

Principles for Improving Federal Chemical Hazard and Risk Assessment Programs



Federal assessments of chemical hazards and risks are a key component to establishing a successful regulatory system. Assessments focus on understanding the inherent properties of substances in order to determine the likelihood of harm from a specific exposure. The public, businesses, and regulators at all levels of government look to these assessments as a reliable source of information about the potential hazards and risks associated with chemicals.

The determinations from assessments are a critical part of the decision-making process for chemical management regulatory programs (e.g., Toxic Substances Control Act) and environmental regulations (e.g., Clean Air Act). Access to accurate and useful data regarding potential hazards and risks is necessary in order for these programs to effectively protect human health and the environment, as well as provide for the development and use of chemicals that are vital to everyday life.

Unfortunately, too many assessments fail to consistently meet the benchmarks of objectivity, transparency, and scientific accuracy. Delays often arise as a result of the need to address shortcomings in draft assessments. Furthermore, flawed assessments may create public confusion, stir unwarranted alarm, and lead to unnecessary regulatory actions, product de-selection, and litigation. All of which only serve to further erode public confidence in chemical management programs.

Given the central role assessments have in regulatory decision making and to ensure that regulatory actions on chemical substances are based on a firm scientific foundation, the U.S. government should incorporate the following principles into chemical assessment programs:

DESIGN

- 1. ENSURE KEY ISSUES ARE IDENTIFIED PRIOR TO INITIATION OF THE ASSESSMENT:** The purpose, scope, and technical approaches that will be used in assessments need to be delineated as part of the design process. Assessments should be tailored to meet the intended purpose, and stakeholders should be engaged during problem formulation. As agencies develop or revise guidance for hazard and risk assessment programs, stakeholders should have the opportunity to provide input as drafts are developed. Draft guidance should be submitted for public comment and peer review.
- 2. UTILIZE MODERN SCIENTIFIC INFORMATION AND TOOLS RATHER THAN CONTINUING TO RELY ON OUTDATED ASSUMPTIONS:** Reliance on defaults should be minimized. In many cases, government hazard and risk assessment programs rely on assumptions and default approaches developed in the 1970s. Today's scientists and health professionals have a wealth of knowledge including 21st-century understanding of how the human body works and the way chemicals interact with the body and the environment at different levels of exposure. This modern-day knowledge must be applied when determining chemical safety.



DATA & METHODS

- 3. INTEGRATE STUDIES TO ASSESS THE OVERALL WEIGHT OF THE EVIDENCE:** Assessments must rely on the best available scientific information, and they must employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure. Scientifically valid, up-to-date data and knowledge of possible hazards and risks of substances should be used. All assessments must be based on a framework that takes into account - and integrates - all relevant studies, while giving the greatest weight to information from the most relevant and highest quality studies.
- 4. DEVELOP AND APPLY CONSISTENT CRITERIA FOR EVALUATING DATA AND FOR SELECTING STUDIES USED IN ASSESSMENTS:** Transparent criteria must be established upfront and then consistently applied throughout the assessment to identify studies and to evaluate their quality, relevance, and reliability.



COMMUNICATION

- 5. ENSURE ASSESSMENTS ARE TRANSPARENT:** Agencies must disclose key information used to develop assessments. When assumptions are used in lieu of data, the assumptions must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated. Publicly available electronic dockets should be used to capture all materials, including supporting documentation, as assessments go through the development and public comment process.
- 6. CHARACTERIZE HAZARDS AND RISKS FULLY AND ACCURATELY:** Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. The characterization should provide a full picture of what is known and what has been inferred and should also present results based on alternative plausible assumptions. When a screening level assessment indicates potential concern, prior to initiating additional risk management actions, a refined assessment should be conducted to more accurately determine hazards or risks. When going beyond screening level, assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks.



REVIEW & ACCOUNTABILITY

- 7. ENHANCE SCIENTIFIC PEER REVIEW AND RESPONSIVENESS:** Assessments must be subject to appropriate review by independent experts based on the importance and complexity of the decision. Peer reviewers must be fully independent from the program issuing the assessment. Peer review panels should be assembled in accordance with appropriate policies to ensure the range of technical expertise required is achieved, perspectives are balanced, and potential financial conflicts of interest are rigorously and fairly evaluated.
- 8. IMPROVE ACCOUNTABILITY:** Processes need to be in place to ensure that public comments and peer review findings and recommendations are completely addressed and that legitimate scientific concerns are not disregarded. An independent accountability procedure should be implemented to verify that revised assessments are accurate, that they are fully responsive to comments and peer review recommendations, and that the necessary scientific and process improvements are embodied in specific chemical assessments.