

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2024-F-1912 for “Filing of Food Additive Petition from Environmental Defense Fund, et al.; Request to Amend the Food Additive Regulations to Remove Fluorinated Polyethylene.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Lillian Mawby, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-4041.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 3B4837), submitted by Environmental Defense Fund, Breast Cancer Prevention Partners, Center for Food Safety, Environmental Working Group, Tom Neltner, and Maricel Maffini, c/o Maricel Maffini, Frederick, MD 21701. The petition proposes that we revoke § 177.1615 (21 CFR 177.1615, “Polyethylene, fluorinated”).

II. Request To Repeal 21 CFR Part 177.1615

In accordance with the procedures for amending or repealing a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to repeal § 177.1615. Specifically, the petitioners state that the fluorinated polyethylene manufactured consistent with § 177.1615 can produce polymeric per- and poly-fluorinated alkyl substances that can migrate to food and, therefore, are not safe pursuant to section 409(c)(5) of the FD&C Act (21 U.S.C. 348(c)(5)).

The petition is available in the docket. We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justifies repealing § 177.1615, we will publish our decision in the **Federal Register** in accordance with § 171.130.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental

impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-09027 Filed 4-25-24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA-R04-OAR-2021-0258; FRL-9562-01-R4]

South Carolina; Approval of State Plan for Control of Emissions From Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the Clean Air Act (CAA or Act) section 111(d)/129 State plan submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SCDHEC), on December 19, 2014, and supplemented on September 17, 2018, and June 19, 2019, and November 5, 2019, for implementing and enforcing the Emissions Guidelines (EG) applicable to existing Commercial and Industrial Solid Waste Incineration (CISWI) units. The State plan provides for implementation and enforcement of the EG, as finalized by the EPA on June 23, 2016, applicable to existing CISWI units for which construction commenced on or before June 4, 2010, or for which modification or reconstruction commenced after June 4, 2010, but no later than August 7, 2013; the State plan also incorporates the CISWI technical amendments finalized by the EPA on April 16, 2019. The State plan establishes emission limits, monitoring, operating, recordkeeping, and reporting requirements for affected CISWI units.

DATES: Comments must be received on or before May 28, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2021-0258 at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *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 <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Mark Bloeth, Communities and Air Toxics Section, Air Analysis and Support Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303. Mr. Bloeth can be reached via telephone at (404) 562-9013 and via email at bloeth.mark@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 129 of the Clean Air Act (CAA or the Act) directs the Administrator to establish performance standards and emission guidelines pursuant to section 111(d) of the Act limiting emissions of nine air pollutants (particulate matter, sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins/furans) from four categories of solid waste incineration units: municipal solid waste; hospital, medical, and infectious solid waste; commercial and industrial solid waste; and other solid waste.

Section 129(b)(2) of the CAA requires States to submit to the EPA for approval State plans and revisions that implement and enforce the EG—in this case, 40 CFR part 60, subpart DDDD. State plans and revisions must be at least as protective as the EG, and they become federally enforceable upon approval by the EPA. The procedures for adoption and submittal of State plans and revisions are codified in 40 CFR part 60, subpart B.

On December 1, 2000, the EPA promulgated new source performance standards (NSPS) and EG to reduce air pollution from CISWI units, which are codified at 40 CFR part 60, subparts CCCC and DDDD, respectively. *See* 65

FR 75338. The EPA revised the NSPS and EG for CISWI units on March 21, 2011. *See* 76 FR 15704. Following promulgation of the 2011 CISWI rule, the EPA received petitions for reconsideration requesting that the EPA reconsider numerous provisions in the rule. The EPA granted reconsideration on certain issues and promulgated a CISWI reconsideration rule on February 7, 2013. *See* 78 FR 9112 (February 7, 2013). Subsequently, EPA received petitions to further reconsider certain provisions of the 2013 NSPS and EG for CISWI units. On January 21, 2015, the EPA granted reconsideration on four specific issues, and it finalized reconsideration of the CISWI NSPS and EG on June 23, 2016. *See* 81 FR 40956. On April 16, 2019, the EPA finalized amendments to the NSPS and EG for CISWI units, which discussed clarifications and/or corrections regarding: (1) an alternative equivalent emission limit for mercury (Hg) for waste-burning kilns, (2) timing of initial test and initial performance evaluation, (3) extension of electronic data reporting requirement, (4) non-delegated authorities, (5) demonstrating initial and continuous compliance when using a continuous emissions monitoring system (CEMS), (6) continuous opacity monitoring requirements, (7) other CEMS requirements, (8) reduced testing requirements, (9) deviation reporting requirements for continuous monitoring data, and (10) clarification of air curtain incinerator requirements (ACI), as well as corrections to typographical errors. *See* 84 FR 15846.

