POSITION STATEMENT

*Statements created after 2011 are dubbed Issue Statements.

Role of Government in Science Regulation

Originally Adopted January 1998; Revision Adopted November 2015

Congress regularly engages in legislative activities that examine the effects of new and existing chemicals, including drugs, in an effort to further strengthen protection of public health and the environment from intentional and unintentional exposure. The Society of Toxicology (SOT) supports these activities provided they are grounded in sound scientific principles and foster science-informed decision making.

Science is constantly evolving as research is conducted, data are collected, and knowledge is accrued. Regulations should recognize the dynamic nature of science and ensure the best available science can be used. Unfortunately, this is not always the case. For example, the Federal Insecticide, Fungicide, and Rodenticide Act (as amended in 1972) mandated the use of specific tests, such as the Draize irritation assay for characterizing the acute effects on the eye for pesticides regulated by this law. Since 1972, this method has largely been replaced in the broader scientific community by more humane and predictive methods. Despite this advancement in the science, the law continues to impede the application of alternative methods for this and other endpoints because specific methods were written into the legislation.

The tremendous progress in our understanding of molecular and biological processes has enabled the science of toxicology to better understand the way chemicals interact with biological systems. With this understanding come improvements in approaches and tools that better predict the effects of chemicals on health and the environment. Legislation and policies should encourage the development of the science to enable improved capabilities. As an example, the Food Quality Protection Act (1996) included an emphasis on protection of children. Since passage of that legislation, developments in the understanding of the immune system and, in particular, developmental immunotoxicology, have progressed, along with tools to characterize effects of chemicals on the developing immune system. As a result, toxicologists can now use a variety of tools that were unavailable in 1996 to generate data to better protect children's health.

It also is important that regulations and government policy encourage application of the highest standards for characterizing and evaluating risk to health and the environment. While the type

and amount of information available on chemicals can vary considerably, regulations and policy should encourage the development and application of approaches that utilize all relevant information and are effective in predicting and preventing adverse effects from chemicals.

Whenever possible, SOT will advocate for three fundamental principles:

1. Legislation should enable the use of the best available science. We believe that sound legislation plans for the future and should protect the authority of regulatory decision makers, working with the scientific community, to judge when and how to apply new techniques and methods as they become available. Legislation should not restrict methods or approaches to those available at the time the legislation is written.

2. Legislation should encourage the development and application of hypothesis-based approaches aimed at understanding the fundamentals of how chemicals or physical agents may adversely affect human health or the environment. We often need to make predictions about risks that we cannot measure directly. Investigations aimed at understanding how chemicals, singularly or in combination in the environment, may adversely affect human health or the environment and the levels that cause effects strengthen our ability to identify hazards, susceptible populations, relevant exposures, and inform risk-management decisions.

3. Legislation and policies intended for management of chemicals for protection of public health should consider that risk-based approaches can lead to more targeted risk management than hazard-based approaches. The evaluation of chemicals should ideally be based on an integration of hazard, dose-response, and exposure.