Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision-Making With Case Study Examples

Prepared by Risk Assessment Forum
PRA Technical Panel Working Groups

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This document was produced by a Technical Panel of the EPA Risk Assessment Forum. The authors drew on their experience in doing probabilistic assessments and interpreting them to improve risk management of environmental and health hazards. Interviews, presentations, and dialogues with risk managers conducted by the Technical Panel have contributed to the insights and recommendations in this summary and the associated White Papers.

Foreword

Throughout most of the Environmental Protection Agency's program offices and regions, various forms of probabilistic methods have been used to answer questions about exposure and risk, to humans and other organisms, and the environment. EPA risk assessors, risk managers and others, particularly within the scientific and research divisions have recognized that sophisticated statistical and mathematic approaches could be still more fully utilized to enhance the quality and accuracy of Agency risk assessment and risk management. Various stakeholders, inside and outside the Agency, have called for a more comprehensive characterization of risks, including uncertainties, in protecting more sensitive or vulnerable populations and life stages.

Therefore, the Office of the Science Advisor of the EPA, together with the Science Policy Council and members of the Risk Assessment Forum (RAF), identified a need to examine the use of probabilistic approaches in Agency risk assessment and risk management. An RAF Technical Panel developed papers (this paper and a managers' summary) which provide a general overview of the value of probabilistic analyses and similar or related methods, and some examples of current applications across the Agency.

The goal of these papers is not only to describe potential and actual uses of these tools in the risk decision process, but also to encourage their further implementation in human, ecological and environmental risk analysis and related decision making. The enhanced use of probabilistic analyses to characterize uncertainty in assessments would not only reflect external scientific advice on how to further advance EPA risk assessment science, but will also help to address specific challenges faced by managers and improve confidence in Agency decisions

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Executive Summary

Probabilistic risk assessment (PRA) is a group of techniques that provide estimates of the range and likelihood of hazard, exposure or risk, rather than a single point estimate. Stakeholders, inside and outside the Agency, have recommended a fuller characterization of risks, including uncertainties, in protecting more sensitive or vulnerable populations and life stages.

The goal of this white paper is to explain how EPA can achieve broader use of probabilistic methods and address uncertainty and variability by capitalizing on the wide array of tools and methods that comprise PRA. The information contained in this document is intended for both risk analysts and managers faced with determining when and how to apply these tools in their decisions. This paper begins with a decision-maker's perspective, proceeds to a more technical discussion, and finally gives a number of illustrative examples of actual EPA applications of probabilistic analyses.

The white paper describes challenges faced by EPA decision makers, defines and explains the basic principles of probabilistic analysis, briefly highlights instances where these techniques have been used in EPA decisions, and describes criteria that may be useful in determining whether application of probabilistic methods may be useful and/or applicable to a specific decision. The white paper also describes commonly employed methods to address variability and uncertainty, including those used in the consideration of uncertainty in scenarios, uncertainty in models, and variability and uncertainty in the inputs and outputs of models. A general description is provided of the range of methods from simple to complex, rapid to more time-consuming, and least to most resource-intensive, and opportunities for utilization. More detailed examples of applications of these methods are provided, in Appendix D titled "Case Study Examples of the Application of Probabilistic Risk Analysis in U.S. Environmental Protection Agency Decision Making."

This document does not prescribe a specific approach but, rather, describes the various stages and aspects of an assessment or decision process in which probabilistic assessment tools may add value. This white paper provides answers to common questions regarding PRA, including key concepts such as scientific and institutional motivations for use of PRA, and challenges in the application of probabilistic techniques. The white paper describes how PRA can both enhance the Agency's credibility and improve decision making.

1. Introduction: Relevance of Uncertainty to Decision making: How Probabilistic Approaches Can Help

1.0. What Is Probabilistic Risk Analysis, and How Does It Address Variability and Uncertainty?

Probabilistic analyses include techniques that can be applied formally to address both variability and uncertainty. Probability is used in sciences, business, economics, and other fields to examine existing data and estimate the chance of an event, from health effects to rain to metal fatigue. One can use probability (chance) to quantify the frequency of occurrence or the degree of belief in information. For variability, probability distributions are interpreted as representing the relative frequency of a given state of the system (i.e., that the data are distributed a certain way), whereas, for uncertainty, they represent the degree of belief or confidence that a given state of the system exists (i.e., that we have the appropriate data) (Cullen and Frey, 1999). PRA often is defined narrowly to mean a statistical or thought process used to analyze and evaluate the variability of available data or to look at uncertainty across data sets.

For the purposes of this document, *PRA* is a term used to describe a process that uses probability to incorporate the variability in data sets, and/or the uncertainty in information such as data or models, into analyses that support environmental risk-based decision making. PRA is used here broadly to include both quantitative and qualitative methods for dealing with scenario, model, and input uncertainty. Probabilistic techniques can be used with other types of analysis, such as benefit-cost analysis, regulatory impact analysis, and engineering performance standards and, thus, is used for a variety of applications and by experts in many disciplines.

1.1. Goals and Intended Audience

The goals of this white paper are to introduce probabilistic analysis (PRA) and how it can be used to better inform and improve the decision-making process, and to provide case studies where it has been used in human health and ecological analyses at EPA (Appendix D). A secondary goal of this paper is to bridge communication gaps regarding PRA among analysts of various disciplines, between these analysts and Agency decision makers, and affected stakeholders. The white paper is also intended to serve as a communication tool to help introduce key concepts and background information on approaches to risk analysis that incorporate uncertainty and provide a more comprehensive treatment of variability. Risk analysts, risk managers, and affected stakeholders can benefit from understanding the potential uses of PRA. PRA and related approaches can be used to identify further research that can decrease uncertainty and more thoroughly characterize variability in a risk assessment. This white paper will explain how PRA is well suited to enhancing the decision-making processes in EPA by addressing inherent uncertainties faced by managers involved in that process.

1.2. Overview of This Document

This document reviews EPA's interest in and experience with addressing uncertainty and variability using probabilistic methods; identifies key questions asked or faced by Agency decision makers; shows how conventional deterministic approaches to risk analysis may not answer these questions fully; provides examples of applications; and shows how and why "probabilistic risk analysis" (broadly defined) provides added value with regard to regulatory decision making by more fully characterizing risk estimates. For the purposes of this white paper, PRA and related tools for both human health and ecological assessments include a range of approaches from statistical tools, such as sensitivity analysis, to multi-dimensional Monte Carlo models, geospatial approaches, and expert elicitation. Key points addressed by this document include definitions and key concepts pertaining to PRA, the need for PRA, benefits and challenges of PRA, a general conceptual framework for PRA, conclusions regarding products and insights obtained from PRA, and examples where EPA has used PRA in human health and ecological analyses. A glossary and a bibliography are provided.

1.3. What Are Common Challenges Facing EPA Risk Decision makers?

EPA decision makers face scientifically complex problems that are compounded by varying levels of uncertainty and variability. In reality, uncertainty in risk decisions is unavoidable, since we cannot perfectly model or predict real world situations, but uncertainty can be reduced or better characterized through knowledge. Variability is inherent in natural systems, and therefore cannot be reduced, but can also be examined and described. Decision makers often want to know who is at risk and by how much, the tradeoffs between alternative actions or decisions, and the likely or possible consequences of decisions. To this end, it is particularly useful to decision makers to understand the distribution of risk across potentially impacted populations and ecological systems. It can be important to know the number of individuals experiencing different magnitudes of risk, the differences in risk magnitude experienced by individuals in different life stages or populations, or the probability of an event which may lead to unacceptable levels of risk. Given the limitations of data, traditional methods of risk analyses are not well suited to produce such estimates. Probabilistic analytical methods are capable of addressing these shortcomings and can contribute to a more thorough recognition of the impact of data gaps on the projected risk estimates.

A defensible decision process explicitly takes into account uncertainties and variability and the rationale or factors influencing how a decision maker addresses these. Factors such as economics, equity, feasibility, stakeholder input, and other considerations may also be part of the decision-making process. Decision making typically contend with several key factors, including multiple, conflicting objectives, uncertainty, and alternative regulatory options available to a decision maker. In addition, decision analysis provides a theoretical foundation for estimating the value of collecting more information to allow for more informed decisions. In the face of uncertainty, decision making is determined not only by science but also by Agency policy. Where not prohibited by statute, the relative costs and benefits of regulatory alternatives may be considered in making decisions.

If uncertainty and variability have not been well characterized or acknowledged, potential complications arise in the process of decision-making that seeks to achieve a balance between over- and under-regulation. Increased uncertainty can make it more difficult to determine with reasonable confidence the balance point between costs of regulation and the implications for avoiding damages and producing benefits. Characterization of these factors, facilitated by probabilistic analyses, can provide insight in weighing the relative costs and benefits of varying levels of regulation and also assist in risk communication activities.

1.4. What Are Key Questions Often Asked by Decision makers?

Determining decision-maker concerns is a critical first step toward developing a useful and responsive risk assessment. For example, the appropriate focus and level of detail of the analysis should be commensurate with decision maker and stakeholder needs as well as appropriate use of science. Often, analyses are conducted at a level of detail dictated by the issue being addressed, the breadth and quality of the available information upon which to base an analysis, and the significance surrounding this decision. The analytical process tends to be an iterative one, and, even though a guiding set of questions may frame the initial analyses, additional questions can arise that further direct or even reframe the analyses.

Based on a series of discussions with Agency decision makers and risk assessors, some questions that are typically posed about risk analyses include the following:

- How representative or conservative is the estimate, (e.g., what is the variability around an estimate)?
- What are the major gaps in knowledge, and what are the major assumptions used in the assessment? How reasonable are the assumptions?
- Would my decision be different if the data were different? Would additional data collection and research likely lead to a different decision? How long will it take to collect the information, how much would it cost, and would the resulting decision be significantly different?
- Will the use of additional resources, such as a probabilistic approach, impact the decision making in a timely manner (i.e., better characterize uncertainties, better identify variability, impact timelines, etc.)?
- What are the liabilities/consequences of making a decision under the current level of knowledge and uncertainty?
- What is the percentile of the population to be protected?
- How do the different alternative decision choices and the interpretation of uncertainty and variability impact the target population?

The questions that arise concerning analyses, including PRA, change depending on the stage and nature of the decision making and analysis, from planning and scoping through risk management. The utility of various levels of analysis and levels of sophistication in answering these questions are illustrated in the case studies section described in Section 1.8 and presented in Appendix D.

1.5. Why Is the Implementation of Probabilistic Risk Analysis Important?

The principal reason for the inclusion of PRA as an option in the risk assessor's toolbox is PRA's ability to refine and improve the information leading to decision making by incorporating known uncertainties. Beginning as early as the 1980s (NRC, 1983), expert scientific advisory groups have been recommending that risk analyses include a clear discussion of the uncertainties in risk estimation. The National Research Council (NRC, 1994) stated the need to describe uncertainty and to capture variability in risk estimates. The Presidential/Congressional Commission on Risk Assessment and Risk Management (PCRARM, 1997) recommended against a requirement or need for a "bright line," or single number, level of risk (see Section 2.5 for more on the scientific community's opinion on use of PRA). Regulatory science often requires selection of a limit for a contaminant, yet that limit always contains uncertainty as to how protective it is. PRA and related tools quantitatively describe the very real variations in natural systems and living things and how they respond to stressors and the uncertainty in estimating those responses. Risk characterization became EPA policy in 1995, and the principles of transparency, clarity, consistency, and reasonableness are explicated in the 2000 Risk Characterization Handbook (EPA, 2000). Transparency, clarity, consistency, and reasonableness criteria require decision makers to describe and explain the uncertainties, variability, and known data gaps in the risk analysis and how they affected resulting decision-making processes (USEPA, 2000, 1992, 1995).

The use of probabilistic methods also has received support from some decision makers within the Agency, and these methods have been incorporated into a number of Agency decisions to date. Program offices such as the Offices of Pesticides, Solid Waste and Emergency Response, Air and Radiation, and Water, as well as the Office of Research and Development have utilized probabilistic approaches in different ways and to varying extents, for both human exposure and ecological risk analyses. In addition, the Office of Solid Waste and Emergency Response has provided explicit guidance on the use of probabilistic approaches for exposure analysis (EPA, 2001). Some program offices have held training sessions on Monte Carlo simulation (MCS) software frequently used in probabilistic analyses.

Where it is useful to refine risk estimates, the use of PRA can help in the characterization and communication of uncertainty, variability, and the impact of data gaps in risk analyses, for assessors, decision makers, and stakeholders including the target population.

1.6. How Does EPA Typically Address Scientific Uncertainty and Communicate Variability?

Environmental assessments can be complex, such as exposures to multiple chemicals in multiple media for a wide ranging population. The Agency often has developed simplified approaches to characterizing risks through the use of point estimates for model variables or parameters. Such an approach typically produces point estimates of risks (e.g., 10^{-5} lifetime probability of cancer risk for an individual). These are often called “deterministic” assessments. As a result of the use of point estimates for variables in model algorithms, deterministic risk results usually are reported as what are assumed to be either average or worst-case estimates and do not contain any quantitative estimate of the uncertainty in that estimate, nor report to what percentile of the exposed population the estimate applies. However, the methods typically used in EPA risk assessments rely on a combination of point values with potentially varying levels of conservatism and certainty, yielding a point estimate of exposure that may be at some unknown point in the range of possible risks.

Because uncertainty is inherent in all risk assessments, it is important that the risk assessment process handle uncertainties in a logical way that is transparent and scientifically defensible, consistent with the Agency’s statutory mission, and responsive to the needs of decision makers (NRC, 1994). Thus, when data are missing, EPA often uses several options to provide some bounds on uncertainty and variability, in an attempt to avoid risk underestimation; attempting to give a single quantification of how much confidence there is in the risk estimate may not be informative or feasible. For example, in exposure assessment, the practice at EPA is to collect new data where needed and where time and resources allow. Alternatives include narrowing the scope of the assessment, using screening level default assumptions that include upper-end values and/or central tendency values that are generally combined to generate risk estimates that fall within the higher end of the population risk range (USEPA, 2004), using models to estimate missing values, using surrogate data (e.g., data on a parameter that come from a different region of the country than the region being assessed), or using professional judgment. The use of individual assumptions can range from qualitative (e.g., assuming one is tied to the residence location and does not move through time or space) to more quantitative (e.g., using the 95th percentile of a sample distribution for an ingestion rate). This approach also can be applied to the practice of hazard identification and dose-response assessment when data are missing. Identifying the sensitivity of exposure or risk estimates to key inputs can help in focusing efforts to reduce uncertainty by collecting more data.

1.7. What Are the Limitations of Relying on Default-Based Deterministic Approaches?

Deterministic risk analysis often is considered a traditional approach to risk analysis because of the existence of established guidance and procedures regarding its use, the ease with which it can be performed, and its limited data and resource needs. The use of defaults supporting deterministic risk assessment provides a procedural consistency that allows for risk assessments to be feasible and tractable. Risk managers and members of the public tend to be relatively familiar with deterministic risk assessment, and use of such an approach addresses assessment-related uncertainties primarily through the incorporation of predetermined default values and conservative assumptions. It addresses variability by combining input parameters intended to be representative of typical or higher end exposure (considered to be conservative assumptions). The intention is often to provide a margin of safety or to construct a screening level estimate of high-end exposure and risk (i.e., an estimate representative of more highly exposed and susceptible individuals).

Deterministic risk assessment provides an estimation of exposures and resulting risks that addresses uncertainties and variabilities in a qualitative manner. The methods typically used in EPA deterministic risk assessments rely on a combination of point values—some conservative and some typical—yielding a point estimate of exposure that is at some unknown point in the range of possible risks. Such an approach is believed to more likely overestimate than underestimate risks. Although this conservative bias (more likely to over- than underestimate risks) aligns with the public health mission of EPA (USEPA, 2004), the degree of conservatism in these risk estimates (and in any concomitant decision) cannot be estimated well or communicated (Hattis and Burmaster, 1994). This results in unquantified uncertainty in risk statements.

Estimates generated using these methods are unaccompanied by quantitative information regarding their precision or potential systematic error and do not account for the distribution of exposures, effects, and resulting risks across different members of an exposed population. Although deterministic risk assessments may present qualitative information regarding the robustness of the estimates, the impact of data and model limitations on the quality of the results cannot be quantified. Reliance on deterministically derived estimations of risk can result in decision making based solely on point estimates with an unknown degree of conservatism, which can complicate comparison of risks or management options. The use of conservative defaults has long been the target of criticism and has led to the presumption by critics that EPA assessments are overly conservative and unrealistic. This criticism may reduce the overall perceived credibility of an Agency decision.

Deterministic risk assessment is not as well suited as PRA for more complex assessments, including those of aggregate and cumulative exposures and time-dependent individual exposure, dose, and effects analyses. Identification and prioritization of contributory sources of uncertainty can be difficult and time consuming when using deterministic methods, leading to difficulties in model evaluation and the subsequent appraisal of risk estimates (Cullen and Frey, 1999). These comprehensive quantitative analyses of model sensitivities are essential for the prioritization of key uncertainties—a critical step in identifying steps for data collection or research to improve exposure or risk estimates.

1.8. What Is EPA's Experience with the Use of Probabilistic Risk Analysis?

To assist with the growing number of probabilistic analyses of exposure data, EPA issued *Guiding Principles for Monte Carlo Analysis* (EPA, 1997). Probabilistic analysis techniques such as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments. The EPA policy for use of probabilistic analysis in risk assessment, released in 1997, is inclusive of human exposure and ecological risk assessments, but does not rule out probabilistic health effects analyses. Subsequently, EPA's Science Advisory Board (SAB) and Scientific Advisory Panel have reviewed PRA approaches to risks by EPA Offices such as Air and Radiation, Pesticides, and others. Several programs have developed specific guidance on use of PRA, including Pesticides and Solid Waste and Emergency Response (EPA, 1998, 2001).

To illustrate the practical application of PRA to problems relevant to the Agency, several example case studies are briefly described here. Appendix D, Case Study Examples of the Application of Probabilistic Risk Analysis in U.S. Environmental Protection Agency Regulatory Decision Making, discusses these and other case studies in greater detail, including the procedures and outcome. The examples are intended to illustrate how some of EPA's programs and offices currently utilize PRA. They demonstrate how information from probabilistic analyses, including sensitivity analysis, MCS, and other techniques, were used in decision making. Some of the approaches that are profiled can be used easily in the planning and scoping of risk assessments and risk management. Other more complex approaches are used to answer more specific questions and provide a richer description of the risks. Most show that PRA can improve or expand information generated by deterministic methods. The case studies illustrate that the Agency already has applied the science of PRA to ecological risk and human exposure estimation and has begun using PRA to describe health effects. Some of the applications have used existing "off the shelf" software, whereas others have required significant effort and resources. Once developed, however, some of the more complex models have been used many times for different assessments. All have stood the test of internal and external peer review. A list of the case study examples presented in Appendix D are provided in Table 1 including categorizations based on type of assessment (i.e., human health or ecological risk assessment); PRA tools used in the assessment; and program office or region responsible for the assessment. In several cases, the examples presented represent components of the overall risk assessment that demonstrate use of multiple PRA techniques.

A few examples that illustrate the variety of PRA uses in EPA are:

- Hudson River PCB-Contaminated Sediment Site: Region 2 evaluated the variability in risks to anglers who consume recreationally caught fish contaminated with PCBs from sediment contamination in the Hudson River. (Case Study 5)
- EMAP program: The Office of Research and Development (ORD) developed and Office of Water (OW) adopted an applied probabilistic sampling techniques to evaluate nation's aquatic resources under CWA Section 305(b) (Case Study 7)
- Chromated Copper Arsenate Risk Assessment: ORD and the Office of Pesticide Programs (OPP) conducted a probabilistic exposure assessment of children's exposure (addressing both variability and uncertainty) to arsenic and chromium from contact with CCA-treated wood playsets and decks. (Case Study 9)
- Evaluating Ecological Effects of Pesticide Uses: OPP developed a probabilistic model which evaluates acute mortality levels in generic and specific ecological species for user-defined pesticide uses and exposures. (Case Study 13)
- $PM_{2.5}$ Health Impacts: The Office of Air and Radiation (OAR) used expert elicitation to more completely characterize, both qualitatively and quantitatively, the uncertainties associated with the relationship between reduction in $PM_{2.5}$ and benefits of reduced $PM_{2.5}$-related mortality. (Case Study 14)

2. Probabilistic Risk Analysis

2.1. What Are Variability and Uncertainty, and How Are They Relevant to Decision-making?

The concepts of variability and uncertainty are introduced here, and the relevance of these concepts to decision making is discussed.

