

409(c)(5) of the FD&C Act, FDA is to “consider among other relevant factors” the following: (1) probable consumption of the additive; (2) cumulative effect of such additive “in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet;” and (3) safety factors “generally recognized” by qualified experts “as appropriate for the use of animal experimentation data.”

Section 409(c)(5) of the FD&C Act does not impose a “legal obligation” for FDA to consider exposure from non-dietary sources in determining safety. Rather, section 409(c)(5) of the FD&C Act makes clear that FDA has discretion to review a number of factors to determine whether a food additive is safe. Besides the factors enumerated in subparagraphs (A), (B), and (C), section 409(c)(5) of the FD&C Act gives us discretion to decide, in our scientific expertise, whether there are other factors that are “relevant” to the safety of a food additive in the context of a particular petition. Moreover, the text of subparagraphs (A) and (B), which contemplate FDA considering *food-related* uses in assessing safety, provides additional support that it is not required for FDA to consider exposure from non-dietary sources as a relevant factor. Specifically, subparagraph (A) states that in determining safety, the Secretary shall consider “the probable consumption of the additive and of any substance formed in or on food because of the use of the additive,” and subparagraph (B) refers to the *diet* of man or animals” (emphasis added). Subparagraph 409(c)(5)(C) of the FD&C Act, which directs FDA to consider safety factors that “are generally recognized as appropriate for the use of animal experimentation data,” does not suggest that FDA must consider exposure from non-dietary sources. Therefore, the objectors’ argument that non-dietary exposure must be part of the safety analysis under section 409(c)(5) of the FD&C Act is incorrect. While the objectors state that other federal agencies “frequently consider background exposures when evaluating and regulating harmful chemicals,” we administer the FD&C Act and not authorities that are applicable to other Federal agencies.

## V. Summary and Conclusions

After evaluating the objections, we conclude that the submission does not provide a basis to support modifying or revoking the denial of FAP 6B4815. Therefore, we are overruling the objections and denying the requests for a public hearing.

## VI. References

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

- \* FDA Memorandum from J. Urbelis to Administrative File for Food Additive Petition (FAP) 6B4815, May 11, 2022.
- \* FDA, Guidance for Industry, “Toxicological Principles for the Safety Assessment of Food Ingredients: Redbook 2000,” July 2007 (available at <https://www.fda.gov/media/79074/download>).
- \* FDA Chemistry Memorandum from R. Brinas to J. Urbelis, May 11, 2022.
- \* FDA Toxicology Memorandum from T-F. Cheng to J. Urbelis, May 11, 2022.
- \* Agency for Toxic Substances and Disease Registry (ATSDR) “Toxicological Profile for Di(2-ethylhexyl) Phthalate (DEHP),” January 2022.
- \* “NTP Technical Report on the Toxicology and Carcinogenesis Studies of Di(2-ethylhexyl) Phthalate Administered in Feed to Sprague Dawley Rats,” December 2021.
- European Food Safety Authority Panel on Food Contact Materials, Enzymes and Processing Aids, “Update of the Risk Assessment of Di-Butylphthalate (DBP), Butyl-Benzyl-Phthalate (BBP), Bis(2-ethylhexyl)Phthalate (DEHP), Di-Isononylphthalate (DINP) and Di-Isodecylphthalate (DIDP) for Use in Food Contact Materials,” *European Food Safety Authority Journal*, 17(12):5838, 2019.
- Conley, J., C.S. Lambricht, N. Evans, et. al., “A Mixture of 15 Phthalates and Pesticides Below Individual Chemical No Observed Adverse Effects Levels (NOAELs) Produces Reproductive Tract Malformations in the Male Rat,” *Environment International*, 156:106615, 2021.
- \*\* 2014 Organization for Economic Cooperation and Development (OECD) Guidance on Grouping of Chemicals.
- \*\* 2014 Chronic Hazard Advisory Panel (CHAP) on Phthalates and Phthalate Alternatives Final Report.
- Howdeshell, K., A.K. Hotchkiss, L.E. Gray Jr., et al., “Cumulative Effects of Antiandrogenic Chemical Mixtures and

Their Relevance to Human Health Risk Assessment,” *International Journal of Hygiene and Environmental Health* 220 (2Pt A):179, 2017.

- Conley, J., C.S. Lambricht, N. Evans, et. al., “Mixed Antiandrogenic Chemicals at Low Individual Doses Produce Reproductive Tract Malformations in the Male Rat,” *Toxicological Sciences* 164(1):166, 2018.

