CHEMICAL RISK ASSESSMENT AND REGULATORY DECISION MAKING

Chemical regulations exist to ensure chemicals sold and/or used in the US do not pose significant risk to human or environmental health throughout a chemical's entire life cycle (manufacture, intended use phase, and disposal). Regulatory decisions require scientific evaluation of potential risks to human and environmental health and thoughtful risk management:

- Risk assessment: A four-step process designed to yield information on the probability of adverse effects following chemical exposures.
    - Hazard Identification (HI) identifies adverse effects posed by exposure.
    - Dose Response (DR) quantifies the relationship between dose and effect.
    - Exposure Assessment (EA) assesses exposure pathways, outcomes, and populations.
    - Risk Characterization (RC) integrates information from the HI, DR and EA steps to generate an estimate of the overall risk to human or environmental health, and integrates uncertainty findings from the first three steps [NRC 2009].
- Risk management: the determination of how best to protect human and environmental health. Selection of the most appropriate regulatory action from potential policy alternatives requires integration of scientific data derived from risk assessments with broader societal, economic, legal, and political concerns. [NRC1983, NRC 2007]

  Although risk assessment and risk management are independent processes, both are necessary to 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 exposures from research and development, manufacturing, and product use, to eventual fate in the environment. While program-specific exposure evaluations are required to comply with applicable laws and regulation, adaptive approaches should be utilized to enable transitioning to a framework based on the exposome as research advances are made to evaluate the totality of exposures (i.e. environmental, consumer, and occupational). [Miller 2014]

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, reproducible science and risk based criteria protective of both human and environmental health.
3. Assessment and management of risk is a scientific process requiring input from researchers, regulators, consumers and manufacturers. The decisions reached have broad societal implications.

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 more than 158,000 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.

4. Government and industry play critical roles in risk assessment and regulation. Toxicological and epidemiological data and safety information must be accessible to regulators to assure safe use and maintain public trust. Baseline assumptions, reasoning, data requirements, and data underlying regulatory decisions must be transparently described. Conclusions should be accessible to consumers in transparent, plain language.
5. Standardization and harmonization of hazard criteria and risk assessment language should be encouraged to ensure all parties are using a common vocabulary.
6. Risk management decisions should consider vulnerable populations, availability of appropriate chemical analogs/substitutes, intended uses, potential interactions, potential environmental transformations, and other relevant considerations.

Recommendations

- ACS supports 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 at regular intervals to incorporate significant changes or updated data to the original evidence based decisions.
- ACS supports the development and use of less toxic and less persistent chemicals based on the application of risk assessment principles, particularly 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.
    - Exposure assessment, which uses best practices for modeling and assessment, including robust exposure data, is essential to understand the extent to which potentially hazardous chemicals are ingested, inhaled, or otherwise taken up by vulnerable populations [NRC 2012].
    - Biomonitoring, which measures a wide range of chemicals and transformation products, is used to understand the environmental and public health implications of chemical exposure by linking biomarkers of exposure to biomarkers of effect. Biomonitoring provides a means to evaluate the success of sustainable molecular design and safer alternatives, engineering changes and control technology and clean-up efforts over time and to identify trends that may be of concern as a basis for future 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]
    - Development of the Integrated Approach to Testing and Assessment (IATA) to identify and validate New Approach Methods (NAMs) for modeling hazards and toxicity, utilizing synthesis of information from traditional and NAMs in key scientific domains including human hazard, exposure, persistence, and bioaccumulation.
    - Endocrine disruption, the alteration of the endocrine system that causes adverse health effects in an organism or its progeny. ACS supports use of NAMs for screening, more rapid advancement by the EPA of the congressionally- mandated Endocrine Disruptor Screening Program effort, and expansion of education and research.
    - Research on nanomaterials to ensure their timely and safe development. Significant actions required include research that identifies and quantifies releases, improves exposure and risk assessment, understands the interplay of processes affecting potential hazards and exposure, examines interactions in complex systems, provides

guidance on the difference between nano and macro materials, and supports an adaptive infrastructure to advance research. [NRC 2012, WHO 2017]

- ACS supports government agencies adopting a tiered approach to risk assessment that encourages the use of NAMs, analog data, and data derived from traditional *in vivo* testing when validated animal alternatives are unavailable.. Agencies should model transparency in baseline assumptions, reasoning, minimum data set requirements and data utilized when assessing risk. Likewise, industry needs to provide information for technical purposes and clear, accessible guidance to consumers and regulators.
- ACS encourages agencies to have clear operational mandates to minimize overlap in responsibilities.

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