2.1.1. Variability

Variability refers to real differences over time, space, or members of a population and is a property of the system being studied (e.g., drinking water rates for each of the many individual adult residents living in a specific location) (Cullen and Frey, 1999). Variability can arise from inherently random processes, such as variations in wind speed over time at a given location or from true variation across members of a population that, in principle, could be explained but that, in practice, may not be explainable using currently available models or data (e.g., the range of blood lead levels in 6-year-old children following a specific degree of lead exposure). Of particular interest in human health risk assessment is inter-individual variability, which typically refers to differences between members of the same population in either behavior related to exposure (e.g., dietary consumption rates for specific food items) or biokinetics related to chemical uptake or toxic response (e.g., gastrointestinal uptake rates for lead following intake).

2.1.2. Uncertainty

Uncertainty is the lack of knowledge of the true value of a quantity or relationships among quantities. For example, there may be a lack of information regarding the true distribution variability between individuals for consumption of certain food items. There are a number of types of uncertainties for both risk analyses and risk management. The following description of types of uncertainty (drawn from Cullen and Frey, 1999) addresses uncertainties that arise during risk analyses. These uncertainties can be separated broadly into three categories: (1) scenario uncertainty, (2) model uncertainty, and (3) input (or data) uncertainty. Each of these is explained below.

Scenario uncertainty refers to errors, typically of omission, resulting from incorrect or incomplete specification of the risk scenario to be evaluated. The risk scenario refers to a set of assumptions regarding the situation to be evaluated, such as (a) the specific sources of chemical emissions or exposure to be evaluated (one industrial facility or a cluster of varied facilities impacting the same study area), (b) the specific receptor populations and associated exposure pathways to be modeled (e.g., indoor inhalation exposure, track-in dust, or consumption of home-produced dietary items), and (c) the times or activities to be considered (e.g., exposure only at home, or consideration of workplace or commuting exposure). Misspecification of the risk scenario can result in underestimation, overestimation, or other mischaracterization of risks. For instance, underestimation may occur because of exclusion of relevant situations or inclusion of irrelevant situations with respect to a particular analysis. Overestimation may occur because of the inclusion of unrealistic or irrelevant situations (e.g., assuming continuous exposure to an intermittent airborne contaminant source rather than accounting for mobility throughout the day.)

Model uncertainty refers to limitations in the mathematical models or techniques that are developed to represent the system of interest and often stems from: (a) simplifying assumptions, (b) exclusion of relevant processes, (c) misspecification of model boundary conditions (i.e., range of input parameters), or (d) misapplication of a model developed for other purposes. Model uncertainty typically arises when the risk model relies on missing or improperly formulated processes, structures, or equations. Refer to the glossary for additional information.

Input or Parameter uncertainty typically refers to errors in characterizing empirical values used as inputs to the model (e.g., engineering, physical, chemical, biological, or behavioral variables). Input uncertainty can stem from random or systematic errors involved in measuring a specific phenomenon (e.g., biomarker measurements such as the concentration of mercury in human hair); from statistical sampling errors associated with small sample sizes (if the data are based on samples selected with a random, representative sampling design); from the use of surrogate data instead of directly relevant data, or the absence of an empirical basis for characterizing an input (e.g., absence of measurements for fugitive emissions from an industrial facility); or from the use of summary measures of central tendency rather than individual observations. Nonlinear random processes can exhibit a behavior that, for small changes in input values, produces large variation in results.

2.2. When Is Probabilistic Risk Analysis Applicable or Useful?

PRA is useful in the following types of situations (Cullen and Frey, 1999).

- When a screening level deterministic risk assessment indicates that risks are possibly higher than a level of concern, and, therefore, a more refined assessment is needed
- When the consequences of using potentially biased point estimates of risk are unacceptably high
- To estimate the value of collecting additional information to reduce uncertainty
- When significant equity issues are raised by inter-individual variability
- To identify promising critical control points and critical levels when evaluating risk management alternatives
- To rank exposure pathways, sites, contaminants, and so on for purposes of prioritizing model development or further research

PRA typically is not necessary in the following types of situations (Cullen and Frey, 1999; EPA 1997).

- When a screening-level deterministic risk assessment indicates that risks are negligible, presuming that the assessment is known to be biased to produce overestimates of risk
- When the cost of averting the exposure and risk is smaller than the cost of probabilistic analysis
- When there is little uncertainty or variability in the analysis (This is a rare situation.)

2.3. How Can Probabilistic Risk Analysis Be Incorporated into Assessments?

As illustrated in the accompanying case studies (Appendix D), probabilistic approaches can be incorporated into any stage of a risk assessment, from problem formulation or planning and scoping to analysis of alternative risk management decisions. In some situations, PRA can be used selectively for components of an assessment. It is common in assessments that some model inputs are known with high confidence (i.e., based on site-specific measurements), whereas values for other inputs are less certain (i.e., based on surrogate data collected for a different purpose). For example, an exposure modeler may determine that there is relevant air quality monitoring data but a lack of detailed information of human activity patterns in different microenvironments. Thus, an assessment of variability in exposure to airborne pollutants might be based on direct use of the monitoring data, whereas assessment of uncertainty and variability in the inhalation exposure component might be based on statistical analysis of surrogate data or use of expert judgment. The uncertainties are likely larger for the latter than the former component of the assessment; thus, efforts to characterize uncertainties associated with pollutant exposures would focus on the latter.

2.4. What Are the Scientific Community's Views on Probabilistic Risk Analysis, and What Is the Institutional Support for Its Use?

The NRC recently emphasized its long-standing advocacy for probabilistic risk assessment (NRC, 2007a,b). Dating from its 1983 *Risk Assessment in the Federal Government* (NRC, 1983)—which first formalized the risk assessment paradigm—through various reports released in the late 1980s, all during the 1990s, and through the early 2000s, various NRC panels have consistently maintained that—because risk analysis involves substantial uncertainties—these uncertainties should be evaluated within a risk assessment. These panels noted,

(1) in 1989, that when evaluating total population risk, EPA should consider the distribution of exposure and sensitivity of response in the population (NRC, 1989);
(2) in 1991, that when assessing human exposure to air pollutants, EPA should present model results along with estimated uncertainties (NRC, 1991);
(3) in 1993, that when conducting ecological risk assessments, EPA should discuss thoroughly uncertainty and variability within the assessment (NRC, 1993); and,
(4) in 1994, an NRC report, *Science and Judgment in Risk Assessment,* stated that "uncertainty analysis is the only way to combat the 'false sense of certainty,' which is *caused* by a refusal to acknowledge and [attempt to] quantify the uncertainty in risk predictions" (emphasis in the original) (NRC, 1994). In 2002, another report suggested that EPA's estimation of health benefits were not wholly credible because EPA failed to deal formally with uncertainties in its analyses (NRC, 2002).

Asked to recommend improvements to the Agency's human health risk assessment practices, EPA's Science Advisory Board echoed the NRC's sentiments and urged the Agency to characterize variability and uncertainty more fully and more systematically and to replace single-point uncertainty factors with a set of distributions using probabilistic methods (Parkin and Morgan, 2007). The key principles of risk assessment cited by the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) include "explicit" characterization of the uncertainties in risk judgments; they go on to cite the National Academy of Science's 2007 recommendation to address "variability of effects across potentially affected populations" (OSTP/OMB, 2007).

2.5. How Can Probabilistic Risk Assessment Provide More Comprehensive, Rigorous Scientific Information in Support of Regulatory Decisions?

External stakeholders in the past have used the Administrative Procedure Act and the Data Quality Act to challenge the Agency for a lack of transparency and consistency or for not fully analyzing and characterizing the uncertainties in risk assessments or risk management decisions (see Fisher et al., 2006). The more complete implementation of PRA and related approaches to deal with uncertainties in decision-making lends support to the overall Agency risk-based decision-making process.

The results of any assessment, including PRA, are dependent on the underlying methods and assumptions. Accompanied by the appropriate documentation, PRA may communicate a more robust representation of risks and corresponding uncertainties. This characterization may take shape in the form of a range of possible estimates as opposed to the more traditionally presented single-point values. Depending on the needs of the assessment, ranges can be derived for variability and uncertainty (or a combination of the two) in both model inputs and resulting estimations of risk.

2.6. Are There Additional Advantages of Using Probabilistic Risk Analysis?

PRA quantifies how exposures, effects, and risks differ among individuals and provides an estimation of the degree of confidence with which these estimates may be made, given the current uncertainty in scientific knowledge and available data. A 2007 NRC panel stated that the objective of PRAs is *not* to decide "how much evidence is sufficient" to adopt an alternative but, rather, to describe the scientific bases of proposed alternatives so that scientific and policy considerations may be more fully evaluated (NRC, 2007a). EPA's SAB similarly noted that PRAs provided more "value of information" through quantitative assessment of uncertainty, and clarify the science underlying Agency decisions (EPA, 2007).

The SAB proposed a number advantages Agency decision-makers could reap from utilization of probabilistic methods (Parkin and Morgan, 2007).

- A probabilistic reference dose could help reduce the potentially inaccurate implication of zero risk below the RfD.
- By understanding and explicitly accounting for uncertainties underlying a decision, EPA can estimate formally the value of gathering more information. By doing so, two benefits follow: (1) EPA can better prioritize its research needs by investing in areas that yield the greatest information value; and (2) when making decisions, the Agency can eschew the less-than-helpful rationale of "too much scientific uncertainty." By candidly acknowledging uncertainty's ubiquity, EPA can base a decision on more intellectually robust concepts of comparing present risks against the costs of gathering more information.
- By adopting PRA, EPA sends the appropriate signal to the intellectual marketplace, thereby encouraging analysts to gather data and to develop methodologies necessary for assessing uncertainties.

2.7. What Are the Challenges to Implementation of Probabilistic Analyses?

Currently, EPA is using PRA in a variety of programs to support decisions, but challenges remain regarding the expanded use of these tools within the Agency; these include those that follow.

- A lack of understanding of the value of PRA to decision making;
- The perception, if not reality, that PRA requires additional resources;
- Limited resources (staff, time, training, or methods) to conduct PRA;
- A lack of clear directive or requirement to utilize PRA in many cases;

- Lack of understanding of how to incorporate the results of probabilistic analyses into decision making and how to establish action levels based on the scope of the assessment.
- The complexity of communicating probabilistic analysis results.
- Fuller characterization of the uncertainties in a risk estimate through use of PRA can lead to more difficult decision making or more complicated risk communication
- The ability to simulate and reanalyze numerous scenarios using various models and input data could lead to prolonged analyses and delay decisions

These challenges are discussed in more detail below.

2.8. How Can Probabilistic Risk Analysis Support Specific Regulatory Decision making?

Decision makers sometimes perceive that the binary nature of regulatory decisions (e.g. Does an exposure exceed a reference dose or not? Do emissions comply with Agency standards or not?) precludes the use of a range of uncertainty, compared with the use of point estimates. Generally, it is legally necessary to explain the rationale underlying a particular decision. PRA's primary purpose is to provide information so that decisions are based on the best available science; it is not to necessarily displace legally mandated decisions with a range of alternatives. By doing a sensitivity analysis of the influence of the uncertainty on the decision-making process, it can be determined how or if PRA can help improve the process.

2.9. Does Probabilistic Risk Analysis Require More Resources Than Default-Based Deterministic Approaches?

PRA can generally be expected to require more resources than standard Agency default-based deterministic approaches. There is extensive experience within EPA in conducting and reviewing deterministic risk assessments. These assessments tend to follow standardized methods that minimize the effort required to conduct them and to communicate the results. Probabilistic assessments often entail a more detailed analysis, and, as a result, there exists a common perception that these assessments require substantially more resources than do deterministic approaches.

Appropriately trained staff and the availability of adequate tools, methods, and guidance are essential for application of PRA. Proper application of probabilistic methods requires not only software and data but also guidance and training for both analysts using the tools and for managers and decision makers tasked with interpreting and communicating the results. In most circumstances, probabilistic assessments may take more time and effort to conduct than conventional approaches, primarily because of the comprehensive inclusion of available information on model inputs.

An upfront increase in resources needed to conduct a probabilistic assessment can be expected, but development of standardized approaches and/or methods can lead to the routine incorporation of PRA in Agency approaches (e.g., the Office of Pesticide Programs' use of DEEM, a probabilistic dietary exposure model). The initial and, in some cases, ongoing resource cost (e.g., that for development of site-specific models for site assessments) may be offset by a more informed decision than a comparable deterministic analysis. Probabilistic methods are useful for identifying effective risk management options and in prioritizing additional data collection or research aimed at improving risk estimation, ultimately resulting in management options that enable improved environmental protection while, simultaneously, conserving greater resources.

2.10. Doesn't Probabilistic Risk Analysis Require More Data Than Conventional Approaches?

There are differences in opinion within the technical community as to whether PRA requires more data than other types of analyses. Although some emphatically believe that PRA requires more data, others argue that probabilistic assessments make better use of all of the available data and information. Stahl et al. (2005) discuss when and how much data are necessary for a decision. PRA can benefit from more data than might be used in a deterministic risk assessment. For example, where deterministic risk assessments may employ selected point estimates (such as mean or 95th percentile values) from available datasets for use in model inputs, PRA facilitates the use of frequency-weighted data distributions, allowing for a more comprehensive consideration of the available data. In many cases, the data that were used to develop the presumptive 95th percentile can be employed in the development of probabilistic distributions.

Restriction of PRA to data-rich situations may prevent its application where it is most useful. Because PRA incorporates information on data quality, variability, and uncertainty into risk models, the influence of these factors on the characterization of risk can become a greater focus of discussion and debate.

A key benefit of using PRA is its ability to reveal limitations, as well as strengths, of data that often are masked by a deterministic approach. In doing so, PRA can help inform research agendas, as well as support regulatory decision making, based on the state of the best available science. In summary, PRA typically requires more time for developing input assumptions than a corresponding deterministic risk assessment, but when incorporated in the relevant steps of the risk assessment process, PRA can demonstrate real added benefits. In some cases PRA can provide additional interpretations that compensate for the additional efforts.

2.11. Can Probabilistic Risk Analysis Be Used To Screen Risks or Only in Complex or Refined Assessments?

Probabilistic methods typically are not necessary where traditional default-based deterministic methods are adequate for screening risks. Such methods are relatively low cost, are intended to produce conservatively biased estimates, and are useful for identifying situations in which risks are so low that no further action is needed. The application of probabilistic methods can be targeted to situations in which a screening approach indicates that a risk may be of concern or when the cost of managing the risk is high, creating a need for information to help inform risk management decisions. PRA fits directly into a graduated hierarchical approach to risk analysis. PRA also could be used to more fully examine the existing default-based methods based on the current state of information and knowledge to determine if such methods are truly conservative and adequate for screening.

2.12. Does Probabilistic Risk Analysis Present Unique Challenges to Model Evaluation?

The concept of "validation" of models used for regulatory decision making has been a topic of heated discussion. In a recent report on the use of models in environmental regulatory decision making, NRC recommended the use of the notion of model "evaluation" rather than "validation," suggesting use of a process that encompasses the entire life cycle of the model and recognizes the spectrum of interested parties in the application of the model, which often extends beyond the model builder and decision maker. Such a process can be designed to ensure that judgment of the model application is based not only on its predictive value determined from comparison with historical data but also on its comprehensiveness, rigor in development, transparency, and interpretability (NRC, 2007b).

Model evaluation is important in all risk assessments. In the case of PRA, there is an additional question as to the validity of the assumptions made regarding probability and frequency distributions for model inputs and their dependencies. Probabilistic information can be accounted for during evaluation analyses by considering the range of uncertainty in the model prediction and whether such a range overlaps with the "true" value based on independent data. Thus, probabilistic information can aid in characterizing the precision of the model predictions and whether a prediction is significantly different from a benchmark of interest. For example, comparisons of probabilistic model results and monitoring data were done for multiple models in developing the cumulative pesticide exposure model. There are also published concurrent PRA model evaluations using a Bayesian analysis (Clyde, 2000).

2.13. How Do You Communicate Results of Probabilistic Risk Analysis?

The approaches for reporting results from PRA vary depending on the assessment objective and the intended audience. Beyond the basic 1997 principles and the policy from the same year, the Risk Assessment Guidance for Superfund: Volume III also provides some guidance on the quality and criteria for acceptance as well as communication basics (EPA, 2001). There have been limited studies of how information from PRA regarding variability and uncertainty can or should be communicated to key audiences such as decision makers and stakeholders (e.g., Morgan and Henrion, 1990; Bloom *et al*., 1993; Krupnick *et al*., 2006). Among the analyst community, there is often an interest in visualization of the structure of a scenario and model using influence diagrams and depiction of the variability and uncertainty in model inputs and outputs using probability distributions in the form of cumulative density functions or probability

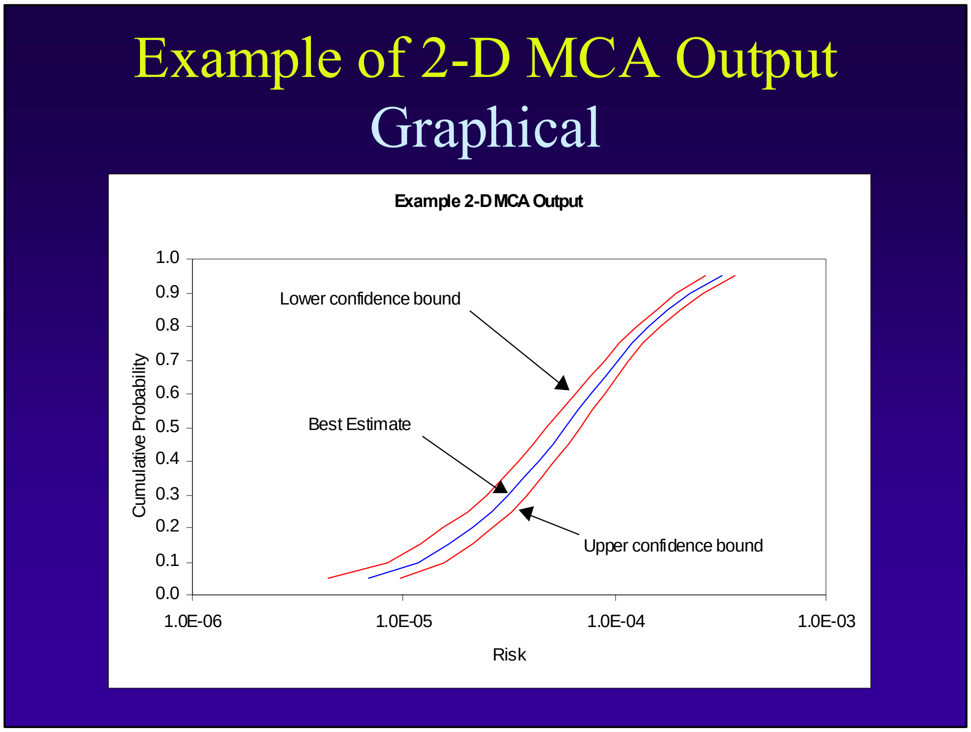

Figure 1. Graphical Description of the Likelihood (Probability of Risk) of Toxicity
(Fitted data distribution and confidence intervals)
Source: Frey, H.C. (2004)

distribution functions (Figure 1). Sensitivity of the model output to variability and uncertainty in model inputs can be depicted using graphical tools.

