Public Policy Statement
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Chemical Risk Assessment and Regulatory Decision Making

The American Chemical Society (ACS) vision of improving people's lives through the transforming power of chemistry requires an appropriate understanding and management of the risks that chemicals may present throughout their life cycle. Risk assessment is the first step in the risk management process. This statement provides principles and recommendations for risk assessment, particularly with regard to government regulation of chemical commerce.

The use of commercial chemicals in medicine, agriculture and other components of the marketplace have improved human health and quality of life. It has also caused some adverse impacts to human health and the environment. The ACS believes that proper design and management of the synthesis, production, use and disposal of chemicals can maximize their utility and minimize their potential adverse impacts. Here, we offer risk assessment principles and recommendations to achieve this balance.

For example, ACS supports the use of green chemistry and engineering principles to develop and use safer chemicals. However, ACS recognizes that the definition of "safe" differs among individuals. In the context of national and international efforts to protect human health and the environment, "safe" is defined by legislators, implemented by regulators and adjudicated by the courts as a level of acceptable risk. These actions are informed by science, but are based on values, politics, economics and other social factors. The proper use of science is to inform decision makers about the inherent hazards and the likelihood of adverse health or ecological effects from particular exposures. Scientists can also assess the strength of evidence, and the uncertainties and variability of currently available information. Such risk assessment information should be considered by decision-makers, but cannot on its own be used to determine what is "safe."

Risk assessment entails three "…analytic steps—hazard identification, dose-response assessment, and exposure assessment—and a fourth step, risk characterization, in which results of the first three steps are integrated to yield information on the probability that the adverse effects described in hazard identification will occur under the conditions described in exposure assessment. Uncertainty findings from the first three steps are also integrated into risk characterization." [NRC 2009] This process provides information for risk management decisions.

There is no single set of analytical tests to conduct risk assessment for the wide range of existing and possible chemistries. Rather, risk assessment is a process for selecting appropriate methods to evaluate the impacts associated with life cycle exposures to a chemical at the different stages of commercialization. New, more efficient tools are being developed for toxicity evaluation. Such progress was highlighted in the 2007 NRC report "Toxicity Testing in the 21st Century: A Vision and a Strategy" [TOX21] and the 2012 NRC report "Exposure Science in the 21st Century: A Vision and A Strategy" [NRC 2012].

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Risk assessment science can be further advanced by the following principles and recommendations.

CHEMICALS RISK ASSESSMENT PRINCIPLES AND RECOMMENDATIONS

The American Chemical Society supports three key risk assessment science principles and makes the following recommendations for each:

1. **Evaluations of chemical safety should be reviewed and informed by sound science and reflect risk-based criteria protective of human health and the environment.**
    - Risk is a function of hazard and exposure. The risk posed by chemical substances must be judged using transparent, published, and state-of-the-art risk assessments that incorporate the best available scientific information, regardless of source. Such risk assessments must inform the regulation of chemical substances and processes.
    - ACS supports adoption of a framework for risk-based decision-making as outlined by the National Academy of Sciences in "Science and Decisions: Advancing Risk Assessment." [NRC 2009a]
    - Risk assessments should be tailored for the type and level of information needed to inform the decision. Less detail is appropriate for low risk/low economic consequence decisions compared to high risk/large economic consequence decisions. Priorities for doing risk assessments need to reflect risk considerations, including
        - scientific understanding of hazard.
        - structural activity relationships.
        - volume in commerce.
        - use (i.e., whether the chemical is in children's products or a community has disproportionately high exposure levels).
        - detection in biomonitoring programs.
        - persistent and bioaccumulative properties.
        - adequacy of available risk information. [OECD]
    - Federal agencies should clearly state the default assumptions and underlying reasoning they use to assess risk.
    - Risk assessments need to clearly state the level of uncertainty and variability of the data.
    - To the extent practical, agencies should develop common frameworks for dose-response assessments to take into account exposure scenarios and exposed populations. Risk assessments should appropriately take into account population variability, stressor exposures, and cumulative chemical exposures when risk potential is high.
    - ACS supports prompt development of more efficient, biology-based validation methods to certify the results of appropriately designed toxicity testing and exposure assessment.
    - ACS supports implementation of the recommendations of the National Research Council "Report on Toxicity Testing in the 21st Century" and the application of its principles to ecological risk assessment. An understanding of appropriate biological targets and modes of action can be used to develop less costly and more efficient and informative tests to aid risk assessment, such as *in vitro* assays and predictive models. [TOX21]
    - U.S. federal agencies need to participate in international efforts to (a) establish adverse outcome pathways for key toxicity endpoints and (b) replace traditional toxicity tests with more informative and efficient tests that reduce or eliminate the use of animals.
    - Agencies should have adequate resources to advance the science of risk assessment.

