Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision Making

Managers' Summary

Prepared by the EPA Risk Assessment Forum Working Group

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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.

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Manager's Summary

EPA has been called upon by numerous advisory bodies such as the Science Advisory Board and U.S. National Academy of Sciences to incorporate probabilistic risk information into the Agency decision making process. Probabilistic risk assessment (PRA) is a group of techniques that provide a range and likelihood estimate for one or more steps of hazard, exposure or risk, rather than a single point estimate. A Risk Assessment Forum PRA technical panel has been formed from representatives of Offices and Regions who conduct PRA. The panel has developed several products to promote enhanced use of PRA, including a white paper describing PRA and its utility and application in Agency decisions, and a compendium of case studies. The panel is developing Agency resources such as a clearinghouse of case studies, best practices, and resources. Seminars are being developed to raise general knowledge of how these tools can be used, and act as a precursor for future training. The purpose of this paper is to present general concepts and principles of PRA, to describe how PRA can improve the bases of Agency decisions, and to provide illustrations of how PRA has been used in risk estimation and to describe the uncertainty in risk decision making.

Why should I care about PRA? Why is it important to risk managers?

The use of PRA is often a major recommendation in reviews of EPA products and procedures (e.g., Science Advisory Board review of EPA practices in 2006, NAS review of the Dioxin Reassessment, OMB's Circular A-4 and Updated Principles for Risk Analysis). The Agency has some basic guidance, as well as some program-specific procedures and applications for PRA. The enhanced use of PRA and characterization of uncertainty would respond to outside recommendations and potentially enhance the overall transparency and quality of EPA assessments. These approaches would provide additional tools to address specific challenges faced by managers and improve confidence in Agency decisions. Specifically, PRA can inform decision makers about specific segments of the population at risk, not just the mean (average) or extreme values. A PRA can also confirm or support the conclusions of a deterministic risk estimate. Having this information can be important to risk managers if a different decision might be made when the upper or lower ends of the range of estimated exposures, doses, or risks are used.

What is PRA? How does it compare with current practice?

A basic characteristic of PRA is that it does not generate a single point estimate but rather produces a range and likelihood that a particular exposure, dose, or effect will occur. Probabilistic risk assessment, in its simplest form, is a group of statistical techniques that allow analysis of variability and uncertainty to be incorporated into exposure and/or risk assessments. As mentioned above, this kind of information can be critical in risk management decisions - especially if one were interested in a specific portion of the population and the likelihood of exposure or risk is known.

What are common challenges facing EPA decision makers?

EPA Offices and Regions are faced with similar mandates; basic attributes critical to decisions are (1) understanding whom or what we are protecting, and (2) what is the appropriate degree of confidence in the estimated protection provided by a particular decision. A further complication is the fact that decisions are often time-sensitive and need to be made based on the current state of knowledge. Health and environmental impacts of environmental exposures cannot be isolated and directly measured. Therefore, risk assessment methods have been developed to estimate health and ecological risks based on available data and information. The risk decision making may also consider other assessments conducted to address other factors, such as economic impacts of risk management actions. Uncertainty can be introduced into any assessment at any step in the process, even when using the most accurate data with the most sophisticated models. As a result, *EPA must always make decisions in the presence of uncertainty*.

How can PRA and enhanced characterization of uncertainty and variability help?

There are several ways in which various types of PRA can enhance risk management decision making. First, a sensitivity analysis (either deterministic or probabilistic) can determine if more refined information about the distribution and range of data can have a substantial effect on the choice of decision options. If so, there are two ways that PRA can improve decisions. First, using PRA one can explicitly address the elements of a risk-based decision – whom or what we are protecting and with what degree of confidence. Secondly, the use of PRA can characterize the inherent uncertainties and the impact of those uncertainties on the decision. When uncertainty is present, PRA can better inform a decision, increase the transparency of the inputs to the decision, and assist in selecting among various management options. Below we describe how PRA can:

1) enhance EPA decisions by providing more information about the possible impacts of alternative regulatory decisions;
2) provide clarity on whom we are protecting and the confidence in the estimates of protection provided by a given regulatory decision;
3) allow for more detailed comparison of alternative risk management options in terms of estimated impacts on both protection and costs; and
4) improve the overall confidence in specific decisions.

