



January 5, 2023

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Lawrence Starfield
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Re: Full Public Disclosure of PFAS-Contaminated Containers Fluorinated by Inhance

Dear Dr. Freedhoff and Mr. Starfield:

The Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER) are deeply concerned about the failure of the Environmental Protection Agency (EPA) to inform the public of the serious human health threat from per- and polyfluoroalkyl substances (PFAS) present in tens of millions of plastic containers “fluorinated” by Inhance Technologies USA (Inhance).

For nearly two years, EPA has known of the formation of these “forever chemicals” during the Inhance fluorination process. It has also known that Inhance is violating the Agency’s July 2020 [significant new use rule](#) (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) substances under the Toxic Substances Control Act (TSCA). Yet EPA has been silent about the occurrence of these unlawful activities and their role in unsafe exposure to PFAS by American workers and consumers.

We call on EPA to immediately disclose to the public the nature and severity of the health threat from PFAS-contaminated plastic containers fluorinated by Inhance, describe how the Agency

plans to protect the public from this threat under TSCA, and make publicly available all relevant information in its possession about the fluorination activities of Inhance and their contribution to PFAS exposure and risk. Insofar as full disclosure is being blocked by Inhance's unjustified claims of Confidential Business Information (CBI), EPA must act quickly to disallow these claims to the full extent of its authority under TSCA.

PFAS Contamination of Fluorinated Containers

Testing conducted by EPA, Notre Dame University researchers, and other organizations has found PFAS chemicals on the inner and outer surfaces of fluorinated containers and in the contents of the containers. These PFAS are likely formed as a result of chemical reactions that occur during the fluorination process conducted by Inhance.

The PFAS detected in fluorinated containers include perfluorooctanoic acid (PFOA), a harmful substance found in the blood of a high percentage of Americans. EPA has [concluded](#) that very low levels of PFOA are unsafe because of the link between PFOA exposure and liver and pancreatic cancer, thyroid problems, reduced immune function and vaccine efficacy and impaired fetal development, among other negative health effects. The major producers agreed to voluntarily phase out the manufacture of PFOA in 2015 at the urging of EPA.

During fluorination, fluorine gas is applied to plastic containers in varying concentrations under high temperatures in order to improve their barrier properties. Inhance conducts fluorination operations at several facilities in the U.S. and is the leading supplier of post-mold fluorination services in the U.S. Tens of millions of plastic containers, used in vast sectors of the economy, undergo fluorination before they are filled with products and distributed to consumers and businesses. Handling or using fluorinated containers may well be a significant pathway for unsafe exposure to PFOA and other PFAS by millions of Americans.

Violations of LCPFAC SNUR

The LCPFAC SNUR, finalized on July 27, 2020, prohibits firms from manufacturing and processing PFOA and other long-chain PFAS until a significant new use notice (SNUN) describing these activities has been submitted to EPA and it has evaluated the safety of these activities and banned or restricted them as necessary to address unreasonable risks to health or the environment.

Inhance did not submit a significant new use notice (SNUN) to EPA when the SNUR took effect on September 25, 2020, but continued manufacturing and processing PFOA and other LCPFACs in violation of TSCA. These activities persisted even after EPA [announced](#) on January 14, 2021 that it had detected PFAS in fluorinated containers and was conducting an investigation of the problem, released additional [test data](#) in March 2021 documenting the presence of PFAS in fluorinated plastic containers, [warned](#) industry that PFAS formation in these containers violated the SNUR in March 2022 and [issued](#) a report providing further confirmatory test data in September 2022.

CEH/PEER Legal Action Under TSCA

On October 24, 2022, CEH and PEER [notified](#) EPA and Inhance of their intent to file a citizens enforcement action to stop ongoing violations of the SNUR. On December 27, 2022, CEH and PEER filed [suit](#) under TSCA section 20 in the U.S. District Court for the District of Columbia. CEH and PEER are seeking a court order restraining Inhance from continued manufacture or processing of PFOA and other LCPFACs in violation of the SNUR, requiring it to stop all distribution of fluorinated containers in commerce until and unless TSCA requirements are met and, directing it to inform purchasers and users of these containers of the dangers of exposure to PFOA and other LCPFACs.

