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April 13, 2015

The Honorable James Inhofe, Chairman  
The Honorable Barbara Boxer, Ranking Member  
Senate Environment and Public Works Committee  
SD-410 Dirksen Senate Office Building  
Washington, D.C. 20510

Dear Chairman Inhofe and Ranking Member Boxer:

The Society of Toxicology (SOT) is pleased to provide comments on S. 725, The Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act. SOT remains committed to further scientific review of future drafts of Toxic Substances Control Act (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. We ask that the committee consider our view if it considers S. 725 during its deliberations on TSCA reform.

As Congress considers revising the 1976 Act (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 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:**

The Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act

**Section 3**

**Definitions**

Definitions are clearly stated and address some of the concerns that we indicated in previous comments. They are now consistent with good scientific terminology except, in our opinion as stated below:

Page 6, Lines 5–10 (16) Safety Assessment. We are pleased to see the continued evolution of the risk assessment language which incorporates hazard, use, and exposure data and information. Because the assessment process is focused on assessing risk as a factor to include in a determination of compliance with a “safety standard,” the definition included in Section 3 should be of “risk assessment” rather than “safety assessment.”

Page 6, Line 16 through Page 7, line 2 - (18) Safety Standard. While the draft bill is clear that the proposed “safety standard” is “...no harm to human health or the environment will result from exposure to a chemical substance...” we continue to have concern for how “no harm” will be defined and how it would be tested. As toxicologists we subscribe to the premise that nothing is without some risk of potential harm. Establishing a scientific basis for determining “no harm” is not possible. We recommend modification of this definition to include acknowledgement that there will always be some non-zero probability of harm under intended or foreseeable conditions of use, for instance to genetically susceptible individuals. However unless these individuals make up a sizeable subpopulation, it would not seem reasonable to regulate to the level of such individuals. We suggest the authors of this legislation take advantage of the scientific resources available to them, such as the National Academy of Sciences, to gain further insight on this important concept in order to develop a standard that is protective of public health and scientifically sound.

#### Policies, Procedures, and Guidance

Page 7, Line 16 through page 8, line 16 - (b) Use of Science. We fully support the concepts in this section including the use of peer review, and the recognition of the importance of analysis of assumptions, variability, and uncertainty, and the encouragement to use well-described test methods and data evaluation processes and appropriate laboratory practices. We suggest, however, that Good Laboratory Practices (GLPs) be included as an example of appropriate laboratory practices since GLPs are the global standard for study record keeping and mutual acceptance of data across regulatory jurisdictions.

Page 8, lines 24 through Page 9, line 9. References to specific National Academy of Science reports are not necessary in this section. While the listed reports contain valuable recommendations for the state of the science today, other Academy reports contain valuable recommendations and all of these recommendations will likely change with time and emerging science. Including specific reference to a subset of relatively recent reports runs counter to our principal of enabling the use of the best available science. We suggest opening up the options to include the latest and most appropriate recommendations provided by knowledgeable experts such as the National Academy of Sciences.

Page 9, Lines 10 through 17—Existing EPA Policies, Procedures, and Guidance. We fully support the use of risk-based approaches including the recognition of the importance of hazard and exposure in the application of all of the EPA policies and guidelines.

## Section 4

Page 12, lines 7 and 8. We agree with the importance of adequate characterization of exposure described in this section but caution that there are many factors that affect delivered dose after exposure, not just the potential for accumulation of a chemical substance in the body. Rather than specifically require that accumulation be addressed, it would be important to ensure that the language of the bill state that all relevant factors, such as absorption, distribution, metabolism and excretion, be addressed on a case-by case basis as appropriate for each chemical assessed. This information would capture any information on accumulation as well.

Page 12, lines 13 through 24. We fully support encouraging the consideration of all available sources of relevant and appropriate information that can aid the Administrator to assess the need for testing with mammals. We suggest that the language in this section make it clear that the list of potential sources of relevant information not be limited to those listed, but that these are currently available examples. Once again, we caution that as the science progresses, there will be more sources of available information and more approaches developed for generating relevant information beyond those currently available.

