consult with other agency components, as FDA deems appropriate.

§ 3.5 Request for designation.

(a) What to file: A request for designation may be submitted only by the sponsor and must be filed in accordance with this section. The request for designation must not exceed 15 pages, including attachments, and must set forth:

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person, email address, and telephone number.

(2) A description of the product, including:

(i) Classification, name of the product and all component products, if applicable;

(ii) Common, generic, or usual name of the product and all component products;

(iii) Proprietary name of the product;

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product.

(v) Chemical, physical, or biological composition;

(vi) Status and brief reports of the results of developmental work, including animal testing;

(vii) Description of the manufacturing processes, including the sources of all components;

(viii) Proposed use or indications;

(ix) Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination;

(x) Schedule and duration of use;

(xi) Dose and route of administration of drug or biological product;

(xii) Description of related products, including the regulatory status of those related products; and

(xiii) Any other relevant information.

(3) The sponsor's recommendation as to the classification of the product as a drug, device, biological product, or combination product, or as to which agency component should have primary jurisdiction. For combination products, the recommendation for primary jurisdiction must be based on the primary mode of action unless the sponsor cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product, in which case the sponsor's recommendation must be based on the assignment algorithm set forth in § 3.4(b) and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product.

(b) How and where to file: All communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer and plainly marked ''Request for Designation.'' Such communications shall be submitted either in hard copy (an original and two copies) or in an electronic format that FDA can process, review, and archive, to the current mailing address or email address, respectively, for the Office of Combination Products as published by FDA.

§ 3.6 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the agency components, specifying the classification of the product at issue or the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the classification of the product or the center with primary jurisdiction, in accordance with § 3.5(a)(3), shall become the designated product classification or agency component.

§ 3.7 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated product classification or agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed such change in designated product classification or agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate agency component officials, a written determination setting forth a statement of reasons for the proposed change in designated product classification or agency component. Such a change in the designated product classification or agency component requires the concurrence of the official in the agency responsible for overseeing the Office of Combination Products.

§ 3.8 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10321 Filed 5–14–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0152; FRL–9978–09–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Interstate Transport Requirements for the 2012 Fine Particulate Matter Standard

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 Delaware. This revision pertains to the infrastructure requirement for interstate transport of pollution with respect to the 2012 fine

particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS). EPA is proposing approval of this revision in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before June 14, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2017–0152 at *http://www.regulations.gov,* or via email to *spielberger.susan@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, 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. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Joseph Schulingkamp, (215) 814–2021, or by email at *schulingkamp.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 2015, the State of Delaware, through the Department of Natural Resources and Environmental Control (DNREC) submitted a SIP revision addressing the infrastructure requirements under section 110(a)(2) of the CAA for the 2012 $PM_{2.5}$ NAAQS. On September 22, 2017, EPA approved all portions of Delaware's submittal except for the portion addressing section 110(a)(2)(D)(i)(I) regarding the interstate transport of emissions. *See* 82 FR 44318. As explained in the final rule, EPA intended to take separate action on that portion of Delaware's submittal and is doing so with today's proposed action.

I. Background

A. General

Particle pollution is a complex mixture of extremely small particles and liquid droplets in the air. When inhaled, these particles can reach the deepest regions of the lungs. Exposure to particle pollution is linked to a variety of significant health problems. Particle pollution also is the main cause of visibility impairment in the nation's cities and national parks. $PM_{2.5}$ can be emitted directly into the atmosphere, or it can form from chemical reactions of precursor gases including sulfur dioxide (SO_2), nitrogen dioxide (NO_2), certain volatile organic compounds (VOC), and ammonia. On January 15, 2013, EPA revised the level of the health based (primary) annual $PM_{2.5}$ standard to 12 micrograms per meter cubed ($\mu g/m^3$). *See* 78 FR 3086.

B. EPA's Infrastructure Requirements

Pursuant to section 110(a)(1) of the CAA, states are required to submit a SIP revision to address the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements to assure attainment and maintenance of the NAAQS—such as requirements for monitoring, basic program requirements, and legal authority. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances of each NAAQS and what is in each state's existing SIP. In particular, the data and analytical tools available at the time the state develops and submits the SIP revision for a new or revised NAAQS affect the content of the submission. The content of such SIP submission may also vary depending upon what provisions the state's existing SIP already contains.

Specifically, section 110(a)(1) provides the procedural and timing requirements for SIP submissions. Section 110(a)(2) lists specific elements that states must meet for infrastructure SIP requirements related to a newly established or revised NAAQS such as requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the NAAQS.

C. Interstate Pollution Transport Requirements

Section 110(a)(2)(D)(i)(I) of the CAA requires a state's SIP to address any emissions activity in one state that contributes significantly to nonattainment, or interferes with maintenance, of the NAAQS in any downwind state. The EPA sometimes refers to these requirements as prong 1 (significant contribution to nonattainment) and prong 2 (interference with maintenance), or jointly as the ''good neighbor'' provision of the CAA. On March 17, 2016, EPA issued a memorandum providing information on the development and review of SIPs that address CAA section 110(a)(2)(D)(i) for the 2012 $PM_{2.5}$ NAAQS (2016 $PM_{2.5}$ Memorandum).[1] Further information can be found in the Technical Support Document (TSD) for this rulemaking action, which is available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2017–0152.

