



ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 10, 2024

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Re: Petition ID No. 001880: Toxic Substances Control Act Section 21 Petition Concerning Regulation of PFOA, PFNA, and PFDA Manufactured during Plastic Fluorination

Dear Ms. Lester, Mr. Kalmuss-Katz, and Mr. Sussman:

The U.S. Environmental Protection Agency received your petition dated April 11, 2024, submitted on behalf of Center for Environmental Health, Public Employees for Environmental Responsibility, Alaska Community Action on Toxics, Clean Cape Fear, Clean Water Action, Delaware Riverkeeper, and Merrimack Citizens for Clean Water, requesting that EPA “establish regulations pursuant to Section 6 of [the Toxic Substances Control Act (TSCA)], 15 U.S.C. [Section] 2605, prohibiting the manufacturing, processing, use, distribution in commerce, and disposal of three per- and polyfluoroalkyl substances ([PFAS])—perfluorooctanoic acid (CASRN 335-67-1) ([PFOA]), perfluorononanoic acid (CASRN 375-

95-1) ([']PFNA[']), and perfluorodecanoic acid (CASRN 335-76-2) ([']PFDA['])—formed during the fluorination of plastic containers.”

This letter is to advise you that the EPA grants the petition. The EPA will promptly commence an appropriate proceeding under TSCA Section 6. The EPA’s grant of this petition is not itself a final agency action and does not signal that EPA will ultimately take any particular final agency action.

Statutory Requirements

TSCA Section 21(b)(1), 15 U.S.C. 2620(b)(1), requires that the petition “set forth the facts which it is claimed establish that it is necessary” to initiate the proceeding requested. 15 U.S.C. 2620(b)(1). TSCA Section 21’s “necessary” language implicitly incorporates the statutory standards that apply to the requested actions. Accordingly, the EPA has reviewed this TSCA Section 21 petition by considering whether petitioners have established it is “necessary” to initiate a proceeding for a rule under TSCA Section 6. Notwithstanding that the burden is on the petitioners to present “the facts which it is claimed establish that it is necessary” for the EPA to initiate the proceeding sought, the EPA in its discretion also considered relevant information that was reasonably available to the agency during the 90-day petition review period.

Summary of the Petition

The petition requests that the EPA promulgate a rule under TSCA Section 6(a) to prohibit the manufacturing, processing, use, distribution in commerce, and disposal of PFOA, PFNA, and PFDA formed during the fluorination of plastic containers (Petition, p. 1). The petition argues that this action is warranted because PFOA, PFNA, and PFDA are hazardous to human health and the environment at low levels, with human health effects including cancer (PFOA, PFNA), developmental harm (PFOA, PFNA, PFDA), reproductive harm (PFOA, PFNA, PFDA), immune system toxicity (PFOA, PFNA, PFDA), liver toxicity (PFOA, PFNA, PFDA), thyroid toxicity (PFOA), and kidney toxicity (PFOA) (Petition, p. 9). The petition also cites research demonstrating environmental harm associated with exposure to PFOA, PFNA, and PFDA, including adverse effects on aquatic organisms, including certain bivalves and bacteria (Petition, p. 9). The petition also references EPA studies showing that PFAS formed during the fluorination process leach from fluorinated plastic containers into the products stored in them (Petition, p. 12). The petition then asserts that exposure to PFOA, PFNA, PFDA, and other PFAS can occur at all stages of the lifecycles of such containers, including during manufacturing, processing, distribution, use, and disposal (Petition, p. 12).

