ALLIANCE FOR AUTOMOTIVE INNOVATION

March 20, 2025

Submitted through https://www.regulations.gov

Ms. Brooke Porter
Existing Chemicals Risk Management Division (7404M)
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

RE: 1,3-Butadiene; Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Availability of Draft Documents and Request for Comment [EPA-HQ-OPPT-2024-0425]

Dear Ms. Porter:

The Alliance for Automotive Innovation (Auto Innovators)[1] appreciates the opportunity to provide comments on EPA's draft risk evaluation for 1,3-butadiene.[2] Auto Innovators represents the full auto industry, including the manufacturers producing most vehicles sold in the U.S., equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers. Our mission is to work with policymakers to realize a cleaner, safer, and smarter transportation future and to ensure a healthy and competitive auto industry that supports U.S. economic and national security.

The draft risk evaluation presents EPA's preliminary determination that 1,3-butadiene presents an unreasonable risk of injury to workers and the general population (including fenceline communities) from inhalation exposure. Based on the assessment of consumer risk and related risk factors, EPA believes that consumer conditions of use (COUs) do not significantly contribute to the unreasonable risk of 1,3-butadiene. Based on the pathways evaluated in this draft risk evaluation, EPA has determined that risk to the environment does not significantly contribute to the unreasonable risk determination for 1,3-butadiene.

We understand the draft risk evaluation to have determined that the industrial use of 1,3-butadiene in adhesives and sealants, including epoxy resins, lubricants and lubricant additives, paints and coatings, including aerosol spray paint; and the commercial use of 1,3-butadiene in "other articles" with routine direct contact during normal use (including rubber articles; plastic articles (hard)), do not contribute significantly to the preliminary unreasonable risk determination.[3]

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[1] Auto Innovators represents the full auto industry, including the manufacturers producing most vehicles sold in the U.S., equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers. Our mission is to work with policymakers to realize a cleaner, safer, and smarter transportation future and to ensure a healthy and competitive auto industry that supports U.S. economic and national security. Representing approximately 5 percent of the country's GDP, responsible for supporting nearly 10 million jobs, and driving $1 trillion in annual economic activity, the automotive industry is the nation's largest manufacturing sector. www.autosinnovate.org.

[2] U.S. Environmental Protection Agency, Draft Risk Evaluation for 1,3-Butadiene (Nov. 2024), *available* at https://www.epa.gov/system/files/documents/2024-12/01.-1-3-butadiene-.-draft-risk-evaluation-.-public-release-.-hero-.-november-2024.pdf.

[3] *Id.* at 156–57.

Our comments below address the criticality of 1,3-butadiene as a building block chemical and the need for a *de minimis* level, as well as two ongoing policy approaches that EPA has used in previous assessments and in this assessment for 1,3-butadiene: (1) the specific COUs that EPA has identified as driving the unreasonable risk determination for 1,3-butadiene; and (2) the workplace controls that are routinely in place in automotive facilities but are not recognized in this assessment.

I. 1,3-Butadiene as a Building Block Chemical: Impacts on Downstream Chemical Production

1,3-butadiene is a considered a "building block chemical," and as such is a basic starting chemistry in a multitude of other chemicals and products. It is used as an intermediate in the production of various synthetic rubbers, plastics, and other polymers, and acts as a base that can be combined with other chemistries to create larger molecules with desired properties for products such as car parts, rubber products, neoprene, etc.

This draft risk evaluation is silent on the issue of how any potential unreasonable risk finding for 1,3-butadiene will impact those downstream production processes and uses. By teeing this chemical up for potential regulation, EPA may create a set of unintended consequences that could result in major supply and economic impacts on a wide array of industrial sectors and products, none of which are recognized in this draft risk evaluation.

If EPA is going to evaluate building block chemicals such as 1,3-butadiene, the evaluations must identify all the downstream uses and be transparent as to how an unreasonable risk determination would impact them.