In some cases, these graphical methods can be useful for those less familiar with PRA, but in many cases there is a need to translate the quantitative results into a message that extracts the key insights without burdening the decision maker with obscure technical details. In this regard, the use of ranges of values for a particular metric of decision-making relevance (e.g., range of uncertainty associated with a particular estimate of risk) may be adequate. The presentation of PRA results to a decision maker may be conducted best as an interactive discussion, in which a principal message is conveyed, followed by exploration of issues such as the source, quality, and degree of confidence associated with the information. There is a need for development of recommendations and a communication plan regarding how to communicate the results of PRA to decision makers and stakeholders, building on the experience of various programs and regions in this area.

2.14. Are the Results of Probabilistic Risk Analysis Difficult To Communicate to Decision-makers and Stakeholders?

Research has shown that the ability of decision makers to deal with concepts of probability and uncertainty is variable. Bloom et al. (1993) surveyed a group of senior managers at EPA and found that many could interpret information about uncertainty if it was communicated in an appropriate manner that was responsive to decision-maker interests, capabilities, and needs. In a more recent survey of ex-EPA officials, Krupnick et al. (2006) concluded that most had difficulty understanding information on uncertainty, and that certain formats used to present uncertainty information were more effective than others. The findings of these studies highlight the need for practical strategies for communication of results of PRA and uncertainty information between risk analysts and decision makers, as well as between decision makers and other stakeholders. The Office of Emergency and Remedial Response has compiled guidance to assist analysts and managers in understanding and communicating the results of PRA (EPA, 2001).

3. Findings and Recommendations

3.1 Findings: How Probabilistic Risk Analysis and Related Analyses Can Improve the Decision-making Process at EPA

PRA is an analytical methodology capable of incorporating information regarding uncertainty and/or variability in analyses to provide insight regarding the degree of certainty of a risk estimate and how the risk estimate varies among different members of an exposed population. Traditional approaches often report risks as "central tendency" or "high end (e.g., 90th percentile or above)," or "maximum anticipated exposure" and PRA can be used to more fully describe uncertainty surrounding such estimates and identify the key contributors to variability or uncertainty in predicted exposures or risk estimates. This information then can be used by decision makers to achieve a science-based level of safety, to weigh alternative risk management options, or to invest in researching areas which have the greatest uncertainty and impact on the risk estimates.

Using PRA, one can obtain insight regarding whether one risk management strategy is more likely to reduce risks compared to another, and by how much. The methodology facilitates the investigation of potential changes in decisions that may result from the collection of additional information that could better characterize variability and potentially reduce uncertainty and helps determine how expenses incurred by activities to reduce uncertainty are offset by improved decision-making capabilities gained from the acquisition of that knowledge. PRA can facilitate the construction and simultaneous consideration of multiple model alternatives. Probabilistic methods offer a number of tools designed to promote robust management and increased confidence in decision making through the incorporation of input variability and uncertainty characterization and prioritization in risk analyses. For example, sensitivity analyses can be used to identify influential knowledge gaps involved in the estimation of risk, allowing for improved transparency and the ability to more clearly communicate or articulate the most relevant information to decision makers and stakeholders. Ultimately, PRA can enhance the Agency's credibility in its approach to science-based decision making.

3.2. Recommendations for Enhanced Utilization of PRA in EPA

The various tools and methods discussed in this paper can be used at all stages of risk analysis and also aid the decision-making process by characterizing inter-individual variability and uncertainties. Probabilistic analyses and related methods are in use in varying degrees across the Agency:

- The use of Monte Carlo or other probability based techniques to derive a range of possible outputs from uncertain inputs is a fairly well-developed approach within EPA.
- Although basic guidance exists at EPA on the use and acceptability of PRA for risk estimation, implementation varies greatly within programs, offices and regions.
- Although highly sophisticated human exposure assessment and ecological risk applications have been developed, use of PRA models to assess human health effects and dose-response has been somewhat limited.

Enhanced use of PRA and consistent applications in support of EPA decision-making requires improved internal capacity for conducting these assessments, as well as interpreting and communicating such information in the context of decisions. Such improvements of internal capacity could be accomplished through sharing of experiences, knowledge, and training, improved policy and guidance, and increased availability of tools and methods.

Some steps to improve implementation include:

- Inform risk managers about the advantages and disadvantages in using PRA techniques in their decision-making process through lectures, webinars, and communication regarding the techniques and their use in EPA.
- Train risk assessors so that they can learn about the various tools available, their applications, software and review considerations, and resources for additional information (e.g., experts and support services within the Agency).
- Meetings and discussions of PRA techniques and their application with both managers and assessors will aid in providing greater consistency and transparency to EPA's risk assessment process and in developing EPA's internal capacity.
- Demonstrate through informational opportunities and resource libraries the various tools and methods that can be used at all stages of risk analysis and also aid the decision-making process by characterizing inter-individual variability and uncertainties.
- Promote the sharing of experience, knowledge, models, and best practices via meetings of risk assessors and risk managers; electronic exchanges, such as the EPA Portal Environmental Science Connector; and more detailed discussions regarding the case studies.
- Provide easily available, flexible, modular training for all levels of experience to familiarize employees to the menu of tools and their capacities.
- Provide introductory as well as advanced training open to all offices.
- Provide live and recorded seminars and Webinars for introductory and supplemental education, as well as periodic, centralized hands-on training sessions on how to utilize software programs.

Risk assessors, risk managers, and decision makers need to be provided the information and training necessary so that they can better utilize these tools. Education and experience will generate familiarity with these tools that will then lead analysts and decision makers to better understand the techniques and consider more fully utilizing these techniques.

3.3 Guidance and Policy

Additional guidance can be developed to help analysts and decision makers decide which statistical tools to use and when to use them, and how probabilistic information can help to inform the basis of those decisions. Both deterministic and probabilistic approaches and other statistical methods may be useful at any stage of the risk analysis and decision-making process, from planning and scoping to characterizing and communicating uncertainty. Such bodies as the EPA's Science Policy Council can play a role in directing guidance development to help implement probabilistic and related tools. Examples of guidance needed include:

- Probabilistic approaches to evaluating health effects data
- Probabilistic approaches to ecological risk assessment

- Integrating probabilistic exposure and risk estimates and communicating uncertainty and variability.

3.4 Challenges

In general terms, while PRA techniques are currently available which would help inform EPA decision-making process, research, as well as guidance, is needed to further improve these methods for more complete implementation of PRA in human health and ecological risk assessment. Some examples include:

- Although highly sophisticated human exposure assessment and ecological risk applications have been developed, use of PRA models to evaluate toxicity data has been very limited. Scientific, technical, and science policy discussions are needed in this area.
- There is no consensus on any one well-accepted general methodology for dealing with model uncertainty, although there are various examples of efforts to do so. Thus, additional research on formal methods for treating model uncertainties will be valuable.
- As noted in Appendix A.3, there are significant challenges to properly account for variability and uncertainty when multiple models are coupled together to represent the source-to-outcome continuum (e.g., the OPP-Environmental Fate and Effects Division's aquatic and terrestrial models). Moreover, the coupling of multiple models (e.g., emissions, air quality, exposure, dose, effect) may need to involve inputs and corresponding uncertainties that are incorporated into more than one model, potentially resulting in complex dependencies (e.g., ambient temperature affects emission rates, air quality, and human activity that influence total emissions and exposures).
- There may be mismatches in the temporal and spatial resolution of each model, which confound the ability to propagate variability and uncertainty from one model to another. For some models, the key uncertainties may be associated with inputs, whereas, for other models, the key uncertainties may be associated with structure or parameterization alternatives

Appendix A: An Overview of Some of the Techniques Used in Probabilistic Risk Analysis

A.1. What Is the General Conceptual Approach in Probabilistic Risk Analysis?

PRA includes several major steps, which parallel the accepted environmental health risk assessment process. These include (1) problem and/or decision criteria identification, (2) getting information, (3) interpreting the information, (4) selecting and applying models and methods for quantifying variability and/or uncertainty, (5) quantifying inter-individual or population variability and uncertainty in metrics relevant to decision-making, (6) sensitivity analysis to identify key sources of variability and uncertainty, and (7) reporting of results.

Problem identification deals with identifying the assessment end points, or issues, that are relevant to the decision-making process, as well as to other stakeholders, and that can be addressed in a scientific assessment process. Following problem identification, information is needed from stakeholders and experts regarding the scenarios to evaluate. Based on the scenarios and assessment endpoints, the analysts select or develop models, which in turn leads to identification of model input data requirements and acquisition of data or other information (e.g., expert judgment encoded as the result of a formal elicitation process) from which to quantify inputs to the models. The data or other information for model inputs is interpreted in the process of developing probability distributions to represent variability, uncertainty, or both for a particular input. Thus, the steps (1) through (4) listed above are highly interactive and iterative in that the data input requirements and how information is to be interpreted depend on the model formulation, which depends on the scenario, which in turn depends on the assessment objective. The assessment objective may have to be refined depending on the availability of information.

Once a scenario, model, and inputs are specified, the model output is estimated. A common approach is to use Monte Carlo or other probabilistic methods for generating samples from the probability distributions of each model input, run the model based on one random value from each probabilistic input, and produce one corresponding estimate of the model outputs. This process is repeated typically hundreds or thousands of times to create a synthetic statistical sample of model outputs. These output data are interpreted as a probability distribution of the output of interest. Sensitivity analysis can be performed to determine which model input distributions are most highly associated with the range of variation in the model outputs. The results may be reported in a wide variety of forms depending on the intended audience, ranging from qualitative summaries to tables, graphs, and diagrams.

Levels of Analyses

- Sensitivity analysis
- Monte Carlo analysis of variability in
  - Exposure data
  - Human health or ecological effect data
- Monte Carlo analysis of uncertainty
- “Cumulative” PRA—multi-pathway or multi-chemical
- Two-dimensional PRA of uncertainty and variability
- Decision uncertainty analysis
- Geospatial analysis
- Expert elicitation

A.2. What Are the Multiple Types of Probabilistic Risk Analyses, and How Are They Used?

There are multiple levels for conducting risk assessments. Graduated approaches to analysis are widely recognized (e.g., EPA, 1997; EPA, 2001; WHO, 2007). The idea of a graduated approach is to choose a level of detail and refinement for an analysis that is appropriate to the assessment objective, data quality, information available, and importance of the decision (e.g., resource implications).

Detailed introductions to PRA methodology are available elsewhere, such as Ang and Tang (1984), Cullen and Frey (1999), EPA (2001), Morgan and Henrion (1990) and EPA, 2001. A few key aspects of PRA methodology are briefly mentioned here. However, readers who seek more detail should consult these references and see the bibliography for additional references.

The deterministic risk assessment approaches described in Section 1.6 are examples of lower levels in a graduated approach to analysis, in which risk at the lower levels of analysis is assessed by conservative, bounding assumptions. If the risk estimate is found to be very low despite use of conservative assumptions, then there exists a great deal of certainty that the actual risks to the population of interest for the given scenario are below levels of concern and, thus, that no further intervention is required, assuming the model specification is correct. However, when a conservative deterministic risk assessment indicates that a risk may be high, it is possible that the risk estimate is biased, and the actual risk may be lower. In such a situation, depending on the resource implications of risk management, it may be appropriate to proceed with a more refined, or higher level, analysis. If the cost of intervention is less than the cost of further analysis, then it may be appropriate to simply proceed to the risk management decision as a preventive measure that is also expedient. In some deterministic assessments, for instance, for ecological risks, the assumptions are not well assured of conservatism and the estimated risks might be biased to appear lower than the unseen actual risk

A more refined analysis could involve applications of deterministic risk assessment methods but with alternative sets of assumptions intended to characterize central tendency and reasonable upper bounds of exposure, effects, and risk estimates, such that the estimates could be for an actual individual in the population of interest (rather than a hypothetical maximally exposed individual). However, such analyses are not likely to provide quantification regarding the proportion of the population at or below a particular exposure or risk level of concern, uncertainties for any given percentile of the exposed population, nor priorities among input assumptions with respect to their contributions to variability and uncertainty in the estimates.

To more fully answer the questions often asked by decision-makers, the analysis can be further refined by incorporating quantitative comparisons of alternative modeling strategies (to represent structural uncertainties associated with scenarios or models), by quantifying ranges of variability and uncertainty in model outputs, and by providing the corresponding ranges for model outputs of interest. When performing probabilistic analyses such as these, choices are made regarding whether to focus on quantification of variability only, uncertainty only, both variability and uncertainty co-mingled (representing a randomly selected individual), or variability and uncertainty distinguished (e.g., in a two-dimensional depiction of probability bands for estimates of inter-individual variability) (see Figure 2). The simultaneous but distinct propagation of variability and uncertainty in a two dimensional framework enables quantification of uncertainty in the risk for any percentile of the population. For example, one could estimate the range of uncertainty in the risk faced by the median member of the population or the 95th percentile member of the population. Such information can be used by a decision maker (for example) to gauge the confidence that should be placed in any particular estimate of risk, as well as to determine whether additional data collection or information might be useful to reduce the uncertainty in the estimates. The OPP assessment of chromated copper arsenate treated wood (see Appendix D) used such an approach.

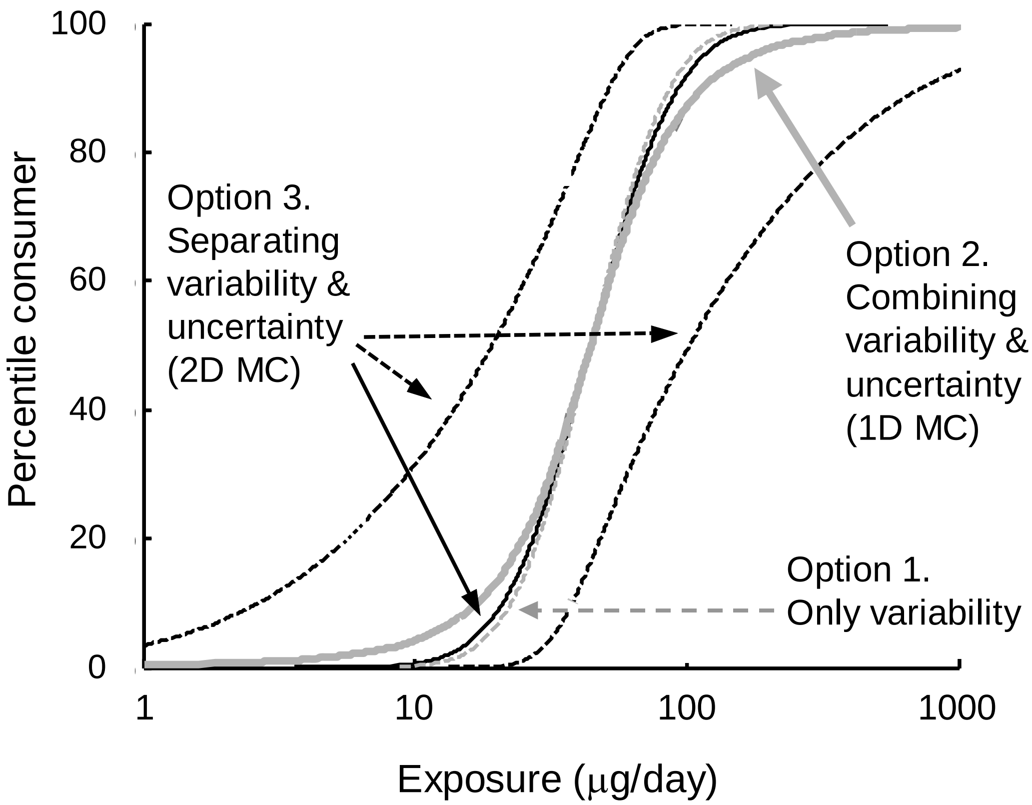

Figure 2: Diagrammatic comparison between three alternative probabilistic approaches for the same exposure assessment. In option 1, only variability is quantified. In option 2, both variability and uncertainty are propagated together. In option 3, variability and uncertainty are propagated separately. MC = Monte Carlo. 1D = one dimensional; 2D = two dimensional. **Source**: WHO (2008)

When conducting an analysis for the first time, it may not be known or clear, prior to analysis, which components of the model or which model inputs contribute the most to the estimate risk or its variability and uncertainty. However, as a result of completing an analysis, the analyst often gains insight into both strengths and weaknesses of the models and input information. Probabilistic analysis and sensitivity analysis can be used together to identify the key sources of quantified uncertainty in the model outputs to inform decisions regarding priorities for additional data collection. Ideally, time should be allowed for collecting such information and refining the analysis to arrive at a more representative and robust estimate of variability and uncertainty in risk. Thus, the notion of *iteration* in developing and improving an analysis is widely recommended.

The notion of iteration can be applied broadly to the risk assessment framework. For example, a first effort to perform an analysis may lead to insight that the assessment questions might be impossible to address, or that there are additional assessment questions that may be equally or more important. Thus, iteration can include reconsideration of the initial assessment questions and the corresponding implications for definition of scenarios, selection of models, and priorities for obtaining data for model inputs. Alternatively, in a time-limited decision environment, such probabilistic and sensitivity analyses may offer insight into the effect of risk management options on risk estimates.

A.3. What Are Some Specific Aspects of and Issues Related to Methodology for Probabilistic Risk Analysis?

This section briefly touches on a few key aspects of PRA, model development, and associated uncertainties. Detailed introductions to PRA methodology are available elsewhere, such as Ang and Tang (1984), Cullen and Frey (1999), EPA (2001), and Morgan and Henrion (1990). Readers who seek more detail should consult these references and see the bibliography for additional references.

A.3.1. Developing a Probabilistic Risk Analysis Model

There are a number of key issues that should be considered in developing a PRA model. Some of these are outlined below.

Structural Uncertainty in Scenarios

A potentially key source of uncertainty in an analysis is the scenario, which includes specification of pollutant sources, transport pathways, exposure routes, timing and locations, geographic extent, and related issues. As yet, there appears to be no formalized methodology for dealing quantitatively with uncertainty and variability in scenarios. Decisions regarding what to include or exclude from a scenario could be recast as hypotheses regarding which agents, pathways, microenvironments, and so on contribute significantly to the overall exposure and risk of interest. In practice, however, the use of qualitative methods tends to be more common, given the absence of a formal quantitative methodology.

Coupled Models

For source-to-outcome risk assessments, it is often necessary to work with multiple models, each of which represents a different component of a scenario. For example, there may be separate models for emissions, air quality, exposure, dose, and effects. Such models may have different spatial and temporal scales. When conducting an integrated assessment, there may be significant challenges and barriers to coupling such models into one coherent framework. Sometimes, the coupling is done dynamically in a software environment. In other cases, the output of one model might be processed manually to prepare the information for input to the next model. Furthermore, there may be feedbacks between components of the scenario (e.g., poor air quality might affect human activity, which, in turn, could affect both emissions and exposures) that are incompletely captured or not included at all. Thus, the coupling of multiple models can be a potentially significant source of structural uncertainty.

A.3.2. Conducting the Probabilistic Analysis

Quantifying Variability and Uncertainty in Model Inputs and Parameters

Once the models are selected or developed to simulate a scenario of interest, attention typically turns to development of input data for the model. There is a substantial amount of literature regarding the application of statistical methods for quantifying variability and uncertainty in model inputs and parameters based on empirical data (e.g,. Ang and Tang, 1984; Cullen and Frey, 1999; Morgan and Henrion, 1990; EPA 2001). For example, a commonly used method for quantifying variability in a model input is to obtain a sample of data, select a type of parametric probability distribution model to fit to the data (e.g., normal, lognormal, or other form), estimate the parameters of the distribution based on the data, critique the goodness-of-fit using graphical (e.g., probability plot) and statistical methods (e.g., Anderson-Darling, Chi-Square, or Kolmogorov-Smirnov tests), and choose a preferred fitted distribution. This methodology can be adjusted to deal with various types of data, such as data that are samples from mixtures of distributions or that contain nondetected (censored) values. Uncertainties can be estimated based on confidence intervals for statistics of interest, such as mean values, or the parameters of frequency distributions for variability. Various texts and guidance documents, both Agency and programmatic, describe these approaches, including the Guiding Principles for Monte Carlo Analysis (EPA, 1997) and the internet site *learner.org*.