II. Review of South Carolina's CISWI State Plan Submittal

South Carolina submitted a State plan to implement and enforce the EG for existing CISWI units in the State¹ on December 19, 2014, with a subsequent supplemental revision on September 17, 2018, an addendum on June 19, 2019, and a final updated State plan on November 5, 2019. The EPA has reviewed the State plan submittals for existing CISWI units in the context of the requirements of 40 CFR part 60, subparts B and DDDD. State plans must include the following nine essential elements: identification of legal authority; identification of mechanism for implementation; inventory of affected facilities; emissions inventory; emission limits; compliance schedules; testing, monitoring, recordkeeping, and reporting; public hearing records; and annual State progress reports on plan enforcement. For the reasons explained

¹ The submitted State plan does not apply in Indian country located in the State.

below, the EPA is proposing to approve South Carolina's CISWI State plan as consistent with those requirements.

In addition to the foregoing statutory and regulatory provisions, South Carolina's regulations also include, through incorporation by reference, 40 CFR part 60, subpart DDDD (as amended most recently at 84 FR 15846 (April 16, 2019)), which includes the following Federal requirements: (1) Increments of Progress, (2) Waste Management Plan, (3) Operator Training and Qualification, (4) Emission Limitations and Operating Limits, (5) Performance Testing, (6) Initial Compliance Requirements, (7) Continuous Compliance Requirements, (8) Monitoring, (9) Recordkeeping and Reporting, (10) Title V Operating Permits, (11) Air Curtain Incinerators, (12) Definitions, (13) a modified Table 1 to include the final compliance date of February 7, 2018, and (14) Tables 2 through 9 of 40 CFR part 60, subpart DDDD.

A. Identification of Legal Authority

Under 40 CFR 60.26 and 60.2515(a)(9), an approvable State plan must demonstrate that the State has legal authority to adopt and implement the EG's emission standards and compliance schedule. In its submittals, South Carolina cites the following State law provisions for its authority to implement and enforce the State plan via its air quality program: South Carolina Code Section 48-1, Chapter 1 of the Pollution Control Act, South Carolina Department of Health and Environmental Control, Chapter 61, Statutory Authority: 1976 Code Section 48-1-10 through Section 48-1-350.; SCDHEC Regulation 61-62.60, Subpart DDDD, State effective on August 23, 2019. The EPA has reviewed the cited authorities and proposes to find that the State has adequately demonstrated legal authority to implement and enforce the CISWI State plan in South Carolina.

B. Identification of Enforceable State Mechanisms for Implementing the Plan

Under 40 CFR 60.24(a), a State plan must include emission standards, defined at 40 CFR 60.21(f) as "a legally enforceable regulation setting forth an allowable rate of emissions into the atmosphere, or prescribing equipment specifications for control of air pollution emissions." *See also* 40 CFR 60.2515(a)(8). South Carolina has adopted enforceable emission standards for affected CISWI units by incorporating by reference 40 CFR part 60, subpart DDDD (as amended most recently at 84 FR 15846), at SCDHEC's Regulation 61-62.60, Subpart DDDD—Performance Standards and Compliance

Times for Existing Commercial and Industrial Solid Waste Incineration Units, as described in South Carolina State Register Vol. 43, Issue 8 (August 23, 2019). The EPA proposes to find that South Carolina's Regulation 61–62.60, Subpart DDDD, meets the emission standards requirement under 40 CFR 60.24(a).

C. Inventory of Affected Units

Under 40 CFR 60.25(a) and 60.2515(a)(1), a State plan must include a complete source inventory of all CISWI units. South Carolina has identified affected units at six facilities: Argos (kiln), DAK Americas (fluidized bed incinerator), Ulmer Brothers, Inc. (air curtain incinerator), Coastal Debris (air curtain incinerator), Advanced Machining & Fabrication, Inc. (air curtain incinerator), and Tri-County Pallet (air curtain incinerator). Omission from this inventory of CISWI units does not exempt an affected facility from the applicable section 111(d)/129 requirements. The EPA proposes to find that South Carolina has met the affected unit inventory requirements under 40 CFR 60.25(a) and 60.2515(a)(1).

