Principles for Improving Chemical Hazard and Risk Assessment Programs

April 25, 2014
Regulators, the public, and industry rely on a number of federal chemical hazard and risk assessment programs to help guide better decisions regarding safe exposures to chemicals.
Key federal chemical hazard and risk assessment programs:

- Integrated Risk Information System
- Report on Carcinogens
- Agency for Toxic Substances and Disease Registry Toxicological Profiles
- Toxic Substances Control Act Existing Chemicals
According to recent reports and studies, the scientific foundation underpinning these programs **must be improved to ensure sound and timely assessments in order to protect human health and the environment.**
Key areas of improvement needed for conducting chemical assessments
Tee up key issues and engage stakeholders in problem formulation and scoping

Utilize modern scientific policies and practices
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 Draft guidance should be submitted for public comment and peer review.

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.
Ensure All Assessments Rely On the Best Available Scientific Data and Methods

Develop and Apply Consistent Criteria for Evaluating Data and for Selecting Studies Used in Assessments
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.

Transparent criteria must be established upfront and then consistently applied throughout the assessment to identify studies and to evaluate their quality, relevance, and reliability.
Ensure transparency by disclosing key information used to develop assessments

Characterize hazards and risks accurately in a manner that is relevant to actual real-world human exposures
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.

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.
Employ a balanced and objective peer review process that is independent from the program office.

Ensure accountability and transparency by improving the process to fully address expert findings and public comments.
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.

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.
Creating an effective process for assessing chemicals is crucial for developing regulations that protect human health and the environment while preserving America’s ability to innovate.

These fundamental improvements are needed to conduct more scientifically-sound and timely assessments of chemicals.

Higher quality assessments will provide regulators, the public, and industry with more accurate and useful information to help guide better decisions about safe exposures to chemicals.