March 3, 2022

Submitted via regulations.gov

Ms. Sarah Cox
Office of Pollution Prevention and Toxics (7404T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Docket ID No: EPA-HQ-OPPT-2019-0237
Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment [86 FR 74082, December 29, 2021]

Dear Ms. Cox:

The Alliance for Automotive Innovation[1] (Auto Innovators) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA) draft risk determination "Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment"[2] (hereafter, "the draft revision"). This draft revision reflects the first time that EPA is implementing several significant changes in the approaches applied during risk determination, and in particular, the changes in assumptions used in the risk assessment that have resulted in substantial and impactful changes in EPA's HBCD risk findings, which will likely have a similar impact on future chemical risk evaluations.

In EPA's draft revision to the HBCD risk determination, EPA has stated:

> This draft revision supersedes the condition of use-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation (and withdraws the associated order) and makes a revised determination of unreasonable risk for HBCD as a whole chemical substance. In addition, this draft revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE).[3]

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[1] Formed in 2020, the Alliance for Automotive Innovation is the singular, authoritative and respected voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, the Alliance for Automotive Innovation represents the manufacturers producing nearly 99 percent of cars and light trucks sold in the U.S. The organization, a combination of the Association of Global Automakers and the Alliance of Automobile Manufacturers, is directly involved in regulatory and policy matters impacting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, technology and other automotive-related companies and trade associations. The Alliance for Automotive Innovation is headquartered in Washington, DC, with offices in Detroit, MI and Sacramento, CA. For more information, visit our website http://www.autosinnovate.org.

[2] 86 FR 74082, December 29, 2021. *Found at:* https://www.federalregister.gov/documents/2021/12/29/2021-28231/cyclic-aliphatic-bromide-cluster-hbcd-draft-revision-to-toxic-substances-control-act-tsca-risk.

[3] 86 FR at 74082.

EPA is requesting comment on its implementation of these new risk assessment approaches, such as the application of the whole chemical approach for HBCD and EPA's new policy of assuming that no occupational use of PPE should be considered in making an unreasonable risk determination for workers.

Auto Innovators is providing comments on the uses identified by EPA in this draft revision and on the implementation of EPA's new policy approaches. In addition, we raise concerns about the potential unintended consequences that those policies may have on unraveling the preemption provisions contained in TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act; public perception of real vs. worst-case scenario risks; and delaying certainty for the regulated community regarding conditions of use that do not pose an unreasonable risk and resultant resource investment in continued data collection and analysis and substitution identification.

I. HBCD Uses in the Automotive Manufacturing Sector

In March 2017, the predecessor organizations to Auto Innovators, the Association of Global Automakers (Global Automakers) and the Alliance of Automobile Manufacturers (Auto Alliance), submitted separate comments that reflected the then-current situation of HBCD uses in the automotive manufacturing sector.[4] A subsequent follow-up submission from the Auto Alliance, on behalf of its member companies, confirmed that HBCD is present only in legacy replacement parts and not in new production parts or vehicles. This submission stated: "[o]ur latest data collection efforts confirmed our earlier findings that HBCD is present only in automotive replacement parts and is not found in production parts."[5]

In the automotive industry, HBCD is no longer being used in new production parts or the manufacture of new replacement parts. The supply of replacement parts that may contain HBCD is continuing to diminish as parts are removed from the channels of trade and from the automobiles they service throughout their useful life. Due to several international regulations and treaties, the automotive sector phased out the use of HBCD in production parts and discontinued the use of HBCD in any new production of replacement parts. We understand our members are following the requirements of the Stockholm Convention, Japan's Chemical Substance Control Law (CSCL), the European Union's REACH requirements under Annex XIV, and Canada's voluntary HBCD phase-out program. Collectively these treaties and programs have assured that HBCD will no longer be used in the automotive sector. Further regulation of HBCD in the automotive sector will be duplicative of these existing requirements and will have little to no impact on a condition of use that is phasing itself out.

Based on the limited legacy uses of HBCD in replacement parts, which will eventually clear the channels of trade, these legacy parts will not contribute in any significant way to any risk found to be associated with HBCD, even when applying the whole chemical approach.

TSCA section 6(c)(2)(D) clearly states that the Administrator "shall" exempt replacement parts unless the Administrator makes the findings contained in section 6(c)(2)(D):

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[4] The manufacturing sector does not reflect uses in repair shops, including but not limited to secondary painting facilities.