- National governments should work together to further develop and use risk assessment science and findings.
- ACS supports better understanding of critical risk assessment science specifically in the areas of
    - Endocrine Disruption: Endocrine disruption is the alteration of the endocrine system that causes adverse health effects in an organism, its progeny, or a (sub)population. ACS supports (a) expansion of endocrine disruptor education and research, (b) more rapid advancement by the EPA of the congressionally-mandated Endocrine Disruptor Screening Program effort, and (c) support for green chemistry research to identify and develop functional alternatives that do not have endocrine disrupting activity.
    - Exposure Assessment, including Biomonitoring: ACS supports the "Research Needs" identified in "Exposure Science in the 21st Century: A Vision and A Strategy" [NRC 2012]. These include exposure assessment to move to an integrated approach that considers exposures from source to dose. There should be continued support for biomonitoring research.
    - Nanomaterials: As recommended by the NRC, the government should build on the current research base and develop a national strategic plan for nanotechnology-related environmental, health, and safety research. The strategy should focus on studies that support the risk assessment and risk management of nanomaterials to ensure their timely and safe development. [NRC 2009b]

2. Companies that manufacture, import, process, distribute, or use chemicals should provide the information necessary to conduct risk assessments.

- The commercial chemical enterprise should have sufficient information to conduct risk assessments for their products' intended uses.
- The commercial chemical enterprise should be required to provide information necessary for agencies and manufacturers to conduct risk assessments.
- Health and environmental data should be transparent throughout the value chain as appropriate to the user; however, legitimate confidential business information should be protected.
- Companies and government should work together to ensure a balance that maximizes public access to chemical health, safety and environmental information.
- Government, the chemical enterprise, the commercial value chain and consumers each have roles in responsible chemical risk management. Those developing, manufacturing, processing and distributing chemicals need to provide information and guidance about safe use. Consumers need to follow that guidance and use the materials safely. Timely and accurate risk communication is essential.

3. Green chemistry and engineering principles should be used to support sustainability goals.

- Chemicals management and regulatory policy should encourage technological innovation and a globally competitive US chemical industry. Advancing research and applying appropriate principles from green and sustainable chemistry and engineering will lead to economically viable, technical innovations. [GC-GE] To this end, ACS supports the government implementation of

- Financial incentives (tax incentives, grants, awards, preferential treatment in government purchasing) for the development and deployment of greener chemicals and processes.
- An expedited regulatory process to incentivize adoption of green and sustainable chemical products and processes. The government should work with industry, academia, scientific organizations, public interest groups, and other stakeholders to develop standards for use in such a regulatory scheme.
- Continued support for research and development by universities, industry and other stakeholders to make new alternatives available and encourage their adoption.
- Support for the training and education of chemical scientists to more uniformly prepare them to understand toxicity and exposures (i.e., risk) associated with chemicals.

REFERENCES

[TOX21] National Research Council, 2007. *Toxicity Testing in the 21st Century: A Vision and a Strategy*

[NRC 2009a] National Research Council, 2009. *Science and Decisions: Advancing Risk Assessment.*

[NRC 2009b] National Research Council, 2009, *Review of the Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*

[NRC 2012] National Research Council, 2012, *Exposure Science in the 21st Century: A Vision and A Strategy*

[GC-GE] Green Chemistry and Engineering Principles

[OECD] Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-Range Transport