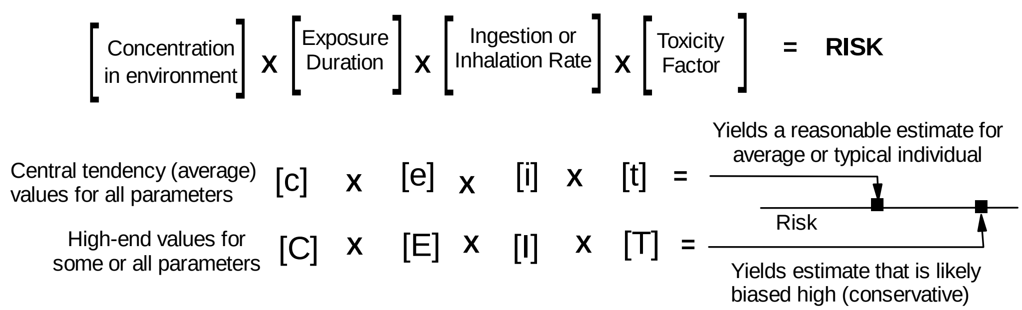
As a manager what do I need to know about PRA?

We all have common baseline experiences with probability, uncertainty and variability such as weather forecasting, political polls, or climate change predictions. PRA can be used on many levels or degrees of sophistication to support or improve decisions. The following sections describe the basics of PRA in more detail, how it can be used to support decisions, and what to consider in pursuing a PRA or using PRA results.

How does EPA typically address variability and scientific uncertainty?

EPA cannot perform a time- and resource-intensive risk assessment for every situation and EPA decision, and therefore, must be strategic in determining whether more intensive assessments are needed. When EPA does not explicitly quantify the degree of confidence in a risk estimate, the Agency attempts to increase the confidence that risk is not underestimated by using default options to deal with uncertainty and variability. As depicted below, EPA most often uses risk assessment methods that rely on default assumptions using a combination of point values -- some conservative (high parameter values that are more likely to overestimate risk) and some typical or average. These values are put into a model or single model structure and the risks are calculated as shown below in Equation 1.

Equation 1:



This approach typically produces a single estimate of risks (e.g., 10^{-6} cancer risk; that is increased risk of 1 in a million additional cancers); these may be referred to as deterministic assessments or point estimates of risk. These point estimates are useful, particularly in screening assessments, but the inherent uncertainties are not fully quantified. These inherent limitations can affect EPA decisions in the following ways:

- Inability to explicitly characterize the basic elements of EPA decisions -- whom or what are we protecting or with what degree of confidence
- Inability to more realistically or accurately compare across alternative risk management choices (e.g., cleanup levels, permit levels, regulations, actions) or risks due to different levels of conservatism
- Decreased ability to make tradeoffs or appropriate balance between benefits and costs
- Liability to criticism and debate of being overly conservative and unrealistic, or of providing inadequate protection; these criticisms frequently cannot be directly answered, which reduces the credibility of EPA decisions.

What are variability and uncertainty and their relevance in risk assessment?

The 2004 Staff Paper *Risk Assessment Principles and Practices* (www.epa.gov/osa) and the PRA White Paper #1 describe uncertainty and variability in some detail and can be referred to for more information.

