Future Directions in EPA Risk Assessment Practice

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Overview

- New Risk Management Challenges for EPA
- Evolving Practice
  - Quantitative analysis of uncertainty and variability
  - Cumulative risk
  - Research and development
- Summary

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New Risk Management Questions

- Much early attention on standard setting, cleanups, etc. – still important
- Now see decisions involving comparisons
  - Priority setting
  - Sustainability
  - Homeland security
  - Alternative regulatory options
  - Cumulative risk

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Need for Robust Risk Science

- Need to support many types of assessments and risk management decisions – e.g., IRIS
- Reflect scientific knowledge, and uncertainty, specific to each compound or assessment
- Quantitatively reflect variability and uncertainty in exposure and dose-response when known
- Keep EPA on the cutting edge of assessment

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Staying at the Forefront of Risk Assessment

- EPA Science Advisory Board
  - **"…the SAB strongly recommended the development of methodologies for quantitative uncertainty and variability analyses of toxicological parameters such as cancer unit risk values and reference doses".**

SAB Memo to Administrator Stephen L. Johnson – Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2007; An Advisory Report by the Science Advisory Board. March 30, 2006

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Staying at the Forefront of Risk Assessment

- NAS Dioxin Report:
  - The committee identified three key areas that require substantial improvement in describing the scientific basis for EPA's dioxin risk assessment to support a sufficient risk characterization
    - Justification of approaches to dose-response modeling for cancer and non cancer endpoints
    - Transparency and clarity in selection of key data sets for analysis
    - **Transparency, thoroughness and clarity in quantitative uncertainty analysis**

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Staying at the Forefront of Risk Assessment

- Proposed OMB Risk Assessment Bulletin
  - The purpose of this Bulletin is to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards.
  - **Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively**. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided. Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates.

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How

- Build on experience and expertise
- Research and development
- Demonstration

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Some Specific Examples

- Cumulative risk
- Quantitative analysis of uncertainty and variability

Cumulative Risk

- Characterization of significant sources of similar risk may be important for risk management
- Cumulative risk approaches have been pioneered for pesticides with development of specific models and guidance
- Need development for other compounds

EPA Efforts in Uncertainty Analysis - Exposure

- Almost 10 years of experience in quantitatively analyzing uncertainty and variability in exposure
  - Expertise
  - Experience
- Challenges remain
  - Data choices
  - Model uncertainty
  - Propagating uncertainty

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EPA Efforts in Uncertainty Analysis - Dose-Response

- Active area of research
- Demonstrations
  - IRIS
  - NAAQS
  - Radiation risks
- Agency-wide workgroups – *e.g.*,
  - Probabilistic analysis
  - Expert elicitation

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EPA Efforts in Uncertainty Analysis - Key Challenges

- Demonstrating methods
- Using wide range of data – “omics”
- Addressing model uncertainty
- Communicating uncertainty
- Concern about loss of “health protective” approach

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Summary

- Enhancing risk assessment practices will better support the many different risk management challenges EPA confronts
- It is important for EPA to stay on the forefront of risk assessment practice
- Many efforts are underway to develop, demonstrate and use state-of-the-art risk assessment practice
- Advice on areas of focus, specific tools and approaches will be very welcome

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