



**AUTO ALLIANCE**  
DRIVING INNOVATION®



June 19, 2019

*Comments submitted electronically to federalregister.gov*

Ana Corado  
Chemical Control Division  
Office of Pollution Prevention and Toxics  
Office of Chemical Safety and Pollution Prevention  
Environmental Protection Agency (Mailcode 7408M)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

**Subject:** “Initiation of Prioritization Under the Toxic Substances Control Act (TSCA)”; Docket ID: EPA-HQ-OPPT-2019-0131

Dear Ms. Corado:

We are writing on behalf of the members of the Alliance of Automobile Manufacturers (Alliance) and the Motor & Equipment Manufacturers Association (MEMA) and appreciate the opportunity to provide comments to the US Environmental Protection Agency (EPA or Agency) on the “Initiation of Prioritization Under the Toxic Substances Control Act (TSCA).”

The Alliance is the leading advocacy group for the auto industry, representing automakers who build 70% of all cars and light trucks sold in the United States. Alliance members are BMW Group, FCA US LLC, Ford Motor Company, General Motors, Jaguar Land Rover, Mazda, Mercedes-Benz USA, Mitsubishi Motors, Porsche, Toyota, Volkswagen Group of America, and Volvo Car USA. Headquartered in Washington, DC, the Alliance also has offices in Sacramento, California and Detroit, Michigan. The Alliance is committed to developing and implementing constructive solutions to policy challenges that promote sustainable mobility and benefit society in the areas of environment, energy, and motor vehicle safety.

Automakers employ tens of thousands of skilled workers in all 50 states and support more than 7.25 million jobs across the nation, with 44 vehicle assembly facilities in 14 states.<sup>1</sup> These good-paying jobs include a wide-range of opportunities that support families and communities nationwide.<sup>2</sup>

Automobile manufacturing drives an astonishing 953 billion dollars in economic activity in the United States every year, from sales to service and from paychecks to tax revenue.<sup>3</sup> The automotive sector constitutes the nation’s largest manufacturing sector and accounts for more than 3% of the gross domestic product.<sup>4</sup>

MEMA represents more than 1,000 companies that manufacture new original equipment (OE) and aftermarket components, systems, and materials for use in passenger cars and heavy trucks.<sup>5</sup> The motor vehicle components manufacturing industry is the nation’s largest direct employer of manufacturing jobs – employing over 871,000 workers in all 50 states – with a total employment impact of 4.26 million jobs.<sup>6</sup> MEMA members develop and produce a multitude of technologies and a wide range of products, components, and systems that make vehicles safer, more efficient, and with reduced emissions.

Automakers and auto suppliers have a long history of corporate stewardship with regard to identifying and reducing specific chemicals or “substances of concern” in automobiles. For more than a decade, automakers have maintained an industry-focused Global Automotive

---

<sup>1</sup> Center for Automotive Research, “Contribution of the Automotive Industry to the Economies of All Fifty States and the United States” January, 2015.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

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

<sup>5</sup> MEMA represents its members through four divisions: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); Motor & Equipment Remanufacturers Association (MERA); and, Original Equipment Suppliers Association (OESA).

<sup>6</sup> “The Employment and Economic Impact of the Vehicle Supplier Industry in the U.S.” based on research undertaken by IHS Markit on behalf of MEMA, January 2017.

Declarable Substance List<sup>7</sup> (GADSL). The GADSL provides certain information about substances relevant to automotive parts and materials furnished by the supply chain to automobile manufacturers. The information is applicable to the use of these parts or materials in the production of a vehicle throughout its lifecycle.

The automakers and suppliers also maintain a sophisticated tracking database, the International Material Data System<sup>8</sup> (IMDS) to actively reduce industry-wide use of substances of concern in global production. The auto industry has invested more than \$2 billion in this system, which now tracks more than 3,000 substances used in automotive components to ensure that restricted substances are not in our products.

We use these advanced techniques to be at the forefront of chemical tracking, management, and stewardship often voluntarily eliminating materials ahead of regulations. For example, through a voluntary national memorandum of understanding, automakers and auto suppliers have eliminated the use of mercury-containing switches and are ahead of schedule in eliminating copper in brake pads. The auto industry continually looks for ways to minimize potential exposures to substances of concern.

## **I. Introduction**

Under TSCA Section 6(b), EPA must implement a new prioritization process to determine if chemical substances are a high priority (HP) or low priority (LP) for risk evaluation. Prioritization is the initial step in evaluating existing chemicals and provides a mechanism for EPA to designate whether a chemical substance requires further risk evaluation or whether risk evaluation is not warranted.

