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

Alaa Kamel, Ph.D.  
Mission Support Division, Office of Program Support  
Office of Chemical Safety and Pollution Prevention  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, DC 20460–0001

RE: Tris(2-chloroethyl) Phosphate (TCEP); Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Letter Peer Review; Notice of Availability, Public Meeting and Request for Comment

Dear Mr. Karmel:

The Alliance for Automotive Innovation<sup>1</sup> (Auto Innovators) appreciates the opportunity to provide comments on EPA's draft risk evaluation for Tris(2-chloroethyl) Phosphate (TCEP). EPA is seeking public comment on both the draft risk evaluation and the draft charge questions for the letter peer review.

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.

Because this is the first draft risk evaluation EPA has released for one of the 20 High-Priority Substances prioritized in 2019, our comments and recommendations will address not only specific issues and concerns with this draft evaluation for TCEP but also policy and procedural issues that should be considered for future risk evaluations. Regarding TCEP, our understanding of findings presented in the draft risk evaluation are that EPA proposes to determine that TCEP, as a whole chemical substance, presents unreasonable risk to human health and the environment.

### **Comments and Recommendations**

Our comments address concerns and recommendations for the following issues:

- A. TSCA Section 6(c)(2)(D) and (E): Risk Evaluations for Articles and Replacement Parts
- B. Lack of Consideration of Minimal Risks Associated with *De Minimis* Levels
- C. Assumptions Regarding Use of Personal Protective Equipment (PPE) and Other Exposure Controls

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<sup>1</sup> 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](http://www.autosinnovate.org).

- D. Preemption: No Unreasonable Risk Determination and Issuance of TSCA Section 6(i)(1) Orders
- E. Questions for Peer Review Panel

#### **A. TSCA Section 6(c)(2)(D) and (E): Risk Evaluations for Articles and Replacement Parts**

Articles and replacement parts are separate conditions of use (COUs) specifically enumerated in the Lautenberg Chemical Safety Act (LCSA) provisions that amended TSCA in 2017. Recognizing these separate COUs are likely to present a much lower exposure potential and subsequent risk profile, LCSA prescribed specific assessment requirements in order to ensure that risk mitigation measures were applied to both these categories only to the extent necessary to address any unreasonable risk that they pose. Therefore, EPA must assess the risk for these COUs separately from the consideration of the chemical as a whole.

Understanding how and when in the process EPA will consider the unique regulatory language that applies to articles and replacement parts is of paramount importance to our members. Taken together, these two categories of potential COUs account for a significant portion of our industrial activities that may be subject to TSCA regulation. The earlier in the risk evaluation process that EPA applies the considerations in these two exposure assessment requirements and makes a determination regarding risks associated with articles and replacement parts, the more focused an effort our members can make on COUs that may be of concern.

##### 1. Articles

Statutory language in the LCSA directs EPA to take a more focused and narrow approach when identifying articles that the Agency believes need to be managed under TSCA Sections 4, 5 or 6.

(E) ARTICLES.—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).<sup>2</sup>

The intent of this new provision was to recognize that, for the most part, articles do not pose the same exposure (and subsequent risk) concerns as the chemicals that may have been used in the manufacture (including import), processing and use of those articles.

TSCA Section 6(c)(2)(E) provides EPA with the authority to regulate articles, but 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)” (emphasis added).

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<sup>2</sup> 15 U.S.C. § 2605(c)(2)(E) (emphasis added).

In this draft risk evaluation, EPA has not identified what exposure(s) are occurring as a direct result of the “exposure to the chemical substance or mixture from the article.” EPA does not appear to have recognized the distinction between the exposures, risks, and impacts associated with direct chemical exposure versus any potential limited or negligible exposure to a manufactured article. The draft risk evaluation for TCEP does not independently assess the exposure or risks associated with any potential exposure to articles, other than articles used in the aerospace sector.

Specifically, EPA does not expect significant releases to occur during the installation of TCEP containing aircraft and aerospace articles into or onto the relevant transportation equipment. After TCEP-containing resins have cured, EPA expects TCEP release will be limited by the hardened polymer matrix. Releases may occur via the mechanism of “blooming” or volatilization from the cured resin surface during the service life of the aircraft or aerospace article, but EPA expects that releases via this mechanism during installation activities will be negligible.<sup>3</sup>

Import and installation of articles used in the manufacture of automobiles present a similar profile to those used in the aerospace sector. Chemicals used in these articles are bound up in the article itself and exhibit a negligible potential for exposure. To reiterate EPA’s own determination: “After TCEP-containing resins have cured, EPA expects TCEP release will be limited by the hardened polymer matrix. Releases may occur via the mechanism of “blooming” or volatilization from the cured resin surface during the service life of the aircraft or aerospace article, but EPA expects that releases via this mechanism during installation activities will be negligible.”<sup>4</sup>

Further, EPA recognizes that “[i]n installation of articles are not expected to lead to significant releases because the articles are expected to already be in final form (e.g., electronic potting) and not expected to undergo further processing (i.e., shaping, sanding cutting, etc.).”<sup>5</sup>

An exposure assessment conducted for purposes of TSCA Section 6(c)(2)(E) would demonstrate that, similar to the aerospace sector and EPA’s specific identification of “transportation equipment” as presenting “no unreasonable risk,” articles used in the manufacture of automobiles should be included in the no unreasonable risk determination category.