[5] November 16, 2018, Auto Alliance letter to Douglas Parsons.

(D) Replacement parts
(i) In general
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. [*emphasis added*]

Based on the limited ongoing presence of HBCD in legacy replacement parts and the low potential for exposure associated with articles, such as replacement parts, these legacy parts do not contribute significantly to any risk posed by HBCD, including to workers, the general population, or a susceptible subpopulation. In fact, EPA did determine that automotive replacement parts do not pose an unreasonable risk in its September 2020 final risk determination.[6] This finding is still justified and appropriate. Thus, even with application of the whole chemical approach, EPA must continue its responsibility to consider and apply the provisions of TSCA section 6(c)(2)(D) and consequently exempt replacement parts.

In addition, and of significant consequence, there could be serious supply chain disruptions, costs to industry, and/or lapses in the ability to repair existing vehicles without access to these existing, but diminishing, supplies of legacy replacement parts containing HBCD.

Therefore, we recommend that EPA affirm the exemption for replacement parts based on the direction in TSCA section 6(c)(2)(D) and also exempt them from the scope of any risk mitigation measures being considered. To provide certainty to the regulated community, EPA should make this determination at the final risk determination phase, as it did in the previous September 2020 risk determination.[7]

II. EPA's Application of New Risk Evaluation Approaches

On June 30, 2021, EPA formally announced a "Path Forward for TSCA Chemical Risk Evaluations."[8] This document included new approaches and policies for risk evaluations that will have significant impacts on EPA's unreasonable risk determinations as demonstrated in the draft revision for HBCD. These policy changes include: (1) the adoption of a whole chemical approach where EPA plans to make the determination of unreasonable risk just once for the whole chemical when it is clear to EPA that the majority of the conditions of use warrant one determination; and (2) assessments that assume no use of personal protective equipment (PPE) in workplace environments.

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[6] EPA, Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD). September 2020, p. 496. https://www.epa.gov/sites/default/files/2020-09/documents/1._risk_evaluation_for_cyclic_aliphatic_bromide_cluster_hbcd_casrn25637-99-4_casrn_3194-5_casrn_3194-57-8.pdf.

[7] If for some reason EPA chooses to proceed with risk mitigation for legacy replacement parts, which would not be appropriate given the current situation and the provisions of TSCA section 6(c)(2)(D), EPA needs to provide a safe harbor provision in any rule that allows replacement parts to be able to clear the channels of trade. We would recommend a minimum ten-year sell down time for that provision to be effective but would work with EPA to determine the appropriate timing for complex products with long useful and service lifetimes.

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

Based on the application of the whole chemical approach and considerations regarding PPE, the HBCD draft revision has significantly expanded the conditions of use now found to pose an unreasonable risk and raises new implementation questions that impact certainty for the regulated community.

A. EPA's Movement to a Whole Chemical Approach May Have a Series of Unintended Consequences that Conflict with Some of the Major Goals of TSCA

Prior to the issuance of this draft revision for HBCD, EPA's risk determination approach had been to make separate unreasonable risk determinations for every relevant condition of use of a chemical. The conditions of use 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."[9] 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. For HBCD, 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 application of a whole chemical approach reduces the clarity and certainty, which were provided by the previous approach of making separate determinations of unreasonable risk for every condition of use of a chemical. The consequences of this new approach will result 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.

1. First Ten TSCA Work Plan Chemicals

Our comments on permanent preemption for the first 10 Work Plan chemicals are based on our understanding that: (1) the first 10 Work Plan chemicals are exempt from pause preemption; and (2) permanent preemption is triggered when EPA issues a final Agency action related to the chemical(s). A final agency action would include an order under TSCA section 6(i)(1) or any final rule issued by EPA related to the chemicals.

EPA's implementation of its whole chemical approach, combined with now a reluctance to make a no unreasonable risk determination at the final risk evaluation stage, appears to undermine or potentially ignore the intent of TSCA section 6(i)(1):

> (i) FINAL AGENCY ACTION.—Under this section and subject to section 18—
> (1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health, or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order[.]

[9] TSCA Section 3(4): Definitions.

