SOT | Society of Toxicology

Creating a Safer and Healthier World by Advancing the Science of Toxicology

April 13, 2015

The Honorable John Shimkus, Chairman
The Honorable Paul D. Tonko, Ranking Member
House Energy and Commerce Subcommittee on Environment and the Economy
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Shimkus and Ranking Member Tonko:

The Society of Toxicology (SOT) is pleased to provide comments on the current bipartisan discussion draft of the TSCA Modernization Act. SOT remains committed to further scientific review of future drafts of TSCA Reform legislation with the hope that a revised TSCA bill will have strong, objective, scientific underpinnings and will protect public health for years to come. Please include this letter in the official record for your subcommittee's April 14, 2015, hearing.

As Congress considers revising the Toxic Substances Control Act of 1976 (TSCA; P.L. 94-469), the Society of Toxicology, with more than 5,000 toxicology professionals in the United States and nearly 8,000 worldwide from 61 nations, strongly urges Congress to ensure the language used in TSCA reform legislation:
1. Affords flexibility in selection of the best available science for generating and evaluating information used in the safety and risk assessment process.
2. Protects the authority of the US Environmental Protection Agency, working with the scientific community, to judge when and how to apply new techniques and methods.
3. Ensures the terms and concepts used in the legislative language that apply to the science of toxicology are consistent, accurate, and unambiguous.

Specific comments:
Discussion Draft of the TSCA Modernization Act

Page 2, lines 16-21 "Potentially Exposed Subpopulation"
The previous bill substituted 'vulnerable subpopulation' for "potentially exposed population.' We were supportive of that change and commented that vulnerable individuals/subpopulations could be more susceptible or more highly exposed. While this concept seems to have been covered in the new bill language, the definition has reverted to the 'potentially exposed subpopulations.' While susceptibility alone might not be a concern without sufficient exposure, it seems that 'potentially vulnerable subpopulations' would be the scientifically preferred descriptor for either more susceptible or more highly exposed subpopulations.

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Page 3, lines 1-5 “Weight of the Scientific Evidence”
The SOT TSCA Task Force supports the inclusion of this definition of “weight of the scientific evidence.” Considering all relevant information in an integrative and objective manner is consistent with the use of the best science for regulatory decision-making.

Page 4-5, lines 23-4 “Applying Requirements”
This language requires a risk evaluation and a positive finding of “unreasonable risk of injury…” to invoke regulation. Unlike other TSCA Reform bills, this language is a bit different than presenting a safety assessment and a safety standard of “no unreasonable risk of harm…” First, we are supportive of the concept of performing a “risk evaluation” as opposed to a safety assessment” and there appears to be no presentation of a “safety standard” in the bill, per se. Second, “injury” may be viewed by some as different from “harm,” particularly when referring to impact on the environment. Other bills all seem to have settled on “harm” as the appropriate term and we would support that perspective.

Page 5, lines 5-17 Conducting Risk Evaluation
Conduct of a risk evaluation seems limited to an Agency action or a request by the manufacturer. In the spirit of openness and transparency of the nomination process, it seems that there should be an opportunity for other informed parties, such as states or other non-manufacturer entities, to make such a request. Since the bill puts the onus on the manufacturer to pay for the risk evaluation if they request it, this language as presented may place limitations on who could afford to request an evaluation and might negatively affect who would or could make such requests.

Page 6, lines 11-15 Threshold Doses

11 ‘‘(D) consider whether the weight of the
12 scientific evidence supports the identification of
13 threshold doses of the chemical substance below
14 which no adverse effects can be expected to
15 occur; and

Under the section on requirements for a risk evaluation, the statement above is included. It would be better stated if it used the approach that EPA uses for describing a reference dose…an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily (oral) exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. As stated in the discussion draft, the language is suggesting the ability to identify a dose where no effect occurs without specifying length of exposure or who is exposed.

Page 6-7, lines 23-8 Risk Evaluations
It is unclear why, and potentially problematic, that there should be a difference in the time required for the assessment depending on who requests it or is paying for it. In our experience, if the EPA, or any scientific body for that matter, is conducting the assessments, the 3 year deadline may be difficult enough to meet, given the complexity of the topics, and the requirements for peer engagement in the process. A six month deadline would be impossible for most chemicals, given past experience.

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Page 8-9, lines 13-8 Determinations of No Unreasonable Risk
It is unclear why these two sections are separated. The concept of "…including vulnerable subpopulation(s)" should just be added into the first section regarding a negative finding. See comment above about "vulnerable" versus "potentially exposed" subpopulations.

Page 10-11, lines 22-8 Alternatives
The SOT Task Force is supportive of inclusion of the language regarding evaluation of alternatives, or replacement chemicals. However, we want to acknowledge the challenges, both logistical (how to identify alternatives and who will do it?) and technical (how to estimate risk with different levels of information?) in requiring such an evaluation.

Page 18-19, lines 8-5 Scientific Standards for Information
The SOT Task Force is supportive of this type of clarity around what constitutes good science and the processes and judgments for getting there. However, we caution the authors that writing this level of detail into the law opens up the possibility for procedural challenges if someone believes that one of these steps was inadequate.

We thank you again for addressing our previous comments and appreciate your consideration of our comments on this latest draft as well. We look forward to the next draft and the opportunity to work with you and your colleagues to comment further on subsequent iterations.

For the Society of Toxicology TSCA Task Force

Most Sincerely,

Norbert E. Kaminski

SOT 2014–2015 President

cc: The Honorable Fred Upton, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Jr., Ranking Member, House Energy and Commerce Committee

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