



*SAB Consultation
September 6, 2006*

EPA Risk Assessment Principles and Practices: Introduction

William H. Farland, Ph.D.
Chief Scientist
Office of the Science Advisor

United States Environmental Protection Agency



Background

- In early 2003, OMB asked for public comments on Federal Agencies' risk assessment practices
- Comments submitted were forwarded to EPA to consider

United States Environmental Protection Agency



EPA Risk Assessment Task Force

- Reviewed comments and grouped them according to common themes (e.g., conservatism, use of worst-case scenarios, susceptibility, uncertainty)
- Published Staff Paper in March 2004 as a description of EPA practices at that time

United States Environmental Protection Agency



Staff Paper Topics

Conservatism
Uncertainty (includes Sensitive Populations)
Extrapolation/Defaults
Site- & Chemical-Specific Discussion
Ecological Risk Assessment
Summary & Recommendations

United States Environmental Protection Agency



Key EPA Staff Paper Recommendations 1

- Development of additional chemical specific data to assess risks, including mode of action data as alternatives to defaults
- Encourage the development of additional data to support and refine defaults and assumptions we now use

United States Environmental Protection Agency



Key EPA Staff Paper Recommendations 2

- Better communication of the data, assumptions and defaults used in our risk assessments, including how we deal with uncertainty.
- Explore the feasibility of probabilistic analysis for all phases of risk assessment.

United States Environmental Protection Agency



Key EPA Staff Paper Recommendations 3

- Need to improve approaches to address cumulative effects of multiple stressors vs. single chemicals in risk assessments
- Need to improve approaches to characterize risks to infants, children, pregnant women, the elderly, or other populations that may be at greater risk

United States Environmental Protection Agency



Key EPA Staff Paper Recommendations 4

- **Transparency in risk assessment and risk management practices is crucial**
 - Continued use of planning and scoping before and during a risk assessment as a means of dialogue between risk assessors and risk managers
 - Encourage work on a decision making framework

United States Environmental Protection Agency



SAB Comments in July 2004

- Support for the effort to move towards a preference to use available and relevant data instead of default assumptions; and
- Support for the application of probabilistic methods, particularly to hazard and dose response assessments.

United States Environmental Protection Agency



Purposes of this SAB Consultation

1. Review key activities since publication of the Staff Paper and key input received;
2. Describe current research efforts related to human health risk assessment;
3. Describe 3 specific Program Office projects to illustrate progress in key areas;
4. Outline some future directions for EPA; and
5. Provide another opportunity for public comment in a FACA setting.

United States Environmental Protection Agency



Outreach Efforts

- Public Comment
- Meetings with EPA groups
- Meetings with members of the broad environmental community, including industrial and environmental groups, and 2 FACA committees, the ORD BOSC and the SAB
- Symposia and Workshops at professional society meetings, including SRA, and SOT

United States Environmental Protection Agency



Public Comments

Of 21 identified themes, the most frequently mentioned were:

- Level of conservatism from bias, defaults, lack of dose data; vs. omission of toxic metabolites
- Advancing probabilistic and distributional approaches;
- Criteria for generating/using sound data;
- Advancing cumulative/aggregate approaches;
- Better framework for screening vs refined assessments;
- Advancing ecological risk assessment;
- Improving risk assessment decision framework; separation of risk management;
- Quality and validity of models;
- Reasonableness of exposure assumptions;
- Consideration of subpopulations and lifestages

United States Environmental Protection Agency



Questions for SAB

- Do our efforts seem on track to advance EPA Risk Assessment practices and in line with comments and recommendations received re:
 - The program office activities presented; and
 - In EPA Research and
 - In our plans for future efforts
- What other areas and improvements should be considered and which would be most important?

United States Environmental Protection Agency



Office of the Science Advisor Web Site

www.epa.gov/osa

United States Environmental Protection Agency