The most commonly used method for estimating a probability distribution in the output of a model, based on probability distributions specified for model inputs, is Monte Carlo Simulation (MCS) (Cullen and Frey, 1999; Morgan and Henrion, 1990). MCS is popular because it is very flexible. MCS can be used with a wide variety of different types of probability distributions as well as different types of models. The main challenge for MCS is that it requires repetitive model calculations to construct a set of pseudo-random numbers for model inputs and the corresponding estimates for model outputs of interest. There are alternatives to MCS that are similar but more computationally efficient, such as Latin Hypercube Sampling (LHS). Techniques are available for simulating correlations between inputs in both MCS and LHS. For models with very simple functional forms, it may be possible to use exact or approximate analytical calculations, but, in practice, such situations are encountered infrequently.

There may be situations in which the data do not conform to a well-defined probability distribution. For such situations, Markov Chain Monte Carlo is an algorithm that samples the data iteratively and randomly to estimate a so-called "likelihood function" (i.e., the probability distribution and parameter estimates that provide the most likely explanation of the data). The likelihood function is a key component of Bayesian inference and, therefore, serves as the basis for some of the analytical approaches to variability and uncertainty described below.

The use of empirical data presumes that the data are a representative, random sample. However, if there are known biases or other data quality problems, or if there is a scarcity or absence of relevant data, then reliance on available empirical data is likely to lead to misleading inferences in the analysis. Alternatively, estimates of variability and uncertainty can be encoded, using formal protocols, based on elicitation of expert judgment (e.g., Morgan and Henrion, 1990). Elicitation of expert judgment for subjective probability distributions is used in situations where there are insufficient data to support a statistical analysis of uncertainty but in which there is sufficient knowledge on the part of experts to make an inference regarding uncertainty. For example, EPA has recently conducted an expert elicitation study on the concentration-response relationship between annual average ambient $PM_{2.5}$ exposures and annual mortality (IEC, 2006; see also Case Studies 6 and 14). Subjective probability distributions that are based on expert judgment can be "updated" with new data as they become available using Bayesian statistical methods.

Structural Uncertainty in Models

There may be situations in which it proves useful to evaluate not just the uncertainties in inputs and parameter values, but also uncertainties regarding whether a model adequately captures, in a hypothesized, mathematical, structured form, the relationship under investigation. A qualitative approach to evaluating the structural uncertainty in a model is to describe critical assumptions within a model, the documentation of a model, or model quality. Quantitative approaches to evaluating structural uncertainty in models are manifold. These include parameterization of a general model that can be reduced to alternative functional forms (e.g., Morgan and Henrion, 1990), enumeration of alternative models in a probability tree (e.g., Evans et al., 1994), comparing alternative models by evaluating likelihood functions (e.g., Royall, 1997; Burnham and Anderson, 2002), pooling results of model alternatives using Bayesian updating (e.g., Hoeting et al., 1999), or testing the causal relationships within alternative models using Bayesian Networks (Pearl 2000).

Sensitivity Analysis: Identifying the Most Important Model Inputs

Sensitivity analysis is complementary to probabilistic methods. There are many types of sensitivity analysis methods, including, for example, simple techniques that involve changing the value of one input at a time and assessing the effect on an output and statistical methods that evaluate which of many simultaneously varying inputs contributes the most to the variance of the model output. Sensitivity analysis can answer the following key questions.
- What is the impact of changes in input values on model output?
- How can variation in output values be apportioned among model inputs?
- What are the ranges of inputs associated with best or worst outcomes?
- What are the key controllable sources of variability?
- What are the critical limits (e.g., emission reduction target for a risk management strategy)?
- What are the key contributors to the output uncertainty?

Thus, sensitivity analysis can be used to inform decision making regarding research priorities and risk management.

Probabilistic methods typically focus on the forward propagation of uncertainty or variability in the input to a model with respect to uncertainty or variability in a model output. However, once a probabilistic analysis is completed, sensitivity analysis typically takes the perspective of looking backwards to evaluate how much of the variation in the model output is attributable to individual model inputs (e.g., Frey and Patil, 2002; Mokhtari et al., 2006; Saltelli et al., 2004).

Iteration

There are two major types of iteration in risk assessment modeling. One is iterative refinement of the type of analysis, perhaps starting with a relatively simple deterministic risk assessment as a screening step in an initial level of analysis and proceeding to more refined types of assessments as needed in subsequent levels of analysis. Examples of more refined levels of assessment include application of sensitivity analysis to deterministic risk assessment; the use of probabilistic methods to quantify variability only, uncertainty only, or co-mingled variability and uncertainty (to represent a randomly selected individual); or the use of two-dimensional probabilistic methods for distinguishing and simultaneously characterizing both variability and uncertainty.

The other type of iteration occurs within a particular level and includes iterative efforts to formulate a model, obtain data, and evaluate the model to prioritize data needs. For example, a model may require a large number of input assumptions. To prioritize efforts of specifying distributions for variability and uncertainty for model inputs, it is useful to determine which model inputs are most influential with respect to the assessment end point. Therefore, sensitivity can be used based on preliminary assessments of ranges or distributions for each model input to determine which inputs are the most important to the assessment. Refined efforts to characterize distributions then can be prioritized to the most important inputs.

Appendix B: Glossary

Analysis. Examination of anything complex to understand its nature or to determine its essential features (WHO IPCS Risk Assessment Terminology)

Assessment. The analysis and transformation of data into policy-relevant information that can assist decision making and action.

Assessment end point. 1. Quantitative or qualitative expression of a specific factor or metric with which a risk may be associated, as determined through an appropriate risk assessment. 2. An explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together, salmon "reproduction and age class structure" form an assessment end point.

Bayesian probability. An approach to probability, representing a personal degree of belief that something will occur..

Critical control point. A controllable variable that can be adjusted to reduce exposure and risk. For example, a critical control point might be the emission rate from a particular emission source. The concept of critical control point is from the hazard assessment and critical control point concept for risk management that is used in space and food safety applications, among others.

Critical limit. A numerical value of a critical control point at or below which risk is considered to be acceptable.

Ecological risk assessment. An ecological risk assessment evaluates the potential adverse effects that human activities have on the plants and animals that make up ecosystems. The risk assessment process provides a way to develop, organize, and present scientific information, so that it is relevant to environmental decisions. When conducted for a particular place, such as a watershed, the ecological risk assessment process can be used to identify vulnerable and valued resources, prioritize data collection activity, and link human activities with their potential effects.

Ecosystem. The interacting system of a biological community (plants and animals) and its nonliving environment.

Expert Elicitation. Expert elicitation (EE) is a systematic process of formalizing and quantifying, typically in probabilistic terms, expert judgments about uncertain quantities.

Environment. The sum of all external conditions affecting the life, development, and survival of an organism.

Frequentist (or frequency) probability. A view of probability that concerns itself with the frequency of events in a long series of trials, or is based upon a data set.

Inputs. Quantities that are input to a model.

Model. 1. A set of constraints restricting the possible joint values of several quantities. 2. A hypothesis or system of belief regarding how a system works or responds to changes in its inputs. 3. A mathematical function with parameters that can be adjusted so the function closely describes a set of empirical data. A mechanistic model usually reflects observed or hypothesized biological or physical mechanisms and has model parameters with real-world interpretation. In contrast, statistical or empirical models selected for particular numerical properties are best fits to data; model parameters may or may not have real-world interpretation. When data quality is otherwise equivalent, extrapolation from mechanistic models (e.g., biologically based dose-response models) often carries higher confidence than extrapolation using empirical models (e.g., logistic models).

Modeling. 1. Development of a mathematical or physical representation of a system or theory that accounts for all or some of its known properties. Models often are used to test the effect of changes of components on the overall performance of the system. 2. Use of mathematical equations to simulate and predict real events and processes. 3. Development or application of conceptual or graphical methods to depict the structure and organization among major elements of the system to be modeled.

***Model uncertainty* (sources of).**
Model structure. Reflects competing sets of conceptual, scientific, or technical assumptions available to develop a model for a particular phenomenon. An example of model structure uncertainty is the use of epidemiologically derived concentration-response functions for modeling cancer risk in humans versus the use of toxicological (animal)-based functions employing human-to-animal extrapolation factors.
Model detail. Reflects simplifying assumptions used to make modeling tractable. For example, complex nonlinear behavior of chemical uptake from the gastrointestinal system into the blood stream may be replaced by a rather simplified linear model, especially for specific exposure (intake) ranges.
Extrapolation. Use of models outside of the parameter space used in their derivation may result in erroneous predictions. For example, a threshold for health effects may exist at exposure levels below those covered by a particular epidemiological study. If that study is used in modeling health effects at those lower levels (and it is assumed that the level of response seen in the study holds for lower levels of exposure), then disease incidence may be overestimated.
Resolution. Selection of spatial or temporal resolution (i.e., grid size) typically reflects a balance between a desired level of precision and resources required to model the system. If the grid size selected is too small, then key patterns of behavior reflected in the smaller step size may be missed altogether, or the behavior of the system may be misrepresented. For example, efforts to capture realistic high-end (near upper-bound) risks to farmers around an incinerator may necessitate a geographical-information-system-based modeling framework precise enough to model exposures for individual farms. If a less resolved exposure model is used, then risk to the most exposed farm may be underpredicted.
Model boundaries. Decisions regarding the time, space, number of chemicals, etc., used in guiding modeling of the system. Risks can be understated or overstated if the model boundary is misspecified. For example, if a study area is defined to be too large and includes a significant number of low-exposure areas, then a population-level risk distribution can be diluted by including less exposed individuals, which can, in turn, result in a risk-based decision that does not protect sufficiently the most exposed individuals in the study area.

Parameter. 1. A variable, measurable property whose value is a determinant of the characteristics of a system (e.g., Temperature, pressure, and density are parameters of the atmosphere.). 2. A constant or variable term in a function that determines the specific form of the function but not its general nature, as “a” in f(x) = ax, where “a” determines only the slope of the line described by f(x). 3. A variable entering into the mathematical form of any probability distribution model such that the possible values of the variable correspond to different distributions.

Probability. 1. Frequentist approach/ The frequency with which samples are obtained within a specified range or for a specified category (e.g., the probability that an average individual with a particular mean dose will develop an illness). 2. Bayesian approach. The degree of belief regarding the different possible values of a quantity.

Probabilistic risk analysis. Application of a computational method, often based on a randomized sampling of available data or information, to produce a probability distribution to more fully describe the data than selecting a single point in the distribution, e.g., the mean.

Risk. 1. Risk includes consideration of exposure to the possibility of an adverse outcome, the frequency with which one or more types of adverse outcomes may occur, and the severity or consequences of the adverse outcomes if such occur. 2. The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment. 3. The probability of adverse effects resulting from exposure to an environmental agent or mixture of agents. 4. The combined answers to (1) What can go wrong? (2) How likely is it? and (3) What are the consequences?

Risk analysis. 1. A process for identifying, characterizing, controlling, and communicating risks in situations where an organism, system, subpopulation, or population could be exposed to a hazard. Risk analysis is a process that includes risk assessment, risk management, and risk communication (WHO). 2. A detailed examination, including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks.

Risk assessment. 1. A process intended to calculate or estimate the risk to a given target organism, system, subpopulation, or population, including the identification of attendant uncertainties following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern, as well as the characteristics of the specific target system (WHO). 2. The evaluation of scientific information on the hazardous properties of environmental agents (hazard characterization), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment) (NRC, 1983). The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree (risk characterization) (USEPA, 2000). 3. Qualitative and quantitative evaluation of the risk posed to human health or the environment by the actual or potential presence or use of specific pollutants.

Risk-informed decision making. An approach to decision making in which insights from probabilistic risk analyses are considered with other insights and factors.

Risk management. A decision making process that takes into account environmental laws, regulations, political, social, economic, engineering, and scientific information, including a risk assessment, to weigh policy alternatives associated with a hazard.

Scenario. 1. An outline or model of an expected or supposed sequence of events. 2. A set of facts, assumptions, and inferences about how exposure takes place and regarding how exposures translate into adverse effects that aides the analyst in evaluating, estimating, or quantifying exposures and risks. Scenarios might include identification of pollutants, pathways, exposure routes, and modes of action, among others.

Sensitivity analysis. A study of how the variation in data inputs (including inputs to models) affect the outputs of a model or choice among potential decision options.

Levels. Refers to various hierarchical levels of complexity and refinement for different types of modeling approaches that can be used in risk assessment. A deterministic risk assessment with conservative assumptions is an example of a lower level type of analysis that can be used to determine whether exposures and risks are below levels of concern. Examples of progressively higher levels include the use of deterministic risk assessment coupled with sensitivity analysis, the use of probabilistic techniques to characterize either variability or uncertainty only, and the use of two-dimensional probabilistic techniques to distinguish between but simultaneously characterize both variability and uncertainty.

Two-dimensional probabilistic analysis. A modeling approach in which inter-individual variability in exposure and risk is characterized using frequency distributions, and in which uncertainty in the estimates of statistics of the frequency distributions (e.g., the mean, median, standard deviation, percentiles) are characterized using probability distributions.

Uncertainty. Occurs because of a lack of knowledge. It is not the same as variability. For example, a risk assessor may be very certain that different people drink different amounts of water but may be uncertain about how much variability there is in water intakes within the population. Uncertainty often can be reduced by collecting more and better data, whereas variability is an inherent property of the population being evaluated. Variability can be better characterized with more data but it cannot be reduced or eliminated. Efforts to clearly distinguish between variability and uncertainty are important for both risk assessment and risk characterization, although they both may be incorporated into an assessment.[I agree with Harvey's comment about this sentence.]

Uncertainty analysis. A detailed examination of the systematic and random errors of a measurement or estimate; an analytical process to provide information regarding uncertainty.

Value of information. A quantitative measure of the value of knowing the outcome of an uncertain variable prior to making a decision. Decision theory provides a means for calculating the value of both perfect and imperfect information. The former value, informally known as the value of clairvoyance, is an upper bound for the latter. Obtaining meaningful value-of-information measurements requires an awareness of important restrictions (concerning the nature of free will) on the validity of this kind of information.

Variability. Refers to true heterogeneity or diversity, as exemplified in natural variation . For example, among a population that drinks water from the same source and with the same contaminant concentration, the risks from consuming the water may vary. This may result from differences in exposure (i.e., different people drinking different amounts of water and having different body weights, different exposure frequencies, and different exposure durations), as well as differences in response (e.g., genetic differences in resistance to a chemical dose). Those inherent differences are referred to as variability. Differences among individuals in a population are referred to as inter-individual variability, differences for one individual over time is referred to as intra-individual variability.

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Appendix D: Case Study Examples of the Application of Probabilistic Risk Analysis in U.S. Environmental Protection Agency Regulatory Decision-Making

Prepared by Risk Assessment Forum
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Foreword

The U.S. Environmental Protection Agency's (EPA's) Risk Assessment Forum was directed by the Science Policy Council in the Office of the Science Advisor to consider how to better and more fully implement probabilistic risk analysis (PRA) and related tools in the EPA decision-making process. A technical panel of senior scientists gathered and identified several ways of moving the agenda to fully implement PRA. This Appendix focuses on examples of how PRA approaches have been used at EPA to inform regulatory decisions.

This White Paper was prepared by representatives from various EPA program offices and regions currently involved in the development and application of PRA techniques. The workgroup selected the case study examples based on the workgroup's knowledge of the specific PRA procedures, the types of techniques demonstrated, availability to the reader through the internet, peer-reviewed, and illustrative of a spectrum of PRA used in EPA. The case studies are not designed to provide an exhaustive discussion of the wide variety of applications of PRA used within the Agency but to highlight specific examples reflecting the range of approaches currently applied within EPA.

Acknowledgments

We would like to acknowledge the scientists and risk assessors who performed the original analyses on which the summaries of these case studies are based. The names of the points of contact are included for each study, and many more contributors were involved and acknowledged in the original work.

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Executive Summary

This Appendix is designed to serve as a resource for risk managers faced with decisions regarding when to apply PRA techniques to inform environmental decisions and for exposure and risk assessors who may not be familiar with the wide range of available PRA approaches. The document outlines categories of PRAs classified by the complexity of analysis to aid the decision-making process. This approach identifies various PRA tools that include techniques ranging from a simple sensitivity analysis (e.g., identification of key exposure parameters or data visualization) requiring limited time, resources, and expertise to develop (Group 1); to probabilistic approaches, including Monte Carlo analysis, that provide tools for evaluating variability and uncertainty separately and require more resources and specialized expertise (Group 2); and to sophisticated techniques of expert elicitation that generally require significant investment of employee time, additional expertise, and external peer-review (Group 3).

This document describes case studies wherein PRA techniques have been used within this ranked framework to provide additional information for risk managers. PRA is a scientific tool to help describe the data or the risk and is one of many inputs considered by the risk manager in the decision-making process. The case study summaries are provided in a format designed to highlight how the results of the PRAs were considered in decision-making. These summaries include specific information on the conduct of the analyses as an aid to determining what tools might be appropriate for developing specific exposure or risk assessments for other assessments.

The case studies range from examples of less resource-intensive analyses that might assist in identifying key exposure parameters or the need for more data to more detailed and resource-intensive approaches. Tools include Monte Carlo modeling, sensitivity analyses, and application of expert elicitation. Examples of applications in human health and ecological risk assessment include the exposure of children to chromated copper arsenate treated wood, the relation between particulates in air and health, dietary exposures to pesticides, modeling sea level change, sampling watersheds, and modeling bird and animal exposures.

1. Introduction

Historically, the U.S. Environmental Protection Agency (EPA) has used deterministic risk assessments, or point estimates of risk, to evaluate cancer risks and noncancer health hazards to high-end exposed individuals (90th percentile or above) and the average exposed individual (50th percentile) and, where appropriate, risks and hazards to populations, as required by specific environmental laws (EPA, 1992a). The use of default values for exposure parameters in risk assessment provides a procedural consistency that allows risk assessments to be feasible and tractable (EPA, 2004). The methods typically used in EPA deterministic risk assessments rely on a combination of point values―some conservative and some typical―yielding a point estimate of exposure that is at some unknown point in the range of possible risks (EPA, 2004).

The development of sophisticated computational tools over the past 10 years has prompted an increased interest in analyses that evaluate the variability and uncertainty in the risk assessments; these include the use of tools such as probabilistic risk analysis, or PRA (EPA, 2001, 2004). These analyses provide the results of the risk assessment as a probability or likelihood of different risk levels in a population (describing variability) or to characterize uncertainty in risk estimates.

This Appendix presents case studies of PRA conducted by EPA over the past 10 to 15 years. Table 1 summarizes the case studies by title, technique demonstrated, classification based on Human Health and Ecological Risk Assessment, and the program office responsible for developing the case studies. This document, by illustration, provides a “snapshot” of utilization of PRA across various programs in EPA.

2. Overall Approach to Probabilistic Risk Analysis at the U.S. Environmental Protection Agency

2.1. U.S. Environmental Protection Agency Guidance and Policies on Probabilistic Risk Analysis

The case studies presented here build on the principles of PRA outlined in EPA's 1996 Policy (EPA, 1996) and Guiding Principles for Monte Carlo Analysis (EPA, 1997b) and subsequent guidance documents on developing and using PRA. Guidance has been developed for the Agency as well as for individual programs that refers to the use of PRA, including the Risk Assessment Guidance for Superfund Part III (EPA, 2001); Risk Assessment Forum Framework for Ecological Risk Assessment (EPA, 1992b); Guidelines for Ecological Risk Assessment (EPA, 1998); Guidance for Risk Characterization (EPA, 1995a); Policy for Risk Characterization (EPA, 1995a); Policy on Evaluating Health Risks to Children (EPA, 1995b); Policy for Use of Probabilistic Analysis in Risk Assessment (EPA, 1997a); Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping (EPA, 1997c ; and Risk Characterization Handbook (EPA, 2000).

