March 17, 2017

Via Electronic Submission

Mr. Ryan Schmit
Immediate Office, Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. N.W.,
Washington, DC 20460-0001

Re: Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act - EPA-HQ-OPPT-2016-0636-0001

Dear Mr. Schmit:

The Independent Lubricant Manufacturers Association ("ILMA" or "Association") submits these comments on the Environmental Protection Agency’s ("EPA" or "Agency") proposed rule to establish internal procedures to prioritize existing chemicals under Section 6(b)(1)(A) of the Toxic Substances Control Act ("TSCA") as amended by the Frank R. Launtenberg Chemical Safety Act for the 21st Century ("LCSA"). Under the LCSA, EPA eventually must review every active chemical on the TSCA Inventory through implementation of "framework rules" that establish a "chemical review pipeline" to accomplish this undertaking, including the proposed prioritization rule.

ILMA generally supports those portions of EPA’s proposed rule that adhere to its statutory obligations under the LCSA to promulgate a final, risk-based screening rule that establishes the process and criteria to prioritize chemicals as either "high priority" for further risk evaluation or "low priority" for which no further evaluation is currently necessary. The Agency’s proposed steps of the prioritization process -- pre-prioritization, initiation, proposed designation, and final designation -- are a practical methodology that implement the statutory requirements while simultaneously providing for transparency and opportunities for public participation. ILMA, however, offers the recommendations below to improve the final rule by streamlining the process for EPA, while allowing for increased clarity for industry.

Introduction of ILMA

ILMA is national trade association with 350 member companies that is headquartered in Alexandria, Virginia. ILMA’s manufacturing members blend, compound, and sell over 25 percent of the United States’ lubricant needs (e.g., passenger car motor oils, gear oils, and
hydraulic fluids) and over 75 percent of the metalworking fluids utilized in the country. Independent lubricant manufacturers are by definition neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks or that produce chemical additives. Base oils are purchased from chemical refiners, who are also competitors in the sale of finished products. Additives are purchased from suppliers, who also may be competitors in the sale of finished products. ILMA members succeed by processing, producing, and distributing high-quality, often specialized, lubricants. ILMA’s manufacturing members are "processors" under TSCA.

**The Pre-Prioritization Phase Must Be Better Defined**

The LCSA mandates fairly rigid compliance deadlines -- a minimum of nine months and a maximum of 12 months -- to complete the prioritization process for a chemical. As a result, the pre-prioritization phase offers an opportunity to pre-review and pre-screen a chemical to gauge it initially without starting the "statutory clock." As noted in the proposed rule, "this timeframe takes on particular significance given that the statute does not authorize EPA to 'pause' or delay prioritization once it has been initiated . . ."

During the pre-prioritization phase, EPA asserts that it can apply the statutory preferences in TSCA § 6(b)(2) to "narrow the pool of candidates" to screen against the TSCA § 6(b)(1)(A) criteria and then select those chemicals for formal "prioritization initiation" that officially commences the statutory clock.

In essence, EPA will "fill the pipeline" with chemicals that are currently screened and identified using a process that lacks sufficient transparency. Once prioritization "initiation" commences, the statute requires EPA to "show its work" and requires at least two opportunities for public comment. However, as currently proposed, the pre-prioritization phase lacks any appreciable opportunity for stakeholders to know and understand what the Agency is doing.

To address this concern, EPA should publish a candidate list (inclusive of the objective criteria used to establish the list and how it was applied) to put industry on notice that a substance used in their operations is under pre-review by the Agency and may be moved to the initiation phase of prioritization. While it would be helpful for industry to know what chemicals are under consideration for further review, EPA must explain that such candidate list is merely that -- a list of possible substances for the Agency to potentially prioritize. At the same time, EPA must take steps to ensure that a pre-prioritization candidates list does not become a "black list" of substances that would potentially cause the public to pre-determine the health and safety implications or a rush-to-judgment conclusion on the safety of a chemical.
Further, EPA should better explain the interplay of chemical pre-prioritization with its expanded testing authority under TSCA § 4 and the forthcoming "fees rule." It will be imperative that industry understands how the procedures will operate going forward and how the Agency envisions dividing the costs of potential testing\(^1\) between EPA and industry through the fees.

The pre-prioritization stage of regulatory review is so critical that another notice-and-comment rulemaking is warranted. Overall, EPA should more fully explain how pre-prioritization will operate in practice\(^2\) and ensure that affected stakeholders have the opportunity to fully participate in the process before the statutory clock starts.