Dated: October 22, 2024.

**Kimberlee Trzeciak,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R08-OAR-2024-0207; FRL-12341-01-R8]

### Air Plan Approval; Revisions to Colorado Common Provisions Regulation

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve revisions to the Common Provisions Regulation of the Colorado State Implementation Plan (SIP). These revisions were submitted by the State of Colorado in response to the EPA’s June 12, 2015, Findings of Substantial Inadequacy and “SIP call” for certain provisions in the SIP related to affirmative defenses applicable to excess emissions during startup, shutdown, and malfunction (SSM) events. The EPA is proposing approval of these SIP revisions because the Agency has determined that they are in accordance with the requirements for SIP provisions under the Clean Air Act (CAA or the Act).

**DATES:** Written comments must be received on or before November 29, 2024.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R08-OAR-2024-0207, to the Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from <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 additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>.

**Docket:** All documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in <https://www.regulations.gov>. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

**FOR FURTHER INFORMATION CONTACT:**

Adam Clark, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD-AQ, 1595 Wynkoop Street, Denver, Colorado 80202-1129, telephone number: (303) 312-7104, email address: [clark.adam@epa.gov](mailto:clark.adam@epa.gov).

**SUPPLEMENTARY INFORMATION:**

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

## I. Background

Prior to the EPA’s 2015 SSM SIP Action,<sup>1</sup> which is discussed later in this section, the Agency had a longstanding interpretation of the CAA with respect to the treatment of excess emissions during periods of SSM in SIPs. This statutory interpretation had been expressed, reiterated, and elaborated upon in a series of guidance documents issued in 1982, 1983, and 1999 described below.

In the 1982 SSM Guidance, the EPA recommended the exercise of enforcement discretion to address

periods of excess emissions occurring during SSM events.<sup>2</sup> Subsequently, in the 1983 SSM Guidance, the EPA expanded on this approach by recommending that a State could elect to adopt SIP provisions providing parameters for the exercise of enforcement discretion by the State’s personnel.<sup>3</sup> In our 1999 SSM Guidance, the EPA interpreted that States could elect to create “affirmative defense” provisions applicable to SSM events in their SIPs.<sup>4</sup> The EPA has defined the term *affirmative defense provision* as a State law provision in a SIP that specifies particular criteria or preconditions that, if met, would purport to preclude a court from imposing monetary penalties or other forms of relief for violations of SIP requirements in accordance with CAA section 113 or CAA section 304.<sup>5</sup> Also in the 1999 Guidance, the EPA established parameters that should be included as part of such an affirmative defense in order to ensure that it would be available only in certain narrow circumstances.<sup>6</sup> Both of the provisions being addressed in today’s action, Colorado Common Provisions Regulation<sup>7</sup> sections II.E. (applicable to qualifying sources during malfunctions), and II.J. (applicable to qualifying sources during periods of startup and shutdown) were approved by the EPA based on our finding that they were consistent with the recommendations of the 1999 Guidance.<sup>8</sup>

On February 22, 2013, the EPA proposed to take action on a petition for rulemaking that the Sierra Club filed with the EPA Administrator on June 30, 2011 (78 FR 12460). In that action, the EPA proposed to grant the Petitioner’s claim in part. The EPA proposed to revise its SSM policy with respect to

affirmative defenses for violations due to excess emissions that occur during startup and shutdown, thus rescinding our prior interpretation that the SSM policy allows for those types of affirmative defenses in SIPs. This was a change from the EPA’s interpretation of the CAA in the 1999 SSM Guidance, in which the EPA had interpreted that States could elect to create such affirmative defense provisions for startup and shutdown events, so long as the provisions were narrowly drawn and consistent with the established criteria to assure that they met CAA requirements. The EPA’s evaluation of the petition and the statutory basis for affirmative defense provisions initiated a review of the appropriateness of affirmative defense provisions applicable during startup and shutdown, which are ordinary modes of operation that are generally predictable and within the control of the source. As explained in more detail in the February 22, 2013, proposal document, the EPA’s evaluation of the Sierra Club Petition in light of then-recent case law<sup>9</sup> caused the EPA to alter its view on the appropriateness of affirmative defenses applicable to planned events such as startup and shutdown. Specifically, the EPA stated that “because these events are modes of normal operation, the EPA believes that sources should be expected to comply with applicable emission limitations during such events.”<sup>10</sup>

