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May 23, 2016

The Honorable Fred Upton, Chairman, House Energy and Commerce
Committee

The Honorable Frank Pallone, Ranking Member

The Honorable John Shimkus, Chairman, Subcommittee on the Environment
and the Economy

The Honorable Paul D. Tonko, Ranking Member

2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Chairman Shimkus and Ranking Member Pallone
and Ranking Member Tonko:

Congratulations to the Committee for the progress made on finalizing H.R.
2576, now entitled the “Frank R. Lautenberg Chemical Safety for the 21st
Century Act.” The Society of Toxicology (SOT) wishes to commend the
United States Congress for reaching compromise on this critical piece of
chemical legislation after months of negotiations by House and Senate
lawmakers and staff.

This bipartisan resolution represents an important step forward in the reform of
TSCA, which has not been updated in nearly 40 years. During that time, our
knowledge and abilities to develop, evaluate, and manage chemicals has
dramatically improved. Reform of TSCA offers an opportunity to take
advantage of these advanced capabilities and ensure a revised law will enable
application of future scientific and technological progress and that the best
science is used to protect public health and the environment.

The SOT has completed its review of the resolution. With these changes, the
revised TSCA bill will have strong, objective, scientific underpinnings, and
will protect public health for years to come. We are heartened to see the
inclusion of sound toxicological principles and risk concepts, including an
emphasis on exposure as well as hazard, which are contained in the bill. Some
specific comments regarding the resolution include our support for:

- An amended definition of “conditions of use” which includes
reasonably foreseen, as well as intended or known, aspects of chemical
manufacturing, processing, distribution, use, and disposal.
- Retention of the concept of “unreasonable risk” in the safety standard
which correctly acknowledges that managing chemical policy to a zero
risk standard is not scientifically justified.

- The definition that a ‘potentially exposed or susceptible subpopulation’ means “a group of individuals within the general population, identified by the Administrator, who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” The phrase “identified by the Administrator” should be set off by commas for clarity in this quotation.
- Use of the term “protocols and methodologies” rather than standards to describe approaches to chemical testing.
- Substitution of the term “information” for “data” throughout the bill.
- Inclusion of a comprehensive statement of need when requiring the development of new information, including the rationale for use of vertebrate animal testing. SOT recognizes the need for animal testing while it continues to support the development of alternative approaches to animal testing.
- Use of a “tiered” approach to testing unless available information justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing. Related to this is acknowledgement of the value of “weight of evidence” approaches that are widely used by the scientific community in characterizing risk.
- Language encouraging input and collaboration from other federal scientific organizations such as the Consumer Product Safety Commission and the US Food and Drug Administration.
- The encouragement of a strategic approach to the reduction of vertebrate animals in testing by refinement of methods and protocols. At some point these approaches will no longer be “alternatives” but will be “accepted practices” for information gathering.

While we are cognizant of the importance of current chemical-specific issues such as mercury or specific analyses like cancer clusters, we are concerned that writing these into legislation reduces the relevance of these sections of the legislation in the future and detracts from the wider range of priority chemical-specific or analytical issues that, as toxicologists, we address every day. We continue to believe that these specific issues are better left out of legislative language so as not to limit priority issues or “freeze” the scientific approaches to address them.

As Congress finalizes its revisions to the Toxic Substances Control Act of 1976 (TSCA; P.L. 94-469), the SOT, with more than 5,000 toxicology professionals in the United States and nearly 8,000 worldwide from 61 nations, strongly urges Congress to continue 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.

SOT hopes you will feel free to draw upon the Society as a resource to address science-based questions that the Committee might have in the future. Additionally, please contact SOT Headquarters via Marcia Lawson at marcia@toxicology.org if the Society can be of further assistance to you on this issue.

On behalf of the Society, this letter is submitted for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "JBM". The signature is fluid and cursive, with a period at the end.

John B. Morris, PhD, ATS
SOT 2016–2017 President