Framework for Human Health Risk Assessment to Inform Decision Making

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Disclaimer

• The views expressed in this presentation are those of the author and do not represent the policy of the U.S. EPA.

Except when they do
NRC Risk Assessment Paradigm

- Dose Response Assessment
- Hazard Identification
- Risk Characterization
- Exposure Assessment
- Risk Management
- Risk Communication
’83 Risk Assessment Paradigm ’12?

Risk Assessment

- Mode of Action
- Hazard Identification
- Exposure Assessment
- Dose Response Assessment
- Risk Characterization

Risk Management

- Risk Management Options
- Statutory, legal considerations
- Politics
- Social Factors
- Available Technology
- Economics

Mode of Action

- Dose Response Assessment
- Hazard Identification
- Exposure Assessment
A lot has changed since ‘83

IPCS FRAMEWORK FOR ANALYSING THE RELEVANCE OF A CANCER MODE OF ACTION FOR HUMANS
Framework for Human Health Risk Assessment

• NRC Silver Book recommendation (Chapter 8 “Improving Utility of Risk Assessment”)
  • To make risk assessments most useful for risk management decisions, the committee recommends that EPA adopt a framework for risk-based decision-making . . . that embeds the Red Book risk assessment paradigm into a process with initial problem formulation and scoping, upfront identification of risk-management options and use of risk assessment to discriminate among these options.
Advantages (Silver Book)

- Systematically identify problems and options
- Expand the range of effects assessed beyond individual end points
- Integrate regulatory policy with other decision-making options and strategies
- Serve needs of a expanded number of decision-makers
- Increase understanding of the strengths and limitations of risk assessment by decision-makers at all levels.
RAF Human Health Risk Colloquium
10/11

- Brought 120 EPA risk assessors and managers together to focus on advancing human health risk assessment
  - NRC Recommendations
    - *Science and Decisions*
    - *Phthalates and Cumulative Risk*
    - *Toxicity Testing in the 21st Century*
  - Administrator Jackson's Priorities
    - Environmental Justice
    - Children's Health Protection
U.S. EPA RAF Technical Panel on HHRA Framework

• In prep for colloquium, planning group polled EPA risk assessors and manages
• Two points of view
  • We could use guidance on planning/ scoping/ problem formulation.
  • We do this all the time – in a more or less formal way.
• RAF tech panel embraced both points of view and collected info on EPA experience
EPA Frameworks

- RAF Ecological risk assessment
- RAF Framework for Cumulative Risk Assessment
- OAR residual risk framework
- Risk Characterization Handbook
- RAF Microbial Risk Assessment
- A Framework for Assessment Health Risk of Environmental Exposures to Children
- Risk Assessment Guidance for Superfund Part A
- OPPT/ OCSPP Risk Assessment Division
Cumulative Risk 1997
Ecological Risk Assessment Framework
Example: OPPT / OCSPPP

http://intranet.epa.gov/opptwork/divisions/rad/index.html
Most Frameworks Include

- Problem Formulation, scoping, planning
- Analysis
- Risk Characterization

What about Silver Book?
• What problem(s) are associated with existing environmental conditions?
• If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
• Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?

Stage 2: Risk Assessment

- **Hazard Identification**
  What adverse health or environmental effects are associated with the agents of concern?
- **Dose-Response Assessment**
  For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?
- **Risk Characterization**
  What is the nature and magnitude of risk associated with existing conditions? What risk decreases (benefits) are associated with each of the options? Are any risks increased? What are the significant uncertainties?
- **Exposure Assessment**
  What exposures/doses are incurred by each population of interest under existing conditions? How does each option affect existing conditions and resulting exposures/doses?

Stage 3: Confirmation of Utility

- Does the assessment have the attributes called for in planning?
- Does the assessment provide sufficient information to discriminate among risk management options?
- Has the assessment been satisfactorily peer reviewed?
Phase 1: Problem formulation and Scoping

- What is the problem to be investigated, and what is its source?
- What are the possible opportunities for managing risks associated with the problem? Has a full array of possible options been considered, including legislative requirements?
- What types of risk assessments and other technical and cost assessments are necessary to evaluate existing conditions and how the various risk-management options alter the conditions?
- What impacts other than health and ecosystem threats will be considered?
- How can the assessments be used to support decisions?
- What is the required timeframe for completion of assessments?
- What resources are needed to undertake the assessments?
Phase 2: Planning and Conduct of Risk Assessment

- **Stage 1: Planning**
  - For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options?
  - What level of uncertainty and variability analysis is appropriate?