*Recommended Revision:*

We request that EPA include industrial and commercial uses for automotive articles, equipment, and products in its identification of COUs that “were determined not to contribute to the unreasonable risk.”

## 2. Replacement Parts

Statutory language in the LCSA directs EPA to exempt replacement parts for complex durable goods under certain conditions.

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<sup>3</sup> Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP), U.S. Environmental Protection Agency (Dec 2023) at 147, available at [https://www.epa.gov/system/files/documents/2023-12/tcep\\_draft\\_risk\\_evaluation\\_20231207\\_hero\\_public\\_release.pdf](https://www.epa.gov/system/files/documents/2023-12/tcep_draft_risk_evaluation_20231207_hero_public_release.pdf).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 49.

(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.<sup>6</sup>

As in the previous discussion regarding the low exposure potential of articles, replacement parts pose little to no potential for exposure to the chemicals that were used to manufacture them, except for when specific risk has been evaluated and assessed by EPA's risk evaluation process. In previous rulemakings such as the proposed rule for Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),<sup>7</sup> EPA has accurately recognized that both new and replacement parts for the automotive sector pose little to no risk based on low concentrations.<sup>8</sup>

Replacement parts are also considered articles (for the most part) and, consistent with the issues presented above under the articles discussion, present a distinctly different exposure pattern than exposure to the chemical itself—in this case TCEP. As EPA has recognized, “[i]nstallation of articles are not expected to lead to significant releases because the articles are expected to already be in final form (e.g., electronic potting) and not expected to undergo further processing (i.e., shaping, sanding cutting, etc.).”<sup>9</sup> Thus, Auto Innovators recommends that this same assertion be applied to replacement parts.

Our understanding of the nexus between the risk assessment and risk management stages of TSCA is that risk management will be based on the findings of the final risk evaluation. Exposure assessments for articles and replacement parts will not be conducted during the risk management phase but rather must be conducted during the risk assessment step in order for consideration to be given to the application of TSCA Section 6(c)(2)(D) and (E). If the exposure assessments for articles and replacement parts are not done as directed, risk mitigation measures may exceed the “only to the extent necessary” standard and lack consideration of the “shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication” standard.

*Recommended Revision:*

We request that EPA include automotive replacement parts in its identification of COUs that “were determined not to contribute to the unreasonable risk.” We ask that EPA consider assessing replacement parts as early in the exposure assessment process as possible. By adopting this approach, EPA would allow the automotive sector to focus on collecting information and data on conditions of use where exposure may be of concern. If EPA does have data or information indicating that exposure to a specific chemical presents a risk as a result of its use or presence in a

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<sup>6</sup> 15 U.S.C. § 2605(c)(2)(D)(i).

<sup>7</sup> 84 Fed. Reg. 36,728 (July 29, 2019).

<sup>8</sup> *Id.* at 36,745 (“EPA is also not generally proposing to use its TSCA section 6(a) authorities to regulate commercial use of products containing the PBT chemicals. ... EPA believes that, for most products containing the PBT chemicals, it would be either extremely burdensome, for vehicles, or unreasonable, because of the low concentrations of PCTP in golf balls, for example, and, thus, impracticable to prohibit or otherwise restrict the continued commercial use of the products”).

<sup>9</sup> Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) at 49.

replacement part, then LCSA directs that inclusion of these conditions of use for further evaluation would be warranted.

## **B. Lack of Consideration of Minimal Risks Associated with *De Minimis* Levels**

In this draft risk evaluation EPA has identified NOELs and Lowest Observable Effects Levels (LOELs) for TCEP.<sup>10</sup> We are concerned, however, that EPA did not address circumstances where a *de minimis* level of TCEP may result in no risk or a negligible risk. Nowhere in the draft risk evaluation or notice does EPA cover how they have addressed (or will address in future evaluations and rules) exposures that fall below a No Observable Effect Level (NOEL). While this may not be appropriate for all chemicals, there should be some discussion and recognition of NOELs and how EPA will compare *de minimis* levels in articles and mixtures to the NOEL for each chemical. Given that EPA is relying on peer reviewed studies to put forward these levels, EPA should set a *de minimis* threshold below which any potential exposure would not present an unreasonable risk.

EPA has previously 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,<sup>11</sup> 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 § 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).<sup>12</sup>

### *Recommended Revision:*

We recommend that EPA identify a *de minimis* level for TCEP and other TSCA chemicals below which EPA has no reasonable basis to conclude that there is an unreasonable risk. We support EPA's rationale for establishing a *de minimis* reporting level as articulated in the LCPFAC supplemental proposal. It is an approach consistent with other EPA reporting requirements, as well as other federal and international chemical regulatory schemes. We recommend that EPA establish a *de minimis* threshold for chemicals in articles and mixtures based on a "reasonable potential for exposure." A standard default *de minimis* of 0.1% would allow EPA to focus on major sources and would allow for more effective use of the automotive industry's long-term investment in its International Material Data System. EPA could use a data-driven approach to establish alternative threshold levels if appropriate.