As shown in the individual case studies, the range and scope of the PRA will depend on the overall objectives of the decision that the analysis will inform. The Guiding Principles for Monte Carlo Analysis lay out the general approach that should be taken in all cases, beginning with defining the problem and scope of the assessment, so that the best tools and approach may be selected. The Guiding Principles also describe the process of estimating and characterizing variability and uncertainty around the risk estimates. Stahl and Cimorelli (2005) and the Risk Assessment Guidance for Superfund Volume III (EPA, 2001) highlight the importance of communication between risk assessor and manager. Stahl and Cimorelli (2005) and Jamieson (1996) indicate it is important to determine whether a particular level of uncertainty is acceptable or not. The authors also suggest this decision is a matter of context, values, and regulatory policy. The Risk Assessment Guidance for Superfund Part III (Chapter 2 and Appendix F in EPA, 2001) describes a process for determining the appropriate level of PRA using a ranked approach from the less resource- and time-intensive approaches to more sophisticated analyses (Chapter 2 in EPA, 2001). Further, the Risk Assessment Guidance for Superfund Part III outlines a process for developing a PRA work plan and a checklist for PRA reviewers (Chapter 2 and Appendix F in EPA, 2001). This guidance also provides information regarding how to communicate PRA results to risk managers and stakeholders (Chapter 6 in EPA, 2001).

The guidance and policies on uncertainty and variability, and application of the principles of PRA, all highlight the ongoing need for communication between the risk assessor and risk manager. The ongoing communication is important in determining the appropriate levels of analysis for the specific decision.

2.2. Categorizing Case Studies

The ranked approach used for categorization is a process for a systematic, informed progression to increasingly more complex risk assessment methods of PRA that is outlined in the Risk Assessment Guidance for Superfund (EPA, 2001). The use of categories provides a framework for evaluating the various techniques of PRA. Higher categories reflect increasing complexity and, in many cases, will require more time and resources. Higher categories also reflect increasing characterization of variability and uncertainty in the risk estimate, which may be important for making specific risk management decisions. Central to the approach is a systematic, informed progression using an iterative process of evaluation, deliberation, data collection, planning and scoping, development and updates to the work plan, and communication. All of these steps focus on deciding

(1) whether or not the risk assessment, in its current state (i.e., deterministic risk analysis), is sufficient to support risk management decisions (a clear path to exiting the process is available at each step); and
(2) if the assessment is determined to be insufficient, whether or not progression to a higher group of complexity (or refinement of the current analyses) would provide a sufficient benefit to warrant the additional effort of performing a PRA.

This paper groups case studies according to level of effort and complexity of the analysis, and the increasing sophistication of the methods used (Table 1). Although each group generally represents increasing effort and cost, this may not always be true. The groups are intended to also reflect the progression from simple to complex analysis that is determined by the interactive planning and scoping efforts of the risk assessors and managers. The use of particular terms to describe the groups, including *tiers*, was avoided due to specific programmatic and regulatory connotations.

2.2.1. Group 1 Case Studies

Assessments within this group typically involve a sensitivity analysis and serve as an initial screening step in the risk assessment. Sensitivity analyses identify important parameters in the assessment where additional investigation may be helpful (Kurowicka and Cooke, 2006). Sensitivity analysis can be simple or involve more complex mathematical and statistical techniques such as correlation and regression analysis to determine which factors in a risk model contribute most to the variance in the risk estimate.

Within the sensitivity analyses, a range of techniques is available: simple, “back of the envelope” calculation, where the risk parameters are evaluated using a range of exposure parameters to determine the parameter that contributes most significantly to the risk (Case Study 1); analyses to rank relative contributions of variables to the overall risk (Case Study 2); and data visualization using graphical techniques to array the data or Monte Carlo simulations (e.g., scatter plots).

More sophisticated analyses may include sensitivity ratios (i.e., elasticity); sensitivity scores (i.e., weighted sensitivity ratios); correlation coefficient or coefficient of determination, r^2 (e.g., Pearson product moment, Spearman rank); normalized multiple regression coefficient; and goodness-of-fit tests for subsets of the risk distribution (EPA, 2001).

The sensitivity analyses typically require limited resources and time to conduct. Results of the sensitivity analyses are useful in identifying key parameters where additional Group 2 or 3 analyses may be appropriate. Sensitivity analyses are also helpful in identifying key parameters where additional research will have the most impact on the risk assessment.

2.2.2. Group 2 Case Studies

Case studies within this group include more sophisticated application of probabilistic tools, including PRA of specific exposure parameters (Case Studies 3 and 4), one-dimensional analyses (Case Study 5), and probabilistic sensitivity analysis (Case Studies 6 and 7).

The Group 2 case studies require larger time commitments for development, specialized expertise, and additional analysis of exposure parameter data sources. Depending on the nature of the analysis, peer involvement or peer review may be appropriate to the evaluation of the products of the analysis.

2.2.3. Group 3 Case Studies

Assessments within this group are the most resource- and time-intensive analyses of the three categories. Risk analyses include two-dimensional Monte Carlo analysis that evaluate model variability and uncertainty (Case Studies 8 through 10); Microexposure Event Analysis, in which long-term exposure of an individual is simulated as the sum of separate short-term exposure events (Case Study 11); and Probabilistic Analysis (Case Studies 12 and 13).

Other types of analyses within this group include the expert elicitation method that is a systematic process of formalizing and quantifying, in terms of probabilities, experts' judgments about uncertain quantities (Case Studies 14 and 15); Bayesian statistics that is a specialized branch of statistics that views the probability of an event occurring as the degree of belief or confidence in that occurrence (Case Study 16); and geostatistical analysis, which is another specialized branch of statistics that explicitly takes into account the geo-referenced context of data and the information (i.e., attributes) attached to the data.

The Group 3 analyses require additional time and expertise in the planning and analysis of the assessment. Within this group, the level of expertise and resource commitments may vary with techniques such as expert elicitation requiring significantly longer time for planning, identification of experts, and meetings, when compared with the other techniques.

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Table 1. Case Study Titles, Description, Type of Assessment (Human Health or Ecological Risk Assessment) and Program Office that Developed Assessment.

Study No.	Title and Case Study Description	HH/ Eco[1]	Program Office
Group 1—Point Estimate - Sensitivity Analysis			
1	**Sensitivity Analysis of Key Variables in Probabilistic Assessment of Children's Exposure to Arsenic in Chromated Copper Arsenate (CCA) Pressure-Treated Wood.** This case study demonstrates use of a point estimate sensitivity analysis to identify exposure variables critical to the analysis summarized in Case Study 9. The sensitivity analysis identified critical areas for future research and data collection and better characterized the amount of dislodgeable residue that exists on the wood surface.	HH	OPP/ORD[2]
2	**Assessment of Relative Contribution of Atmospheric Deposition to Watershed Contamination.** An example of a workbook that demonstrates how "back-of-the-envelope" analysis of potential exposure rates can be used to target resources to identify other inputs before further analysis of air inputs in watershed contamination. Identification of key variables aided in identifying uncertainties and data gaps to target resource expenditures for further analysis. A case study example of the application of this technique is also identified.	Eco	ORD
Group 2—Probabilistic Risk Analysis, One-Dimensional Monte Carlo Analysis, and Probabilistic Sensitivity Analysis			
Probabilistic Risk Analysis			
3	**Probabilistic Assessment of Angling Duration Used in Assessment of Exposure to Hudson River Sediments via Consumption of Contaminated Fish.** A probabilistic analysis of one parameter in an exposure assessment—the time an individual fishes in a large river system. Development of site-specific information regarding exposure, with an existing data set for this geographic area, was needed to represent this exposed population. This information was used in the one-dimensional PRA described in Case Study 5.	HH	Region 2/ Superfund
4	**Probabilistic Analysis of Dietary Exposure to Pesticides for Use in Setting Tolerance Levels.** The probabilistic Dietary Exposure Evaluation Model (DEEM) provides more accurate information on the range and probability of possible exposures.	HH	OPP

[1] HH = Human Health Risk Assessment; Eco = Ecological Risk Assessment.
[2] OPP, Office of Pesticides Programs; ORD, Office of Research and Development; OAR, Office of Air and Radiation; OW, Office of Water.

Study No.	Title and Case Study Description	HH/ Eco	Program Office
Group 2 (cont'd.)			
One-Dimensional Monte Carlo Analysis			
5	**One-Dimensional Probabilistic Risk Analysis of Exposures to Polychlorinated Biphenyls (PCBs) via Consumption of Fish from a Contaminated Sediment Site.** An example of a one-dimensional PRA (1-D Monte Carlo analysis of the *variability* of exposure as a function of the variability of individual exposure factors.) to evaluate the risks to anglers who consume recreationally caught fish from a PCB-contaminated river.	HH	Region 2/ Superfund
Probabilistic Sensitivity Analysis.			
6	**Probabilistic Sensitivity Analysis of Expert Elicitation of Concentration-Response Relationship Between $PM_{2.5}$ Exposure and Mortality.** An example of how the probabilistic analysis tools can be used to conduct a probabilistic sensitivity analysis following an expert elicitation (Group 3) presented in Case Study 14.	HH	OAR
7	**Environmental Monitoring and Assessment Program (EMAP): Using Probabilistic Sampling Techniques To Evaluate the Nation's Ecological Resources .** A probability-based sampling program designed to provide unbiased estimates of the condition of an aquatic resource over a large geographic area based on a small number of samples.	Eco	ORD
Group 3—Advanced Probabilistic Risk Analysis—Two-Dimensional Monte Carlo Analysis Including Microexposure Modeling, Bayesian Statistics, Geostatistics, and Expert Elicitation			
Two- Dimensional Probabilistic Risk Analysis			
8	**Two-Dimensional Probabilistic Risk Analysis of *Cryptosporidium* in Public Water Supplies, with Bayesian Approaches to Uncertainty Analysis.** An analysis of variability in the occurrence of *Cryptosporidium* in raw water supplies and in the treatment efficiency, as well as the uncertainty in these inputs. This case study includes an analysis of the dose-response relationship for *Cryptosporidium* infection.	HH	OW
9	**Two-Dimensional Probabilistic Model of Children's Exposure to Arsenic in Chromated Copper Arsenate (CCA) Pressure-Treated Wood.** A two-dimensional model that addresses both variability and uncertainty in the exposures of children to CCA pressure-treated wood. The analysis was built on the sensitivity analysis described in Case Study 2.	HH	OPP/ORD

Study No.	Title and Case Study Description	HH/ Eco	Program Office
	Group 3 (cont'd.)		
10	**Two-Dimensional Probabilistic Exposure Assessment of Ozone** A probabilistic exposure assessment that addresses short-term exposures to ozone. Population exposure to ambient ozone levels was evaluated using EPA's Air Pollutants Exposure (APEX) model, also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model.	**HH**	**OAR**
	Group 3—Microexposure Event Modeling		
	Microexposure Event Analysis		
11	**Analysis of Microenivironmental Exposures to Particulate Matter ($PM_{2.5}$) for a Population Living in Philadelphia, PA.** A microexposure event analysis to simulate individual exposures to $PM_{2.5}$ in specific microenvironments including the outdoors, indoor residences, offices, schools, stores, and a vehicle.	**HH**	**Region 3 and ORD**
	Probabilistic Analysis		
12	**Probabilistic Analysis in Cumulative Risk Assessment of Organophosphorus Pesticides.** A probabilistic computer software program used to integrate various pathways, while simultaneously incorporating the time dimensions of the input data to calculate margins of exposure.	**HH**	**OPP**
13	**Probabilistic Ecological Effects Risk Assessment Models for Evaluating Pesticide Uses.** A multimedia exposure/effects model that evaluates acute mortality levels in generic or specific avian species over a user-defined exposure window.	**Eco**	**OPP**
	Group 3—Expert Elicitation and Bayesian Belief Network		
	Expert Elicitation		
14	**Expert Elicitation of Concentration-Response Relationship Between Particulate Matter ($PM_{2.5}$) Exposure and Mortality.** An expert elicitation used to derive probabilistic estimates of the uncertainty in one element of a cost-benefit analysis used to support the $PM_{2.5}$ regulations**.**	**HH**	**ORD/ OAR**
15	**Expert Elicitation of Sea-Level Change Resulting from Global Climate Change.** An example of a PRA that describes the probability of sea level rise and parameters that predict sea level change.	**Eco**	
16	**Expert Elicitation for Bayesian Belief Network Model of Stream Ecology.** An example of a Bayesian belief network model of the effect of increased fine-sediment load in a stream on macroinvertebrate populations.	**Eco**	**ORD**

3. Case Study Summaries

Group 1 Case Studies

Case Study 1: Sensitivity Analysis of Key Variables in Probabilistic Assessment of Children's Exposure to Arsenic in Chromated Copper Arsenate (CCA) Pressure-Treated Wood

This case study provides an example of the application of sensitivity analysis to identify important variables for population exposure variability for a Group 2 assessment (**Case Study 9**) and to indicate areas for further research. Specifically, EPA's Office of Research and Development (ORD), in collaboration with the Office of Pesticide Programs (OPP) used sensitivity analyses to identify the key variables in children's exposure to CCA treated wood.

Approach. The sensitivity analyses used two approaches. The first approach estimated baseline exposure by running the exposure model with each input variable set to its median (50^{th} percentile) value. Next, alternative exposure estimates were made by setting each input to its 25^{th} or 75^{th} percentile value while holding all other inputs at their median values. The ratio of the exposure estimate calculated when an input was estimated at its 25^{th} or 75^{th} percentile to the exposure estimate calculated when the input was at its median value provided a measure of that input's importance to the overall exposure assessment. The second approach applied multiple stepwise regression analysis to the data points generated from the first approach. The correlation between the input variables and the exposure estimates provided an alternative measure of the input variable's relative importance in the exposure assessment. These two approaches were used in tandem to identify the critical inputs to the exposure assessment model.

Results of Analysis. The two sensitivity analyses together identified six critical input variables that most influenced the exposure assessment. The critical input variables were: wood surface residue-to-skin transfer efficiency, wood surface residue levels, fraction of hand surface area mouthed per mouthing event, average fraction of nonresidential outdoor time spent playing on a CCA-treated playset, frequency of hand-washing, and frequency of hand-to-mouth activity.

Management Considerations: The results of the sensitivity analyses were used to identify the most important input parameters in the treated wood risk assessments. The process also identified critical areas for future research. In particular, the assessment pointed to a need to collect data on the amount of dislodgeable residue that is transferred from the wood surface to a child's hand upon contact, and to better characterize the amount of dislodgeable residue that exists on the wood surface.

Document Availability.

Title: The final report on the probabilistic exposure assessment of CCA-treated wood. Zartarian, V.G., J. Xue, H. A. Ozkaynak, W. Dang, G. Glen, L. Smith, and C. Stallings. A Probabilistic Exposure Assessment for Children Who Contact CCA-treated Playsets and Decks Using the Stochastic Human Exposure and Dose Simulation Model for the Wood Preservative Scenario (SHEDS-WOOD), Final Report. U.S. Environmental Protection Agency, Washington, DC, EPA/600/X-05/009. http://www.epa.gov/heasd/sheds/cca_treated.htm

See also: Xue, J., Zartarian, V.G., Özkaynak, H., Dang, W., Glen, G., Smith, L., and Stallings, C. A probabilistic arsenic exposure assessment for children who contact chromated copper arsenate (CAA)-treated playsets and decks, Part 2: Sensitivity and uncertainty analyses. Risk Analysis 26:533, 2006.

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Case Study 2: Assessment of Relative Contribution of Atmospheric Deposition to Watershed Contamination

Watershed contamination can result from several different sources, including direct release into a water body, input from upstream water bodies, and deposition from airborne sources. Efforts to control water body contamination begin with an analysis of the environmental sources in order to identify those parameters providing the greatest contribution and to determine where mitigation and/or analysis resources should be directed.

Approach. This case study provides an example of a back-of-the envelope analysis of the contribution of air deposition to overall watershed contamination to identify uncertainties and/or data gaps as well as to target resource expenditures. (Group 1: Deterministic Analysis). Nitrogen inputs have been studied in several east and Gulf Coast estuaries due to concerns about eutrophication. Nitrogen from atmospheric deposition is estimated to be as high as 10 to 40% of the total input of nitrogen to many of these estuaries and perhaps higher in a few cases. For a watershed that has not already been studied, a back-of-the envelope calculation could be prepared based on information based on nitrogen deposition rates measured in a similar area. To estimate the deposition load directly to the waterbody, one would multiply the nitrogen deposition rate by the area of the waterbody. The analyst could then estimate the nitrogen load from other sources, (e.g., point source discharges and runoff) to estimate a total nitrogen load for the waterbody. The estimate of loading due to atmospheric deposition could then be divided by the total nitrogen load for the waterbody to estimate the percent contribution directly to the waterbody from atmospheric deposition.

The May 2003 report by the Casco Bay Air Deposition Study Team titled "Estimating Pollutant Loading from Atmospheric Deposition Using Casco Bay, Maine" is an analysis using the methodology described above. The Casco Bay Estuary, located in the southwestern Maine, is used as a case study. The paper also includes the results of a field air deposition monitoring program conducted in Casco Bay (1998 - 2000) and favorably compares the estimates developed for rate of deposition of nitrogen, mercury and PAHs to the field monitoring results. The estimation approach is a useful starting point for understanding the sources of pollutants entering water bodies that cannot be accounted for through run-off or point source discharges.

Results of Analysis. The approach outlined above was applied to the Casco Bay Estuary in Maine. Resources, tools and strategies for pollution abatement can be effectively targeted at priority sources if estuaries are to be protected. Understanding the sources and annual loading of contaminants to an estuary guides good water quality management by defining the range of controls of both air and water pollution needed to achieve a desired result. The cost of conducting monitoring to determine atmospheric loading to a water body can be prohibitively high. Also, collection of monitoring data is a long-term undertaking, since a minimum of three years of data is advisable in order to "smooth out" inter-annual variability. The estimation techniques described in this paper can serve as a useful and inexpensive "first-cut" at understanding the importance of the atmospheric as a pollution source, and can help to pinpoint those areas where field measurements are needed to guide future management decisions.

Management Consideration: If a review of information on air deposition available for the analysis indicates a wide range of potential deposition rates, then further study of this input would lead to better characterization of the air contribution to overall contamination. If the back-of-the envelope analysis suggests that air deposition is very small relative to other inputs, then resources should be targeted at studying or reducing other inputs before proceeding with further analysis of the air inputs.

Document Availability. The back-of-the envelope calculation is outlined in Frequently Asked Questions about Atmospheric Deposition: A Handbook for Watershed Managers (available at http://www.epa.gov/air/oaqps/gr8water/handbook/airdep_sept.pdf).

Further analysis is available in Deposition of Air Pollutants to the Great Waters - Third Report to Congress (available at http://www.epa.gov/air/oaqps/gr8water/3rdrpt/index.html)

The Casco Bay Estuary examples is available at: www.epa.gov/owow/airdeposition/index.html.

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Group 2 Case Studies

Case Study 3: Probabilistic Assessment of Angling Duration Used in Assessment of Exposure to Hudson River Sediments via Consumption of Contaminated Fish

In assessing the health impact of contaminated Superfund sites, exposure duration typically is assumed to be the same as the length of time an individual lives in a specific area (i.e., residence duration). In conducting the human health risk assessment for the Hudson River PCB Superfund Site, however, there was concern that exposure duration based on residence duration may underestimate the time spent fishing (i.e., angling duration).

Risk Analysis. An individual may move from one residence to another and continue to fish in the same location, or an individual may choose to stop fishing irrespective of the location of his or her home. EPA Region 2 developed a site-specific distribution of angling duration using the fishing patterns reported in a New York State-wide angling survey (Connelly et al., 1991) and migration data for the five counties surrounding the 40-plus miles of the Upper Hudson River collected as part of the U.S. Census.

Results of Analysis. The 50th and 95th percentile values from the distribution of angling durations were higher than the default values based on residence duration using standard default exposure assumptions for residential scenarios and were used as bases for the central tendency and reasonable maximum exposure point estimates, respectively, in the deterministic assessment.