- **Stage 2: Risk Assessment**

- **Stage 3: Confirmation of the Utility**
  - Does the assessment have the attributes called for in planning?
  - Does the assessment provide sufficient information to discriminate among risk-management options?
  - Has the assessment been satisfactorily peer reviewed?
Phase 3: Risk Management

- What are the relevant health or environmental benefits of the proposed risk-management options?
- How are other decision-making factors (technologies, costs) affected by the proposed options?
- What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
- How should the decision be communicated?
- Is it necessary to evaluate the effectiveness of the decision? If so, how should this be done?
Why Not Just Adopt the Silver Book Framework?
Some General Points

- This framework represents an organizing process. It is not to subsume or replace any existing or developing guidance or Guidelines. Rather it presents a series of questions or issues to consider in formulating a risk assessment.
- The purpose is to develop an overarching human health risk assessment framework consistent with NRC recommendations in Science and Decisions and existing EPA guidance.
PHASE I: PROBLEM FORMULATION AND SCOPING

• What problem(s) are associated with existing environmental conditions?
• If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
• Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?

PHASE II: PLANNING AND CONDUCT OF RISK ASSESSMENT

Stage 1: Planning
- For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?

Stage 2: Risk Assessment
- Hazard Identification
  What adverse health or environmental effects are associated with the agents of concern?
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Stage 3: Confirmation of Utility
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PHASE III: RISK MANAGEMENT

- What are the relative health or environmental benefits of the proposed options?
- How are other decision-making factors (technologies, costs) affected by the proposed options?
- What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
- How should the decision be communicated?
- Is it necessary to evaluate the effectiveness of the decision?
- If so, how should this be done?

FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES
- The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.
Cumulative Risk: P&S vs. PF
Planning and Scoping

- Overall purpose and general scope of the risk assessment
- Legal considerations
- RA products for informed decision-making, or for other analyses (e.g. economic)
- Resources (e.g. data, models, $, personnel available or pending)
- Coordination with other organizations
- Identification of those involved and their roles (e.g. technical, legal, or stakeholder advisors)
- Schedule to be followed (including peer review)

Problem Formulation

- Approaches, including a review of the risk factors and technical elements that may be evaluated in the assessment
- Relationships, if established, among potential assessment end points (e.g., magnitude of estimated health outcomes and risk metrics) and risk management options
- Analysis Plan and Conceptual Model
Conceptual Model

- Consists of
  - written description
  - visual representation
- Describes actual or predicted relationships between humans (or populations or population segments) and the chemicals or other stressors to which they may be exposed.
A Generalized Conceptual Model

with example of possible elements and linkages (adapted from USEPA, 2002; 2003)

<table>
<thead>
<tr>
<th>Sources</th>
<th>Stressors</th>
<th>Exposure Pathways/Routes</th>
<th>Receptors</th>
<th>Endpoints</th>
<th>Risk Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities that generate/release Stressors or types of stressor releases</td>
<td>Chemical, physical or biological agents that cause an effect</td>
<td>Physical processes or interactions by which a stressor is brought into contact with receptor</td>
<td>Populations and/or lifestages exposed to the stressor</td>
<td>Measures of stressor effects or biological systems affected</td>
<td>Metrics by which risk is quantified (e.g., disease cases, hazard quotients, magnitude of effect)</td>
</tr>
</tbody>
</table>
Drinking water disinfection

Variable mixture Chemicals; Dependent on treatment & source water.

Ingestion of Chemical mixture in drinking water

Consumers of drinking water; includes sensitive populations & life stages

Cancer, any site or type

Combined risk of cancer from subset Chemical in mixture

Work in progress for group of chemicals Under SDWA
Some Lessons Learned

- Many plans and conceptual models can benefit from peer review
- Data quality objectives should be designed, stated early in the process
- Each new assessment may not need a new Problem Formulation
  - Some boundaries are set by legislative mandate
  - Some standard operating procedures can be set
- Benefits of transparency are worth the investment
A Big Lesson

- Confirmation of utility is not a final step
- Fit for purpose of the risk assessment must be considered in all phases

“In EPA’s Framework described here, the utility of risk assessment is not something that is evaluated as a separate step in the process or a final check that occurs once the risk assessment is completed. Rather, consistent with the NRC’s emphasis on consideration of risk management needs early in the process, our Framework emphasizes attention to utility throughout the process, beginning with planning and scoping, and including a specific focus on the applicability of the risk assessment for informing risk management decisions.”
Some Questions from NRC

