November 29, 2023

Kevin Miller
Assistant General Counsel
General Law Office; Office of General Counsel
United State Environmental Protection Agency
1200 Pennsylvania Avenue N.W.
Washington, DC 20004

Re: Unjustified Withholding of Information Subject to Disclosure Under TSCA

Dear Mr. Miller:

Thank you for meeting with Public Employees for Environmental Responsibility (PEER) and the Center for Environmental Health (CEH) on November 21, 2023 to discuss our concerns about the unjustified withholding of information submitted by Inhance Technologies to the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

As we explained at the meeting, Inhance fluorinates plastic containers that contain perfluorooctanoic acid (PFOA) and eight other long-chain perfluoroalkyl carboxylate (LCPFAC) substances subject to EPA's July 2020 Significant New Use Rule (SNUR) under section 5 of TSCA. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) is reviewing significant new use notices (SNUNs) for these harmful substances, which are present in tens of millions of consumer and industrial products used across a broad cross-section of the US economy.

During the three years EPA has been investigating Inhance's fluorination process, the company has submitted voluminous test data documenting the levels of LCPFACs found in fluorinated containers. It has also submitted extensive information on the functions and applications of these containers. On January 5, 2023, CEH and PEER requested access to these data under the Freedom of Information Act (FOIA). However, in its initial FOIA responses, EPA redacted this information on the basis of Inhance's claims of Confidential Business Information (CBI).

As we demonstrated at our meeting, section 14(b)(2) of TSCA precludes CBI protections for "health and safety studies" while section 14(b)(3) requires disclosure of aggregated information on the "industrial, commercial or consumer functions and uses" of chemicals. In view of these requirements, EPA has no statutory basis for withholding the test data and use information that Inhance has claimed as CBI and should make this information available to the public as soon as possible.

Contamination of fluorinated containers by Per- and Polyfluoroalkyl Substances (PFAS) has attracted considerable media and Congressional interest; how EPA acts on the pending SNUNs will be closely scrutinized. The information EPA is withholding is vital for understanding health risks to millions of workers and consumers who handle, use, process and dispose of fluorinated plastic products and are thereby exposed to harmful PFAS. To accept Inhance's aggressive and unwarranted CBI claims will defeat the transparency about public health risks that EPA strives to promote.

At our meeting, you indicated that EPA's typical practice is to delay reviewing CBI claims until it has fully processed a FOIA request and released redacted materials to the requestor. At that point, EPA initiates a CBI review, informs the information submitter of its determinations and provides an opportunity to object to disclosure, and then considers these objections and discloses any information for which CBI protection is deemed unwarranted. Although the PEER/CEH FOIA request has been pending for nearly a year, EPA's "interim" responses to date have been limited and we believe that a large quantity of responsive documents is still being withheld. To wait for completion of a full FOIA response and then a CBI review would add months if not years of delay to the release of important information that does not warrant CBI protection and is relevant to serious health risks that the public faces today. With no immediate prospect that EPA would challenge unjustified CBI claims, companies like Inhance would have an incentive to seek blanket CBI protections in order to conceal sensitive information from the public as long as possible.

EPA's general CBI regulations provide an efficient mechanism for making an upfront determination that the Inhance data do not qualify for CBI treatment. Under 40 CFR § 2.207, OGC "may make and issue a class determination" if —

(1) EPA possesses, or is obtaining, related items of business information;

(2) One or more characteristics common to all such items of information will necessarily result in identical treatment for each such item under one or more of the provisions in this subpart, and that it is therefore proper to treat all such items as a class for one or more purposes under this subpart; and

(3) A class determination would serve a useful purpose."

In appropriate cases, a class determination may conclude that "all of the information in the class . . . [f]ails to satisfy one or more of the applicable substantive criteria, and is therefore ineligible for confidential treatment."

A "class" determination makes obvious sense here because the test data Inhance has submitted to EPA have common characteristics that bring them within the definition of "health and safety study" in TSCA and EPA regulations. The same is true of aggregated use and application

information that likewise fall within TSCA's exemptions from CBI requirements. With a minimum expenditure of resources, EPA can thus make an upfront finding that CBI protections do not apply, permitting immediate disclosure of important information on the risks of PFAS present in widely used consumer and industrial products fluorinated by Inhance.