II. Summary of SIP Revisions and EPA Analysis

Delaware's December 14, 2015 SIP submittal asserted that the State's SIP presently contains adequate provisions prohibiting sources from emitting air pollutants in amounts which will contribute significantly to nonattainment or interfere with maintenance of the 2012 $PM_{2.5}$ NAAQS. Delaware also asserted under Delaware Code, Title 7, Chapter 60, Subsection 6010(c), ''Rules and regulations; plans,'' that the State has the legal authority to regulate sources whose emission could transport to areas in nonattainment or to areas currently attaining the NAAQS. Delaware also describes ambient air quality data for New Castle, Kent, and Sussex Counties as all being below the NAAQS. A detailed summary of Delaware's submittal and EPA's review and rationale for approval of this SIP revision as meeting CAA section 110(a)(2)(D)(i)(I) for the 2012 $PM_{2.5}$ NAAQS may be found in the TSD for this rulemaking action, which is available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2017–0152.

EPA used the information in the 2016 $PM_{2.5}$ Memorandum and additional information for the evaluation and came to the same conclusion as Delaware. As

[1] ''Information on the Interstate Transport ''Good Neighbor'' Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I),'' Memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards (March 17, 2016). A copy is included in the docket for this rulemaking action.

discussed in greater detail in the TSD, EPA identified the potential downwind nonattainment and maintenance receptors identified in the 2016 $PM_{2.5}$ Memorandum, and then evaluated them to determine if Delaware's emissions could potentially contribute to nonattainment and maintenance problems in 2021, the attainment year for moderate $PM_{2.5}$ nonattainment areas. Specifically, the analysis identified the following areas as potential nonattainment and maintenance receptors: (i) 17 potential receptors in California; (ii) one potential receptor in Shoshone County, Idaho; (iii) one potential receptor in Allegheny County, Pennsylvania; (iv) data gaps exist for the monitors in four counties in Florida; and (v) data gaps exist for all monitors in Illinois. For the 17 receptors in California and one potential receptor in Idaho, based on EPA's evaluation of distance and wind direction, EPA proposes to conclude that Delaware's emissions do not significantly impact those receptors. For the potential receptor in Allegheny County, EPA expects the air quality affecting that monitor to improve to the point where the monitor will not be a nonattainment or maintenance receptor by 2021 and is therefore unlikely to be a receptor for purposes of interstate transport. For the four counties in Florida and the monitors in Illinois with data gaps, EPA initially treats those receptors as potential nonattainment or maintenance receptors. For the Florida receptors, it is unlikely that they will be nonattainment or maintenance receptors in 2021 and in any event, modeling from the Cross-State Air Pollution Rule (CSAPR) indicates that Delaware's emissions do not contribute to them. For the monitors in Illinois, the most recent air quality data (from 2015 and 2016) indicates that all monitors are likely attaining the $PM_{2.5}$ NAAQs and are therefore unlikely to be nonattainment or maintenance concerns in 2021. Therefore, EPA proposes to conclude that Delaware emissions will not contribute to any of these receptors. For these reasons, EPA is proposing to find that Delaware's existing SIP provisions as identified in the December 14, 2015 SIP submittal are adequate to prevent its emission sources from significantly contributing to nonattainment or interfering with maintenance in another state with respect to the 2012 $PM_{2.5}$ NAAQS.

III. Proposed Action

EPA is proposing to approve the December 14, 2015 Delaware SIP revision addressing the interstate transport requirements for the 2012 $PM_{2.5}$ NAAQS because the submittal adequately addresses section 110(a)(2)(D)(i)(I) of the CAA. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, addressing the 2012 $PM_{2.5}$ interstate transport obligations for Delaware, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

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

Dated: May 1, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2018–10342 Filed 5–14–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2003–0194; FRL–9977–74–OAR]

RIN 2060–AT70

National Emission Standards for Hazardous Air Pollutants: Leather Finishing Operations Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On March 14, 2018, the Environmental Protection Agency (EPA) proposed a rule titled, ''National Emission Standards for Hazardous Air Pollutants: Leather Finishing Operations Residual Risk and Technology Review.'' The EPA is reopening the comment period on the proposed rule that closed on April 30, 2018. The EPA is taking this action because the supporting document—Analysis of Demographic Factors for Populations Living Near Leather Finishing Operations—was inadvertently not included in the docket for this proposed rule. As this analysis is now available to the public, the EPA has reopened the comment period for an additional 30 days.

DATES: The public comment period for the proposed rule published in the **Federal Register** on March 14, 2018 (83 FR 11314), is reopened. Written comments must be received on or before June 14, 2018.