

**Motor & Equipment Manufacturers Association**

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*Via Regulations.gov*

March 20, 2017

Ms. Wendy Cleland-Hamnett  
Acting Assistant Administrator  
Office of Pollution Prevention and Toxics  
William Jefferson Clinton Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460-0001

**RE: Notice of Proposed Rulemaking: Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act**  
[Docket No. EPA-HQ-OPPT-2016-0654]

Dear Ms. Cleland-Hamnett:

The Motor & Equipment Manufacturers Association (MEMA) offers the following comments in response to the Notice of Proposed Rulemaking (NPRM) "Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act" (Procedures for Chemical Risk Evaluation or Chemical Risk Evaluation) issued by the U.S. Environmental Protection Agency (EPA) on January 19, 2017.<sup>1</sup>

MEMA represents more than 1,000 companies that manufacture motor vehicle systems and component parts for use in the light- and heavy-duty vehicle original equipment and aftermarket industries.<sup>2</sup> Motor vehicle component manufacturers are the largest sector of manufacturing jobs in the U.S. and directly employ over 871,000 workers in all 50 states.

MEMA supported the passage of the "Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act" (LCSEA) amending the Toxic Substances Control Act (TSCA). MEMA is a proponent of a cohesive federal chemical law that provides certainty for our members who manufacture, supply and sell motor vehicle components across the United States. MEMA supports an updated federal chemical regulation framework that improves the regulation of chemicals in commerce that will give consumers and our customers confidence that chemicals are being used safely. The long-term success of LCSEA depends on a transparent, systematic, science-based procedure for evaluating the safety of chemicals. To that end, Procedures for Chemical Risk Evaluation is of interest to MEMA.

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<sup>1</sup> 82 Fed Reg 7562

<sup>2</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).



These comments are intended to align with MEMA's comments on the Inventory Reset and Process for Prioritization proposed rules.

MEMA provides the following recommendations to the NPRM on the Procedures for Chemical Risk Evaluation:

- Provide more details on how risk evaluations will be conducted;
- Take a flexible, but broad approach to conditions of use and risk evaluation scope;
- Exclude Department of Labor's Occupational Safety and Health Administration (OSHA) regulated uses from scopes of TSCA risk evaluations; and,
- Provide appropriate timeframes for stakeholder comment.

### **EPA Must Provide More Details on How Risk Evaluations Will Be Conducted**

MEMA urges the Agency to define and further explain terms and processes that will be used in the TSCA risk evaluations in the final rule. EPA declines to define statutory terms included in TSCA § 26 such as "best available science," and, "weight of evidence." EPA states that defining these terms would unduly restrict "the specific science that will be used to conduct the evaluations."<sup>3</sup> Further, the Agency explains that these terms will evolve and continue to change overtime.<sup>4</sup>

These terms need to be defined because these terms often have multiple definitions or mean different things to different stakeholders. The terms have also been around for decades and have not changed or "evolved." However, if the Agency feels the specific definitions need to be changed in the future, the Agency is always able to update the modifying definition in a future rulemaking. Other TSCA § 26 terms, such as "sufficiency of information," will be important for manufacturers and third party risk assessors to clearly understand. Stakeholders will need to recognize what types of data will be considered "sufficient" early enough in the process so that they can collect the relevant information prior to risk evaluation. Therefore, EPA must define in the final rule how these terms will be interpreted so the regulated community has transparency on how EPA will conduct risk evaluations.

### **EPA Must Take a Flexible, But Broad Approach to Conditions of Use and Risk Evaluation Scope**

MEMA supports EPA taking a broad approach on interpreting the term "conditions of use." MEMA agrees with EPA's interpretation that the statute directs EPA to evaluate all "intended, known, or reasonably foreseeable" uses of a chemical.<sup>5</sup> However, "conditions

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<sup>3</sup> 82 Fed. Reg. 7567

<sup>4</sup> 82 Fed. Reg. 4828

<sup>5</sup> 82 Fed. Reg. 7565



of use” should not be interpreted as meaning EPA needs to evaluate misuse and speculative future conditions of use.

Further, because our members are downstream processors, MEMA supports a broad-based approach for the risk evaluation scope. We support EPA making a safety determination on all individual conditions of use for the chemical substance outlined in the scoping document. If all conditions of use are looked at in the prioritization process, and then certain uses are dropped from the scope of the risk evaluation, then those uses remain open for state regulation. MEMA supported LCSA because we wanted a strong federal framework that preempts the state regulation of chemicals, preventing a burdensome patchwork of chemical regulations. If this approach is adopted, MEMA urges EPA to communicate the risk evaluation determination on every condition of use clearly and effectively.

MEMA also supports EPA’s proposal to “lock down’ the conditions of use included in a risk evaluation at the time of scoping. By providing opportunity for comment.”<sup>6</sup> We agree that it would not be practicable for EPA to meet the statutory deadlines if stakeholders are free to identify conditions of use later in the process.

EPA recognizes that TSCA sets up aggressive deadlines that will be challenging for EPA to meet. While, MEMA supports a broad approach on the scope of the risk evaluation, we acknowledge the Agency is allowed to use its discretion to make common-sense decisions about the scope of conditions of use considered in the risk evaluation. We also recognize that a more flexible approach – narrowing the conditions of use will be considered in the risk evaluation – will help free EPA to focus on the conditions of use more likely to present health and environmental concerns. If a more flexible approach is adopted, MEMA urges EPA to effectively communicate why each condition of use was not included in the scope of the risk evaluation. For instance, if some of the conditions of use for a chemical are determined to pose an unreasonable risk, and there are conditions of use for that chemical that were dropped from the scope of the risk evaluation, that sends confusing market signals for those conditions of use that were dropped.

Thus, MEMA supports EPA considering all conditions of use and using a broad-based approach for the risk evaluation scope as this approach to chemical risk evaluations will be beneficial to downstream users. This comprehensive approach will lead to a strong federal framework preempting state regulation and will allow downstream users more certainty and will avoid confusing market signals.

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<sup>6</sup> 82 Fed. Reg. 7566

### **EPA Must Exclude OSHA Regulated Uses from Scopes of TSCA Risk Evaluations**

The LCSEA specifically includes “workers” as possible category of “potentially exposed or susceptible subpopulation.” However, any consideration of worker exposure must acknowledge that worker exposures are regulated and under the jurisdiction of OSHA and the Occupational Health and Safety Act of 1970.

Further, Congress also left in TSCA § 9(d) which requires EPA to consult and coordinate with OSHA “for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdensome duplicative requirements on those subject to [TSCA] and for other purposes.” Before risk evaluations are scoped, EPA should ensure this consultation occurs. In instances where worker exposures do not present a significant risk of health impairment under current conditions of use, EPA should not include worker populations within the scope of the risk assessment as this is unduly burdensome and duplicative.

### **EPA Must Provide Appropriate Timeframes for Stakeholder Comments**

MEMA urges the Agency to provide a minimum of a 60-day comment period for the proposed scoping document and a minimum of a 60-day comment period for the draft risk evaluation. These documents are often complicated and lengthy; thus, collecting industry use data can be time consuming. The regulated community needs an appropriate timeframe to review and submit meaningful comments on these important documents.

MEMA welcomes the opportunity to work further with EPA on this and other critical TSCA framework issues. Please contact me at (202) 312-9247 or [lholmes@mema.org](mailto:lholmes@mema.org) if you have questions or require further information on these comments.

Respectfully Submitted,



Laurie Holmes  
Senior Director, Environmental Policy