Management Considerations. The information provided in this analysis was used in the point estimate analysis. The full distribution was used in conducting a Group 2 PRA for the fish consumption pathway, which is presented as **Case Study 6**.

Document Availability. The final risk assessment was released in November 2000 (available at http://www.epa.gov/hudson/reports.htm).

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Case Study 4: Probabilistic Analysis of Dietary Exposure to Pesticides for use in Setting Tolerance Levels

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA may authorize a tolerance or exemption from the requirement of a tolerance, to allow a pesticide residue in food, only if the Agency determines that such residues would be “safe”. This determination is made by estimating exposure to the pesticide and comparing the estimated exposure to a toxicological benchmark dose (i.e., a dose where there is reasonable certainty of no harm). Until 1998, Office of Pesticide Programs (OPP) used a software program called the Dietary Risk Evaluation System (DRES) to conduct its acute dietary risk assessments for pesticide residues in foods. Acute assessments conducted with DRES assumed that 100% of a given crop with registered uses of a pesticide was treated with that pesticide and that all such treated crop items contained pesticide residues at the maximum legal (tolerance) level matching this to a reasonably high consumption value (around 95th percentile). The resulting DRES acute risk estimates were considered "high-end" or "bounding" estimates. However, it was not possible to know where the pesticide exposure estimates from the DRES software fit in the overall distribution of exposures due to the limits of the tools being used.

Approach: To address these deficiencies, OPP has developed an acute probabilistic dietary exposure guidance in order to use a model to estimate exposure to pesticides in the food supply. Rather than the crude "high-end," single point estimates provided by deterministic assessments, the probabilistic Dietary Exposure Evaluation Model (DEEM) provides specific information on the range and probability of possible exposures and depending upon the characterization of the input, 95th percentile regulation generally for lower tiers that do not include percent crop treated, to the 99.9th percentile for the more refined assessments which would include percent of crop treated information.

Probabilistic Analysis. This case study provides an example of a one-dimensional probabilistic risk assessment of dietary exposure to pesticides (Group 2). The DEEM generates acute, probabilistic dietary exposure assessments using data on (1) the distribution of daily consumption of specific commodities (e.g., wheat, corn, apples, etc.) by specific individuals, and (2) the distribution of concentrations of a specific pesticide in those food commodities. Data on commodity consumption are collected by USDA in its Continuing Survey of Food Intake by Individuals (CSFII). Pesticide residue concentrations on food commodities are generally obtained from crop field trials, USDA’s Pesticide Data Program (PDP) data, Food and Drug Administration (FDA) monitoring data, or market basket surveys conducted by the registrants. Using these data, DEEM is able to calculate an estimate of the risk to the general U.S. population in addition to 26 population subgroups, including five subgroups for infants and children (infants less than 1, children 1-2, children 3-5, youth 6-12 and teen 13-19).

Results of Analysis. DEEM has been used in risk assessments to support tolerance levels for several pesticides (e.g., phosalone) and as part of cumulative risk assessments for organophosphorus compounds (see **Case Study 11**) and other pesticides.

Management Considerations: Using the DRES, risk management decisions were being made without a full picture of the distribution of risk among the population, and also without full knowledge of where in the distribution of risk the DRES risk estimate lay. This was of concern not only for regulators interested in public health protection, but also for the pesticide registrants who could argue that the Agency was being arbitrary in selecting the level at which to regulate. For most cases reviewed by OPP to date, estimated exposure at the 99.9th percentile calculated by DEEM probabilistic techniques is significantly lower than exposure calculated using DRES-type deterministic assumptions at the unknown percentile.

Document Availability.

Link to DEEM model available at http://www.epa.gov/oppsrrd1/cumulative/methods_tools.htm

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Case Study 5: One-Dimensional Probabilistic Risk Analysis of Exposure to Polychlorinated Biphenyls (PCBs) via Consumption of Fish from a Contaminated Sediment Site

EPA Region 2 conducted a preliminary deterministic human health risk assessment at the Hudson River PCBs Superfund site. The deterministic risk analysis showed that consumption of recreationally caught fish provided the highest exposure among relevant exposure pathways and resulted in cancer risks and noncancer health hazards that exceeded regulatory benchmarks.

Probabilistic Analysis. Because of the size, complexity, and high level of public interest in this site, EPA Region 2 implemented a Group 2 probabilistic assessment to characterize the variability in risks associated with the fish consumption exposure pathway. The analysis was a 1-Dimensional Monte Carlo analysis of the *variability* of exposure as a function of the variability of individual exposure factors. Uncertainty was assessed using sensitivity analysis of the input variables. Data to characterize distributions of exposure parameters were drawn from the published literature (e.g., fish consumption rate) or from existing databases such as the U.S. Census data (e.g., angling duration, see **Case Study 3**). Mathematical models of the environmental fate, transport, and bioaccumulation of PCBs in the Hudson River previously developed were used to forecast changes in PCB concentration over time.

Results of Analysis. The results of the PRA were in line with the deterministic results. For the Central Tendency individual, point estimates were near the median (50th percentile). For the Reasonable Maximum Exposure individual, point estimate values were at or above the 95th percentile of the probabilistic analysis. The deterministic and probabilistic risk analyses were the subject of a formal peer review by a panel of independent experts.

The Monte Carlo base case scenario is the one from which point estimate exposure factors for fish ingestion were drawn, thus the point estimate RMEs and the Monte Carlo base case estimates can be compared. Similarly, the point estimate central tendency (average) and the Monte Carlo base case midpoint (50th percentile) are comparable. For cancer risk, the point estimate RME for fish ingestion (1×10^{-3}) falls approximately at the 95th percentile from the Monte Carlo base case analysis. The point estimate central tendency value (3×10^{-5}) and the Monte Carlo base case 50th percentile value (6×10^{-5}) are similar. For non-cancer health hazards, the point estimate RME for fish ingestion (104 for young child) falls between the 95th and 99th percentiles of the Monte Carlo base case. The point estimate central tendency hazard index (HI) (12 for young child) is approximately equal to the 50th percentile of the Monte Carlo base case HI of 11. Figures 1 and 2 provide a comparison of results from the probabilistic analysis with that of the deterministic risk analysis for cancer risks and non-cancer health hazards.

Management Considerations. Early and continued involvement of the community improved public acceptance of the results. In addition, careful consideration of the methods used to present the probabilistic results to the public lead to greater understanding of the findings.

Document Availability. The final risk assessment was released in November 2000 (available at http://www.epa.gov/hudson/reports.htm**).**

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A comparison of results from the probabilistic analysis with that of the deterministic risk analysis for cancer risks and non-cancer health hazards. Figures 1 and 2 plot percentiles for 72 combinations of exposure variables (e.g., distributions from creel angler surveys; residence duration; fishing locations; cooking losses, etc.) of the non-cancer Hazard Index values and the cancer risks, respectively. In each of these figures, the variability of cancer risk or non-cancer HIs for anglers within the exposed population is plotted on the y axis for particular percentiles within the population. This variability is a function of the variations in fish consumption rates, fishing duration, differences in fish species ingested, etc. The uncertainty in the estimates is indicated by the range of either cancer risk or non-cancer HI values plotted on the x-axis. This uncertianty is a function of the 72 combinations of the exposure factor inputs examined in the sensitivity analysis. This analysis provides a semi-quantitative confidence interval for the cancer risks and HI values at any particulate percentile. As these figures show, the intervals span somewhat less than two orders of magnitude (e.g., < 100 fold). The vertical lines indicate the deterministic endpoints.

Figure 1. Monte Carlo Cancer Summary Based on a **One-Dimensional Probabilistic Risk Analysis of Exposure to Polychlorinated Biphenyls (PCBs) via Consumption of Fish from a Contaminated Sediment Site. From Phase 2 Report: Further Site Characterization and Analysis. Volume 2F – Revised Human Health Risk Assessment, Hudson River PCBs Reassessment RI/FS. U.S. EPA, November 2000.**

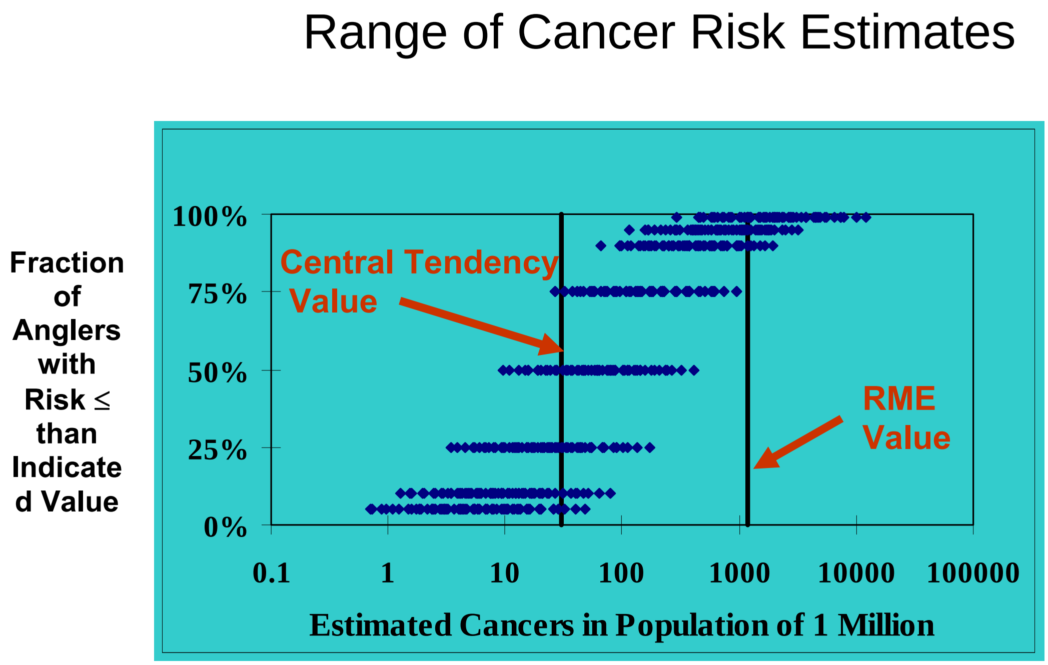
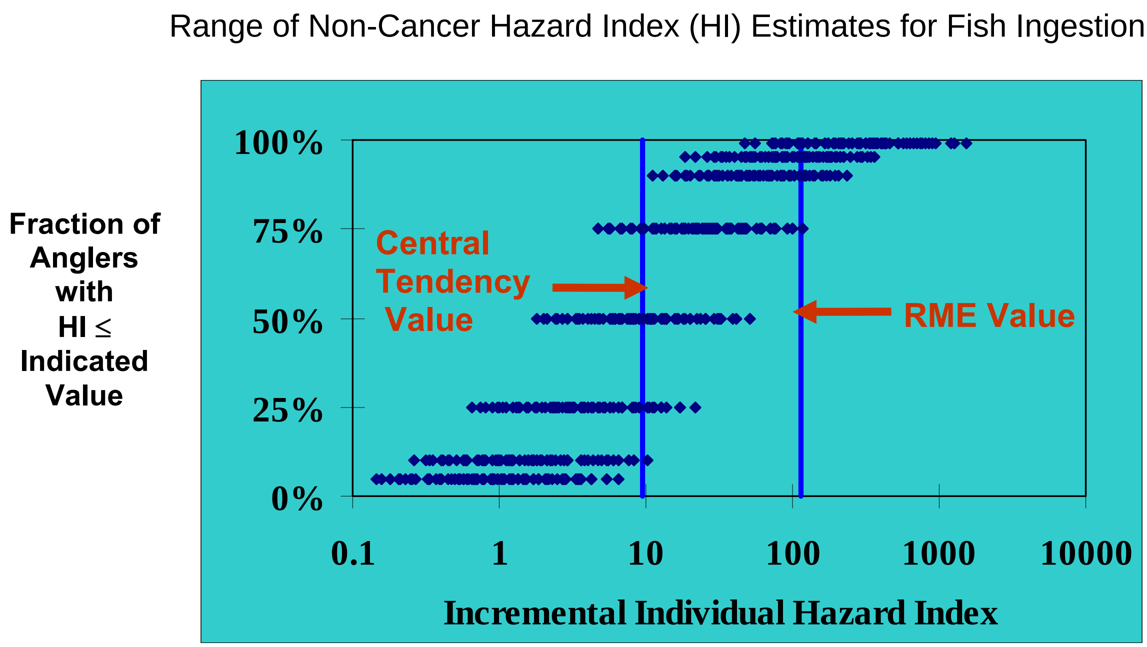


Figure 2. Monte Carlo Non-Cancer Hazard Index Summary Based on a **One-Dimensional Probabilistic Risk Analysis of Exposure to Polychlorinated Biphenyls (PCBs) via Consumption of Fish from a Contaminated Sediment Site. From Phase 2 Reprot: Further Site Characterization and Analysis. Volume 2F – Revised Human Health Risk Assesment, Hudson River PCBs Reassessment RI/FS. U.S. EPA, November 2000.**



Case Study 6: Probabilistic Sensitivity Analysis of Expert Elicitation of Concentration-Response Relationship Between Particulate Matter (PM2.5) Exposure and Mortality

In 2002, the National Research Council (NRC) recommended that EPA improve its characterization of uncertainty in the benefits assessment for proposed regulations of air pollutants. NRC recommended that probability distributions for key sources of uncertainty be developed using available empirical data or through formal elicitation of expert judgments. In response to this recommendation, EPA conducted an expert elicitation evaluation of the concentration-response relationship between $PM_{2.5}$ exposure and mortality, a key component of the benefits assessment of the $PM_{2.5}$ regulation. Further information on the expert elicitation procedure and results is provided in **Case Study 12**. To evaluate the degree to which the results of the assessment depended on individual experts' judgments or on the methods of expert elicitation, a probabilistic sensitivity analysis was performed of the results

Probabilistic Risk Analysis. The expert elicitation procedure used carefully constructed interviews to elicit from each of 12 experts an estimate of the probabilistic distribution for the average expected decrease in U.S. annual, adult, all-cause mortality associated with a 1 $\mu g/m^3$ decrease in annual average $PM_{2.5}$ levels. This case study provides an example of the use of probabilistic sensitivity analysis (Group 2) as one element of the overall assessment. For the sensitivity analysis, a simplified benefits analysis was conducted to assess the sensitivity of the results to the responses of individual experts and to three factors in the study design: (1) the use of parametric or nonparametric approaches by experts to characterize their uncertainty in the $PM_{2.5}$ -mortality coefficient, (2) participation in the Pre-elicitation Workshop, and (3) allowing experts to change their judgments after the Post-elicitation Workshop. The individual quantitative expert judgments were used to estimate a distribution of benefits, in the form of number of deaths avoided, associated with a reduction in ambient, annual average $PM_{2.5}$ concentrations from 12 to 11 $\mu g/m^3$. The 12 individual distributions of estimated avoided deaths were then pooled using equal weights to create a single overall distribution reflecting input from each expert. This distribution served as the baseline for the sensitivity analysis, which compared the means and standard deviations of the baseline distribution with several variants.

Results of Analysis. The first analysis examined sensitivity of the mean and standard deviation of the overall mortality distribution to the removal of individual experts' distributions. In general, the results suggested a fairly equal split between those experts whose removal shifted the distribution mean up and those who shifted it down and relatively modest impacts of individual experts. The standard deviation of the combined distribution also was not affected strongly by removal of individual experts. The second analysis evaluated whether the use of parametric or nonparametric approaches affected the overall results. The results suggested that the use of parametric distributions led to distributions with similar or slightly increased uncertainty compared with distributions provided by experts who offered percentiles of a nonparametric distribution. The last analyses evaluated whether participation in the Pre- or Post-elicitation Workshops impacted the results. Participation in either workshop did not appear to have a significant effect on experts' judgments, based on measures of change in the baseline distribution. Overall, the sensitivity analyses demonstrated that the assessment was robust, with little dependence on individual experts' judgments or on the specific elicitation methods evaluated.

Management Considerations. The sensitivity analysis demonstrated the robustness of the PM 2.5 expert elicitation-based assessment by showing that the panel of experts was generally well balanced and that alternative elicitation methods would not have markedly altered the overall results.

Document Availability. The details of this analysis are provided in the IEC document titled: "Expanded Expert Judgment Assessment of the Concentration-Response Relationship Between PM2.5 Exposure and Mortality" Final Report, September 21, 2006 (www.epa.gov/ttn/ecas/regdata/uncertainty/pm_ee_report.pdf).

The expert elicitation assessment, along with the Regulatory Impact Analysis (RIA) of the $PM_{2.5}$ standard, is available at http://www.epa.gov/ttn/ecas/ria.html.

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Case Study 7: Environmental Monitoring and Assessment Program (EMAP): Using Probabilistic Sampling to Evaluate the Condition of the Nation's Aquatic Resources

Monitoring is a key tool used to identify where the environment is in healthy biological condition and requires protection, and where environmental problems are occurring and need remediation. However, most monitoring is not currently done in a way that allows for statistically-valid assessments of water quality conditions in unmonitored waters (GAO 2000). States thus cannot adequately measure the status and trends in water quality in their waters as required by Clean Water Act Section 305(b).

EMAP's focus has been to develop unbiased statistical survey design frameworks, and sensitive indicators that allow the condition of aquatic ecosystems to be assessed at state, regional, and national scales. A cornerstone of EMAP has been the use of probabilistic sampling to allow representative, unbiased, cost-effective condition assessments for aquatic resources over large areas. EMAP's statistical survey methods are very efficient, requiring relatively few sample locations to make valid scientific statements about the condition of aquatic resources over large areas (e.g., the condition of all the wadeable streams in the Western US).

Probabilistic Analysis. This research program had a number of case studies using probabilistic sampling designs for different aquatic resources (estuaries, streams, and rivers). An EMAP probability-based sampling program provides an unbiased estimate of the condition of an aquatic resource over a large geographic area from a small number of samples. The principal characteristics of a probabilistic sampling design are: the population being sampled is unambiguously described; every element in the population has the opportunity to be sampled with a known probability; and sample selection is carried out by a random process. This approach allows statistical confidence levels to be placed on the estimates and provides the potential to detect statistically significant changes and trends in condition with repeated sampling. In addition, this approach permits the aggregation of data collected from smaller areas to predict the condition of a large geographic area.

The EMAP design framework allows the selection of unbiased, representative sampling sites and specifies the information to be collected at these sites. The validity of the overall inference rests on the design and subsequent analysis to produce regionally representative information. The EMAP uses Generalized Random Tessellation Stratified (GRTS) Spatially-Balanced Survey Designs for Aquatic Resources. The spatially-balanced aspect spreads out the sampling locations geographically, but still ensures that each element has an equal chance of being selected.

Results of the Analysis. Data collected using the EMAP approach has allowed the Agency to make scientifically defensible assessments of the ecological condition of large geographic areas for reporting to Congress under CWA 305(b). The EMAP approach has been used to provide the first reports on the condition of the nation's estuaries, streams, rivers and lakes, and it is scheduled to used for wetlands. EMAP findings have been included in EPA's *Report on the Environment*, and the Heinz Center's *The State of the Nation's Ecosystems*. Data collected through an EMAP approach improve the ability to assess ecological progress in environmental protection and restoration, and provide valuable information for decision-makers and the public.

The use of probabilistic analysis methods allows meaningful assessment and regional comparisons of aquatic ecosystem conditions across the United States. Finally, the probabilistic approach provides scientific credibility for the monitoring network and aids in identifying data gaps.

Management Considerations. Use of an EMAP approach addresses criticisms from the General Accounting Office, the National Academies of Sciences (NAS), the Heinz Center (a nonprofit environmental policy institution), and others who noted the nation lacked the data to make scientifically valid characterizations of water quality regionally and across the United States. The program provides cost-effective, scientifically defensible, and representative data, to permit the evaluation of quantifiable trends in ecosystem condition, to support performance-based management, and to facilitate better public decisions regarding ecosystem management. EMAP's approach has now been adopted by the EPA's Office of Water (OW) to collect data on the condition of all the nation's aquatic resources. OW, Office of Air and Radiation and Office of Prevention, Pesticides, and Toxic Substances now have environmental accountability endpoints using EMAP approaches in their Agency performance goals.