The petition cites the agency’s November 2023 “Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011, as well as “TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances,” in which EPA determined that the manufacture, processing, distribution in commerce, use, or disposal of PFOA, PFNA, and PFDA, when manufactured or processed during the fluorination of plastic containers, presents an unreasonable risk of injury to health or the environment (Petition, p. 1). The petition further cites a conclusion as stated in the TSCA Section 5 order that the agency cannot control these potential exposures to PFOA, PFNA, and PFDA through means other than a prohibition on the manufacture of these substances (Petition, p. 2). The petition argues, as a result: (1) the unreasonable risk determination under TSCA Section 5 obligates EPA to grant the petition and initiate a rulemaking under TSCA Section 6(a) to eliminate the unreasonable risks caused by the production and processing of PFOA, PFNA, and PFDA during plastic

fluorination and by the use, distribution in commerce, and disposal of fluorinated containers (Petition, p. 1); and (2) a prohibition of PFAS production during fluorination of plastic containers is necessary to eliminate the unreasonable risks presented by PFOA, PFNA, and PFDA created during the fluorination process (Petition, p. 2). Finally, the petition suggests that the EPA adopt an immediately effective proposed rule, arguing based on the EPA's risk assessment that the TSCA Section 6(d)(3) factors were met and that allowing the manufacture of PFOA, PFNA, and PFDA during the plastic fluorination process to continue unabated would present an "unreasonable risk of serious or widespread injury" (Petition, pp. 16-17).

EPA's Evaluation of the Petition

The petition, taken together with information reasonably available to the EPA, sets forth facts establishing that it is necessary to initiate an appropriate proceeding under TSCA Section 6 to address PFOA, PFNA, and PFDA formed during the fluorination of plastic containers. The petitioners submitted sufficient evidence to show that PFOA, PFNA, and PFDA formed during the fluorination of plastic containers presents risk of concern. This evidence is contained in two exhibits accompanying the petition itself. The first exhibit is a risk assessment developed by EPA in the context of the Agency's review of two consolidated significant new use notifications submitted by Inhance Technologies, LLC related to nine PFAS (including PFOA, PFNA, and PFDA) formed during the surface coating via fluorination of high-density polyethylene fuel and non-fuel storage containers. The second exhibit is the aforementioned order issued by EPA to address the risk identified in the risk assessment.¹ Additionally, the EPA in its discretion may consider all reasonably available information when evaluating a petition, and has done so in this instance.

In its November 2023 "Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011," the Agency determined that PFOA, PFNA, and PFDA (among nine total PFAS assessed) are persistent, bioaccumulative, and toxic chemicals and noted those three PFAS are well studied. PFOA and PFDA have EPA-reviewed toxicity assessments that have been made public. In addition, EPA concluded in the risk assessment that there are potential or expected environmental releases of PFOA, PFNA, and PFDA and these releases are expected to result in human exposures and exposures to aquatic life, based on the manufacture, processing, distribution, use, and disposal of the fluorinated containers where these substances are present. Thus, EPA concluded there is risk of concern from the manufacture, distribution, use, and disposal of the PFOA, PFNA, and PFDA.

Expected Actions on PFOA, PFNA, and PFDA Formed during the Fluorination of Plastic Containers under TSCA

The agency will promptly commence an appropriate proceeding under TSCA Section 6 associated with the formation of PFOA, PFNA, and PFDA during the fluorination of plastic containers. As part of that proceeding, the EPA intends to request information, including the number, location, and uses of fluorinated containers in the United States; alternatives to the fluorination process that generates PFOA, PFNA, and PFDA; and measures to address risk from PFOA, PFNA, and PFDA formed during the fluorination of plastic containers. This action will build on efforts underway among governments (e.g., federal, Tribal, and state), non-governmental organizations, academia, and industry, to ensure that any risks associated with PFOA, PFNA, and PFDA are appropriately evaluated and managed.

¹ This order was subsequently vacated by the U.S. Court of Appeals for the Fifth Circuit in *Inhance Technologies, LLC v. EPA*, Case No. 23-60620. The court's opinion in this case did not specifically address the conclusions of the risk assessment.

Thank you for your continued interest in reducing exposure to PFOA, PFNA, and PFDA formed during the fluorination of plastic containers. If you have any questions relating to your petition or the EPA's guidelines for TSCA Section 21 petitions, feel free to contact Thomas Groeneveld of my staff at (202) 566-1188 or groeneveld.thomas@epa.gov.

Sincerely,

**MICHAL
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