---

<sup>7</sup> <https://www.gadsl.org/>.

<sup>8</sup> <https://www.mdssystem.com/imdsnt/startpage/index.jsp>.

On March 21, 2019, EPA issued a list of 40 chemicals which triggered the prioritization process. Under TSCA, publication of the list of 40 chemicals in the Federal Register (FR) activated the prioritization process and thus the statutory requirement for EPA to complete the prioritization process in the next nine to twelve months. Therefore, EPA must designate 20 chemicals as high priority and 20 chemicals as low priority by December 22, 2019.

As this is an unprecedented event in policymaking, Alliance and MEMA appreciate EPA providing us with the opportunity to comment on candidate chemicals in advance of prioritization and to be part of the rulemaking process. We realize that the approach developed now will guide EPA's chemical regulatory decisions in the future.

## **II. Appreciation for EPA's Efforts to Date**

We would like to begin by thanking EPA for employing many favorable elements outlined in its pre-prioritization working approach document, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization"<sup>9</sup> (Prioritization White Paper). The procedural guidance put forth in that document was well-developed in many areas such as methods for data searches and we appreciate EPA's transparency in describing its sources of information accordingly. We appreciate that EPA defined the literature search and selection strategies that it used to identify the most relevant data for consideration in the pre-prioritization process. We support EPA's approach of applying peer review and rigorous quality control and quality assurance reviews to ensure data used to support its conclusions will be robust.

The Prioritization White Paper also supports an iterative process, which EPA is engaging. To ensure consistency and objectivity in this process, it is critical that EPA continues to provide transparency and accept public input throughout its pre-prioritization and prioritization

---

<sup>9</sup> 83 Fed. Reg. 50366, Oct. 5, 2018.

processes. The iterative nature of the process, allowing for re-evaluation and potential changes to the methods at several points throughout the course of the development of this novel policy, is critical for its success. For example, as new information emerges, or if EPA realizes that a particular previous choice (*e.g.*, a specific search strategy) did not perform as expected the Agency may revise its approach as needed.

And in the spirit of the cooperative method, we urge the Agency to consider the points put forth in these comments:

- Transparency and Information Exchange Is Critical to the Success of Future Pre-Prioritization Efforts
- The Comment Period Should be Extended During Pre-prioritization
- EPA Should Not Pre-Determine the Outcome of the Prioritization Process During the Pre-Prioritization Phase as Suggested in § 702.5(a)-(b)
- Potential Problems with Streamlined Approaches
- EPA Should Define "Sufficiency of Information" and Address the Role of Data Gaps in Pre-prioritization
- EPA Should Strive to Use Current Sources of Information
- The Alliance Agrees that EPA Should Clearly Communicate How Final Priority Designations Should Be Interpreted
- "Fit-for-Purpose" Approach
- EPA Should Establish Risk-Based Screening Process and Criteria

### **III. Recommendations for Future Pre-Prioritization Efforts**

#### **a. Transparency and Information Exchange Is Critical to the Success of Future Pre-Prioritization Efforts**

We appreciate EPA's efforts to support a healthy information exchange to date, and we urge EPA to continue to seek input from the regulated community in future pre-prioritization efforts. Well-informed selections for prioritization will help prevent unwelcome surprises, both for the regulated community and for EPA.

Stakeholders then have the opportunity to productively gather information to help ensure that EPA's decisions during the prioritization process are well informed and not rushed and that chemicals are not misidentified.

**b. The Comment Period Should be Extended During Pre-prioritization**

We recognize that this 90-day comment period is intended to provide a chance for stakeholders to submit relevant information and we thank EPA for engaging chemical manufacturers, processors, and downstream users during the pre-prioritization phase. We acknowledge that EPA has requested specific chemical data including hazard and exposure potential, persistence and bioaccumulation information, production volumes, and other related data. Although we understand EPA's need and appreciate this opportunity, we must remind EPA that collecting specific chemical data is time and resource intensive. Although we have sophisticated data tracking and management tools as mentioned earlier, the systems do have limitations. Also, it takes considerable effort among Alliance members to gather information from a complex international supply chain, to aggregate the data, and then to analyze the information. Therefore, although Alliance and MEMA have used the IMDS to collect data on the conditions of use in articles, for the 20 HP candidate chemicals, we do not yet have data ready to share with EPA at this time. Additionally, we are still in the process collecting data on conditions of use in our automotive facilities. In conclusion, we look forward to continuing to work with EPA as the evaluation process continues. We plan to continue to exchange information with EPA but urge the Agency to consider providing six months lead time in future pre-prioritization efforts.

