



March 25, 2022

Via E-Mail

The Honorable Michal Ilana Freedhoff, Ph.D.
Assistant Administrator
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Avenue, N.W.
Mail Code: 7101M
Washington, DC 20460

Re: TSCA Inventory Correction

Dear Dr. Freedhoff:

The TSCA New Chemicals Coalition (NCC)¹ writes to express its grave concerns with the U.S. Environmental Protection Agency's (EPA) February 25, 2022, surprise announcement that it is "phasing out" the Toxic Substances Control Act (TSCA) Inventory correction process. 87 Fed. Reg. 10781. For the reasons set forth below, the NCC believes EPA's decision-making process would benefit greatly from stakeholder input and urges EPA to suspend the phaseout set to occur on April 26, 2022, and to reconsider the revocation of the 1980 corrections guidelines set to occur May 31, 2022. Both decisions invite significant unintended consequences, and stakeholder comment may well provide information that could persuade EPA to go in a different direction.

Background

EPA's *Federal Register* notice provides a succinct summary of the origin of the Inventory correction process and will not be repeated here. Where EPA and the NCC, and quite possibly other industrial chemical stakeholders, part paths is EPA's statement that it has "become increasingly evident that the 1980 guidelines have outlived the purpose for which they were intended." *Id.* at 10781 (col 2). Even more disturbingly, EPA appears to be of the view that the process "may be used improperly by entities attempting to avoid submission of a [premanufacture notice (PMN)] or exemption notice for a new chemical substance." *Id.* at 10782 (col 3).

¹ The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA and work collaboratively with EPA and other stakeholders to address them.



The Honorable Michal Ilana Freedhoff, Ph.D.

March 25, 2022

Page 2

Implicit in EPA's rationale is that the Inventory correction process when originally created was somehow time limited, its expiration date has come and gone, and its continuing availability to industrial chemical stakeholders is facilitating improper, PMN-submission-avoiding mischief. We vigorously disagree and believe EPA's apparent understanding of the process is premised on an inadequate understanding of the fundamental purpose of the Inventory and the inherent need for a functioning and ongoing correction process. Contrary to EPA's implicit misunderstanding, manufacturers do not routinely reassess the identities of products they manufacture. As a result, the notion that the passage of a certain amount of time is sufficient for all stakeholders to correct all identities is simply unfounded.

As stakeholders in the industrial chemical community, we appreciate, perhaps now more than ever, that any number of global actions may trigger the need to revisit or question a chemical's identity for TSCA Inventory purposes. There is nothing nefarious about these external trigger events.

Take, for example, the European Union's (EU) enactment of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in 2006. The passage of time, the ready availability of new and more precise technologies used to assess chemical identities, and the sheer magnitude of REACH's impact on the global industrial chemical community occasioned significant focus on chemical identity and the need to align European and domestic chemical identity classifications. The Inventory correction process was a critical tool industry used to address chemical identity anomalies disclosed at the time. To our knowledge, all such efforts reflected well-intentioned, good faith efforts to reconcile legitimate chemical identity questions that arose because of REACH's enactment.

The evolution of analytical techniques used to characterize chemical identity plays a huge role in this area. When the Inventory was formed decades ago, it is our view that the correction process anticipated scientific developments and the need for an ongoing process to revisit chemical identity to make adjustments necessitated by ever more discerning and exacting technological advancements in the field of chemical identity. There is no time limitation to evolution, and nor should there be any expectation that the chemical identities captured on the TSCA Inventory are static. Given the emphasis the Agency has placed on following the science, the implications that flow from EPA's presumptive logic in this regard do not reflect the underlying scientific reasons why adjustments are occasionally needed.

We note also the role of changes in corporate ownership. These kinds of business decisions are not typically of great concern to EPA and other regulatory authorities who rightfully



The Honorable Michal Ilana Freedhoff, Ph.D.

