

significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
(i) *Hazard communication.*

Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: Skin irritation; eye irritation; respiratory complications; central nervous system effects; internal organ effects; reproductive effects; developmental effects. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to manufacture or process the substance without implementing the engineering controls/processes described in the TSCA Order for the substance. It is a significant new use to manufacture or use the substance other than in liquid formulations.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11554 Halogenated sodium alkylbenzoate (generic) (P-19-184).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenated sodium alkylbenzoate (PMN P-19-184) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
(i) *Hazard communication.*

Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: Skin irritation; eye irritation; respiratory complications; central nervous system effects; internal organ effects; reproductive effects; developmental effects. Alternative hazard and warning statements that

meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to manufacture or process the substance without implementing the engineering controls/processes described in the TSCA Order for the substance. It is a significant new use to manufacture or use the substance other than in liquid formulations.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

§ 721.11555 Halogenated sodium alkylbenzoate (generic) (P-19-187).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenated sodium alkylbenzoate (PMN P-19-187) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
(i) *Hazard communication.*

Requirements as specified in § 721.72(a) through (f), (g)(1), (g)(2)(i) through (iii), and (g)(5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: Skin irritation; eye irritation; respiratory complications; central nervous system effects; internal organ effects; reproductive effects; developmental effects. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) and (q). It is a significant new use to manufacture or process the substance without implementing the engineering controls/processes described in the TSCA Order for the substance. It is a significant new use to manufacture or use the substance other than in liquid formulations.

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (f) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2021-0580; FRL-8967-02-R1]

Air Plan Approval; Rhode Island; 2015 Ozone NAAQS Interstate Transport Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Rhode Island as meeting the Clean Air Act (CAA) requirement that each State's SIP contain adequate provisions to prohibit emissions that will significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone national ambient air quality standards (NAAQS) in any other state. This action is being taken in accordance with the CAA.

DATES: This rule is effective on January 10, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2021-0580. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, 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 at <https://www.regulations.gov> or at the U.S.

Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 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 and facility closures due to COVID-19.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05-2), Boston, MA 02109-3912, tel. (617) 918-1684, email simcox.alison@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 September 15, 2021, EPA published a notice of proposed rulemaking (NPRM) for the State of Rhode Island. See 86 FR 51310. The NPRM proposed approval of a Rhode Island SIP revision that addresses the CAA requirement to prohibit emissions from the state that significantly contribute to nonattainment or interfere with maintenance of the 2015 8-hour ozone NAAQS in other states. See CAA section 110(a)(2)(D)(i)(I) (the “good neighbor provision”). The SIP revision was submitted to EPA by Rhode Island on September 23, 2020. The rationale for EPA’s proposed action is given in the NPRM and will not be repeated here. EPA received two public comments on the NPRM, which are addressed below.

II. Response to Comments

One anonymous comment supported the EPA’s proposed action and suggested that EPA solicit information from residents of the State of Rhode Island as well as from residents of downwind states. We note that, before providing the submission to EPA, the Rhode Island Department of Environmental Management (RIDEM) distributed it to the public via the RIDEM website and an electronic mailing list. RIDEM also gave state residents and other interested parties a 30-day period to request a public hearing and provide public comments. In addition, EPA provided the public

with a 30-day period to comment in the **Federal Register**, the official journal of the U.S. Government that is available to all downwind states, on the proposed approval of Rhode Island’s SIP revision following publication on September 15, 2021.

The other commenter questioned why the analyses considered the effects of emissions from Rhode Island on Connecticut and New York, but seemingly not on Massachusetts—particularly Bristol County, Massachusetts, parts of which lie directly east of Rhode Island. The comment states that “prevailing winds [in this region] travel eastward” and that “EPA data shows [sic] that Bristol County . . . experiences a disproportionately high ‘Percent of Total US Anthropogenic Ozone from Upwind States’ compared to other Mass counties.”