**c. EPA Should Not Pre-Determine the Outcome of the Prioritization Process During the Pre-Prioritization Phase as Suggested in § 702.5(a)-(b)**

EPA appears to have predetermined the outcome of the prioritization process during the pre-prioritization phase by selecting candidate chemicals the Agency

already considers to be High- or Low-Priority substances. Additionally, EPA has not proposed any alternate chemicals. Since EPA is now gathering additional information on hazard, exposure, and use, the ultimate priority designation of the substance may change. In future pre-prioritization efforts, it would benefit EPA to allow the data to drive the priority designation and not select substances with a predetermined outcome in mind. EPA should not separate candidates into potential High-Priority (§ 702.5(a)) and potential Low-Priority (§ 702.5 (b)) but instead merge the considerations into a singular section for potential candidates for prioritization. This way the Agency is not selecting chemicals that it has already predetermined are High- or Low-Priority Substances since doing so defeats the intent of the prioritization process.

**d. Potential Problems with Streamlined Approaches**

i. Categories

The Alliance understands that in future efforts to streamline the prioritization process, EPA may select categories of similar chemicals to prioritize together. Chemicals could be grouped into categories based on similar molecular structure, similar physical, chemical and biological properties, similar use in certain sectors, or similar exposure routes to humans or the environment.

While the Alliance understands the reasoning behind this approach, we urge EPA to consider how difficult, and even impossible, it can be for industry to obtain data on categories which may constitute hundreds of chemicals. If the EPA takes this approach, we urge the agency to make sure that the categories have clear and well-defined boundaries.

The Agency should further clarify the criteria used to define chemical categories, such as similarities on structure, biology, or use. Additionally, while nothing in the TSCA statute prohibits EPA from initiating the prioritization process on an "inactive" chemical (*i.e.*, a chemical that has not been used in U.S. commerce during the past ten years), EPA should indicate that "active" chemicals will be prioritized over "inactive" chemicals for the prioritization process.

The Alliance also urges EPA to continue to provide a CAS Number<sup>10</sup> for each chemical in the entire category. We are pleased that EPA provided Chemical Abstracts Service (CAS) Numbers for all of the current candidate chemicals. CAS Numbers are essential to ensure that the regulated community has proper notice of the specific chemicals that are subject to prioritization or may be in the future. Auto Alliance member databases are organized and searchable by CAS Number, but not by class descriptors (e.g., functional group, etc.).

Lastly, the Alliance has concerns that this approach will sometimes make it difficult to choose a chemical that is representative of an entire category—it is important to be sure that the chemical accurately depicts the level of concern appropriate for all the other chemicals associated with the category.

ii. Binning

The Alliance understands that in future efforts EPA may consider using a “binning” approach to group active substances on the TSCA inventory. The

---

<sup>10</sup> A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature.

binning approach would consider human hazard relative to exposure, ecological hazard relative to exposure, genotoxicity, susceptible subpopulations, persistence, and bioaccumulation. The binning process would use a tiered approach when considering toxicity information with various degrees of uncertainty.

The Alliance has several concerns with the binning approach. First, we urge EPA to clearly define binning and to make sure it is well understood that “binning” is not the same as “categories.”

The Alliance also urges EPA to explain how stakeholders can determine which chemicals in a category are high-priority and which are low-priority if the EPA does not identify chemicals by CAS Numbers.

**e. EPA Should Define "Sufficiency of Information" and Address the Role of Data Gaps in Pre-prioritization**

EPA does not define the term “sufficiency of information” in the context of initiating a chemical for prioritization. In the draft prioritization rule, EPA refers to the definition provided in EPA's Risk Characterization Handbook. However, the Handbook only vaguely defines sufficient information as "sufficient to provide evidence that the chemical can reasonably be anticipated to pose a hazard to humans." One would presume that sufficient information to warrant a hazard classification would be slightly different than sufficient information to initiate a chemical for prioritization. A clearer definition of "sufficiency of information" would help industry submit necessary information during the prioritization process.