II. Need for a *De Minimis* Level

Consistent with other federal and international regulatory agencies, Auto Innovators requests that EPA establish a default *de minimis* level for 1,3-butadiene. EPA has itself recognized the practicality of a *de minimis* threshold. In EPA's "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal," EPA put forward sound arguments for establishing a *de minimis* threshold:

> Establishment of a threshold could be based on one or more of the following rationales: (1) Below the selected threshold level, there is no ''reasonable potential for exposure'' within the meaning of section 5(a)(5) (i.e., the risk of exposure is very low); and (2) below the selected threshold level, there is a ''reasonable potential for exposure'' (or, alternatively, there may be such a potential), but the potential does not ''justif[y] notification'' (i.e., potential for risk is very low in light of the low level of LCPFAC present in the surface coating).[4]

As another example, in the European Union's REACH regulation, "notification" or reporting of chemicals contained in articles has a *de minimis* threshold of 0.1% in product. The EU producers or importers of articles must notify only if their articles contain a substance on their Candidate List and only if the substance is present in those articles in quantities totaling over one ton per producer or

[4] 85 Fed. Reg.12,479, 12,482 (Mar. 3, 2020).

importer per year and if the substance is present in those articles above a concentration of 0.1%. This system has proven to be effective in allowing the EU to focus on chemical manufacturing and use scenarios where the volume of the chemical is significant enough to pose a concern for exposure.

III. COUs Driving Unreasonable Risk as a Result of EPA's "Whole Chemical" Approach

While EPA has discarded the terminology "whole chemical approach," it continues to make a single risk determination for a chemical substance rather than making separate determinations for each COU. Auto Innovators has raised concerns about this approach in previous comments.[5]

Prior to the issuance of the draft revision for HBCD,[6] EPA's risk determination approach had been to make separate unreasonable risk determinations for every relevant COU of a chemical. The COUs reflected those identified in the associated scoping document and were those uses "as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[7] The resultant risk determinations were clear in terms of which conditions of use were determined to pose an unreasonable risk and which conditions of use did not pose an unreasonable risk. The determinations that a particular condition of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1) and therefore were covered by TSCA's preemption provisions.

EPA's adoption and application of a whole chemical approach has reduced the clarity and certainty provided by the previous approach of making separate determinations of unreasonable risk for every condition of use of a chemical. The consequences of this approach have resulted in prolonged uncertainty for the regulated community, continued use of resources to research uses which pose no risk, and a negatively biased whole chemical "finding" that will undoubtedly be used to push back on uses that may not have an unreasonable risk. It may also potentially result in regrettable substitutions, as manufacturers seek to quickly implement functional alternatives.

We recommend that EPA reevaluate its assessment approach and return to its approach of making separate unreasonable risk determinations for every relevant condition of use of a chemical.

IV. Assumptions That Personal Protective Equipment Is Not Routinely Used

In the initially issued final risk evaluations for the first 10 Work Plan chemicals, estimates of worker exposure were calculated both with and without the use of personal protective equipment (PPE), assuming the use of PPE as stipulated by the Occupational Safety and Health Act (OSH Act) standards. Since then, EPA has determined that it is now more appropriate, when conducting risk evaluations, to assume that PPE is not used by workers when making a risk determination. Information related to PPE use will be considered by EPA during the risk management phases. This new approach is reflected in EPA's June 30, 2021, press release announcing EPA's new approaches to risk evaluations.

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[5] Comments submitted by Alliance for Automotive Innovation, EPA-HQ-OPPT-2016-0725-0080.
[6] U.S Environmental Protection Agency, Unreasonable Risk Determination (June 2022), https://www.epa.gov/system/files/documents/2022-06/HBCD_Final%20Revised%20URD_June%202022.pdf.
[7] 15 U.S.C. § 2602(4).

> Use of Personal Protective Equipment
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> In the final risk evaluations for the first 10 chemicals, the previous administration generally assumed that workers were always provided, and used, personal protective equipment (PPE) appropriately. However, data on violations of PPE use suggest that assumptions that PPE is always provided to workers, and worn properly, are not justified. Continued use of this assumption could result in risk evaluations that underestimate the risk, and in turn, risk management rules may not provide the needed protections.
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> EPA is therefore revisiting the assumption that PPE is always used in occupational settings when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process.
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> The first 10 risk evaluations already include exposure analysis with and without PPE. Therefore, removing this assumption does not create need for new analysis. However, this shift could change some of the conclusions about risk on some conditions of use for six of the first 10 chemicals for which "no unreasonable risk" findings were made based on the use of PPE. Specifically, this shift could impact conclusions about risk for some conditions of use for methylene chloride, 1-bromopropane, HBCD, NMP, perchloroethylene, and 1,4-dioxane.[8]