Variability refers to the inherent natural variation, diversity, and heterogeneity across time and/or space, or individuals within a population. While we can better describe and understand variability in the world, or a particular system, it is unavoidable and cannot be reduced. Variability is present in all aspects of the source to effect continuum (Figure 1 below):

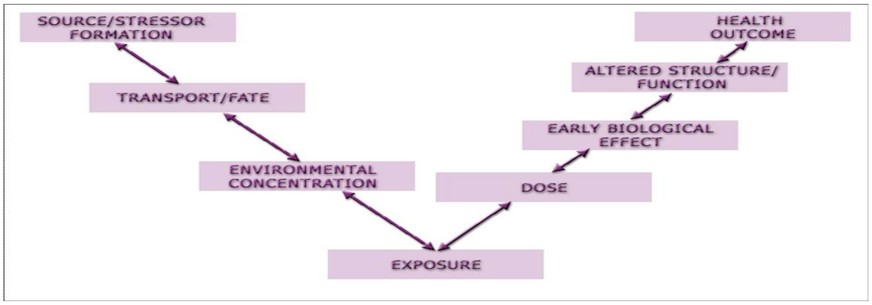


Figure 1. Source-to-Effect Continuum

- in how pollutants are released (e.g., effectiveness of emission controls),
- influenced by environmental conditions once released (e.g., meteorology – wind and precipitation),
- exposure to receptors (e.g., inhalation or ingestion rates),
- effect (e.g., endpoint, health status, genetic susceptibility).

An example of variability is the amount of water consumed by a population. For example, if we conducted a survey of 1,000 people and asked them how much water they consumed, we might have the following distribution (i.e., plot of the data in Figure 2) which shows that 5% of the population consumes 2.41 liters of water/day or higher while the average individual consumes 1.4 liters of water/day , based on studies identified in the Exposure Factors Handbook (EPA, 1997).

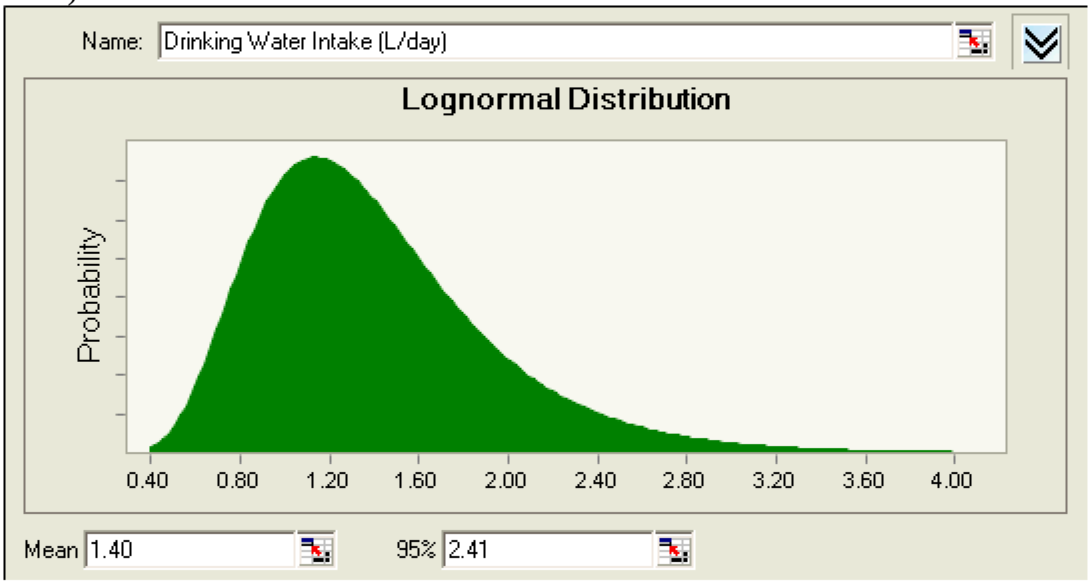


Figure 2. Probability Distribution of Drinking Water Intake

Uncertainty refers to imperfect knowledge or lack of precise knowledge of the real world, either for specific values of interest or in the description of the system. While numerous schemes for classifying uncertainty have been proposed, most focus on two broad categories.

Parameter uncertainty refers to uncertainties in specific estimates or values used in a model.