**EPA Should Place Further Emphasis on Low-Priority Chemicals**

Given the statutory requirements, EPA likely will focus most of its attention and resources on designating and evaluating high-priority chemicals. However, there is a significant benefit if the Agency actively identifies more low-priority chemicals than the LCSA mandates. It signals to industry that a chemical is likely to be prospectively available, thereby allowing businesses to better plan their operations.

EPA states in the proposed rule that its Safer Chemicals Ingredient List is a "good starting point" to identify possible low-priority substances; however, the Agency should add a more explicit procedure (inclusive of the criteria used) that intentionally reviews chemicals in accordance with the standards and actively seeks to achieve a process to designate more chemicals as low priority than required.

EPA champions this concept in the proposed rule, noting "[t]here is also value in identifying low priority substances as part of the process, as it gives the public notice of chemical substances for which potential risks are likely low or non existent, and industry some insight into which chemical substances are likely not be regulated under TSCA."

\(^1\) EPA has previously suggested that § 4 test orders would only be utilized after review of the available data and interactions with manufacturers on currently existing information and data points. It is imperative that the Agency gathers available information before requiring a company to generate it.

\(^2\) EPA must also avoid being arbitrary during the pre-prioritization phase and the process must have an explicit procedure and protocol to ensure that industry understands how the chemical got to that stage of review and ensure that scrutiny for prioritization was not solely the result of a staff person’s perception or issue with a particular chemical.
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EPA Must Incorporate Section 26 in the Final Rule

In its proposed rule, EPA acknowledges that TSCA § 26 requires the Agency to make decisions based upon a weight-of-the-evidence ("WOE") approach, but argues that "while these requirements are relevant to the prioritization of chemical substances, EPA is not obligated to include them in this proposed rule."

ILMA urges EPA to revisit this stance in the final rule and incorporate a requirement to utilize and predicate decisions for high-priority and low-priority designations on a WOE approach. Even if EPA’s interpretation of the LCSA is reasonable, the Agency nevertheless should implement a WOE approach to ensure appropriate conclusions are reached at this initial stage of existing chemical review.

Conditions of Use Must Be Reasonable

In the proposed rule, EPA says that it will designate the priority of chemical as a whole and will not limit it to a specific use of the substance based on its interpretation of the LCSA that designation and evaluation of a chemical must be predicated upon all conditions of use.³ If the Agency is adamant that the statute does not allow it to assess only certain uses of a chemical, then EPA must be reasonable in its interpretation of known, intended, or reasonably foreseen uses. The Agency must not get bogged down in a "fishing excursion" and scour for every possible use of a substance – no matter how unlikely it may be. Further, a passing reference to an off-label use, perhaps one expressly disapproved by the manufacturer, by an online commentator should not automatically render that use known, intended, or reasonably foreseen. EPA must reasonably ascertain the universe of conditions of use.

EPA Must Not Punish "Data Rich" Chemicals

EPA has stated that it must wait to officially commence the initiation phase of the prioritization process until it determines that it has sufficient information to proceed. The Agency wants to ensure it will be able to comply with the relevant statutory deadlines. This makes sense, but ILMA would caution the Agency not to punish “data rich” chemicals for which manufacturers and processors have spent significant time and resources to generate information.

³ That is defined as “the circumstances, as determined by the Administrator, under which a chemical substances is intended, known, or reasonably foreseen to be manufactured, processes, distributed in commerce, used, or disposed of.” 15 U.S.C. 2602.
EPA should encourage product stewardship and proper testing. If the Agency “cherry picks” those chemicals with the most human health and environmental effects data, it is effectively discouraging the upfront generation of that information until a manufacturer would be required to do so by a TSCA § 4 test order or rule.

EPA, therefore, must strive to achieve a balance between reviewing those chemicals for which much data exists (and therefore is easier to make a high or low priority determination) and those chemicals that are data deficient. The Agency must be evenhanded in its review process so that each substance has a similar probability for prioritization, regardless of the health and environmental data that might exist.

The U.S. and Canada Should Align Their Approaches Through the Regulatory Cooperation Council

EPA and Environment Canada/Health Canada ("EC&HC") have been working together through the Regulatory Cooperation Council ("RCC") to achieve increased regulatory transparency and coordination between the two countries. Prioritization of existing chemicals presents an invaluable opportunity for EPA and EC&HC to work collaboratively to unify their approach. This would provide greater regulatory certainty for North American companies that do extensive business in both countries and would minimize duplicative reviews and/or reduce the possibility of reaching alternative conclusions on a chemical’s risk potential. To the extent the regulatory regimes in both countries allow for it, the chemical risk prioritization process should be uniform.

Conclusion

ILMA appreciates this opportunity to comment and encourages the Agency to incorporate the Association’s suggested improvements in the final rule.

Sincerely,

Holly Alfano
Chief Executive Officer