D. Inventory of Emissions From Affected CISWI Units

Under 40 CFR 60.25(a) and 60.2515(a)(2), a State plan must include an emissions inventory of the pollutants regulated by the EG. Emissions from CISWI units may contain cadmium, carbon monoxide, dioxins/furans, hydrogen chloride, lead, mercury, nitrogen oxides, particulate matter, and sulfur dioxide. South Carolina submitted an emissions inventory for CISWI units as part of its State plan. This emissions inventory contains CISWI unit emissions rates for each regulated pollutant. Therefore, the EPA proposes to find that South Carolina has met the emissions inventory requirements of 40 CFR 60.25(a) and 60.2515(a)(2).

E. Emission Limitations, Operator Training and Qualification, Waste Management Plan, and Operating Limits for CISWI Units

Under 40 CFR 60.24(c) and 60.2515(a)(4), the State plan must include emission standards that are no less stringent than the EG. 40 CFR 60.2515(a)(4) also requires operator training and qualification requirements, a waste management plan, and operating limits. At its Regulation 61–62.60 Subpart DDDD, South Carolina has incorporated by reference the EG's emission standards, operator training and qualification requirements, waste management plan, and operating limits

for CISWI units. Therefore, the EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(c) and 60.2515(a)(4).

F. Compliance Schedules

Under 40 CFR 60.24(a), (c), and (e) and 40 CFR 60.2515(a)(3), each State plan must include a compliance schedule, which requires affected CISWI units to expeditiously comply with the State plan requirements. In the State plan at Regulation 61–62.60 Subpart DDDD, South Carolina requires that affected sources comply with the EG initial compliance requirements for CISWI units, which the EPA has codified at 40 CFR 60.2700 through 40 CFR 60.2706. Therefore, EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(a), (c), and (e) and 40 CFR 60.2515(a)(3).

G. Testing, Monitoring, Recordkeeping, and Reporting Requirements

Under 40 CFR 60.24(b)(2), 60.25(b), and 60.2515(a)(5), an approvable State plan must require that sources conduct testing, monitoring, recordkeeping, and reporting. South Carolina's State plan incorporates by reference the model rule provisions of the EG at Regulation 61–62.60 Subpart DDDD, including performance testing provisions at 40 CFR 60.2690 through 60.2695, monitoring provisions at 40 CFR 60.2730 through 60.2735, and recordkeeping and reporting provisions at 40 CFR 60.2740 through 60.2800. Additionally, all reports required under 40 CFR 60.2795(a), (b)(1), and (b)(2) must be submitted to SCDHEC as well as to the EPA. Therefore, the EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(b)(2), 60.25(b), and 60.2515(a)(5).

H. A Record of Public Hearing on the State Plan Revision

Requirements at 40 CFR 60.23 sets forth the public participation requirements for each State plan. The State must conduct a public hearing; make all relevant plan materials available to the public prior to the hearing; and provide notice of such hearing to the public, the Administrator of the EPA, each local air pollution control agency, and, in the case of an interstate region, each State within the region. Under 40 CFR 60.2515(a)(6) requires each State plan include certification that the hearing was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief

written summary of each presentation or written submission.

In its submittal, South Carolina submitted records, including transcripts, of three public hearings. A public hearing was held on November 24, 2014, for the original December 19, 2014, State plan submittal. South Carolina held a second hearing on May 30, 2018, for the September 17, 2018, supplemental State plan submission which addressed the EPA's June 23, 2016, CISWI amendments and reconsideration. See 81 FR 40956 (June 23, 2016). South Carolina held a third public hearing on October 29, 2019, for the November 5, 2019, final supplement to the SCDHEC State plan submittal. South Carolina provided notice and made all relevant plan materials available prior to each hearing. Additionally, South Carolina certifies in each of its State plan submittals that hearings were held, and that the State received no written or oral comments on the plan. Therefore, the EPA proposes to find that South Carolina's CISWI plan satisfies the requirements of 40 CFR 60.23 and 60.2515(a)(6).

