March 17, 2017

Ms. Susanna W. Blair  
Immediate Office, Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1200 Pennyslvanian Ave., N.W.  
Washington, DC 20460-0001

Re: Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act – EPA-HQ-OPPT-2016-0654

Dear Ms. Blair:

The Independent Lubricant Manufacturers Association1 (“ILMA” or “Association”) submits these comments on the Environmental Protection Agency’s (“EPA” or “Agency”) proposed rule to establish an internal procedure to conduct chemical risk evaluations under the Toxic Substances Control Act (“TSCA”) as amended by the Frank R. Launtenberg Chemical Safety for the 21st Century Act (“LCSA”).

The new law requires that EPA eventually review every active chemical on the TSCA Inventory. As part of this statutory mandate, EPA must promulgate a final rule by June 22, 2017 that describes the internal procedures the Agency will utilize to conduct risk evaluations to “determine whether a chemical substance presents an unreasonable risk of injury to [human] health or the environment,

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1 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.
without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed subpopulation(s)\(^2\) identified as relevant to the risk evaluation by the Administrator under the conditions of use\(^3\).”

EPA will first publish a draft scope that identifies the hazards, conditions of use, potentially exposed subpopulations, hazards, exposures, a conceptual model\(^4\), and an analysis plan\(^5\). The Agency states in the proposed rule that the draft scope will be published in the *Federal Register* within three months after the risk evaluation process commences, and it will allow for public comment. The final scope will be published in the *Federal Register* within six months after initiating the risk evaluation process and will outline what specifically will be addressed in the risk evaluation.

EPA then will proceed with the full risk evaluation, which will contain a risk characterization, hazard assessment, exposure assessment, data quality summaries, alternative interpretations of data points, and environmental risks. From the information in the risk evaluation, the Agency will make its unreasonable risk determination, using the weight-of-evidence approach and publish its draft evaluation in the *Federal Register* and allow at least 30 days for public comment. The final evaluation will be published as soon as practicable after comments are considered, but not to exceed the statutory deadline of three years (with a potential six-month extension) from when the evaluation commenced.

ILMA supports the Agency’s efforts to establish a transparent process to evaluate a chemical’s potential risk. However, given the statutory deadlines that require EPA to complete its work quickly, the Association makes the following recommendations to streamline the process.

**EPA Must Not Consider Every Remote Condition of Use in its Evaluations**

In the proposed rule, EPA states that the Agency formerly could conduct risk assessments on selected uses of chemicals; however, it interprets the LCSA to require the Agency to now analyze all conditions of use. Specifically, EPA argues that LCSA § 6 (b)(4)(A)

\(^2\) Means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health risk from exposure to a chemical substance or mixture, including but not limited to infants, children, pregnant women, workers, or the elderly.


\(^4\) That describes actual or predicted relations between the chemical and humans and the environment.

\(^5\) That describes the approaches, methods, and metric to assess exposures effects and risk.
requires an overall evaluation of a chemical substance and not on individual conditions of use.

EPA notes in the proposed rule that a key feature of the LCSA is to systematically review all chemicals in commerce and suggests that it would never accomplish that objective if the Agency constantly had to reevaluate different uses of a chemical. ILMA appreciates this concern; however, the Association would caution EPA that it would be unlikely to complete a risk evaluation within the statutory constraints if it entertains every possible use, no matter how remote. The better reading of the statute is to evaluate only plausible and relevant conditions of use within the scope of the risk evaluation. Indeed, LSCA § 6(b)(4)(D) states that EPA should identify the conditions of use that the Agency anticipates it will consider in a risk evaluation. This provision firmly suggests that Congress intended to grant EPA the discretion to include only those conditions of use that are plausible and relevant in the specific circumstance of an individual chemical review.

Nowhere within the statute does Congress explicitly demand that the all conditions must be considered within the scope of an evaluation. Such a “shotgun” approach is antithetical to the policy considerations underlying the LSCA amendments. Congress was clear that it expects EPA to conduct thorough risk evaluations using LCSA § 26 requirements and timely complete its work within the statutory deadlines. ILMA does not believe that EPA can effectuate Congress’ intent if it attempts to include every condition of use, no matter how implausible. EPA should revise its approach in the final rule and only consider plausible and relevant conditions of use within the scope of its risk evaluations.

EPA also must specifically articulate how it will consider “off label” use for products that a manufacturer explicitly does not recommend. For example, a statement from an online e-commerce seller/buyer that a particular chemical substance is helpful for a particular application should not be given credence and analyzed as a condition of use. Conditions of use must be firmly rooted in the realm of reasonable and plausible. Analysis of remote or highly improbable conditions of use does not nothing but add to Agency’s workload for an individual chemical evaluation without a corresponding public health benefit.