- Does the assessment design meet the objectives and have the attributes identified in the problem formulation step?
- Does the assessment, as implemented, meet the initial objectives? Or, if the initial objectives have been modified (e.g., as a result of changed risk management options or issues) does the assessment meet the modified objectives?
- Does the assessment have the attributes identified in planning?
- If the assessment requires peer review, has this been done appropriately and have the issues raised during the peer-review been addressed?
- How will the results of the risk assessment be communicated to the risk managers and stakeholders?
- Does the assessment inform choices among risk management options? Are there any additional risk assessment needs for discriminating between or implementing risk management options?
Fig. 9.1 A Solutions-based Framework for Improved Risk Management

Improving Risk Assessment Requires Embedding it in a Problem-Solving Framework
(See Text for Discussion of Steps in the Framework)

Planning for Risk Management

Assessing for Risk Management

Acting for Risk Management

Strategies for Risk Assessment

- What attributes are necessary to evaluate?
- What risk changes are associated with implementation of solutions?

- What health and environmental risks?
- With no solution?
- With proposed solutions?
- What uncertainties?

Solutions Assessment

- What do the proposed solutions accomplish?
- What do any costs?
- What uncertainties?

- How should uncertainties be accounted for?

Analysis of Risk Management Options

- What are the relative merits of the proposed solutions?
- How should they be justified?

Decisions

Formal Provisions for Stakeholder Involvement at All Stages

The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the process leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its...
• What are the relative health or environmental benefits of the proposed options?
• How are other decision-making factors (technologies, costs) affected by the proposed options?
• What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
• How should the decision be communicated?
• Is it necessary to evaluate the effectiveness of the decision?
• If so, how should this be done?

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FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES
• The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.
What problems are associated with existing environmental conditions?

If existing conditions may pose a threat to human health, what are options to alter those conditions?

What are the management goals and decisions needed?

What risk and other technical assessments are needed to evaluate risk management options?

What legal/statutory requirements affect risk management options and the level of analysis required?

Are there environmental justice or life stage considerations that affect risk management options?

What resources are available to conduct the assessment?

What is the public health protection provided by the proposed option?

How are other factors (technologies, costs, social considerations, environmental justice, sustainability, etc) affected by the proposed options?

How can effectiveness of the decision be evaluated?

Will the outcome change if the data are interpreted differently?
Risk assessments should not be conducted unless it is clear that they are designed to answer specific questions, and that the level of technical detail and uncertainty and variability analysis is appropriate to the decision context” (NRC 2009, p. 247).
Conclusions

- Framework **does not** determine the outcome of assessment
  - Framework **does**
    - Facilitate data organization
    - Prompts description of decision rationales
    - Can improve consistency and transparency
  - Fit for purpose is a good thing

- **Next Steps**
  - Complete responses to internal (EPA) reviewers
  - Send for external peer review
RAF Technical Panel

- Kathryn Gallagher Co-chair OW
- Rita Schoeny, Co-chair ORD
- Kacee Deener, ORD
- Chris Dockins Office of Policy
- Michael Firestone OCHP
- Margaret McDonough, Region 1
- Dierdre Murphy OAR
- Marian Olsen, Region 2
- Kathleen Raffaele, OSWER
- Julie Fitzpatrick, OSA/RAF Staff
Questions?
Analysis Plan

• How are we going to do this?
• May include
  • Assessment design and rationale for relationships addressed,
  • Data and information, methods and models to be used in the analyses, (including the uncertainty analyses),
  • Associated data gaps.
• May be phased or tiered risk approach to facilitate management consideration, scientific review and/or public involvement.
• As long and explicit as it needs to be
More on Analysis Plan

- Risk metrics should be defined
- Examples
  - Incidence of specific health outcomes;
  - Risk of specific health outcomes;
  - Occurrences of exposures above health-based benchmarks or comparison points;
  - Potential for occurrence of exposure above health-based benchmarks;
  - Margins of Exposure
  - Hazard Quotients
Problem Formulation

- **EPA’s Guidelines on Ecological Risk Assessment**
  - the analytical phase of the assessment wherein “the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined”

- Part of the planning process that systemically identifies the major factors to be considered in a particular assessment
  - Draws from the regulatory and policy context of the assessment
  - Provides the foundation for the technical approach of the assessment.

- Comprised of
  - Conceptual Model
  - Analytic Plan