 51.120, which are to implement the Ozone Transport Commission (OTC) LEV program. As noted above, Connecticut subsequently adopted the California LEV and LEV II programs. Furthermore, today's proposed approval of Connecticut's revised LEV II and adopted LEV III programs, if finalized, will add California's even more stringent standards into Connecticut's SIP. Thus, Connecticut has satisfied 40 CFR 52.381, and therefore, EPA is proposing to remove 40 CFR 52.381 from the Code of Federal Regulations. In addition, on March 11, 1997, the U.S. Court of Appeals for the District of Columbia Circuit vacated the provisions of 40 CFR 51.120. See *Virginia v. EPA*, 108 F.3d 1397. Because of the vacatur, EPA concludes that 40 CFR 52.381 is, in any event, obsolete.

EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference Connecticut's regulations cited in Section IV of this proposed rulemaking. The EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and at the appropriate EPA.

¹ See EPA's October 29, 2007 letter to Manufacturers regarding "Sales of California-certified 2008–2010 Model Year Vehicles (Cross-Border Sales Policy)," with attachments. https://iaspub.epa.gov/otaqpub/display_file.jsp?docid=16888&flag=1.

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, 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 Clean Air Act. Accordingly, this proposed 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);

- 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 Clean Air Act; 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 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 2, 2018.

Ken Moraff,

Acting Regional Administrator, EPA New England.

[FR Doc. 2018-00477 Filed 1-12-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 257

[EPA-HQ-OLEM-2017-0613; FRL-9972-95-OLEM]

Oklahoma: Approval of State Coal Combustion Residuals State Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comment.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is proposing to approve the application submitted by the Oklahoma Department of Environmental Quality to allow the Oklahoma Coal Combustion Residuals (CCR) state permit program to operate in lieu of the Federal CCR program. EPA has preliminarily determined that Oklahoma's program meets the standard for approval under RCRA. Once approved, the State program requirements and resulting permit provisions will be subject to EPA's inspection and enforcement authorities under RCRA and other applicable statutory and regulatory provisions as discussed below. This notice also announces that EPA is seeking comment on this proposal during a 45-day public comment period, and is providing an opportunity to request a public hearing within the first 15 days of this comment period.

DATES: Comments must be received on or before March 2, 2018. In addition, a public hearing request must be submitted on or before January 31, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OLEM-2017-0613, at <https://www.regulations.gov> or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [regulations.gov](https://www.regulations.gov). 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 the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Mary Jackson, Office of Resource Conservation and Recovery, Environmental Protection Agency; telephone number: (703) 308-8453; email address: jackson.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document "we," "us," and "our" means the EPA.

I. General Information

A. Overview of Proposed Actions

EPA is proposing to approve Oklahoma's CCR state permit program application, pursuant to RCRA 4005(d)(1)(B). Oklahoma's proposed program would allow the Oklahoma Department of Environmental Quality (ODEQ) to enforce rules promulgated under its solid waste statute related to CCR activities in non-Indian Country, as well as to handle permit applications and to enforce permit violations. If approved, Oklahoma's CCR permit program will operate in lieu of the Federal CCR program, codified at 40 CFR part 257, subpart D.

This notice also announces that EPA is seeking comment on this proposal, and providing an opportunity to request a public hearing on whether the State's program is at least as protective as the federal program. If there is significant interest shown in holding a public