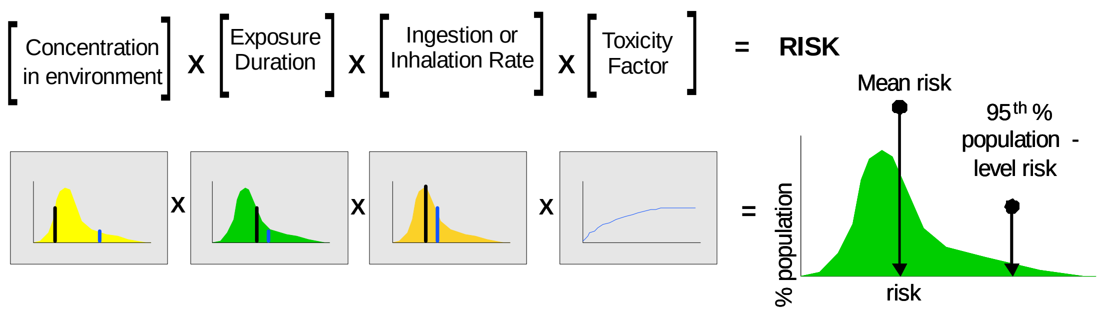
Model uncertainty refers to the gaps in scientific knowledge or theory that is required to make accurate predictions.

From a risk manager's perspective, both are important in that variability is related to our understanding of whom or what we are protecting and uncertainty relates to our confidence in the estimate and the level of protection.

How does PRA address variability and uncertainty?

By contrast, as depicted below PRA uses distributions of values that reflect variability and/or uncertainty in parameters and/or models; the result is an overall probability statement of the risk (e.g., what are the risks to the average or mean individual and high end individual such as the 95th percentile as illustrated in Equation 2 below). This hypothetical example illustrates the approach for estimating individual risk. In some cases exposure and health risk are estimated for the entire population or particular subgroups of the population.

Equation 2:



What is the impact of uncertainty on decisions?

When uncertainty is present -- where data and information are incomplete or are inadequate -- *making informed decisions is more difficult and there is greater potential for decision errors*. In the case of environmental regulations, specific decisions may either lead to over- or under-regulation compared to decisions that could be made with perfect information. Setting an environmental standard that is too lax may threaten public health, while a standard that is unnecessarily stringent may impose a significant economic cost for a marginal gain in public health and environmental protection.

What key questions can be asked or considered by decision makers?

The PRA Technical Panel conducted several dialogues with EPA decision makers, asking them what questions arise when they are faced with the task of making decisions in the presence of uncertainty. The following questions represent typical concerns.

- 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?

How can PRA help inform decisions?

PRA can provide information to decision makers on specific questions related to uncertainty and variability. For questions of uncertainty and to minimize the likelihood of unintended consequences, PRA can help provide the following types of information:

- Characterize uncertainty in estimates (what is the degree of confidence in the estimate?). That is, could the prediction be off by a factor of 2, a factor of 10, or a factor of 1,000?
- Identify the critical parameters and assumptions which most impact or influence a decision and the risk assessment;
- Identify the “tipping points” where the decision option chosen would be different if the risk estimates were different, or a different assumption were valid;
- Estimate the likelihood that critical data values exist or the validity of assumptions;
- Estimate the degree of confidence in a particular decision and/or the likelihood of specific decision errors
- Estimate, (in conjunction with other techniques, such as sensitivity analysis and value of information) the possibility of alternative outcomes with additional information, or estimate trade-offs related to different risks or risk management decisions;
- Identify impact of additional information on decision making considering the cost and time to obtain the information and resulting change in decision (that is, value of information).

For consideration of variability, PRA for example can provide the following types of information for exposures:

- Explicitly define the exposures for various sectors of the population (whom are we trying to protect?) That is, will the regulatory action keep 50% of the population, 90% of the population 99.9% or some other fraction of the population below a specified exposure, dose, or risk target?
- Provide information including the variability in the exposures among the population, and information on the percentile of the population that is being evaluated in the risk assessment (i.e., people who consume a glass of water/ day or people who consume a gallon of water/day). This information is helpful in addressing comments:
  - from the regulatory community on conservatism of EPA's risk assessments;
  - from the community regarding concerns whether their particular exposures were assessed in the risk assessment,
  - about whom or what is being protected by a risk management action, and
  - whether and what additional research may be needed to reduce uncertainty.