Page 13, lines 7 through 19—Screening Level. We suggest broadening the scope of sources of screening level information for hazard beyond those listed (*in silico*, *in vitro*, and *in vivo*). Other sources such as *ex vivo*, and results from various sources of human exposures also are likely sources of relevant information. Rather than try to list them all and run the risk of omitting some current or future sources of information, we suggest the language simply include those listed as examples but that others may be appropriate as they are developed and scientifically acceptable.

Page 14, line 13. We suggest the title be changed to Risk Assessments and Safety Determinations to better reflect the process described in this section. See our comments on definitions found on Page 6 of the bill.

Page 16, line 13 to page 17, line 3. We are encouraged to see the focus on both aggregate and cumulative exposure in the bill with appropriate definitions of each. Consideration of different sources for the same chemical or other chemicals which affect similar processes to produce hazard are required to really understand potential for risk.

Page 18, line 1. We support the development of the new Scientific Advisory Committee on Chemicals. However, it will be important to ensure that the reviews of this committee are completed in a timely manner to facilitate meeting the agreed upon schedules and that the establishment of this Committee does not exclude the use of other, topic-specific advisory panels convened by the EPA.

Page 19, lines 10-15. Setting deadlines for response to the National Academy reports is an important addition to this bill, although the 120-day time frame may be too tight, particularly if the Administrator wants to receive input from the broader scientific community on the appropriate response to the recommendations.

Page 26, line 15. We fully support the use of all appropriate methods for reducing the reliance on mammalian testing and we encourage the use of language that enables current and future methods as they become available. The specific reference to toxicity pathway-based risk assessment is just one of many approaches that are, or will be, useful for this purpose. Other biologically-based, systems approaches are also likely to be useful as they are developed in the future.

Page 31, lines 1-8. We encourage the authors of the bill to ensure the list of priority chemicals considered by the Administrator is commensurate with the resources available to the EPA. Each chemical on the priority list will need to be considered on a case-by-case basis and the effort and resources necessary to complete an evaluation can, and will likely, vary considerably. The bill should ensure the resources available match the requirements specified in the bill.

Page 38, lines 20-22. We agree that substances that accumulate in the body deserve consideration but not to the exclusion of other factors mentioned above that affect the exposure to dose continuum. We suggest using language to expand the range of factors to be considered to those that are appropriate for each chemical on a case-by-case basis.

## **Section 5**

Beginning on page 41—New Chemicals and Significant New Uses—We are appreciative that the bill has enabled the use of scientific judgment by the Administrator to determine the appropriate test to use and there is no minimum data set requirement. This demonstrates recognition by the authors of the necessity to enable the application of the best science.

## **Section 6**

Beginning on page 54— Safety Assessments and Determinations. See our comments from Section 3 about the Safety Standard.

Page 69, lines 1 through 9—List of PBTS. This section relies on a hazard-based approach for identifying chemicals of concern. While there is some language for consideration of use and exposure, it is unclear how this section will further address chemicals of concern beyond what is already in consideration for priority chemicals (section 4).

Page 73, lines 17 through 8. The specific mention of asbestos appears out of place here. It appears to us it would be a more suitable topic in section 7 or included as an example in the discussion of high-priority chemicals (section 4).

### **New Sections— Disease clusters, analysis, and research appropriations**

We support the overall goal of these new sections and the flexibility it provides to apply the best science without being prescriptive of the science that could be applied. Specifically the language on page 144, lines 9–25 direct the Administrator, together with the ATSDR, to develop and publish the guidelines for meeting the goals of these sections. We caution that this process should be inclusive of risk-based principals for identifying the causes of disease clusters and the recommendations for resolution. Because this is a significant expansion of EPA's authority, we are pleased to see the suggestion for authorizing additional appropriations to cover the costs of this program and the Regional Centers. Because CDC has a long history of cluster investigations and has published guidance on these studies in the past, it would be appropriate that the legislation would recognize the need to build on these past efforts.

Thank you for your consideration of our comments. We look forward to continuing to comment as the TSCA reform process proceeds and are available to respond to any comments or questions you may have.

For the Society of Toxicology TSCA Task Force,



Norbert E. Kaminski  
SOT 2014–2015 President