EPA has announced that it intends to withdraw the previously issued TSCA 6(i)(1) orders for those conditions of use for which no unreasonable risk was found for all the first 10 risk evaluations. Since TSCA does not provide for pause preemption when EPA is preparing risk evaluations for the initial batch of 10 Work Plan chemical substances (i.e., those that must be identified under section 6(b)(2)(A) of TSCA[10]), if risk findings are not made separately for each condition of use for these chemicals based on the final risk evaluation, orders of "no unreasonable risk" will not be issued. As a result, states may implement patchwork regulations on all uses until EPA issues a final risk mitigation rule. At the time of a final risk mitigation rule, permanent preemption would apply to both uses found to present an unreasonable risk and those found not to present an unreasonable risk unless EPA were to grant a permanent preemption waiver to a state that could show good cause for a separate and different approach. Given the length of time between EPA's initial risk determinations for the 10 Work Plan chemicals and the time that a final risk management rule may be issued, states may choose to fill the void with their own risk management programs and use that as justification for requesting and receiving a waiver from preemption. In that case, conditions of use that EPA ultimately finds present no unreasonable risk may be captured in these potential state programs.

For example, in the September 2020 HBCD final risk evaluation, the determinations that certain conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1). This action was considered a final Agency action and precluded states from promulgating risk management rules for those conditions of use covered by TSCA section 6(i)(1) orders. If EPA were to withdraw those orders and issue a risk evaluation that HBCD as a whole chemical poses an unreasonable risk, states would be free to promulgate risk mitigation measures until such time as EPA promulgates a final risk management rule.

One of the compelling TSCA amendments was the preemption provision that provided assurance that in most cases TSCA regulatory actions would preempt a patchwork of inconsistent state regulations of the same chemical. By issuing orders of "no unreasonable risk" findings at the final risk evaluation phase for certain conditions of use, those specific uses would automatically be granted permanent preemption, effective at the time the TSCA section 6(i)(1) orders were issued. These final agency actions would preclude any inconsistent state regulations.

To manufacture an automobile to meet multiple and often inconsistent individual state chemical regulations would be technically and economically prohibitive. The consequence of allowing states to issue chemical regulations while EPA assesses a chemical and until EPA issues a final risk management rule could create an unworkable and confusing set of requirements for any sector, including the automotive sector.

While EPA has announced intent to withdraw the TSCA section 6(i)(1) orders for the 10 Work Plan chemicals, Auto Innovators believes there is no compelling reason to withdraw these orders at this time. These orders could, and should, remain in place until EPA has completed its second round of final risk evaluations for the 10 Work Plan chemicals and has determined which conditions of use would be subject to risk management action. By keeping these orders in place, EPA would have time to review additional input that will be submitted on the revised draft risk evaluations for the 10 Work Plan chemicals and adjust their unreasonable risk findings as appropriate.

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[10] EPA, "TSCA Work Plan Chemicals." Found at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals.

Given that EPA's new assumptions about the use of PPE (discussed further below) are driving many of the shifts to "unreasonable risk" determinations, it is highly likely that risk determinations will be revised to their original "no unreasonable risk" findings. Auto Innovators recommends that EPA maintain the TSCA section 6(i)(1) orders for the first 10 Work Plan chemicals until the risk management rule is completed. As part of the rulemaking process, EPA can propose to remove these orders, given new risk determinations and its proposal to manage such risks, and then as part of the final risk management rule, EPA can finalize the withdrawal of the orders, if this action is needed. This approach would provide industry with more certainty surrounding the conditions of use that have already been evaluated, until such time as the risk management rule supersedes any existing orders.

2. High Priority Substances

While the first 10 Work Plan chemicals have been exempted from the application of pause preemption, EPA's revised approach also raises questions about the application of preemption for the high priority substances. These concerns are based on our understanding that: (1) chemicals designated as high priority substances under TSCA are subject to pause preemption, and that pause preemption is activated when EPA issues the scoping document for a high priority substance; (2) pause preemption ceases when EPA issues a final risk evaluation or reaches the statutory deadline for publication of the final risk evaluation; and (3) permanent preemption is activated when EPA issues a final Agency action related to the chemical(s). A final agency action would include an order under TSCA section 6(i)(1) or any final rule issued by EPA related to the chemicals. Our comments also assume that EPA will adopt a whole chemical approach for the majority of the high priority substances, given the volume of uses for each of these chemicals, and assume that no PPE is used by workers, occupational non-users, and consumers.

