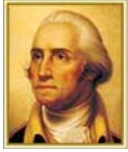




Improving the Utility of Risk Assessment

Professor George Gray
School of Public Health and Health Services
George Washington University
Washington, DC USA



THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON DC

Hard Choices





The Role of Risk Assessment

- Risk assessment is a way of assembling available scientific information to inform decisions
- Risk management is the process of making and implementing those decisions
- Increasing the utility of risk assessment should mean making it more useful for the decisions faced by individuals, communities and society



Science and Decisions

- Product of National Research Council of National Academy of Sciences
- Requested by EPA
- Delivered to Agency in 2009
- Two main foci are improving the technical basis of risk assessment and improving the utility of risk assessment





Science and Decisions on the Utility of Risk Assessment

Given the complexities of the current problems and potential decisions faced by EPA, the committee grappled with designing a more coherent, consistent, and transparent process that would provide risk assessments that are relevant to the problems and decisions at hand and that would be sufficiently comprehensive to ensure that the best available options for managing risks were considered.

NRC (2009) Page 10

Focus on Decisions

- The committee recommendsthat risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk rather than as an end in itself.
- Risk assessment should continue to capture and accurately describe what various research findings do and do not tell us about threats to human health and to the environment, but only *after* the risk-management questions that risk assessment should address have been clearly posed, through careful evaluation of the options available to manage the environmental problems at hand...



Changing Risk Questions

- Early risk assessment focused on standard setting (“safety assessment”)
- Now asking questions that involve tradeoffs
 - MeHg and fish consumption advisories
 - Disinfection by-products and microbial pathogens
 - Homeland security
 - Climate change strategies (e.g., biofuels, nuclear, renewables)

How do we make decisions that enhance sustainability?



What Needs to be Improved?

- Better risk information coverage
- Ability to predict outcomes
- Better understanding of changes in risk with changes in exposure
 - Exposure - response relationships
 - Cumulative exposure and attributable risk
- Central estimates of risk with quantitative uncertainty information for comparisons
- A way to compare risks of different types



More Information for Risk Decisions

- In many situations the default assumption is “no assessment - no risk” Must look at risks on all sides of a decision
- Some substitution risks not considered in choices
- Need approaches to estimate risk in data-sparse situations - acknowledging uncertainty
- Use new science approaches, empirical relationships, state of the art analysis tools
- Makes risk analysis helpful tool, not impediment

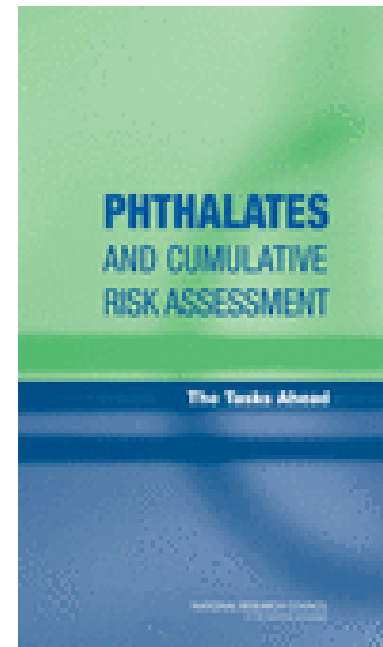


Predicting Outcomes

- Weighing alternatives will mean we need to compare actual outcomes, *e.g.*,
 - Δ disease
 - Δ injury
 - Δ lives saved
 - Δ species
- Requires estimation of risk not identification of a “safe” level of exposure

Cumulative Risk

- Characterization of significant sources of similar risk may be important for risk management
- Understand possible interactions of exposures and other determinants of health





Estimating Risks - A Key Distinction

- Actuarial Risks
 - based on previous experience with the same risk
 - predictions can be made with a great deal of precision – often “best estimates” of risk
 - examples include diseases, auto accidents, etc.
- Modeled Risks
 - based on data and theory not direct observation of the risk
 - predictions often subject to considerable uncertainty – sometimes use “conservative” or “protective” estimates of risk
 - examples include cancer risk from chemicals, climate change, etc.

Central Estimates

- Evaluating alternative solutions requires weighing risks
- Need estimates of risk without a thumb on the scale
- Compare “like with like”





Characterizing Uncertainty is Critical

- When we are confronted by tradeoffs
- When uncertainty is differential across risks
- When there are real dangers to making the wrong choice



Why Quantify Uncertainty? – Better Comparisons

- Numbers, especially single point estimates, may hide important differences between compounds
- Standard assumptions and methods of risk assessment are more scientifically plausible for some risks than for others
- Degree of conservatism in estimates varies between risks

Comparing Risks

- Broad approach means we will be comparing the risks of disparate outcomes
- Need tools to put risks in similar metric
 - €/£/\$?
 - Quality/Disability Adjusted Life Years (QALY/DALY)?
 - Others?

- Quality Adjusted Life Years (QALYs) are widely used in medical decision making to account for changes in both mortality and morbidity
- A QALY is a life year weighted to reflect quality of life during that period
 - A year of life in perfect health is worth 1 QALY
 - QALYs go to zero at death
 - A year of life in less than perfect health is worth between 0 and 1 QALY



The Key – Assessment Fits Decision

- Complexity of analysis only that necessary to identify superior choice
- Characterization of uncertainty commensurate with potential influence on choice
- Opportunity for application of Value of Information thinking
 - new options
 - new science



Summary

- The chief utility of risk assessment is in helping make better decisions about health and the environment
- The questions asked, and decisions to be made, are getting more complex
- Risk assessment practice will have to evolve to maximize its utility

- Necessary enhancements include:
 - Better risk information coverage
 - Prediction of actual outcomes
 - Better understanding of exposure and response
 - Central estimates of risk with quantitative portrayal of uncertainty
 - A means to compare different types of risk
- Need to look to future uses to make sure we are appropriately improving the utility of risk assessment

This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumers DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.