

CHEMICAL RISK ASSESSMENT AND REGULATORY DECISION MAKING

Chemical regulations exist to protect society and the environment from unnecessary and undue hazards from exposure, while allowing society to benefit from chemical sciences. Regulatory actions involve two distinct elements:

- Risk assessment: a process that consists of 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]
- Risk management: the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. [NRC1983]
- Together they evaluate, quantify, and mitigate the impacts of a hazard. Risk assessment of chemical hazards must include analysis of acute short-term hazards as well as chronic long-term impacts, covering the entire life cycle from research and development, manufacturing, and product use, to fate in the environment.

Principles

1. Biological responses occur following exposure to virtually all substances, both natural and synthetic. Identification of risks to human health and the environment from exposure to potentially harmful substances informs regulatory decisions. Information about risk and hazard should be widely, transparently, and publically available.
2. Evaluations of chemical safety should be based on robust science and risk based criteria protective of human health and the environment.
3. Science informs regulatory decisions- Determining and managing acceptable risk to human health and the environment is both technical and societal, involving scientists, government, industry, consumers, and the public. Resulting actions are based on science, but are ultimately value based judgments.
4. Government and industry play critical roles in risk assessment and regulation. Toxicological data and safety information must be accessible to consumers and regulators to assure safe use and public trust. Baseline assumptions, reasoning, data requirements, and data underlying regulatory decisions must be transparently described.
5. Risk management decisions should consider sensitive populations, cost, availability of substitutes, and other relevant considerations.

Recommendations

The American Chemical Society (ACS) Board of Directors Committee on Public Affairs and Public Relations adopted this statement on behalf of the Society at the recommendation of the Committees on Environmental Improvement, and Corporation Associates. ACS is a non-profit scientific and educational organization, chartered by Congress, with nearly 157,000 chemical scientists and engineers as members. The world's largest scientific society, ACS advances the chemical enterprise, increases public awareness of chemistry, and brings its expertise to state and national matters.

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- 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] Evaluations and recommendations should be revisited after a determined time period to incorporate any changes or added data to the original science based decisions.
- ACS supports the development and use of less toxic and less persistent chemicals by all means, including the use of green chemistry and sustainable molecular design principles. ACS further supports alternatives assessment as defined by the National Research Council [2014] as a process for identifying, comparing, and selecting safer alternatives to chemicals of concern on the basis of their hazards, comparative exposure, performance, and economic viability.
- ACS supports better understanding of critical risk assessment science in specific areas.
 - Research needs identified in *Exposure Science in the 21st Century: A Vision and A Strategy* [NRC 2012]. Exposure assessment is essential to understand the extent to which potentially hazardous chemicals are ingested, inhaled, or otherwise taken up by at risk populations.
 - Biomonitoring, which involves the measurement of a wide range of chemicals and transformation products in humans and other species to understand the environmental and public health implications of exposure to chemicals by linking biomarkers of exposure to biomarkers of effect. Biomonitoring also provides a basis to evaluate the success of sustainable molecular design and safer alternatives, control technology and clean-up efforts over time and to identify trends that may be of concern as a basis for mitigation.”[NRC 2006]
 - Implementation of the recommendations of the National Research Council *Toxicity Testing in the 21st Century: A Vision and Strategy* to develop informative and more efficient means of toxicity testing and the application of its principles to human and ecological risk assessment and computational tools. [NRC 2007]
 - Endocrine disruption, the alteration of the endocrine system that causes adverse health effects in an organism or its progeny. ACS supports high throughput assays and computational tools for the endocrine disruptor screening, more rapid advancement by the EPA of the congressionally- mandated [Endocrine Disruptor Screening Program](#) effort, and expansion of endocrine disruptor education and research. [
- ACS supports studies that focus on the risk assessment and risk management of nanomaterials to ensure their timely and safe development. Significant actions required include research that identifies and quantifies nanomaterial releases and identifies the populations and environments being exposed, increases understanding of processes that affect both potential hazards and exposure, examines nanomaterial interactions in complex systems ranging from subcellular to ecosystems, and supports an adaptive research and knowledge infrastructure to advance research. [NRC 2012]
- ACS supports government agencies clearly stating baseline assumptions, reasoning, data requirements, and data utilized when assessing risk. Likewise, industry needs to provide information for technical purposes and clear, accessible guidance to consumers and regulators.

References

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