EPA further affirms this approach in the 1,3-butadiene risk assessment, stating:

> EPA conducts assessments of risk and makes its determination of unreasonable risk from a scenario that does not assume use of respiratory protection or other personal protective equipment (PPE).[9]

If EPA believes that assuming the use of PPE in workplace facilities will *underestimate* potential exposure to certain subpopulations of workers, such as occupational non-users or self-employed individuals, assuming no use of PPE in any workplace will likely *overestimate* worker exposure. As a result, the draft and final risk determinations may be inaccurate and misleading and result in extra workload and resources for EPA and the regulated community alike going into the risk management phase. This approach doesn't appear to fix a perceived problem but rather replace it with a potentially greater problem—creating a false and misleading perception of worker risk. For the extended period between EPA's release of its risk assessments and its issuance of final risk management rules, the public will likely be left with the perception that risks are greater than they are and that manufacturing facilities are out of compliance with federal and state safety standards.

If EPA believes that workers not covered by Occupational Safety and Health Administration (OSHA) standards are at a greater exposure risk, using TSCA in place of the OSH Act through this

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[8] EPA, "EPA Announces Path Forward for TSCA Chemical Risk Evaluations." *Press Release*, June 30, 2021. https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations (emphasis added).

[9] https://www.epa.gov/system/files/documents/2024-12/01.-1-3-butadiene-.-draft-risk-evaluation-.-public-release-.-hero-.-november-2024.pdf

workaround approach is inappropriate. The more straightforward approach would be to identify real and actual risks and then to coordinate with OSHA to update and enforce its requirements and compliance program, as appropriate under the OSH Act. For workers not covered by OSHA standards, we recommend that EPA work with OSHA to find an appropriate means for providing any necessary requirements, preferably under the OSH Act, if unreasonable risk is determined.

Further, if EPA believes that certain workplace risks are not being adequately controlled, then EPA has an obligation under TSCA section 9(a) to consult with OSHA before superseding OSHA authority. Any such result from coordination and consultation with OSHA should also be made publicly available to further transparency, process, and due diligence. In the case of the 1,3-butadiene assessment, any such information has not been made available to the public, i.e., via the docket, to date, as would be expected under the requirements of 15 U.S.C. § 2608.[10]

Waiting until EPA proceeds to the risk management phase to include the use of OSHA-required PPE and related workplace standards creates a false impression of risk that lacks transparency, will be misleading to the public, and overestimates the risk of exposure in workplaces that require workers to follow PPE practices. In addition, it creates an extra layer of work for EPA and industries to work through the risk management phase when adequate protections may already be in place.

We recommend that EPA conduct its risk assessment of 1,3-butadiene and other TSCA chemicals incorporating standard industry safety practices as reflected in Material Safety Data Sheets and OSHA requirements.

V. Conclusion

Auto Innovators requests that EPA consider our comments as EPA moves forward with a final risk evaluation and risk management strategy for 1,3-butadiene.

EPA should reconsider the two referenced risk determination policy approaches—the whole chemical approach and PPE usage—that it has applied in this assessment of 1,3-butadiene. As discussed in detail above, there appears to be no significant benefit to adopting a whole chemical approach in risk determinations; rather, it results in less clarity in several scenarios. Nor are there any clearly articulated benefits to assessing exposure for workers in OSHA-covered facilities without the use of PPE. Auto Innovators recommends that EPA continue to assess individual conditions of use for each chemical and make any "no unreasonable risk" findings at the final risk determination phase via 6(i)(1) orders for those uses. We also recommend that EPA continue to assess worker exposures by applying OSHA workplace requirements, which are standard industry practice for our

[10] 15 U.S.C. § 2608(a)(1) states that: "…the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A) (i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register."

sector. If EPA is concerned about workplaces that are not subject to OSHA requirements, then adding an exposure estimate specific to that concern may be appropriate if clearly identified as such.

Thank you for your consideration of our comments. We welcome any additional discussion or questions regarding this submission.

Sincerely,

Catherine Palin
Alliance for Automotive Innovation