If EPA Considers All Conditions of Use, It Must Be Reasonable

If the Agency remains adamant that the LCSA 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. Known, intended, or reasonably foreseen -- qualify the universe of conditions of use EPA is to consider; EPA must appropriately utilize them as modifiers in its existing chemical reviews.
“Known” and “intended” are fairly straightforward in their application, “reasonably foreseeable” or “reasonable foreseeability” warrant further discussion. In tort law, “foreseeability” is a much discussed and analyzed topic. In his treatise, Professor Dobbs notes:

Courts often use the term foreseeable as shorthand expression. They might say, for example, that a defendant is negligent if harm was foreseeable. Such statement should not ordinarily be taken in a literal way. Harm is a foreseeable consequence of almost all acts, but courts definitely do not mean that all acts are negligent. Courts are likely to use the term foreseeable to mean that harm was not only foreseeable but was also likely to occur to justify risk it would add precautions. Similarly, courts sometimes speak about some harms as more foreseeable than others, which can be understood to mean that the risk or probability of harm is greater in some cases than it in others. Along the same lines, when courts say that harm is unforeseeable, they may mean that although harm was actually foreseeable on the facts of the case, a reasonable person would not have taken action to prevent it because the risk of harm was low, and harm was so improbable that a reasonable person would not have taken safety precautions. Put differently, to say that harm was unforeseeable often seems to mean only that the foreseeable harm was not probable enough to require precaution...⁶ [emphasis added.]

While foreseeability in personal injury and other legal contexts are slightly different than in this circumstance, Professor Dobbs’ analysis is illuminating and instructive for EPA as it considers the realm of “foreseeable” conditions of use. The Agency should incorporate that analysis when making determinations regarding the universe of conditions of use for a particular chemical.

**Risk Management Applicability Must Be Clarified**

If a risk evaluation results in one or more unreasonable risk conclusion, EPA must proceed to risk management. From the proposed rule, it seems that EPA will only proceed to risk management for specific conditions of use for a substance that warrant it. For example, in the course of a risk evaluation, it is plausible that the Agency would determine ten conditions of use for a chemical exist and would analyze them, resulting in nine “no unreasonable risk” determinations and one “unreasonable risk” conclusion. In that instance, EPA should only proceed with risk management for the one condition of use that resulted in the unreasonable risk conclusion and not implement a blanket risk management measure for all uses. It appears that this is the Agency’s intended path forward; however, it should be made explicit in the final rule.

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⁶ 1 Dobbs on Torts § 143 (2001).
Any Uses EPA Does Not Have Authority to Regulate Should Not Be Considered

EPA must make explicitly clear in the final rule that it cannot and will not consider uses in its risk evaluation for which it does not have jurisdiction to regulate, including:

- [a]ny mixture,
- any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;
- tobacco or any tobacco product,
- any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),
- any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [i.e., firearms and ammunition]...
- any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Further, while Congress recognized that EPA might regulate “workers” as a potentially exposed subpopulation, the Agency must recognize the Occupational Safety and Health Administration’s (“OSHA”) regulatory preeminence in this area, as it administers the Occupational Safety and Health Act (“OSH Act”) to protect worker health and safety. EPA should be deferential to OSHA in this area and should only impinge upon this space after close consultation with the Administration. Further, EPA must explain its interaction with OSHA prior to an evaluation and why both agencies believe that EPA should consider “workers” within the scope of the risk evaluation.

Peer Review is Imperative in Most Circumstances

In the proposed rule, EPA requested comments on whether situations exist where peer review may not be warranted. Peer review is imperative in virtually all circumstances to ensure that the scientific basis for an unreasonable risk determination is sound. It is essential that EPA’s Science Advisory Boards act in accordance with their charters and provide truly independent, third-party advice to EPA on the scientific underpinnings of its risk evaluations. Further, peer review for influential and highly influential scientific assessments must be given particular care and attention. Overall, it is sensible to release peer review plans in conjunction with the draft scoping documents. This will allow industry to review EPA’s plan and offer comments, if merited, on any improvements to its intended approach.
Requested Definitions for Key Terms

In addition to comments on its overall proposed evaluation process, EPA specifically requested comments on whether definitions for key scientific terms (e.g., best available science, weight-of-evidence) are warranted. ILMA agrees with the definitions set forth by the American Chemistry Council in its comments and incorporates them herein by reference.

Conclusion

ILMA appreciates this opportunity to submit these comments to EPA and encourages the Agency to incorporate the Association’s suggested revisions in the final rule.

Sincerely,

Holly Alfano
Chief Executive Officer

CC: ILMA Board of Directors
    ILMA SHERA and MWF Committees
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