Decision-Making Under Uncertainty

Conference on Real World Applications and Solutions to Microbial Risk Assessment

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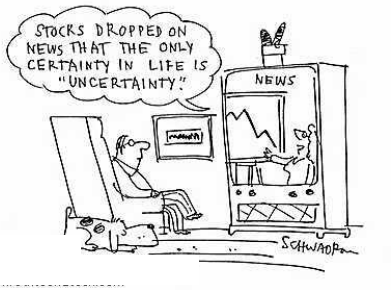

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EPA Is a Risk-Based Agency

- Agency manages risk to human health and the environment – complex decisions require sound information
- Risk assessment plays a key role in identifying important hazards and in developing management strategies
- Risk is considered a function of exposure and hazard (or toxicity), both of which have inherent uncertainties

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Supporting Agency Decisions

- EPA recognizes many new risk situations where characterizing uncertainty important for good decisions
  - –Priority setting
  - –Sustainability
  - –Regulatory options
  - –Homeland security
- Additional utility for VOI and research planning
- Will help Agency meet its transparency goals

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Microbial Risk Assessment in EPA

- Multiple programs and media
  - –Pesticides
  - –Water
  - –Solid Waste
- Decision makers are confronted with
  - –Complex problems
  - –Complex assessments
  - –Limited data
  - –Short timelines

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Chemical vs. Microbial Uncertainties

- Hazard Identification
  - –Methodology
- Dose-response relationships
  - –Reconstructing exposure from epidemiological data
- Species extrapolation
  - –Microbial specificity
- Environmental persistence
  - –Decay kinetics
- Sensitive groups or populations
  - –Modes of action

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Increasing Analysis of Uncertainty and Variability: Exposure

- Almost 10 years of experience in quantitatively analyzing uncertainty and variability in exposure
- Some challenges remain:
  - Data choices
  - Model uncertainty
  - Propagating uncertainty

Increasing Analysis of Uncertainty and Variability: Toxicity

- New emphasis on uncertainty and variability in toxicity values
- Some resistance to quantifying uncertainty
- Recent scientific advice to the Agency
  - SAB (Ethylene Oxide)
  - NAS (Dioxin, TCE)

General Advice From Scientific Community

- Increase quantitative characterization of uncertainty in dose-response assessments
- Consideration and use of multiple data sets and endpoints
- Explicit reporting of criteria for data selection
- Quantitative presentation of alternative low dose extrapolation models

Supporting Enhanced Consideration of Uncertainty

- Efforts primarily focusing on chemical risk assessment
- Need to apply knowledge to microbial issues
- Some EPA product and activities
  - Risk Characterization Handbook
  - NAS/Institute of Medicine project
  - Probabilistic Risk Assessment workgroup

Risk Characterization Handbook

- Principles of
  - Transparency
  - Clarity
  - Consistency
  - Reasonableness
- Risk Characterization helps decision makers
  - Achieve a better-informed decision
  - Understand the science
  - Build trust and credibility with staff, public and stakeholders

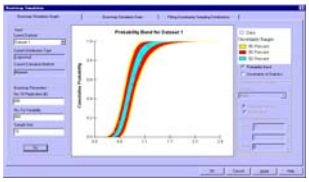
NAS/IOM Panel

- Panel provides independent advice
- Tasked with providing advice on how to improve decision-making under uncertainty
  - Benefits
  - Tools
  - Communication
  - Implementation
- Panel has sought advice from
  - Agencies
  - Industry
  - Academia
  - Environmental groups
- Report expected in fall 2008

Advancing Probabilistic Assessment at EPA

Office of Science Advisor Activity:

- White Paper on PRA Utility
- Case Studies
- Compiling tools, methods, best practices
- Expanded training



Looking to the Future

- Approaches to public health and environmental decision-making under uncertainty:
  get beyond "we won't know how to use this information"
- Specific tools and methods for informing decisions with quantitative analysis reflecting uncertainty in risks of specific outcomes.
- Methods for communicating uncertainty in risk information to a range of interested parties including decision makers and citizens

Thank You!