PRA helps inform decisions by identifying the alternatives available to the decision maker, the uncertainty they face, and by providing evaluation measures of outcomes (often referred to as decision analysis). Uncertainties are often represented as probabilities or probability distributions, in graphs or numerically.

A few hypothetical examples of the types of risk management questions which can explicitly be addressed through PRA are illustrated in Figure 3 below.

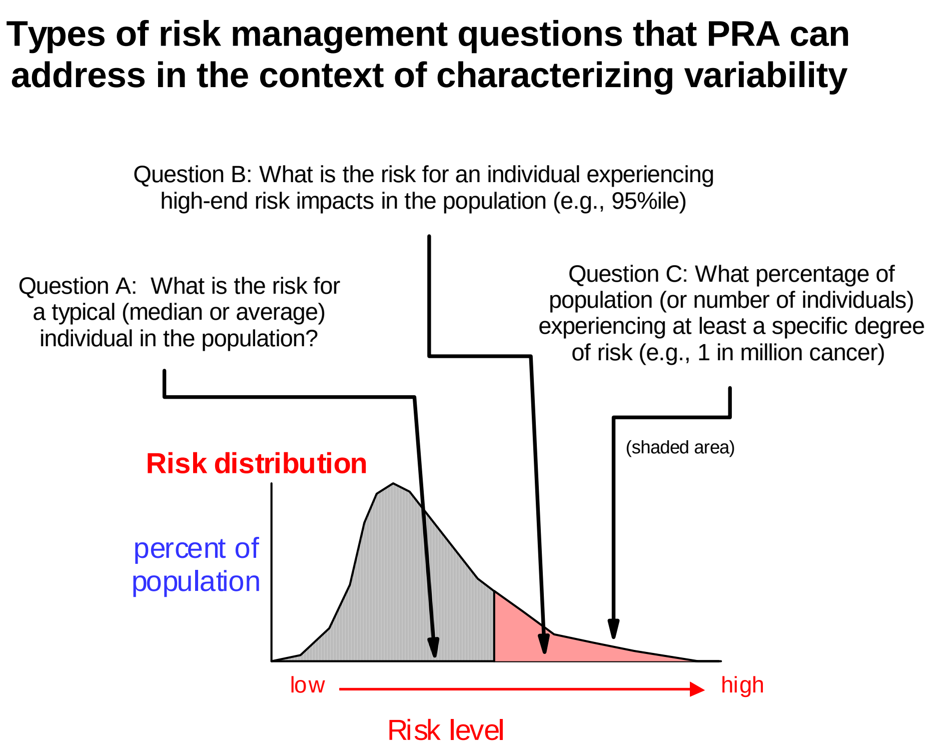


Figure 3. What Questions Can PRA Address?

What are some of the limitations of PRA?

PRA relates to the application of probabilistic techniques to one or more phases of the risk assessment paradigm, including hazard characterization, exposure, toxicity, and/or risk assessment. Data may not be available to support probabilistic techniques at all of these stages in the same assessment, requiring the risk assessor to continue to apply some deterministic science-policy assumptions and conversions. If science-policy assumptions, or default values for parameters are applied to a PRA, they should to be clearly articulated in the dissemination of results. PRA typically requires more time to develop than a deterministic assessment, but these techniques fit into a graduated, or tiered approach, to risk analysis. Additional limitations are that:

- PRA is generally more data intensive, requiring additional financial, time and analytic resources to obtain the necessary statistical distribution input data for each aspect of the risk assessment. It is anticipated that more routine incorporation of probabilistic designs in risk assessment and its supporting research could reduce this cost differential.

- PRA techniques have been most successful on the exposure aspect of human health risk assessment.