Furthermore, the definition provided in EPA's Risk Characterization Handbook omits the exposure and use elements of the prioritization framework, even

though exposure is an integral part of the draft prioritization framework. As such, EPA should clarify the role of exposure data gaps in the pre-prioritization process. In the pre-prioritization stage, it is unclear if EPA will address all life cycle stages (direct use, indirect emission), near-field exposure to chemicals in consumer products and in-home sources, and far-field exposure to chemicals released into the environment. In addition, EPA needs to further clarify how the Agency will treat exposure data-gaps to meet the definition of "sufficiency of information" (*i.e.*, will the chemical automatically be initiated or will EPA request data from suppliers or use modeling software such as ExpoCast?).

**f. EPA Should Strive to Use Current Sources of Information**

EPA must rely upon "reasonably available" information in the prioritization process, which includes public literature and gray literature to identify information on toxicity and exposure. However, we urge EPA to strive to use the most current data and not rely on older data that has been updated. Using the most up-to-date literature review available will help ensure that EPA meets the TSCA requirement to use information in a manner consistent with the best available science.

**g. The Alliance Agrees that EPA Should Clearly Communicate How Final Priority Designations Should Be Interpreted**

The Alliance and MEMA appreciate that the Agency recognizes the importance of carefully communicating final priority designations to the regulated community and public given the potential for confusion or misinterpretation regarding the designation, specifically in a High-Priority designation. The Alliance and MEMA reiterate its request that EPA should explicitly convey that a High-Priority substance designation is not confirmation that the substance presents an

unreasonable risk. The EPA can provide this disclaimer language on its website, in each of the High-Priority designations in the Federal Registrar, or through other methods of transmission.

#### **IV. Recommendations for EPA in the Next Stage of the Prioritization Process**

##### **a. “Fit-for-Purpose” Approach**

In the EPA’s Final Rule<sup>11</sup> on procedures for prioritization, the agency determined that “certain activities generally should not be considered to be “conditions of use.” Thus, early in the prioritization process, EPA will identify the “circumstances” that constitute the “conditions of use” for each chemical substance.”<sup>12</sup>

Therefore, once the HP chemicals have been designated, we urge EPA to continue to use a “fit-for-purpose” approach in evaluating chemicals because the method can be tailored to meet the needs of each chemical. A chemical may meet the high priority criteria in only one or a small number of conditions of use, whereas in other conditions of use does not present an unreasonable risk at all. This is an important method to continue to employ because when EPA makes known the specific chemical uses it may be considering, it prevents stigmatizing large number of chemicals by incorrectly suggesting that entire categories of chemicals are unsafe for any type of use, regardless of exposure potential. We expect the proposed determination regarding conditions of use to be clearly presented for public comment in the next stage of prioritization.

---

<sup>11</sup> Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act. 82 Fed. Reg. 33753, July 20, 2017.

<sup>12</sup> *Id.* at 33755.

**b. EPA Should Establish Risk-Based Screening Process and Criteria**

The prioritization process fails to consider the hazard and exposure potential of a chemical substance together. EPA should not decouple the hazard and exposure elements from the risk equation and transform them into independent considerations. EPA should assess hazard and risk together. The Agency should consider the degree of hazard and exposure together, as a part of the risk-based screening process, before making a determination regarding the severity of the potential risk.

Exposure is a critical element of the risk-based screening process, particularly for chemicals encased in articles.<sup>13</sup> The use of a chemical to manufacture a finished product (*i.e.*, article) does not necessarily mean that the substance is available in the finished product or that users will be exposed to said chemical. Alliance and MEMA recommend that EPA specifically address chemicals used in articles, such as automobiles, and their low exposure potential because these chemicals are not designed to be released from the article and because the article is an interior component of the consumer product to which consumers are not generally exposed over the life of the product.

---

<sup>13</sup> Manufactured item which is formed to a specific shape or design during manufacture; which has end use function(s) dependent in whole or in part upon its shape or design during end use; and which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

V. **Conclusion**

In conclusion, Alliance and MEMA urge EPA to consider the issues we have raised in these comments. Please do not hesitate to contact us with questions or if we may provide additional information. We look forward to continuing to work with EPA as it moves forward through this process.



Stacy Tatman  
Director, Environmental Affairs  
Alliance of Automobile Manufacturers  
202.326.5551  
[statman@autoalliance.org](mailto:statman@autoalliance.org)



Laurie Holmes  
Senior Director, Environmental Policy  
Motor & Equipment Manufacturers Association  
202.312.9247  
[lholfmes@mema.org](mailto:lholfmes@mema.org)