Non-Disclosure of EPA Legal Action

On December 19, 2022, after nearly two years of inaction and in the wake of the CEH and PEER notice of intent to sue, EPA finally took legal action against Inhance under TSCA, filing its own [suit](#) in the Eastern District of Pennsylvania. However, EPA has not announced this suit publicly and the Complaint in the public docket is heavily redacted, removing all references to the LCPFAC SNUR and PFAS and providing no indication that Inhance is engaged in the fluorination of plastic containers or that PFOA and other PFAS are formed in the fluorination process.

Equally troubling, it is apparent from the redacted Complaint that EPA and the company have interacted extensively for nearly 2 years, with EPA issuing a subpoena to Inhance on January 14, 2021 and then a Notice of Violation on March 1, 2022 and Inhance responding by submitting extensive data and other information. Knowledge of these submissions would be invaluable in understanding the causes and scope of PFAS contamination in fluorinated containers but they have not been shared with the public

Rejecting Unwarranted CBI Claims

It is our understanding that this lack of disclosure is the result of Inhance's extensive claims of TSCA CBI protection. We believe these claims are excessive and legally unjustified. EPA has ample tools under section 14 of the law to conclude that information wrongly claimed CBI is not entitled to confidentiality. For example, Inhance's fluorination business is a matter of public record; the formation of PFAS during fluorination is documented in the scientific literature and test data disclosed to the public by EPA; and EPA itself has publicly recognized the application of the LCPFAC SNUR to PFAS found in fluorinated containers. There is no basis in TSCA to withhold any of this information as CBI since it is in the public domain. Moreover, any non-public data and analysis on PFAS formation submitted to EPA by Inhance would be "information from health and safety studies" exempt from CBI protection under section 14(b)(2) of TSCA. Finally, EPA should have completed its review of Inhance's substantiation of its CBI claims within 90 days of receipt under section 14(g)(1) and should now be in a position to promptly reject these claims if this substantiation is inadequate. If this review is not yet underway, it should be initiated immediately and completed as soon as possible.

Apart from these limits on CBI treatment, section 14(d)(3) provides that information claimed CBI "shall be disclosed if the Administrator determines that disclosure is necessary to protect

health or the environment against an unreasonable risk of injury to health or the environment.” This standard has plainly been met here because the presence of PFOA and other PFAS in fluorinated containers presents “an unreasonable risk to health” and disclosure is necessary to protect workers and end-users of containers against this risk. A similar exemption from CBI treatment is afforded by section 14(d)(7), under which information “may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this chapter.” The lawsuits filed by EPA and CEH and PEER comprise such a “proceeding.”

Concurrent with this letter, PEER and CEH are submitting a comprehensive request under the Freedom of Information Act (FOIA) for all information relating to the formation of PFAS during the fluorination of plastic containers by Inhance and exposure to PFAS during the distribution and end-use of these containers. EPA should respond to this request as soon as possible.

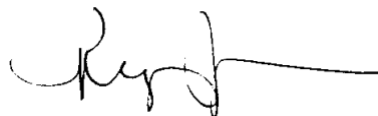
We are hopeful that you and staff will give the highest priority to full public disclosure of the serious health risks of PFAS-contaminated fluorinated containers and take immediate action to make all relevant information available to the full extent permitted by TSCA.

Please contact our lead counsel Bob Sussman to follow-up on this letter at 202-716-0118 or bobsussman1@comcast.net

Sincerely yours,



Tim Whitehouse
Executive Director
Public Employees for Environmental
Responsibility



Regina Jackson
Interim Chief Executive Officer
Center for Environmental Health

cc: Denise Keehner (OPPT)
Mark Hartman (OPPT)
Rosemarie Kelley (OECA)
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Richard Gladstein (DOJ)
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