- The dissemination of a statistical distribution or probability output number should be carefully related to the quality and coverage of the input statistical distribution data, otherwise the PRA results could lead to a false sense of accuracy.
- PRA can be used to characterize the uncertainty and variability in situations with limited data. As yet, there is not extensive experience using PRA to characterize the range of effects or the dose-response for populations, including sensitive populations and life-stages.

What is EPA's experience in PRA?

In the past, EPA has usually, but not always, relied on deterministic or point estimates to evaluate risk; (e.g., 10^{-6} or one in a million risk of cancer). However, the use of PRA to evaluate uncertainty and variability in risk assessments is increasing. These efforts are varied across Programs and Regions, as well as in complexity and applications. Many PRA applications focused on specific elements of a risk assessment (e.g., exposure), variability, or uncertainty. The document *Case Study Examples of the Application of Probabilistic Risk Assessment in EPA Regulatory Decision Making* contains summary examples of PRAs that have been conducted to support regulatory decisions and/or regulatory impact analyses. A few examples of PRA use in EPA include:

- EMAP program: The Office of Research and Development (ORD) developed and Office of Water (OW) adopted applied probabilistic sampling techniques to evaluate nation's aquatic resources under CWA Section 305(b)

- 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.
- 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.
- 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.
- $PM_{2.5}$ 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.

EPA's experience with PRA includes not only individual assessments or applications but also the development of general guidance and policies such as these:

- Policy for Use of Probabilistic Analysis in Risk Assessment (1997),
- Guiding Principles for Monte Carlo Analysis (1997), and
- Risk Assessment Guidance for Superfund, Volume III – Part A. Process for Conducting Probabilistic Risk Assessment.

How should a risk manager approach a PRA? What should a manager consider?

There is a range of probabilistic risk analysis techniques that may be useful to support environmental decisions. Communication between the risk managers and risk assessors is critical for clear definition of the specific needs of the decision maker and the questions to be addressed by the PRA. The risk assessor and risk manager should evaluate the types of techniques appropriate to meet the goals of the assessment and establish a process for completing and reviewing the PRA in a cost-effective and timely manner. The dialogue should continue until the PRA is completed to everyone's satisfaction.

When should we consider doing PRA?

Conducting a sensitivity analysis within the context of the decision can help managers determine whether having such information is critical and that the time and resources spent to perform PRA are warranted in specific cases. PRA may not be needed when the decision is routine, legislatively mandated, or a standard methodology is prescribed. Furthermore, PRA may not be needed when there is high confidence in the data and models used to support the decision. On the other hand planning and scoping discussions or a preliminary analysis may indicate that information from a PRA may be critical or influence the risk management decision. Some examples include :

- A specified target level of protection in a population is identified (e.g., 95^{th} percentile), and it is necessary to demonstrate that this goal is met;

- Significant equity issues are raised by variation in risks among the exposed population of concern;
- Screening level point estimates of risk are higher than the level of concern;
- Uncertainty is high, and decisions are contentious or have large resource implications;
- Specific critical risk estimates and assumptions point to different risk management alternatives;
- Scientific rigor and quality of the assessment is critical to credibility of the EPA decision.

What is the right level of analysis?

As is the case for risk assessment in general, approaches to PRA and specific analytical methods may vary dramatically in terms of complexity and resource implications. The concept of iterative or tiered analyses to address this continuum is widely accepted in risk assessment, and the same principle applies to PRA as well. There is a wide range of methods and approaches to PRA, of varying complexity and rigor, which can be applied for different purposes ranging from sensitivity analysis to integrated analysis of uncertainty and variability. The goal is to choose a level of detail and refinement for an analysis appropriate to the overall objectives of the decision and the types of available data and analyses needed to support decisions. Early and continued dialogue between risk manager and risk assessor is critical to developing a clear understanding of overall project objectives, needs of the decision maker, timing, and how PRA may play a role. These discussions should focus on deciding the following:

(1) whether or not the risk assessment, in its current state, is sufficient to support risk management decisions (a clear path to exiting the process is available); and

(2) if the assessment is determined to be insufficient, whether or not progression to a higher level of complexity would provide a sufficient benefit to warrant the additional effort of performing a PRA.