March 25, 2022

Page 3

focus on compliance with applicable regulatory standards. Changing ownership of chemical manufacturing entities, however, routinely brings to light anomalies in chemical identity. The assignment of a chemical identity is subject to interpretation, and reasonable and sophisticated regulatory chemists can and do vigorously debate the merits of chemical identity for TSCA Inventory purposes. This discourse is not a pretext for evading TSCA chemical notification. Quite the contrary; it reflects the scientific discipline and precision TSCA’s drafters expected in preparing and curating the Inventory. To eliminate the correction process is to ignore a critically important fact in the industrial chemical community -- chemical identities can be subject to legitimate questions, and the industrial chemical community needs a process to answer these questions and get the chemical identity right. This can especially become known as part of financial due diligence or more general regulatory compliance reviews that may occur. EPA’s unsupported concern, as expressed in the *Federal Register*, that the process “may be used improperly” seems to us entirely disproportionate to the ongoing value of and critical need for an effective correction process.

While it is understandable that “the passage of time is also making it more difficult for the original submitters or their legal successors to provide the necessary documentation supporting a request for a correction,” a point cited as a rationale for the policy change, that difficulty should not prejudice persons who can provide the necessary documentation to support a request for correction. *Id.* (col 2). Business entities are prepared to do what it takes to satisfy the core requirements of the correction process and, to our knowledge, have worked hard to fulfill them. Their relative difficulty should not influence the legitimacy of the correction process.

Importantly also, the NCC questions whether EPA has thought through the implications of its decision, as we see significant unintended consequences. EPA appears to be of the view that chemical producers and their downstream customers can commercially tolerate a hard stop in the event a legitimate question regarding chemical identity arises and there is no process available to address the question short of the submission of a PMN or exemption notice.

Apparently, under EPA’s thinking, the producer, that would otherwise have access to the correction process, would immediately stop production, notify its customers of this fact, prepare a PMN or exemption notice, and wait an indeterminate period for EPA to process PMNs and exemption notices. As EPA is aware, the determination process can take years. During this time, the producer and its customers endure the logistical, commercial, and legal consequences of stopping production, adding significant and entirely avoidable supply chain uncertainty to a world already convulsing with supply chain uncertainty. Importantly also, it may be the case that others supplying the same product have not yet become aware of the inaccuracy of the nomenclature. In this case, others might continue to supply the product under the old identity, putting the entity seeking to correct



The Honorable Michal Ilana Freedhoff, Ph.D.
March 25, 2022
Page 4

at a substantial commercial disadvantage simply because it has the knowledge that the other manufacturers do not. The NCC questions the prudence and fairness of EPA's decision under these circumstances.

With regard to EPA's unsupported statements about the "improper" use of the correction process, the appropriate remedy is for EPA to enforce TSCA, not eliminate a much needed and well-established correction process. The NCC vigorously disagrees that the correction process is used improperly, but if EPA believes such abuse exists, it has selected the wrong remedy. EPA can certainly expand upon its guidance to clarify what is required to support a correction request.

Finally, we also question the legality of EPA's decisions. After four decades of EPA's uniform application of the Inventory correction process, the chemical community has come to rely on these guidelines, akin to reliance on the criteria established in the Inventory Reporting Regulations at [40 C.F.R. Part 710](#). EPA's use of these guidelines in practice as controlling criteria resulted in the expectation of the ability to comply with and rely reasonably upon the Inventory correction process. Its unilateral "disappearing" seems to mark a decision-making process that imposes legal obligations on stakeholders without obtaining public input. EPA's significant alteration of these procedures imparts meaningful and significant consequences on affected stakeholders in a manner that may satisfy the two-prong test in *Bennett v. Spear* for a final regulatory action for which we believe notice and comments should be provided.

For these reasons, the NCC urges EPA to address these concerns now by suspending its decisions to revoke the guidelines and "phaseout" of the Inventory correction process and seeking comment on its plans. We would be pleased to speak with you if you have any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "L. Botelho", with a long horizontal line extending to the right.

Ligia Duarte Botelho
Manager, TSCA New Chemicals Coalition

cc: Mr. Mark A. Hartman (via e-mail)
Tala Henry, Ph.D. (via e-mail)