I. Annual State Progress Reports to EPA

Under 40 CFR 60.25(e) and (f) and 40 CFR 60.2515(a)(7), the State must provide in its State plan for annual reports to EPA on progress in enforcement of the plan. Accordingly, South Carolina provides in its plan that it will submit reports on progress in plan enforcement to the EPA on an annual (calendar year) basis, commencing with the first full reporting period after plan revision approval. The EPA proposes to find that South Carolina's CISWI plan satisfies the requirements of 40 CFR 60.25(e) and (f) and 40 CFR 60.2515(a)(7).

III. Incorporation by Reference

In this action, 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 South Carolina Regulation 61–62.60, Subpart DDDD, State effective August 23, 2019, which includes provisions regarding applicability, emission limits, operating, testing, monitoring, recordkeeping, reporting, compliance schedules, and all other relevant requirements contained in EPA's emission guidelines for existing CISWI units and further described in Section II of this preamble. The EPA has made, and will continue to make these materials generally available through <http://www.regulations.gov>, Docket ID No. EPA–R04–OAR–2021–0258, and at

the EPA Region 4 Office (please contact the person identified in the “For Further Information Contact” section of this preamble for more information).

IV. Proposed Action

Pursuant to CAA section 111(d), CAA section 129, and 40 CFR part 60, subparts B and DDDD, the EPA is proposing to approve South Carolina’s State plan for regulation of CISWI units as submitted on December 19, 2014, with a subsequent supplemental revision submitted on September 17, 2018, an addendum submitted on June 19, 2019, and a final updated State plan submitted on November 5, 2019. In addition, the EPA is proposing to amend 40 CFR part 62, subpart B to reflect this action.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a 111(d)/129 plan submission that complies with the provisions of the CAA and applicable Federal regulations. In reviewing 111(d)/129 plan submissions, the EPA’s role is to approve State choices, provided they meet the criteria and objectives of the CAA and the EPA’s implementing regulations. 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 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 (Public Law 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); and
- 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.

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that the human health and environmental conditions that exist prior to this action result in, or have the potential to result in, disproportionate and adverse human health or environmental effects on people of color, low-income populations, and/or Indigenous peoples. Certain areas of the State include communities that are pollution-burdened and underserved according to demographic data. EPA performed a screening-level analysis using EPA’s EJSCREEN to identify environmental burdens and susceptible populations in communities surrounding CISWI units in the State. The results of the demographic analysis are presented in the *EJ Screening Report for South Carolina CISWI Units*, a copy of which is available in the docket for this action, Docket ID No. EPA–R04–EPA–2021–0258.

The EPA believes that this action is not likely to change existing disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples because the State plan implements national standards in the CISWI EG that would result in reductions in emissions of a wide array of air pollutants released due to the incineration of solid waste at commercial and industrial facilities. Some such pollutants exist in the waste feed material and are released unchanged during combustion, and some are generated as a result of the combustion process itself. These pollutants include particulate matter, sulfur dioxide, hydrogen chloride,

oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins/furans. These pollutants are associated with certain negative health effects; for example, SO₂ and NO_x are precursors for the formation of PM_{2.5}, which is associated with health effects such as premature mortality for adults and infants, cardiovascular morbidity such as heart attacks, and respiratory morbidity such as asthma attacks, acute bronchitis, and other respiratory symptoms. Reducing these emissions will decrease the amount of such pollutants to which all affected populations are exposed. The EPA has determined that this action increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or income or environmental effects on any population, including any minority, low-income, or Indigenous populations. To the extent that any minority, low-income, or Indigenous subpopulation is disproportionately impacted by emissions of any of the pollutants identified above due to the proximity of their homes to sources of these emissions, that subpopulation also stands to see increased environmental and health benefits from the emission reductions called for by this action.

In addition, this proposed approval of South Carolina’s State plan for CISWI units does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the EPA is not proposing to approve the submitted plan to apply in Indian country located in the State, and because the submitted plan will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 62

Administrative practice and procedure, Air pollution control, Aluminum, Environmental protection, Fertilizers, Fluoride, Incorporation by reference, Industrial facilities, Intergovernmental relations, Methane, Ozone, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds, Waste treatment and disposal.

Authority: 42 U.S.C. 7411.

Dated: April 19, 2024.

Jeaneanne M. Gettle,

Acting Regional Administrator Region 4.

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