EPA acknowledges that the prevailing winds described by the commenter do generally move from west to east in the New England area, and therefore, Massachusetts is downwind of Rhode Island. In fact, EPA’s modeling analysis does consider the impact of emissions from Rhode Island on all downwind areas within the contiguous 48 states, including Bristol County, Massachusetts, and, indeed, the data indicate that the highest projected contribution in 2021 from Rhode Island sources to an out-of-state area is 2.50 ppb to Bristol County (monitoring site 250051004; line number 242 on the Design Values and Contributions spreadsheet).¹

As explained in the NPRM for this action, EPA uses a four-step interstate transport framework to address the requirements of the good neighbor provision for the 2015 ozone NAAQS. The first step is to identify downwind areas that may have problems attaining and maintaining the standard (*i.e.*, receptors). The Bristol County monitor’s projected average design value is 63.4 ppb and projected maximum design value is 65.5 ppb in 2021, which are both below the 2015 ozone NAAQS of 70 ppb. Using EPA’s definition of a projected nonattainment or maintenance receptor provided in the NPRM (a definition that Rhode Island adopted), EPA’s analysis indicates that the monitor in Bristol County, Massachusetts, is not projected to be a nonattainment or maintenance receptor

in 2021 or later years for the 2015 ozone NAAQS.

While Bristol County is considered downwind of, and impacted by, Rhode Island’s emissions, EPA’s analysis in this first step did not identify Bristol County as a receptor expected to have problems maintaining the 2015 ozone NAAQS. Thus, EPA concluded that emissions from Rhode Island sources, while having an impact on ozone levels in Bristol County, do not contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in Bristol County (or elsewhere in Massachusetts), which is the relevant inquiry under CAA section 110(a)(2)(D)(i)(I).

By comparison, EPA’s analysis at step one identified other receptors, including monitoring sites west of Rhode Island in Connecticut and in New York that are projected to have problems attaining and maintaining the 2015 ozone NAAQS. For these receptors, EPA proceeded to step 2 of the four-step interstate transport framework, which considers whether emissions from Rhode Island impact air-quality problems at those receptors sufficiently such that the state is considered “linked” to those receptors and therefore warrants further review and analysis.

Based on the results of EPA’s air-quality analysis described in the proposal of this action, EPA determined that Rhode Island contributes well below the screening threshold of one percent of the 2015 ozone NAAQS (0.70 ppb) to any of these Connecticut or New York receptors, and is, therefore, not linked to downwind nonattainment and/or maintenance receptors.^{2 3} EPA also analyzed emissions trends for ozone precursors, concluding that emissions from sources in Rhode Island will continue to decline, which lends further support to the findings from the air-quality analysis.

In sum, EPA’s analysis considered the impact of emissions from Rhode Island sources on Massachusetts (including Bristol County) but found that Rhode Island does not contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in Massachusetts, because that state is not expected to have problems

² See Section I of the NPRM for an explanation of EPA’s use of a one percent screening threshold at step 2 of the four-step interstate transport framework.

³ For instance, and as noted in the NPRM, the data indicate that the highest contribution in 2021 from Rhode Island to an area projected to have problems maintaining the NAAQS is 0.09 ppb to the maintenance receptor in Fairfield County, Connecticut.

¹ The data are given in the “Air Quality Modeling Technical Support Document for the Revised Cross-State Air Pollution Rule Update” and “Ozone Design Values and Contributions Revised CSAPR Update.xlsx,” which are included in the docket for this action.

maintaining ozone concentrations below the NAAQS. Furthermore, EPA's entire analysis concluded that Rhode Island does not significantly contribute to nonattainment or interfere with maintenance in any other state for the 2015 ozone NAAQS.

III. Final Action

EPA is approving a Rhode Island SIP revision, which was submitted on September 23, 2020. This submission is approved as meeting CAA section 110(a)(2)(D)(i)(I) requirements that Rhode Island's SIP includes adequate provisions prohibiting any source or other type of emissions activity within the State from emitting any air pollutant in amounts that will contribute significantly to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

IV. 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 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.*);
- 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).

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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 8, 2022. 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 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 3, 2021.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations 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 OO—Rhode Island

- 2. In § 52.2070(e), amend the table by adding an entry for "Transport SIP for the 2015 Ozone Standard" to the end of the table to read as follows:

§ 52.2070 Identification of plan.