The EPA distinguished between affirmative defense provisions for startup and shutdown and those for malfunctions, stating “the distinction that makes affirmative defenses appropriate for malfunctions is that by definition those events are unforeseen and could not have been avoided by the owner or operator of the source, and the owner or operator of the source will have taken steps to prevent the violation and to minimize the effects of the violation after it occurs.”<sup>11</sup> Because of this distinction, in the February 22, 2013 proposal, the EPA proposed to grant the Sierra Club’s petition with respect to Colorado Common Provisions section II.J., “Affirmative Defense Provision for Excess Emissions During Startup and Shutdown,” but to deny the Sierra Club’s petition with respect to Common Provisions section II.E., “Affirmative Defense Provision for

<sup>2</sup> Memorandum to Regional Administrators, Region I–X; From: Kathleen M. Bennett, Assistant Administrator for Air, Noise and Radiation; Subject: Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions. September 28, 1982.

<sup>3</sup> Memorandum to Regional Administrators, Regions I–X; From: Kathleen M. Bennett, Assistant Administrator for Air, Noise and Radiation; Subject: Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions. February 15, 1983.

<sup>4</sup> Memorandum to Regional Administrators, Regions I–X; From: Steven A. Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Bob Perciasepe, Assistant Administrator for Air and Radiation; Subject: Policy on Excess Emissions During Malfunctions, Startup, and Shutdown. September 20, 1999.

<sup>5</sup> 79 FR 55923 (September 17, 2014).

<sup>6</sup> 1999 SSM Guidance.

<sup>7</sup> The Common Provisions Regulation is codified at 5 Colorado Code of Regulations (CCR) 1001–2 of the Colorado SIP.

<sup>8</sup> 71 FR 8958 (February 22, 2006) and 73 FR 45880 (August 7, 2008).

<sup>9</sup> Court decisions confirmed that this requirement for continuous compliance prohibits exemptions for excess emissions during SSM events. *See, e.g., Sierra Club v. EPA*, 551 F.3d 1019, 1021 (D.C. Cir. 2008); *US Magnesium, LLC v. EPA*, 690 F.3d 1157, 1170 (10th Cir. 2012).

<sup>10</sup> 78 FR 12480.

<sup>11</sup> 78 FR 12480.

<sup>1</sup> “State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA’s SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction.” 80 FR 33840, June 12, 2015.

Excess Emissions During Malfunctions.”<sup>12</sup>

Subsequent to the EPA's issuance of the February 22, 2013 proposal, on April 18, 2014, the U.S. Court of Appeals for the District of Columbia Circuit ruled that CAA sections 113 and 304 preclude the EPA the authority to create affirmative defense provisions in the Agency's own regulations imposing emission limits on sources, because such provisions purport to alter the jurisdiction of Federal courts to assess liability and impose penalties for violations of those limits in private civil enforcement cases.<sup>13</sup> In light of this decision, on September 17, 2014, the EPA issued a supplemental proposed rulemaking which outlined our updated policy that affirmative defense SIP provisions, even if they are narrowly tailored and applicable only to malfunctions, are not consistent with CAA requirements. Accordingly, the EPA proposed to grant the portion of the Sierra Club's petition with regard to affirmative defenses in the case of malfunctions that it had previously proposed to deny, including Colorado Common Provisions section II.E.<sup>14</sup> In that supplemental proposal, the EPA stated that the reasoning of the court in that decision indicates that the States, like the EPA, have no authority in SIP provisions to alter the statutory jurisdiction of Federal courts under CAA section 113 and 304 to assess penalties for violations of CAA requirements through affirmative defense provisions. We additionally noted that if States lack authority under the CAA to alter the jurisdiction of the Federal courts through affirmative defense provisions in SIPs, then the EPA also lacks authority to approve any such provision in a SIP. (*Id.* at 79 FR 55929).

On June 12, 2015, pursuant to CAA section 110(k)(5), the EPA finalized “State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction,” (80 FR 33839, June 12, 2015), hereafter referred to as the “2015 SSM SIP Action.” The

2015 SSM SIP Action clarified, restated, and updated the EPA's interpretation that SSM exemptions and affirmative defense SIP provisions are inconsistent with CAA requirements. The 2015 SSM SIP Action found that certain SIP provisions in 36 States, including Colorado, were substantially inadequate to meet CAA requirements and issued a SIP call to those States to submit SIP revisions to address these inadequacies. The EPA established an 18-month deadline by which the affected States had to submit such SIP revisions. With regard to the Colorado SIP, in the 2015 SSM SIP Action, the EPA determined that two affirmative defense provisions in the Colorado SIP (Common Provisions Regulation sections II.E. and II.J.) were substantially inadequate to meet CAA requirements (80 FR 33840, 33970).