If I am going to use PRA what are things to consider?

If one decides that the use of PRA would provide valuable information in support of a decision, some other things to consider in moving forward include:

- **Resources** needed to develop the PRA and review the document,
- **Expertise** of EPA staff to develop a PRA or review a PRA submitted by a contractor or member of the regulated community;
- **Data availability** and format (e.g., electronic or paper copy) to develop distributions to include in the PRA,
- **Time** needed for the development and review of the analyses,
- **Funding**, either intramural or extramural that may be necessary for development and review of the document,
- **Peer-review** including either internal and/or external review which has time and cost implications, and

- **Communicating results** to the scientific community, Agency executives, stakeholders and the general public.

What are the resources and costs needed to conduct a PRA?

PRA can be expected to require more time, effort and resources than standard default-based deterministic assessments. The costs and resources will vary depending on the tool or approach that is selected. That is, there is a continuum of PRA approaches to choose from, ranging from simple approaches such as sensitivity analyses to complex approaches such as two-dimensional Monte Carlo analyses In some cases, simple sensitivity analyses, which may require limited time and risk assessor resources, can be conducted in-house. More sophisticated analyses may require specific expertise or use of specific tools or models. Proper application of probabilistic methods requires not only software and data, but also guidance and training for both analysts using the tools as well as for managers and decision makers tasked with interpreting and communicating the results. While increases in resources needed to conduct a probabilistic assessment can be expected, the development of standardized approaches and/or methods can lead to the routine incorporation of PRA in Agency approaches and greatly reduced costs in future applications.

Does PRA require more data than conventional approaches?

In general, PRA requires more data than conventional approaches because distributions of values rather than single values are used. How much more data is required is often the topic of debate in the technical community. Minimum data needs vary depending on the analytical approach used; empirical-based (observational or frequentist) methods have significant data requirements compared to so called subjective methods. However, some of the data that would be applied in a frequentist approach may already be available as part of the underlying data set used in standard deterministic analyses. As a result, PRA can be applied in most cases, as long as methods used are appropriate for the available body of evidence and data.

Communication of PRA Results to the Manager and Community. **Does presentation of results matter?**

The lack of familiarity with PRA presents a challenge in effectively presenting results to managers, stakeholders, and the public. Many view PRA as a highly technical discipline utilizing sophisticated mathematics and requiring extensive training to understand. Single point estimates are easy to grasp for most people, based in part on familiarity with the approach over the history of EPA. While some people initially have difficulty interpreting probability distributions of values, we all have common baseline experiences with probability, uncertainty and variability (e.g., weather forecasting); these could be used to frame discussion of results. It is not necessary to understand the underlying mathematics or even to include results as full distributions. Results can be distilled to the critical essence or decision-meaningful value of interest.

The audience and its range of knowledge and expertise must be considered in developing materials for effective communication. It is helpful when a decision is made to conduct a PRA to consider early explanation or training of the community, managers, and others in the basic principles before the final decision is presented. Alternatively, it may be helpful to present the results of the PRA with the point estimate to provide context for the results.

How can I get more information on PRA?

This document provides a general overview and basic concepts to establish some familiarity and a foundation for further education on PRA. The white paper entitled "Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision making – Uses and Case Studies in EPA" provides more of a detailed discussion of PRA and EPA's experience with it. There are numerous additional resources for more detail on PRA. Additionally, the RAF PRA technical panel has been tasked with developing resources to facilitate the understanding and implementation of PRA. It is developing an electronic clearinghouse of resources (policies, guidance, tools, case studies) as well as specific training seminars which will soon be available. More information on the PRA technical panel and the clearinghouse can be found at www.epa.gov/raf or on the Environmental Science Connector. See also the EPA source for links to risk assessment methods and policies: www.epa.gov/risk.

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.

***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.

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

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

***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.

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 or event.

Probabilistic risk analysis*.* Application of a computational method, based on a randomized sampling of available data or information or probabilities obtained from experts, 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.

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.