Document Availability. Available at http://www.epa.gov/emap/index.html.
U. S. EPA. 2002. Research Strategy. Environmental Monitoring and Assessment Program. U.S. EPA, Office of Research and Development, National Health and Environmental Effects Research Laboratory. U.S. EPA, Research Triangle Park, NC. Available at www.epa.gov/emap/html/pubs/docs/resdocs/emap_research_strategy.pdf.
Information on EMAP monitoring designs is available at http://www.epa.gov/nheerl/arm/designpages/monitdesign/monitoring_design_info.htm

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Group 3 Case Studies

Case Study 8: Two-Dimensional Probabilistic Risk Analysis of Cryptosporidium in Public Water Supplies, with Bayesian Approaches to Uncertainty Analysis

Probabilistic assessment of the occurrence and health effects associated with *Cryptosporidium* bacteria in public drinking water supplies was used to support the economic analysis of the final Long-Term 2 Enhanced Surface Water Treatment Rule (LT2). EPA's Office of Ground Water and Drinking Water (OGWDW) conducted this analysis and established a baseline disease burden attributable to *Cryptosporidium* in Public Water supplies that use surface water sources. Next, it models the source water monitoring and finished water improvements that will be realized as a result of the Rule. Post-Rule risk is estimated and the Rule's health benefit is the result of subtracting this from the baseline disease burden.

Probabilistic Risk Analysis. Probabilistic assessment was used for this analysis as a means of addressing the variability in the occurrence of *Cryptosporidium* in raw water supplies, the variability in the treatment efficiency, as well as the uncertainty in these inputs and in the dose-response relationship for *Cryptosporidium* infection. This case study provides an example of a PRA that evaluates both variability and uncertainty at the same time and is referred to as a two-dimensional probabilistic risk assessment. The analysis also included probabilistic treatments of uncertain dose-response and occurrence parameters. Markov Chain Monte Carlo samples of parameter sets filled this function. This Bayesian approach (treating the unknown parameters as random variables) differs from classical treatments, which would regard the parameters as unknown, but fixed (Group 3: Advanced PRA). The risk analysis used existing datasets (e.g., occurrence of *Cryptosporidium* and treatment efficacy) to inform the variability of these inputs. Uncertainty distributions were characterized based on professional judgment or by analyzing data using Bayesian statistical techniques.

Results of Analysis. The risk analysis identified the *Cryptosporidium* dose-response relationship as the most critical model parameters in the assessment, followed by the occurrence of the pathogen and treatment efficiency. By simulating implementation of the Rule using imprecise, biased measurement methods, the assessment provided estimates of the number of public water supply systems that would require corrective action and the nature of the actions likely to be implemented. This information afforded a realistic measure of the benefits (in reduced disease burden) expected with the LT2 rule. In response to SAB comments, additional *Cryptosporidium* dose-response models were added to more fully reflect uncertainty in this element of the assessment.

Management Considerations. The rule underwent external peer review, review by EPA's Science Advisory Board (SAB) and intense review by the Office of Management and Budget (OMB). Occurrence and dose-response components of the risk analysis model were communicated to stakeholders during the Rule's Federal Advisory Committee Act (FACA) process. Due to the rigor of the analysis and the signed FACA "Agreement in Principle", the OMB review was straight-forward.

Document Availability. The final assessment of occurrence and exposure to *Cryptosporidium* was released in December 2005 (available at http://www.epa.gov/safewater/disinfection/lt2/regulations.html).

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Case Study 9: Two-Dimensional Probabilistic Model of Children's Exposure to Arsenic in Chromated Copper Arsenate (CCA) Pressure-Treated Wood

Probabilistic models were developed in response to EPA's October 2001 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) recommendations to use probabilistic modeling to estimate children's exposures to arsenic from chromated copper arsenate (CCA) treated playsets and home decks.

Probabilistic Risk Analysis. EPA's Office of Research and Development (ORD), in collaboration with the Office of Pesticide Programs (OPP) developed and applied a probabilistic exposure assessment of children's exposure to arsenic and chromium from contact with CCA-treated wood playsets and decks. This case study provides an example of the use of two-dimensional (i.e., addressing both variability and uncertainty) probabilistic exposure assessment (Group 3: Advanced PRA). The two-dimensional assessment employed a modification of the ORD's SHEDS (Stochastic Human Exposure and Dose Simulation) model to simulate children's exposure to arsenic and chromium from CCA-treated wood playsets and decks, and surrounding soil. Staff from both ORD and OPP collaborated in the development of the SHEDS-Wood model.

Results of Analysis. A draft of the probabilistic exposure assessment received SAP review in December, 2003; the final report was released in 2005. The results of the probabilistic exposure assessment were consistent with or in the range of the results of deterministic exposure assessments conducted by several other organizations. The model results were used to compare exposures under a variety of scenarios, including cold vs. warm weather activity patterns, use of wood sealants to reduce the availability of contaminants on the surface of the wood, and different hand-washing frequencies. The modeling of alternative mitigation scenarios indicated that the use of sealants could result in the greatest exposure reduction, while increased frequency of hand-washing could also reduce exposure.

OPP used the SHEDS-Wood exposure results in their probabilistic children's risk assessment for CCA (EPA, 2008). This included recommendations for risk reduction (use of sealants and careful attention to children's hand-washing) to homeowners with existing CCA wood structures. In addition, the exposure assessment was used to identify areas for further research, including: the efficacy of wood sealants in reducing dislodgeable contaminant residues, the frequency with which children play on or around CCA wood, and transfer efficiency and residue concentrations. In order to better characterize the efficacy of sealants in reducing exposure, EPA and the Consumer Product Safety Commission conducted a 2-year study of how dislodgeable contaminant residue levels changed with the use of various types of commercially-available wood sealants.

Management Considerations. The SHEDS-wood model was one of Agency's first probabilistic modeling assessments for regulatory purposes. The OPP used SHEDS results directly in their final risk assessment for children playing on CCA treated playground equipment and decks. The model enhanced risk assessment and management decisions and prioritized data needs related to wood preservatives. The modeling product was pivotal in the risk management and re-registration eligibility decisions for CCA, and in advising the public how to minimize health risks from existing treated wood structures. Industry is also using SHEDS to estimate exposures to CCA and other wood preservatives. Some states are using the risk assessment as guidance in setting their regulations for CCA related playground equipment.

Document Availability.

The model results were included in the final report on the probabilistic exposure assessment of CCA-treated wood surfaces:

Zartarian, V.G., J. Xue, H. A. Ozkaynak, W. Dang, G. Glen, L. Smith, and C. Stallings. A Probabilistic Exposure Assessment for Children Who Contact CCA-treated Playsets and Decks Using the Stochastic Human Exposure and Dose Simulation Model for the Wood Preservative Scenario (SHEDS-WOOD), Final Report. U.S. Environmental Protection Agency, Washington, DC, EPA/600/X-05/009. http://www.epa.gov/heasd/sheds/cca_treated.htm

The final probabilistic risk assessment based on the SHEDS-Wood exposure assessment can be found at: http://www.epa.gov/oppad001/reregistration/cca/final_cca_factsheet.htm

Results of the sealant studies were released in January, 2007 (available at http://www.epa.gov/oppad001/reregistration/cca/index.htm#reviews).

The results of the analysis were published as:
Zartarian, V.G., Xue, J., Özkaynak, H., Dang, W., Glen, G., Smith, L., and Stallings, C. A probabilistic arsenic exposure assessment for children who contact chromated copper arsenate (CAA)-treated playsets and decks, Part 1: Model methodology, variability results, and model evaluation. Risk Analysis 26:515, 2006.

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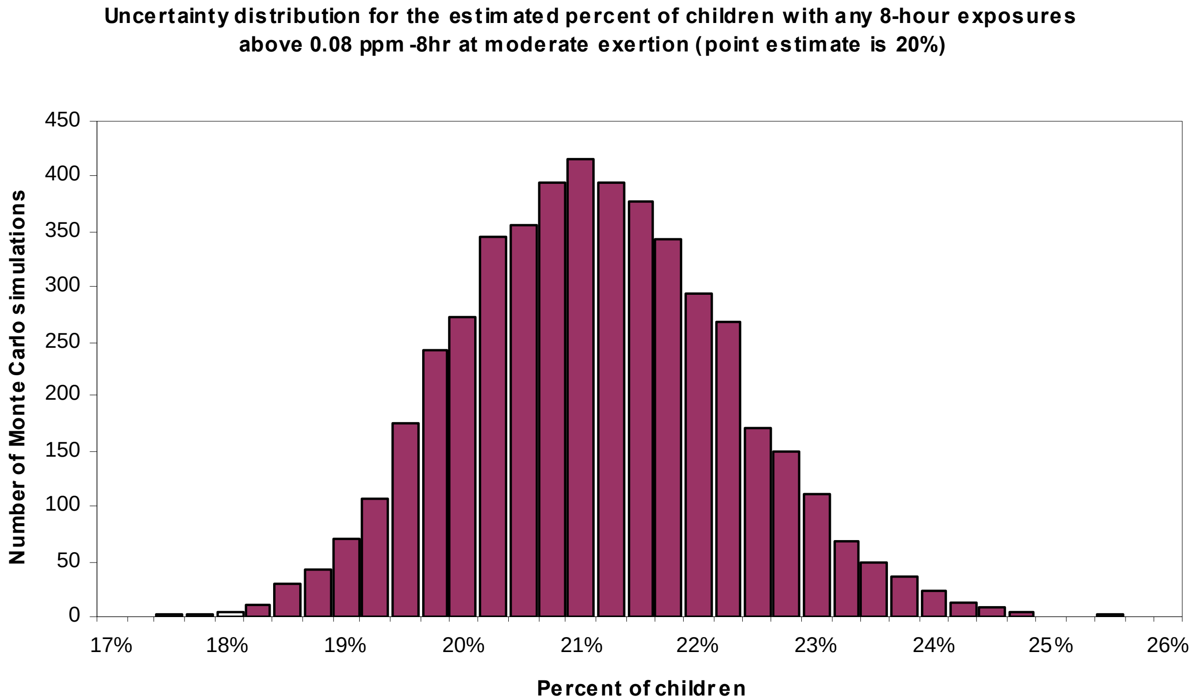
Case Study 10: Two-Dimensional Probabilistic Exposure Assessment of Ozone

As part of EPA's recent review of the ozone National Ambient Air Quality Standards (NAAQS), the Office of Air Quality Planning and Standards (OAQPS) conducted detailed probabilistic exposure and risk assessments in evaluating potential alternative standards for ozone. At different stages of this review, the Clean Air Scientific Advisory Committee (CASAC) Ozone Panel (an independent scientific review committee of EPA's SAB) and the public reviewed and provided comments on analyses and documents prepared by EPA. A scope and methods plan for the exposure and risk assessments was developed in 2005 (EPA, 2005). This plan was intended to facilitate consultation with CASAC, as well as public review, and to obtain advice on the overall scope, approaches, and key issues in advance of the completion of the analyses. This case study describes the probabilistic exposure assessment, addressing short-term exposures to ozone. The exposure estimates were used as an input to the health risk assessment for lung function decrements in all children and asthmatic school-aged children based on exposure-response relationships derived from controlled human exposure studies.

Probabilistic Exposure Analysis. Population exposure to ambient ozone levels was evaluated using EPA's APEX model, also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model. Exposure estimates were developed for recent ozone levels, based on 2002 to 2004 air quality data, and for ozone levels simulated to just meet the existing 0.08 ppm, 8-h ozone NAAQS and several alternative ozone standards, based on adjusting 2002 to 2004 air quality data. Exposure estimates were modeled for 12 urban areas located throughout the United States for the general population, all school-age children, and asthmatic school-age children. This exposure assessment is described in a technical report (EPA, 2007b). The exposure model, APEX, is documented in a user's guide and technical document (EPA, 2006a,b). A Monte Carlo approach was used to produce quantitative estimates of the uncertainty in the APEX model results, based on estimates of the uncertainties for the most important model inputs. The quantification of model input uncertainties, a discussion of model structure uncertainties, and the results of the uncertainty analysis are documented in Langstaff (2007).

Results of Analysis. Uncertainty in the APEX model predictions results from uncertainties in the spatial interpolation of measured concentrations, the microenvironment models and parameters, people's activity patterns, and, to a lesser extent, model structure. The predominant sources of uncertainty appear to be the human activity pattern information and the spatial interpolation of ambient concentrations from monitoring sites to other locations. The primary policy-relevant finding was that the uncertainty in the exposure assessment is small enough to lend confidence to the use of the model results for the purpose of informing the Administrator's decision on the ozone standard.

The following figure illustrates the uncertainty distribution for one model result, the percent of children with exposures above 0.08 ppm-8hr while at moderate exertion. The "point estimate" of 20 percent is the result from the APEX simulation using the best estimates of the model inputs. The corresponding result from the Monte Carlo simulations ranges from 17 to 26 percent, with a 95 percent uncertainty interval (UI) of 19 to 24 percent. Note that the uncertainty intervals are not symmetric since the distributions are skewed.



Management Considerations. The exposure analysis also provided information on the frequency with which population exposures exceeded several potential health effect benchmark levels that were identified based on evaluation of health effects in clinical studies.
The exposure and risk assessments are summarized in Chapters 4 and 5, respectively, of the Ozone Staff Paper (EPA, 2007a). The exposure estimates over these potential health effect benchmarks were part of the basis for the Administrator's March 27, 2008, decision to revise the ozone NAAQS from 0.08 to 0.075 ppm, 8-h average (see 73 FR 16436).

Document Availability.

Langstaff, J. E. (2007). Analysis of Uncertainty in Ozone Population Exposure Modeling. OAQPS Staff Memorandum to Ozone NAAQS Review Docket (OAR-2005-0172). Available at http://www.epa.gov/ttn/naaqs/standards/ozone/s_ozone_cr_td.html.

EPA (2007a). Review of National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information - OAQPS Staff Paper. OAQPS, U.S. EPA, RTP, NC. Available at http://www.epa.gov/ttn/naaqs/standards/ozone/s_ozone_cr_sp.html.

EPA (2007b). Ozone Population Exposure Analysis for Selected Urban Areas. OAQPS, U.S. EPA, RTP, NC. Available at http://www.epa.gov/ttn/naaqs/standards/ozone/s_ozone_cr_td.html.

EPA (2006a,b). Total Risk Integrated Methodology (TRIM) - Air Pollutants Exposure Model Documentation (TRIM.Expo / APEX, Version 4) Volume I: User's Guide; Volume II: Technical

Support Document. OAQPS, U.S. EPA, RTP, NC. June 2006. Available at http://www.epa.gov/ttn/fera/human_apex.html.

EPA (2005). Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment. OAQPS, U.S. EPA, RTP, NC. Available at http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_pd.html.

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Case Study 11: Analysis of Microenvironmental Exposures to Particulate Matter (PM2.5) for a Population Living in Philadelphia, PA

This case study used the Stochastic Human Exposure and Dose Simulation model for particulate matter (SHEDS-PM) developed by EPA's National Exposure Research Laboratory (NERL) to prepare a probabilistic assessment of population exposure to particulate matter (PM) in Philadelphia, PA. This case study simulation was prepared to accomplish three goals: 1) to estimate the contribution of PM of ambient (outdoor) origin to total PM exposure, 2) to determine the major factors that influence personal exposure to PM, and 3) to identify factors that contribute the greatest uncertainty to model predictions.

Probabilistic Risk Analysis. The two-dimensional probabilistic assessment used a microexposure event technique to simulate individual exposures to PM in specific microenvironments (outdoors, indoor residence, office school, store, restaurant or bar, and in a vehicle). The assessment used spatially and temporally interpolated ambient $PM_{2.5}$ measurements from 1992-93 and 1990 U.S. Census data for each census tract in Philadelphia. This case study provides an example of both two-dimensional (variability and uncertainty) probabilistic assessment and microexposure event assessment (Group 3: Advanced PRA).

Results of Analysis. Results of the analysis showed that that human activity patterns did not have as strong an influence on ambient $PM_{2.5}$ exposures as was observed for exposure to indoor $PM_{2.5}$ sources. Exposure to $PM_{2.5}$ of ambient origin contributed a significant percent of the daily total $PM_{2.5}$ exposures, especially for the segment of the population without exposure to environmental tobacco smoke in the residence. Development of the SHEDS-PM model using the Philadelphia $PM_{2.5}$ case study also provided useful insights into data needs for improving inputs to the SHEDS-PM model, reducing uncertainty and further refinement of the model structure. Some of the important data needs identified from the application of the model include: daily PM measurements over multiple seasons and across multiple sites within an urban area, improved capability of dispersion models to predict ambient PM concentrations at greater spatial resolution and over a year time period, measurement studies to better characterize the physical factors governing infiltration of ambient $PM_{2.5}$ into residential microenvironments, further information on particle-generating sources within the residence, and data for the other indoor microenvironments not specified in the model.

Management Considerations: The application of the SHEDS-PM model to the Philadelphia population gave insights into data needs and areas for model refinement. The continued development and evaluation of the SHEDS-PM population exposure model are being conducted as part of EPA/ORD's effort to develop a source-to-dose modeling system for PM and air toxics. This type of exposure and dose modeling system is considered to be important for scientific and policy evaluation of the critical pathways, as well as exposure factors and source types influencing human exposures to a variety of environmental pollutants, including particulate matter.

Document Availability.

The assessment is available at http://www.epa.gov/heasd/pm/pdf/exposure-model-for-pm.pdf.

The results of the analysis were published as:
Burke, J., Zufall, M., and Özkaynak, H. A population exposure model for particulate matter: Case study results for PM2.5 in Philadelphia, PA. Journal of Exposure Analysis and Environmental Epidemiology 11: 470, 2001.

Georgepoulos, P.G., Wang, S.-W., Vyas, V.M., Sun, Q., Burke, J., Vedantham, R., McCurdy, T., and Ozkayanak, H. A source-to-dose assessment of poulation exposure to fine PM and ozone in Philadelphia, PA, during a summer 1999 episode. J. Expos. Analysis and Environm. Epi. 1-19, 2005.

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Case Study 12: Probabilistic Analysis in Cumulative Risk Assessment of Organophosphorus Pesticides

In 1996, Congress enacted the Food Quality Protection Act (FQPA), which requires EPA to consider "available evidence concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity" when setting pesticide tolerances (i.e., the maximum amount of pesticide residue legally allowed to remain on food products). FQPA also mandated that EPA completely reassess the safety of all existing pesticide tolerances (those in effect since August 1996) to ensure that they are supported by up-to-date scientific data and meet current safety standards. Because organophosphorus pesticides (OPs) were assigned priority for tolerance reassessment, these pesticides were the first "common mechanism" group identified by EPA's OPP. The ultimate risk management goal associated with this cumulative risk assessment (CRA) was to establish safe tolerance levels for this group of pesticides, while meeting the FQPA standard for protecting infants and children.

Probabilistic Risk Analysis. This case study provides an example of an advanced probabilistic assessment (Group 3). In 2006, EPA analyzed exposures to 30 OPs through food consumption, consumption of drinking water, and exposure via pesticide application. EPA used Calendex, a probabilistic computer software program (available at http://www.exponent.com/calendex_software), to integrate various pathways, while simultaneously incorporating the time dimensions of the input data. Based on the results of the exposure assessment, EPA calculated margins of exposure (MOEs) for the total cumulative risk from all pathways.