Based on the current changes in the HBCD draft revision, a whole chemical approach is likely to interfere with long-term preemption for the high priority substances. As with the 10 Work Plan chemicals, if EPA takes a whole chemical approach for the high priority substances, EPA will not issue 6(i)(1) orders at the final risk determination stage, which would cease pause preemption, and as a result, states may implement regulations on all uses until EPA issues a final risk mitigation rule. It is unclear what benefit is to be gained by extending the period before EPA signals that a condition of use does not present an unreasonable risk. Choosing to create a lengthy period of uncertainty when some conditions of use could be removed from regulatory consideration appears to have no upside.

B. Assumptions that Personal Protective Equipment Is Not Routinely Used

In the initially issued final risk evaluations for the 10 Work Plan chemicals, estimates of worker exposure were calculated both with and without the use of PPE, assuming the use of PPE as stipulated by the Occupational Safety and Health Act (OSHA) standards. Since then, EPA has determined that it is now more appropriate to assume that PPE is not used by workers when making a risk determination. Instead, information on 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, as follows:

Use of Personal Protective Equipment

> 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.
>
> *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*.
>
> 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.[11] [*emphasis added*]

EPA further clarifies this approach in the HBCD draft revision, stating:

> Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.[12]

Nonetheless, EPA's plan to incorporate information on use of PPE or other industry practices used to protect workers only during the risk management process will likely impact risk determinations for some conditions of use for the first six of 10 Work Plan chemicals, but also for a majority of the high priority substances currently undergoing risk determination.

Further, 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

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[11] 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.
[12] 86 FR at 74082.

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 OSHA standards are at a greater exposure risk, using TSCA in place of the OSHA through this 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 OSHA. 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 OSHA, 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's 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 HBCD draft revision, 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.[13]

Moreover, the first 10 risk evaluations already include exposure analysis with and without PPE. If EPA feels compelled to assess chemicals with and without PPE, then Auto Innovators recommends that it continue the approach of presenting both scenarios in its risk determinations for all future risk determinations – with and without PPE. This dual scenario would provide the appropriate bounding scenarios for risk exposures in the workplace. Moreover, when businesses provide information during the risk determination stage that demonstrates compliance with PPE and/or other information that demonstrates workplace exposures are limited or minimal, e.g., a closed-loop manufacturing process, then EPA should apply that information as part of the risk determination.

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

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[13] 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."

and industries to work through the risk management phase, when adequate protections may already be in place.

In ensuring appropriate and necessary workplace protection, workers should be given high priority. The auto industry employs millions of workers at our U.S.-based facilities and has spent decades designing safe and compliant workplaces for our workers and building state-of-the-art manufacturing facilities to efficiently, safely, and consistently produce the vehicles that our customers rely on. It is our intent to work with EPA to find ways to make sure that EPA is accurately accounting for the protections in place in our facilities, identifying risks where real exposures may be occurring and appropriate use scenarios. In addition to assessing risk with and without PPE use, it would be appropriate for EPA to review and revise its modeling assumptions specific to automotive manufacturing to ensure it reflects the state-of-the-art facilities used today. We have raised this issue on several occasions with EPA staff but have not seen any updated models that reflect current industry practices.

III. Conclusion

Based on the limited supply of legacy replacement parts that remain in commerce, the fact that new production parts do not contain HBCD and our industry's compliance with a series of international HBCD requirements, EPA should exercise its authority under TSCA section 6(c)(2)(D) and categorically exempt replacement parts from further review and regulation for HBCD.

We also recommend that EPA reconsider the two new risk determination policy approaches that it has applied in this draft revision of HBCD. As discussed in detail above, there appears to be no significant benefit to adopting a whole chemical approach in risk determinations. Instead, this approach results in less clarity in several scenarios, without any clearly articulated benefits to assessing exposure for workers in OSHA-covered facilities without the use of PPE. We recommend 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. At a minimum, if EPA proceeds with the current approach, EPA should maintain the existing 6(i)(1) orders until the final risk management rule is effective.

Issuing "no unreasonable risk" orders would allow EPA, the regulated community, and the public to focus time and resources on any uses that pose an unreasonable risk. We also recommend that EPA continue to assess worker exposures by applying OSHA workplace requirements, which are standard industry practice for our 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. Finally, we recommend that EPA work with OSHA if unreasonable risks in any circumstances are identified.

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

Sincerely,

Julia M. Rege
Vice President, Energy & Environment