

March 10, 2014

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

Dear Chairman Shimkus:

The Society of Toxicology is pleased to be able to provide comments on the draft entitled the “Chemicals in Commerce Act (CICA).” We have limited our review and comments to the elements of the draft related to the science of toxicology and risk assessment.

As Congress considers revising the Toxic Substances Control Act of 1976 (TSCA; P.L. 94-469) through legislation such as CICA, the Society of Toxicology (SOT), representing 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. Allows flexibility in the choice of the most appropriate specific techniques for generating information used in the safety and risk assessment process.
2. Protects the authority of the EPA to judge when, and how, to apply new techniques and methods for generating information for safety and risk assessment within TSCA.
3. Applies terms and concepts used in the safety and risk assessment process consistently throughout proposed legislation.

Our comments on this draft reflect those principles.

We wholeheartedly agree with the concept included in your draft bill recognizing the importance of applying the “Best Available Science.” The Society of Toxicology believes protection of public health deserves the use of the best capabilities to predict effects (i.e., toxicity testing), and to accurately characterize risks (i.e., risk assessment).

While we agree with the objectives of “best available science,” we think this concept could be further clarified by providing a description of the basis for

achieving those objectives. From our perspective, there are three key concepts that serve as that basis:

1. The methods used are based on, and relevant to, the underlying biology.
2. The science that is applied has a collective integrity where findings can be duplicated across a variety of experimental designs and by independent investigators in an open and transparent manner.
3. The tools and methods used reflect the current standard of practice by the scientific community. It should also be stressed that this standard of practice is not static but is constantly evolving.

We encourage you to incorporate these elements into the language defining “best available science.”

In addition, in this same section on page 4, there is reference to the use of publicly available information. In the interest of transparency, using publicly available information is preferred, but not all information available to the agency will be so. Premanufacturing notices (PMNs), pesticide registrations, significant new use notifications, and those otherwise submitting information for the agency to consider may need to submit reports that have been developed for regulatory purposes, but have not been published in the public literature. Some studies, particularly those with no significant effects to report, are not considered suitable for publication by journals or the scope of the work is too narrow to be of interest to the broader scientific community and therefore likewise, not suitable for publication. We suggest modifying the language of the draft bill to enable the agency to consider information that has not been published.

The current draft includes numerous references to specific methods and approaches such as *in silico*, tiered testing, high throughput screening, etc. (Pages 7, 8, 9, 10, 11, 12, 13, 38 and others). It is our understanding that reference to these methods are meant to serve as examples only and do not mandate their use. However, we suggest the language in the bill be further refined to make it clear that these are possible approaches but choices are not limited to those listed in the bill. Without doing so, some could interpret the listing of these specific methods as required. Methods that are available and preferred today may become obsolete as research and development improves our understanding and capabilities. Mandates to use specific methods could hamper the ability of the EPA, and those submitting information to the EPA, to use the “best available science” as it becomes available.

We agree that the use of “alternative methods” represents another important aspect of “best available science” and we encourage the promotion of this concept in the bill. However, we suggest further clarity around this concept and the language used to define it. The bill, as currently written, uses a

variety of terms such as “non-animal test procedures: and “alternative methods” without distinction. Are all the alternative methods in the bill meant to be non-animal methods? Related to that, there is also reference to “non-vertebrate” animals. We ask that this classification be clarified and language used that ensures testing at all levels of biological organization be well characterized and suitable for predicting biological effects.

In addition, many promising and important methods, such as bioengineered tissues, including organs on a chip, are not animal-free although they constitute a very important segment of alternative approaches that may improve our ability to detect and predict potentially toxic effects while significantly reducing animal use. We ask that the language of the bill be inclusive of those types of methods as well.

The draft bill refers to a “safety determination” on page 5 that is to be used under the provisions of section 6(b). However, the fundamental approach used by TSCA as it exists today and as described in this draft bill is risk-based decision making. We suggest eliminating reference to “safety determination” and, instead, use risk-based language such as “risk assessment” or “risk determination.” The Administrator is not required to make a positive statement of safety, i.e. the absence of potential harm, for any of the provisions in the draft bill. All decisions are risk-based and the agency takes possible action on those substances where the risk under conditions of intended use fails a safety standard.

We thank you again for meeting with us on February 26th and appreciate the opportunity you offered to provide comments on this draft. SOT welcomes the opportunity to comment further on subsequent versions.

Most Sincerely,



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