On November 21, 2016, Colorado submitted SIP revisions to Common Provisions Regulation sections II.E. and II.J. in response to the SIP call issued in the 2015 SSM SIP Action, which did not include removal of the affirmative defense provisions. On September 8, 2021, Plaintiffs Sierra Club, Environmental Integrity Project, and Natural Resources Defense Council (collectively, Plaintiffs) filed a complaint in the United States District Court for the Northern District of California, Oakland Division, alleging that the EPA had failed to, among other things, take final rulemaking action on Colorado's November 21, 2016 SIP submission.<sup>15</sup> The EPA established a consent decree with the Plaintiffs which required the EPA to take final action on the Colorado November 21, 2016 submission by May 31, 2023, unless Colorado withdrew the submission.<sup>16</sup> On May 31, 2023, Colorado withdrew the November 21, 2016, submission. As discussed further below, Colorado submitted new revisions to Common Provisions Regulation sections II.E. and II.J. on June 26, 2023.

The EPA issued a Memorandum in October 2020 (2020 Memorandum), which stated that certain provisions governing SSM periods in SIPs, including affirmative defense provisions, could be viewed as consistent with CAA requirements.<sup>17</sup>

<sup>15</sup> *Sierra Club et al. v. Regan*, No. 21–cv–6956 (N.D. Cal., September 8, 2021).

<sup>16</sup> 87 FR 21118 (April 11, 2022).

<sup>17</sup> October 9, 2020 memorandum “Inclusion of Provisions Governing Periods of Startup, Shutdown, and Malfunctions in State Implementation Plans,” from Andrew R. Wheeler, Administrator. The 2020 Memorandum stated that it “did not alter in any way the determinations made in the 2015 SSM SIP Action that identified specific State SIP provisions that were substantially inadequate to meet the requirements of the Act.”

However, on September 30, 2021, the EPA's Deputy Administrator withdrew the 2020 Memorandum and announced the EPA's return to the policy articulated in the 2015 SSM SIP Action (2021 Memorandum).<sup>18</sup> As articulated in the 2021 Memorandum, SIP provisions that contain exemptions or affirmative defense provisions are not consistent with CAA requirements and, therefore, generally are not approvable if contained in a SIP submission.

On March 1, 2024, the D.C. Circuit Court of Appeals issued a decision in *Environ. Comm. Fl. Elec. Power v. EPA*, 94 F.4th 77, 115 (D.C. Cir. 2024). The case was a consolidated set of petitions for review of the 2015 SSM SIP Action. The Court granted the petitions in part, vacating the SIP call with respect to SIP provisions that the EPA identified as automatic exemptions, director's discretion provisions, and affirmative defenses that are functionally exemptions; and denied the petitions in part as to other provisions that the EPA identified as overbroad enforcement discretion provisions or affirmative defense provisions that would preclude or limit a court from imposing relief in the case of violations, which the Court also refers to as “specific relief.” This is juxtaposed against the Court's granting of the petition as to affirmative defenses that are functionally exemptions because they “create an exemption from the normal emission rule.”<sup>19</sup> The EPA finds that the affirmative defense provision in the 2008 Billings/Laurel SO<sub>2</sub> FIP to be “specific relief” as interpreted by the Court, as the provision specifically states that an owner or operator “may assert an affirmative defense to a claim for civil penalties for exceedances of such limits during periods of malfunction, startup, or shutdown,” and “to establish the affirmative defense and to be relieved of a civil penalty in any action to enforce such a limit, the owner or operator of the facility must meet the notification requirements of paragraph (i)(2) of this section in a timely manner and prove by a preponderance of evidence. . . .”<sup>20</sup> The EPA has assessed the impact of the decision with respect to our proposed approval of Colorado's removal of the specific affirmative defense provisions

Accordingly, the 2020 Memorandum had no direct impact on the SIP call issued in 2015.

<sup>18</sup> September 30, 2021, memorandum “Withdrawal of the October 9, 2020, Memorandum Addressing Startup, Shutdown, and Malfunctions in State Implementation Plans and Implementation of the Prior Policy,” from Janet McCabe, Deputy Administrator.