*	*	*	*	*
(e)	*	*	*	*

RHODE ISLAND NON REGULATORY

Name of non regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approved date	Explanations
* Transport SIP for the 2015 Ozone Standard.	* Statewide	* Submitted 9/23/2020	* 12/10/2021, [Insert Federal Register citation].	* State submitted a transport SIP for the 2015 ozone standard which shows that it does not significantly contribute to ozone nonattainment or maintenance in any other state. EPA approved this submittal as meeting the requirements of Clean Air Act Section 110(a)(2)(D)(i)(I).

[FR Doc. 2021-26674 Filed 12-9-21; 8:45 a.m.]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 431, 435, 438, 440, and 457

[CMS-9115-N2]

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notification of enforcement discretion.

SUMMARY: This notification is to inform the public that CMS is exercising its discretion in how it enforces the payer-to-payer data exchange provisions. As a matter of enforcement discretion, CMS does not expect to take action to enforce compliance with these specific provisions until we are able to address certain implementation challenges.

DATES: The notification of enforcement discretion is effective on December 10, 2021.

FOR FURTHER INFORMATION CONTACT: Alexandra Mugge, (410) 786-4457; or Lorraine Doo, (443) 615-1309.

SUPPLEMENTARY INFORMATION: On May 1, 2020, we published the CMS Interoperability and Patient Access final

rule (85 FR 25510) to establish policies that advance interoperability and patient access to health information. The rule required Medicare Advantage (MA) organizations, Medicaid managed care plans, Children’s Health Insurance Program (CHIP) managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FfEs) (collectively referred to as “impacted payers”), to facilitate enhanced data sharing by exchanging data with other payers at the patient’s request, starting January 1, 2022, for:

- MA organizations (42 CFR 422.119(f)); or
- Medicaid managed care plans (42 CFR 438.62(b)(1)(vi)); and CHIP managed care entities (42 CFR 457.1216).

For plan or policy years beginning on or after January 1, 2022, for QHP issuers on the FfEs (45 CFR 156.221(f)), as applicable. We also required these impacted payers to incorporate and maintain the data they receive through this payer-to-payer data exchange into the enrollee’s record, with the goal of increasing transparency for patients, promoting better coordinated care, reducing administrative burden, and enabling patients to establish a collective patient health care record as they move throughout the health care system (see applicable regulations at (§ 422.119(f) for MA organizations; § 438.62(b)(1)(vi) for Medicaid managed care plans (and by extension under existing rules at § 457.1216, to CHIP managed care entities); and § 156.221(f)(i) through (iii) for QHP issuers on the FfEs). These policies are collectively referred to as the payer-to-payer data exchange requirement.

To provide payers with flexibility to support timely adoption and rapid implementation, CMS did not require an application programming interface (API) or any a specific mechanism for the payer-to-payer data exchange. Rather,

we required impacted payers to receive data in whatever format it was sent and to send data in the form and format it was received, which ultimately complicated implementation by requiring payers to accept data in different formats.

Since the rule was finalized in May 2020, multiple impacted payers have indicated to CMS that the absence of a required standard or specification for the payer-to-payer data exchange requirement is creating challenges for implementation and may lead to differences in implementation across industry, poor data quality, operational challenges, and increased administrative burden. For example, payers expressed concerns about receiving volumes of portable document format (pdf) documents and files from other payers using a variety of technical approaches—from file transfer protocols (FTP), to email, to Fast Healthcare Interoperability Resources (FHIR). Payers explained that differences in implementation approaches may create gaps in patient health information that conflict directly with the intended goal of an interoperable payer-to-payer data exchange.

After listening to stakeholder concerns about implementing the payer-to-payer data exchange requirement and considering the potential for negative outcomes that impede, rather than support, interoperable payer-to-payer data exchange, CMS published three frequently asked questions (FAQs) on the CMS and HHS Good Guidance websites¹ to announce that it would be exercising enforcement discretion for the payer-to-payer data exchange requirement. In one of the FAQs, CMS encouraged payers that have already developed FHIR-based application API

¹ Link to CMS website with FAQs for interoperability rule, and enforcement discretion: <https://www.cms.gov/about-cms/health-informatics-and-interoperability-group/faqs#122>.