The benefits of an upfront class determination are underscored by several provisions of EPA's TSCA CBI regulations that point to the need for rapid disclosure of information that Congress has determined does not warrant CBI protection:

- Section 14(b)(5) of TSCA provides that if EPA receives a FOIA request for information "that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of" the CBI protections in FOIA exemption 4. Yet EPA has effectively rejected the PEER/CEH FOIA request by withholding information that on its face is not entitled to CBI protection under the express exceptions in sections 14(b)(2) and (3). This is a clear violation of section 14(b)(5).

- Section 14(f)(2) provides that EPA "shall review a claim for protection of information" on CBI grounds where "necessary to determine whether the information" should be disclosed in response to a FOIA request. This requirement is formalized in EPA's FOIA regulations at 40 C.F.R § 703.8. Its clear implication is that EPA should examine the validity of CBI claims when reviewing information for disclosure under FOIA, not in a separate process that begins only after EPA has "responded" to the FOIA request by disclosing heavily redacted documents.

- Section 14(f)(2) also directs that EPA "shall review" CBI claims where it "has a reasonable basis to believe that the information does not qualify for protection from disclosure under" section 14. Plainly, such a basis exists here given PEER/CEH's demonstration that the withheld data are ineligible for CBI treatment as "health and safety studies" under section 14(b)(2) or aggregated function and use information under section 14(a)(3) of TSCA. Significantly, § 703.7(f)(5) of the TSCA CBI regulations expressly recognizes that "[i]nformation from health and safety studies respecting any chemical . . . for which notice is required under section 5 of the Act is not entitled to confidential treatment."

- Section 14(g)(1)(A) sets a 90 day deadline by which EPA "must review and approve, approve in part and deny in part, or deny" CBI claims. Under section 14(g)(1)(G), EPA may discharge this obligation by "review[ing] a representative subset, comprising at least 25 percent, of" requests for CBI protection. These provisions for expedited review of CBI claims confirm that, in the 2016 TSCA Amendments, Congress sought to address overly broad and unwarranted claims of CBI that were thwarting transparency and public review of EPA chemical safety determinations. The high priority Congress placed on rapid EPA

action on CBI claims demands an expeditious process for determining the validity of the claims asserted by Inhance.

- Section 14(d)(7) authorizes disclosure of information claimed CBI if EPA "determines that disclosure is relevant in a proceeding under this chapter." EPA's SNUN review process under section 5 of TSCA plainly qualifies as a "proceeding under this chapter." The high public interest in PFAS contamination of fluorinated containers and the effectiveness of EPA's public comment process for section 5 notices would both be well-served by disclosing information that are highly relevant to EPA's determinations of unreasonable risk for Inhance's SNUN submissions.

As we noted at our November 21 meeting, Inhance's September 29 submissions to EPA included an extensive report by the NERA consulting firm on the economic impacts of limiting or eliminating the Inhance post-mold fluorination process. The entire body of this report was redacted as CBI. EPA must conduct a CBI review of these redactions as soon as possible so that the public can meaningfully review the sweeping conclusions of the NERA report.

In summary, we ask EPA to expeditiously review the validity of Inhance's CBI claims, direct the company to unredact and resubmit test data and other information that is not eligible for CBI protection under TSCA, and disclose this information to PEER and CEH under FOIA and by posting it on ChemView.

As we requested during our call, PEER and CEH seek another meeting with OGC to discuss how the Agency plans to respond to our requests. If EPA is not willing to meet, we ask you to convey your views to us in writing within two weeks.

For the record, we are attaching our presentation at the November 21 meeting.

Sincerely yours,

/*s/ Robert Sussman*
Robert M. Sussman
Counsel for Center for Environmental Health

/s/ Paula Dinerstein
Paula Dinerstein
General Counsel
Public Employees for Environmental Responsibility

cc: Randy Hill
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