<sup>19</sup> See *Environ. Comm. Fl. Elec. Power v. EPA*, 94 F.4th 77, 115 (D.C. Cir. 2024).

<sup>20</sup> See 40 CFR 52.1392(i)(1).

<sup>12</sup> 78 FR 12530.

<sup>13</sup> *NRDC v. EPA*, 749 F.3d 1055 (D.C. Cir. 2014).

<sup>14</sup> “State Implementation Plans: Response to Petition for Rulemaking; Findings of Substantial Inadequacy; and SIP Calls To Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction; Supplemental Proposal To Address Affirmative Defense Provisions in States Included in the Petition for Rulemaking and in Additional States.” 79 FR 55920, September 17, 2014.

at issue in the State's June 26, 2023, submission. We have concluded that the previously stated reasons for the inappropriateness of affirmative defense provisions like Common Provisions sections II.E. and II.J., as articulated in the 2015 SSM SIP Action and 2021 Memorandum, are consistent with the recent D.C. Circuit decision, as these are affirmative defense provisions against specific relief.<sup>21</sup> The Court upheld the EPA's 2015 SSM SIP Action with regard to affirmative defenses against specific relief, finding that because CAA 304(a) and 113(b) authorize citizens and the EPA to seek injunctive relief and monetary penalties against sources that violate a SIP's emission rules, such an affirmative defense would "block that aspect of the Act's enforcement regime."<sup>22</sup>

On June 26, 2023, Colorado submitted, among other revisions to the Colorado SIP that will be addressed in a separate rulemaking action, revisions to sections II.E. and II.J. of the Common Provisions Regulation which removed these rules from the Colorado SIP by making them State-only and therefore not federally enforceable under the CAA. The June 26, 2023, revision to sections II.E. and II.J. of the Common Provisions Regulation was submitted in response to the SIP call in the 2015 SSM SIP Action, and it is this SIP revision that the EPA is proposing to approve with today's action.

## II. Analysis of SIP Submission

As discussed in detail in the 2015 SSM SIP Action, affirmative defense provisions like those in the Colorado SIP at sections II.E. and II.J. of the Common Provisions Regulation are inconsistent with CAA requirements. The EPA is proposing to find that the portion of Colorado's June 26, 2023, SIP submission removing these provisions from the SIP by making them State-only is consistent with CAA requirements and that it adequately addresses the specific deficiencies that the EPA identified in the 2015 SSM SIP Action with respect to the Colorado SIP.

## III. Proposed Action

The EPA is proposing to approve the portion of Colorado's June 26, 2023, SIP submission revising the Colorado SIP by removing Common Provisions Regulation sections II.E. and II.J. from the SIP by making them State-only. We are proposing approval of the SIP revisions because we have determined

that they are consistent with the requirements for SIP provisions under the CAA. The EPA is further proposing to determine that finalizing such SIP revisions would correct the deficiencies identified in the 2015 SSM SIP Action. The EPA is not reopening the 2015 SSM SIP Action and is only taking comment on whether these SIP revisions are consistent with CAA requirements and whether they address the "substantial inadequacy" of the specific Colorado SIP provisions identified in the 2015 SSM SIP Action.

## IV. Incorporation by Reference

In this action, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5 the EPA is proposing to incorporate by reference the revisions that would designate them as State-only, and thus remove from "5 CCR 1001-02, Common Provisions Regulation" of the Colorado SIP, sections II.E., "Affirmative Defense Provision for Excess Emissions During Malfunctions," and II.J., "Affirmative Defense Provision for Excess Emissions During Startup and Shutdown," as described in section III. of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through <https://www.regulations.gov> and in hard copy at the EPA Region 8 office.

## V. Statutory and Executive Order Reviews

Under the CAA, 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, the EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve 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 14094 (88 FR 21879, April 11, 2023);
- 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
  - 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
- 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 proposed 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). Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." The EPA further defines the term fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies."

Colorado did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this proposed

<sup>21</sup> 80 FR 33840, 33970 (June 12, 2015) and 79 FR 55920, 55946 (September 17, 2014).

<sup>22</sup> *Environ. Comm. Fl. Elec. Power v. EPA*, 94 F.4th 77, 114-115 (D.C. Cir. 2024).

action. Due to the nature of the action being proposed here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this proposed action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of

color, low-income populations, and Indigenous peoples.

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and

recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: October 22, 2024.

**K.C. Becker,**

*Regional Administrator, Region 8.*

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