



October 31, 2024

Submitted via <https://www.regulations.gov>

Ms. Sarah Soliman
Office of Pollution Prevention and Toxics (7201M)
Office of Chemical Safety and Pollution Prevention (OCSPP)
Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

RE: Public Engagement Webinars; Pre-Prioritization and Consideration of Existing Chemical Substances for Future Prioritization Under the Toxic Substances Control Act (TSCA), EPA-HQ-OPPT-2023-0606-0008

Dear Ms. Soliman:

On August 28, 2024, EPA published a notice of availability and request for comment on its approach to Pre-Prioritization and Consideration of Existing Chemical Substances for Future Prioritization Under the Toxic Substances Control Act (TSCA). The Alliance for Automotive Innovation¹ (Auto Innovators) appreciates the opportunity to provide comments to EPA on this action taken under the authority of TSCA, which requires EPA to evaluate existing chemicals via a three-stage process. The focus of this notice is on the first stage: prioritization, in preparation for risk evaluation and potential risk management. Prioritization is the initial step in the process of evaluating existing chemicals under TSCA section 6(b) and implementing regulations at 40 CFR Part 702. Our understanding is that the purpose of prioritization is to designate a chemical substance as either high priority for immediate further risk evaluation, or low priority, for which risk evaluation is not warranted at the time.

Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell around 95% of the new light-duty vehicles in the United States. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal transportation and to work together on policies that further these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

We would like to recognize that EPA has actively pursued a more robust engagement process for this pre-prioritization process than earlier efforts and appreciate the outreach to all of the potentially impacted stakeholders. This additional step in the process should provide EPA with valuable information and insights into the role that these potential candidates play in the U.S. manufacturing sector.

We offer the following comments on the approach that EPA has used for pre-prioritization of these 27 chemicals.

¹ From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer and smarter personal transportation future. www.autosinnovate.org.

A. *Types of information that could help characterize exposure to communities and potentially associated health effects resulting from exposure.*

While EPA has identified a relatively comprehensive list of information that could be used to characterize potential exposure, we believe there are at least three additional data points that are critical to assessing exposure. The first of those is the potential for exposure from articles where a chemical may have been used in the manufacture of that article, and where the chemical is fully encapsulated in the article or is present only as an impurity.

Section 6(c) of TSCA specifically requires EPA to apply prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks **from exposure** to the chemical substance or mixture from the article:

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or the category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).²

We request EPA specifically identify the unique exposure characteristics of articles as a critical source of information that can serve as an indicator of potential exposure and related risk.

The second source of exposure data that should be clearly identified is the minimal contribution that replacement parts may have to overall chemical exposures, especially as EPA continues to focus on the whole chemical approach.

TSCA Section 6(c)(2)(D) directs EPA to exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of a rule under TSCA Section 6(a).

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts **contribute significantly to the risk**, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.³

We request EPA specifically identify the unique exposure characteristics of replacement parts as a critical source of information that can serve as an indicator of potential exposure and related risk.

The third area of key consideration for potential exposure is the identification of *de minimis* levels of a chemical—the concentration or level of a chemical that is considered insignificant enough to not have an adverse impact on human health or the environment. For carcinogens, the *de minimis* level

² 15 U.S.C. § 2605(c)(2)(E).

³ *Id.* § 2605(c)(2)(D).

is usually significantly lower than for non-carcinogenic chemicals, often set at 0.1% compared to 1% for other chemicals.

We request EPA specifically recognize that *de minimis* levels of an identified chemical may not contribute in any significant way to risk.

B. Lack of identification of conditions of use.

While the notice of availability provides a significant amount of detail regarding the approach EPA used to support the proposed designation for each chemical substance and instructions on how to access the chemical-specific information, analysis, and the basis EPA used to make the proposed designation for each chemical substance, it lacks any indication of what conditions of use EPA may be considering for assessment. In the absence of such information, it is difficult to comment on whether and how the selection of these chemicals may impact the automotive sector.

In order to provide meaningful comment on these 27 chemicals, we urge EPA to provide a sense of the scope of the conditions of use that it is considering.

C. De facto regulation of other chemicals.

By selecting many “building block” chemicals in this pre-prioritization process, EPA may be assessing and potentially regulating other chemicals that are dependent on these chemicals for synthesis. For example, styrene (100-42-5) serves as the backbone for styrenic plastics commonly used in vehicles, so restrictions on the use of this substance in manufacturing scenarios would impact the auto industry. Depending on how EPA chooses to identify conditions of use for chemicals such as styrene, EPA may be expanding this designation to include other plastics dependent on styrene as a starter chemical. By selecting building block chemicals, EPA may well ultimately be assessing many more chemicals that are dependent on these for manufacture.

We recommend that EPA limit its assessment and evaluation to these specific chemicals and not expand its assessment to look at synthesis products that may be manufactured with these chemicals.

D. Metals.

EPA identified four metals by groups to include “and compounds” for prioritization, including cobalt and cobalt compounds and lead and lead compounds. The identification of the substances to include “and compounds” is not specific enough to allow a robust review of the full scope of what is covered by this listing.

Recognizing that metals are specifically called out in the Lautenberg Chemical Safety Act under Section 6(b)(2)(E), if a metal is selected as a high-priority substance, the risk evaluation method is specified by statute—specifically, EPA is required to use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor. This document may be significantly outdated.

We request EPA provide a list of specific metal substances with CAS numbers, not generic groups, and we recommend EPA revise and update the 2007 Framework document with the latest science using an open and transparent process that include stakeholder involvement and review by the

Science Advisory Committee on Chemicals (SACC). The Agency should start this process now given the timeframe normally required to revise a document of this significance. No metal should be selected for prioritization until the March 2007 Framework for Metals Risk Assessment is revised, updated, and reviewed by the SACC.

E. Need for CAS numbers.

Medium- and long-chain chlorinated paraffins (MCCPs and LCCPs) were identified for prioritization without naming CAS numbers for more precise targeting. We request EPA provide a list of specific CAS numbers for the substances that are included within each M/LCCP group.

In conclusion, we appreciate the outreach effort EPA has put forward and offer the above comments in an effort to make that outreach process even more effective. We believe that EPA needs to include additional key factors that would further identify potential exposure concerns and additional information about the scope of the conditions of use being considered by EPA. Additionally, we caution about the potential to expand assessments to include chemicals not specifically identified in this pre-prioritization process and to prepare for the process that is required to assess metals.

Please feel free to reach out to me should you have any questions.

Sincerely,



Catherine Palin
Senior Attorney & Director of Environmental Policy
Alliance for Automotive Innovation