The food component of the OPs CRA was highly refined, as it was based on residue monitoring data from the USDA's PDP and supplemented with information from the FDA's Surveillance Monitoring Programs and Total Diet Study. The residue data were combined with actual consumption data from USDA's Continuing Survey of Food Intakes by Individuals using probabilistic techniques. The CRA evaluated drinking water exposures on a regional basis. The assessment focused on areas where combined OP exposure is likely to be highest within each region. Primarily, the analysis used probabilistic modeling to estimate the co-occurrence of OP residues in water. Monitoring data were not available with enough consistency to be the sole basis for the assessment; however, they were used to corroborate the modeling results. Data sources for the water component of the assessment included USDA Agricultural Usage Reports for Field Crops, Fruits, and Vegetables; USDA Typical Planting and Harvesting Dates for Field Crops and Fresh Market and Processing Vegetables; local sources for refinements; and monitoring studies from the U.S. Geological Survey and other sources. Finally, exposure via the oral, dermal, and inhalation routes resulting from applications of OPs in and around homes, schools, offices, and other public areas were assessed probabilistically for each of the seven regions. The data sources for this part of the assessment included information from surveys and task forces, special studies and reports from published scientific literature, EPA's *Exposure Factors Handbook* (USEPA, 1997), and other sources.

Results of Analysis. The OPs CRA presented potential risk from single-day (acute) exposures across a year and from a series of 21-day rolling averages across the year. MOEs at the 99.9th percentile were approximately 100 or greater for all populations for the 21-day average results.

The only exception is a brief period (roughly 2 weeks) in which drinking water exposures resulting from phorate use on sugarcane result in MOEs near 80 for children aged 1 to 2 years. Generally, exposures through the food pathway dominated total MOEs, and exposures through drinking water were substantially lower throughout most of the year. Residential exposures were substantially smaller than exposures through both food and drinking water.

The OPs CRA was very resource intensive. Work began in 1997 with the preparation of guidance documents and the development of a CRA methodology. Over 2 to 3 years, more than 25 people spent 50 to 100% of their time working on the assessment, with up to 50 people working on the CRA at critical periods. EPA has spent approximately $1 million on this assessment (e.g., for computers, models, and contractor support).

Management Considerations. The OP CRA was a landmark demonstration of the feasibility of a regulatory level assessment of the risk from multiple chemicals. On its completion, EPA presented the CRA at numerous public technical briefings and FIFRA SAP meetings, and made all of the data inputs available to the public. OPP's substantial effort to communicate methodologies, approaches, and results to the stakeholders aided in the success of the OPs CRA. The stakeholders expressed appreciation for the transparent nature of the OPs CRA and recognized the innovation and hard work that went into developing the assessments.

Document Availability. The 2006 assessment and related documents are available at http://www.epa.gov/pesticides/cumulative/common_mech_groups.htm#op.

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Case Study 13: Probabilistic Ecological Effects Risk Assessment Models for Evaluating Pesticide Uses

As part of the process of developing and implementing a probabilistic approach for ecological risk assessment, an illustrative case was completed in 1996. The illustrative case involved both deterministic and probabilistic risk analysis for effects of a hypothetical chemical X on birds and aquatic species. Following the recommendations of the SAP and in response to issues raised by OPP risk managers, the Agency began an initiative to refine the ecological risk assessment process for evaluating the effects of pesticides to terrestrial and aquatic species within the context of FIFRA, the main statutory authority for regulating pesticides at the Federal level. Among the key goals and objectives of EPA's initiative were to:

- incorporate probabilistic tools and methods to provide an estimate on the magnitude and probability of effects;
- build on existing data requirements for registration;
- utilize, wherever possible, existing databases and create new ones from existing data sources to minimize the need to generate additional data; and
- focus additional data requirements on reducing uncertainty in key areas.

After proposing a four-level risk assessment scheme, with higher levels reflecting more refined risk assessment techniques, the Agency developed pilot models for both terrestrial and aquatic species. Refined risk assessment models (Level II) were then developed and used in a generic chemical case study that was presented to the SAP in 2001.

Probabilistic Analysis. This case study describes an advanced probabilistic model for ecological effects of pesticides (Group 3). The terrestrial Level II model (version 2.0) is a multimedia exposure/effects model that evaluates acute mortality levels in generic or specific avian species over a user-defined exposure window. The spatial scale is at the field level, which includes the field and surrounding area. Both areas are assumed to meet the habitat requirements for each species, and contamination of edge or adjacent habitat from drift is assumed to be zero. For each individual bird considered in a run of the Level II model, a random selection of values is made for the major exposure input parameters to estimate an external oral dose equivalent for that individual. The estimated dose equivalent is compared to a randomly assigned tolerance for the individual preselected from the dose/response distribution. If the dose is greater than the tolerance, the individual is scored "dead," if not, the individual is scored "not dead." After multiple iterations of individuals, a probability density function of percent mortality is generated.

May 29-31, 1996, the Agency presented two ecological risk assessment case studies to SAP for review and comment. Although recognizing and generally reaffirming the utility of EPA's current deterministic assessment process, SAP offered a number of suggestions for improvement. Foremost among their suggestions was a recommendation to move beyond the existing deterministic assessment approach by developing the tools and methodologies necessary to conduct a probabilistic assessment of effects. Such an assessment would estimate the magnitude and probability of the expected impact and define the level of certainty and variation involved in the estimate, information that risk managers within EPA's OPP also had requested in the past.

The aquatic Level II model is a two-dimensional Monte Carlo risk model consisting of three main components: (1) exposure, (2) effects, and (3) risk. The exposure scenarios used at Level II are intended to provide estimates for vulnerable aquatic habitats across a wide range of geographical conditions under which a pesticide product is used. The Level II risk evaluation process yields estimates of likelihood and magnitude of effects for acute exposures. For the estimate of acute risks, a distribution of estimated exposure and a distribution of lethal effects are combined through a two-dimensional Monte Carlo analysis to obtain a distribution of joint probability functions. For the estimate of chronic risks, a distribution of exposure concentrations is compared to a chronic measurement endpoint. The risk analysis for chronic effects provides information only on the probability that the chronic end point assessed will be exceeded, not on the magnitude of the chronic effect expected.

Results of Analysis. As part of the process of developing and implementing a probabilistic approach for ecological risk assessment, a case study was completed. The case study involved both deterministic and probabilistic risk analyses for effects of ChemX on birds and aquatic species. The deterministic screen conducted on ChemX concluded qualitatively that it could pose a high risk to both freshwater fish and invertebrates and showed that PRA was warranted. Based on the probabilistic analysis, it was concluded that the use of ChemX was expected to infrequently result in significant freshwater fish mortalities but routinely result in reduced growth and other chronic effects in exposed fish. Substantial mortalities and chronic effects to sensitive aquatic invertebrates were predicted to routinely occur after peak exposures.

Management Considerations. In its review of the case study, the FIFRA SAP congratulated the Agency on the effort made to conduct PRA of pesticide effects in ecosystems. The panel commented that the approach had progressed greatly from earlier efforts, and that the intricacy of the models was surprisingly good, given the time interval in which the Agency had to complete the task. Following the case study, the Agency refined the models based on the SAP comments. In addition, the terrestrial Level II model was refined to include dermal and inhalation exposure.

Document Availability. An overview of the models is available at http://www.epa.gov/oppefed1/ecorisk/fifrasap/rra_exec_sum.htm#Terrestrial.

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Case Study 14: Expert Elicitation of Concentration-Response Relationship Between Particulate Matter ($PM_{2.5}$) Exposure and Mortality

In 2002, the NRC recommended that EPA improve its characterization of uncertainty in the benefits assessment for proposed regulations of air pollutants. NRC recommended that probability distributions for key sources of uncertainty be developed using available empirical data or through formal elicitation of expert judgments. A key component of EPA's approach for assessing potential health benefits associated with air quality regulations targeting emissions of $PM_{2.5}$ and its precursors is the effect of changes in ambient $PM_{2.5}$ levels on mortality. Avoided premature deaths constitute, on a dollars basis, between 85 and 95% of the monetized benefits reported in EPA's retrospective and prospective Section 812A benefit-cost analyses of the Clean Air Act (EPA, 1997 and 1999) and in Regulatory Impact Analysis (RIAs) for rules such as the Heavy Duty Diesel Engine/Fuel Rule (EPA, 2000) and the Non-road Diesel Engine Rule (EPA, 2004). In response to the National Research Council (NRC) recommendation, EPA conducted an expert elicitation evaluation of the concentration-response relationship between $PM_{2.5}$ exposure and mortality.

Probabilistic Risk Analysis. This case study provides an example of the use of expert elicitation (Group 3) to derive probabilistic estimates of the uncertainty in one element of a cost-benefit analysis. Expert elicitation uses carefully structured interviews to elicit from each expert a best estimate of the true value for an outcome or variable of interest, as well as their uncertainty about the true value. This uncertainty is expressed as a subjective probabilistic distribution of values and reflects each expert's interpretation of theory and empirical evidence from relevant disciplines, as well as their beliefs about what is known and not known about the subject of the study. For the $PM_{2.5}$ expert elicitation, the process consisted of development of an elicitation protocol, selection of experts, development of a briefing book, conducting elicitation interviews, the use of expert workshops prior to and following individual elicitation of judgments, and the expert judgments themselves. The elicitation involved personal interviews with 12 health experts who have conducted research on the relationship between $PM_{2.5}$ exposures and mortality.

The main quantitative question asked each expert to provide a probabilistic distribution for the average expected decrease in U.S. annual, adult, and all-cause mortality associated with a 1-$\mu g/m^3$ decrease in annual average $PM_{2.5}$ levels. When answering the main quantitative question, each expert was instructed to consider that the total mortality effect of a 1-$\mu g/m^3$ decrease in ambient annual average $PM_{2.5}$ may reflect reductions in both short-term peak and long-term average exposures to $PM_{2.5}$. Each expert was asked to aggregate the effects of both types of changes in their answers.

The experts were given the option to integrate their judgments about the likelihood of a causal relationship or threshold in the concentration-response function into their own distributions or to provide a distribution "conditional on" one or both of these factors.

Results of Analysis. The project team developed the interview protocol between October 2004 and January 2006. Development of the protocol was informed by an April 2005 symposium held by the project team, where numerous health scientists and analysts provided feedback; by detailed pretesting with independent EPA scientists in November 2005; and by discussion with the participating experts at a pre-elicitation workshop in January 2006. The elicitation interviews were conducted between January and April 2006. Following the interviews, the experts reconvened for a post-elicitation workshop in June 2006, in which the project team anonymously shared the results of all experts with the group.

The median estimates for the $PM_{2.5}$ mortality relationship were generally similar to estimates derived from the two epidemiological studies most often used in benefits assessment. However, in almost all cases, the spread of the uncertainty distributions elicited from the experts exceeded the statistical uncertainty bounds reported by the most influential epidemiologic studies, suggesting that the expert elicitation process was successful in developing more comprehensive estimates of uncertainty for the $PM_{2.5}$ mortality relationship. The uncertainty distributions for $PM_{2.5}$ concentration-response resulting from the expert elicitation process were used in the RIA for the revised NAAQS standard for $PM_{2.5}$ (promulgated on September 21, 2006). Because the NAAQS are exclusively health based standards, this RIA played no part in EPA's determination to revise the Pm2.5 NAAQS. Benefits estimates in the RIA were presented as ranges and included additional information on the quantified uncertainty distributions surrounding the points on the ranges, derived from both epidemiological studies and the expert elicitation results. OMB's review of the RIA was completed in March 2007.

Management Considerations. The NAAQS are exclusively health-based standards, so these analyses were not used in any manner by EPA in determining whether to revise the NAAQS for PM2.5. Moreover, the request to engage in the expert elicitation did not come from the Clean Air Scientific Advisory Committee, or CASAC, the official peer review body for the NAAQS, so that a decision to conduct the analyses does not reflect CASAC advice that such analyses inform NAAQS determinations. The analyses addressed comments from the National Research Council that recommended that probability distributions for key sources of uncertainty be addressed. The analyses were used in EPA's retrospective and prospective Section 812A benefit-cost analyses of the Clean Air Act (EPA, 1997 and 1999) and in RIAs for rules such as the Heavy Duty Diesel Engine/Fuel Rule (EPA, 2000) and the Non-road Diesel Engine Rule (EPA, 2004). In response to the NRC recommendation, EPA conducted an expert elicitation evaluation of the concentration-response relationship between $PM_{2.5}$ exposure and mortality.

Document Availability. The assessment is available at http://www.epa.gov/ttn/ecas/ria.html.

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Case Study 15: Expert Elicitation of Sea-Level Rise Resulting from Global Climate Change

The United Nations Framework Convention on Climate Change requires nations to implement measures for adapting to rising sea level and other effects of changing climate. To decide on an appropriate response, coastal planners and engineers weigh the cost of these measures against the likely cost of failing to prepare, which depends on the probability of the sea rising a particular amount. The U.S. National Academy of Engineering recommended that assessments of sea level rise should provide probability estimates. Coastal engineers regularly employ probability information when designing structures for floods, and courts use probabilities to determine the value of land expropriated by regulations. This case study describes the development of a probability distribution for sea level rise, using models employed by previous assessments, as well as the expert opinions of 20 climate and glaciology reviewers about the probability distributions for particular model coefficients.

Probabilistic Analysis. This case study provides an example both of an analysis describing the probability of sea level rise, as well as an expert elicitation of the likelihood of particular models and probability distributions of the coefficients used by those models to predict future sea level rise (Group 3). The assessment of the probability of sea level rise used existing models describing the change in five components of sea level rise associated with greenhouse-gas-related climate change (thermal expansion, small glaciers, polar precipitation, melting and ice discharge from Greenland, ice discharge from Antarctica). To provide a starting point for the expert elicitation, initial probability distributions were assigned to each model coefficient based on the published literature.
Once the initial probabilistic assessment was completed, the draft report was circulated to expert reviewers considered most qualified to render judgments on particular processes for revised estimates of the likelihood of particular models and the model coefficients' probability distributions. Experts representing both extremes of climate change science (those who predicted trivial consequences and those who predicted catastrophic effects; those whose thinking had been excluded from previous assessments) were included. The experts were asked to provide subjective assessments of the probabilities of various models and model coefficients. These subjective probability estimates were used in place of the initial probabilities in the final model simulations. Different reviewer opinions were not combined to produce a single probability distribution for each parameter, but, rather, each reviewer's opinions were used in independent iterations of the simulation. The group of simulations resulted in the probability distribution of sea level rise.

Results of Analysis. The analysis, completed with a budget of $100,000, provided a probabilistic estimate of sea level rise for use by coastal engineers and regulators. The results suggested that there is a 65% chance that sea level will rise 1 mm/year more rapidly in the next 30 years than it has been rising in the last century. Under the assumption that nonclimatic factors do not change, the projections suggested that there is a 50% chance that global sea level will rise 45 cm, and a 1% chance of a 112-cm rise by the year 2100. The median prediction of sea level rise was similar to the midpoint estimate of 48 cm published by the Intergovernmental Panel on

Climate Change (IPCC, 2006) shortly thereafter.. The report also found a 1% chance of a 4-5 meter rise over the next two centuries.

Management Considerations: Both reports (EPA 1995; Titus and Narayanan 1996) discuss several uses of the results of this study. By providing a probabilistic representation of sea level rise, the assessment allows coastal residents to make decisions with recognition of the uncertainty associated with predicted change. Rolling easements that vest when the sea rises to a particular level can be properly valued in both arms-length transaction sales or when calculating the allowable deduction for a charitable contribution of the easement to a conservancy. Cost-benefit assessments of alternative infrastructure designs—which already consider flood probabilities—can also consider sea level rise uncertainty. Assessments of the benefits of preventing an acceleration of sea level rise can more readily include low-probability outcomes, which can provide a better assessment of the true risk when the damage function is nonlinear, which is often the case.

Document Availability.

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Case Study 16: Expert Elicitation for Bayesian Belief Network Model of Stream Ecology

The identification of the causal pathways leading to stream impairment is a central challenge to understanding ecological relationships. Bayesian belief networks (BBNs) are a promising tool for modeling presumed causal relationships, providing a modeling structure within which different factors describing the ecosystem can be causally linked, and uncertainties expressed for each linkage.

BBNs can be used to model complex systems that involve several interdependent or interrelated variables. In general, a BBN is a model that evaluates situations where some information is already known, and incoming data are uncertain or partially unavailable. The information is depicted with influence diagrams that present a simple visual representation of a decision problem, for which quantitative estimates of effect probabilities are assigned. As such, BBNs have the potential for representing ecological knowledge and uncertainty in a format that is useful for predicting outcomes from management actions or for diagnosing the causes of observed conditions. Generally, specification of a BBN can be performed using available experimental data, literature review information (secondary data), and expert elicitation. Attempts to specify a BBN for the linkage between fine sediment load and macroinvertebrate populations using data from literature reviews have failed because of the absence of consistent conceptual models and lack of quantitative data or summary statistics needed for the model. In light of these deficiencies, an effort was made to use expert elicitation to specify a BBN for the relationship between fine sediment load resulting from human activity and populations of macroinvertebrates. The goals of this effort were to examine whether BBNs might be useful for modeling stream impairment and to assess whether expert opinion could be elicited to make the BBN approach useful as a management tool.

Probabilistic Risk Analysis. This case study provides an example of expert elicitation in the development of a BBN model of the effect of increased fine sediment load in a stream on macroinvertebrate populations (Group 3). For the purpose of this study, a stream setting (a Midwestern, low-gradient stream) and a scenario of impairment (introduction of excess fine sediment) were used. Five stream ecologists with experience in the specified geographic setting were invited to participate in an elicitation workshop. An initial model was depicted using influence diagrams, with the goals of structuring and specifying the model using expert elicitation. The ecologists were guided through a knowledge elicitation session in which they defined factors that described relevant chemical, physical, and biological aspects of the ecosystem. The ecologists then described how these factors were connected and were asked to provide subjective, quantitative estimates of how different attributes of the macroinvertebrate assemblage would change in response to increased levels of fine sediment. Elicited input was used to restructure the model diagram and to develop probabilistic estimates of the relationships among the variables.

Results of Analysis. The elicited input was compiled and presented in terms of the model as structured by the stream ecologists and their model specifications. The results were presented both as revised influence diagrams and with Bayesian probabilistic terms representing the elicited input. The study yielded several important lessons. Among these were the elicitation process takes time (including an initial session by teleconference as well as a 3-day workshop), defining a scenario with an appropriate degree of detail is critical, and elicitation of complex ecological relationships is feasible.

Management Considerations. The study was considered successful for several reasons. First, the feasibility of the elicitation approach to building stream ecosystem models was demonstrated. The study also resulted in the development of new graphical techniques to perform the elicitation. The elicited input was interpreted in terms of predictive distributions to support fitting a complete Bayesian model. Further, the study was successful in bringing together a group of experts in a particular subject area for the purpose of sharing information and learning about expert elicitation in support of model building. The exercise provided insights into how best to adapt knowledge elicitation methods to ecological questions and informed the assembled stream ecologists on the elicitation process and on the potential benefits of this modeling approach. The explicit quantification of uncertainty in the model not only enhances the utility of the model predictions but also can help guide future research.

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List of Acronyms and Abbreviations

APEX	Air Pollutants Exposure Model
BBN	Bayesian belief network
CASAC	Clean Air Scientific Advisory Committee
CCA	chromated copper arsenate
CRA	cumulative risk assessment
CSFII	Continuing Survey of Food Intake by Individuals
DEEM	Dietary Exposure Evaluation Model
DRES	Dietary Risk Evaluation System
Eco	ecological risk assessment
EMAP	Environmental Monitoring and Assessment Program
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
HH	human health
LT	long-term
MOEs	margins of exposure
NAAQS	National Ambient Air Quality Standards
NRC	National Research Council
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OGWDW	Office of Groundwater and Drinking Water
OMB	Office of Management and Budget
OP	organophosphorous pesticide
ORD	Office of Risk Analysis
OW	Office of Water
PCB	polychlorinated biphenyl
PDP	Pesticide Data Program
PM	particulate matter
PRA	probabilistic risk analysis
RIA	Regulatory Impact Analysis
SAB	Science Advisory Board
SAP	Scientific Advisory Panel
SHEDS	Stochastic Human Exposure and Dose Simulation
TRIM	Total Risk Integrated Methodology
TRIM.Expo	Total Risk Integrated Methology/Exposure Model
UI	Uncertainty Interval
USDA	U.S. Department of Agriculture