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<sup>10</sup> *Id. passim.*

<sup>11</sup> 85 Fed. Reg. 12,479 (Mar. 3, 2020).

<sup>12</sup> *Id.* at 12,482.

### **C. Assumptions Regarding the Use of PPE and Other Exposure Controls**

When conducting risk evaluations, EPA makes several assumptions regarding the use of personal protective equipment (PPE). Those assumptions do not include the use of all PPE as required by the National Institute for Occupational Safety and Health (NIOSH) and/or EPA. Since the safety and protection of our industry's workers remains one of the highest priorities at our facilities, the automotive industry maintains procedures and worker requirements that meet or exceed the recommended safety protections and PPE. It is therefore important that EPA base its evaluations on manufacturing scenarios where the automotive sector is fully utilizing all required PPE.

By adopting an assumption during the risk assessment phase that no PPE is used, there is a great potential to overestimate risk. By adopting this approach, EPA also fails to recognize that many other worker safety practices are in place at our industrial facilities—many of which are more protective than traditional PPE. Our facilities strive as a first step to eliminate or control all serious potential hazards. We select controls according to a hierarchy that emphasizes engineering solutions (including elimination or substitution) first, followed by safe work practices, the use of certification and training as a tool for risk management, administrative controls, and finally PPE. Our facilities follow OSHA requirements and where PPE is required, we strive to comply with those requirements. If EPA believes that some facilities may not follow OSHA requirements, then EPA needs to identify those facilities and target risk mitigation to those facilities.

Further, if EPA believes that assuming the use of PPE in workplace facilities will underestimate potential exposure to certain subpopulations of workers, assuming no use of PPE in any workplace will overestimate worker exposure. 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. If EPA believes that workers not covered by OSHA standards are at a greater exposure risk, using TSCA in place of the Occupational Safety and Health Act through this workaround approach is inappropriate.

#### *Recommended Revision:*

We recommend that EPA ensure that OSHA workplace standards and requirements of the OSHA general duty clause be taken into consideration when assessing the potential exposures associated with any industrial use of TCEP including maintenance, and cleaning activities. We believe that when EPA takes these workplace practices into consideration, it will find that exposures in the workplace would present only de minimis exposures or otherwise insignificant risks.

### **D. Preemption: No Unreasonable Risk Determination and Issuance of TSCA Section 6(i)(1) Orders**

Our understanding is 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 chemical(s).

We request that when EPA issues its final risk evaluation for TCEP (and all subsequent high priority chemicals), EPA also issue TSCA Section 6(i)(1) orders for COUs that have been determined to pose no unreasonable risk. This will provide some degree of certainty for the regulated community and safeguard against a patchwork of state and local regulations that create an unworkable regulatory environment for goods entering commerce across the nation.

#### **E. Questions for Peer Review Panel**

In addition to the questions that EPA staff have identified for the Peer Review Panel, we request that the following questions be included in the Panel charge.

1. Has EPA taken into consideration the lower exposure potential associated with a chemical that is bound up in an article? For example, has EPA assessed the exposure to TCEP in cured paints versus as a paint additive?
2. Has EPA appropriately assessed exposure to articles and replacement parts as directed by TSCA Section 6(c)(2)(D) and (E)?
3. Is it appropriate for EPA to assume that no PPE or other exposure controls are in place in workplaces where TCEP is present? Does this approach overestimate the risk? At a minimum, should EPA conduct exposure assessments that assess risk both with and without OSHA-required risk mitigation requirements?

#### **Conclusion**

We appreciate the opportunity to provide comments on this draft risk evaluation. Our goal in providing these comments is to work with EPA to develop risk assessments that provide a realistic and defensible evaluation of potential exposures and subsequent risks. These assessments are a critical step in the risk management process, and if inaccurate they will result in over- (or under-) management of chemical risk, while many of the subject chemicals serve essential functions and have no currently available drop-in substitutes.

Performing the exposure assessments required by TSCA Section 6(c)(2)(D) and (E) is an essential component of the risk assessments for the high priority chemicals. Auto Innovators urges EPA to develop specific assessments for articles and replacement parts to avoid unnecessary risk mitigation controls. Similarly, failing to establish a *de minimis* level for a chemical where no risk would be present would result in the application of risk mitigation measures that may be unnecessary and overly burdensome.

EPA's assumptions regarding the use of PPE and other exposure controls have resulted in an overestimation of exposure and risk. At a minimum, EPA should assess exposure both with and without PPE and other exposure controls in order to ensure a realistic risk assessment.

We further recommend that EPA pose the questions we have provided to the Peer Review panel members for an independent opinion on how EPA has been assessing articles and replacement parts.

I would be happy to provide any additional information on behalf of our members.

Sincerely,



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