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Framework for Human Health Risk Assessment to Inform Decision Making

Office of the Science Advisor
Risk Assessment Forum

Framework for Human Health Risk Assessment to Inform Decision Making

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U.S. Environmental Protection Agency
Office of the Science Advisor
Risk Assessment Forum

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The Risk Assessment Forum dedicates this Framework to

Ira William Leighton Jr.

Deputy Regional Administrator – Region 1
2000-2013
41 Years of Service to the U.S. Environmental Protection Agency

for his dedication to risk assessment and in response to his 2010 challenge to the Risk Assessment Forum to produce *actionable* products that advance risk assessment and improve real life decision making.

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Disclaimer

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Foreword

This document is a direct result of the 2010 EPA Human Health Risk Assessment Colloquium, where approximately 120 risk assessors and decision makers from across the Agency convened to develop a plan to advance human health risk assessment at EPA, focusing on the recommendations presented in three National Academy of Sciences (NAS) National Research Council (NRC) reports: *Science and Decisions: Advancing Risk Assessment*; *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*; and *Toxicity Testing in the 21st Century: A Vision and A Strategy* (NRC 2007, 2008, 2009).

In *Science and Decisions*, the NRC recommended that EPA adopt a framework for risk-based decision making that maximizes the utility of risk assessment. The EPA Risk Assessment Forum Colloquium Planning Committee assembled a work group that presented a framework for discussion at the 2010 Colloquium. The framework considered the NRC's recommendations and built upon existing Agency guidance. During the Human Health Framework Subgroup session at the Colloquium, participants agreed that adopting a human health risk assessment framework would increase the Agency's ability to maximize the utility of risk assessment by emphasizing the need to focus the design of risk assessments on the decision-making process. The Subgroup suggested that the framework should tie together existing human health frameworks and guidance, as well as be flexible enough to accommodate the range of assessments conducted across the Agency and changes in the science of risk assessment. They also agreed with the NRC that the framework should integrate concepts regarding risk assessment processes such as planning and scoping, as well as problem formulation, which are described in the *Framework for Ecological Risk Assessment*, *Guidelines for Ecological Risk Assessment*, and *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (USEPA 1992a, 1997a, 1998a). This document is a product of the Colloquium participants' recommendations and the subsequent work of the Risk Assessment Forum's Human Health Risk Assessment Framework Technical Panel.

Capacity building, including Agency-wide outreach and training for both risk assessors and risk managers, is needed to institutionalize the concepts presented herein into Agency risk assessment practices. It is critical that this outreach and training occur to make this Framework a living, high-impact document that will enhance the utility of risk assessments in decision making.

As mentioned above, many people from across the Agency were involved in the 2010 EPA Human Health Risk Assessment Colloquium and the development of this Framework, as guided by EPA's Risk Assessment Forum and Science and Technology Policy Council. Special acknowledgment is given to the Human Health Risk Assessment Framework Technical Panel and the Risk Assessment Forum staff who worked together diligently to develop this high-quality document in a timely manner.

It is with great pleasure that I present the *Framework for Human Health Risk Assessment to Inform Decision Making.*

Glenn Paulson, Ph.D.
EPA Science Advisor

Preface

This document describes the EPA framework for conducting human health risk assessments that are responsive to the Agency's decision-making needs. It is intended to provide information on the overarching process for conducting human health risk assessments to the U.S. Environmental Protection Agency's (EPA or Agency) staff and managers, external stakeholders, and the public. This Framework is expected to promote and increase the transparency of the human health risk assessment process at the EPA. It highlights the important roles of planning and scoping, as well as problem formulation, in designing a risk assessment that will fulfill a specific need and purpose. Consistent with longstanding EPA policy, it also emphasizes the importance of scientific peer review and public, stakeholder and community involvement. This document is not intended to supersede existing EPA guidance; by citing and discussing existing guidance, it is intended instead to foster increased implementation and utility of such guidance.

The Framework was prepared by a Technical Panel composed of senior risk assessors and risk managers from across the Agency overseen by the Risk Assessment Forum. The Risk Assessment Forum is a standing committee of senior EPA scientists that was established to promote Agency-wide consensus on risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance.

In preparing this document, the Technical Panel considered the recommendations presented in three NRC reports that explored advancing risk assessment, adopting a cumulative approach to risk assessment and rethinking toxicity testing (NRC 2007, 2008, 2009). One of the key recommendations provided to the Agency by the NRC in *Science and Decisions: Advancing Risk Assessment* was to adopt a framework for risk-based decision making that maximizes the utility of risk assessment. This Framework has been developed with particular consideration of this NRC recommendation in light of EPA's broad array of decision-making contexts. The Framework is inherently flexible with regard to the type of and context for risk assessments, and the potential for Agency methods to evolve in response to changes in the science of risk assessment. Thus, the Framework is expected to facilitate the development of risk assessments focused on and in support of the Agency needs of the decision-making process now and in the future.

List of Acronyms

ADAF	Age-Dependent Adjustment Factor
AIEO	American Indian Environmental Office
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CWA	Clean Water Act
EJ	Environmental Justice
EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GIS	Geographic Information System
HPV	High Production Volume
IRIS	Integrated Risk Information System
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
MOA	Mode of Action
NAAQS	National Ambient Air Quality Standards
NAS	National Academy of Sciences
NRC	National Research Council
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
PCB	Polychlorinated biphenyl
PCCRARM	Presidential/Congressional Commission on Risk Assessment and Risk Management
PMN	Premanufacture Notice
REA	Risk and Exposure Assessment
SAB	EPA Science Advisory Board
SDWA	Safe Drinking Water Act
TCCR	Transparency, Clarity, Consistency and Reasonableness
TSCA	Toxic Substances Control Act

Executive Summary

The purpose of this document is to describe a process for conducting human health risk assessments that are responsive to the decision-making needs of EPA. The *Framework for Human Health Risk Assessment to Inform Decision Making* (Framework) is further intended to facilitate implementation of existing and future EPA guidance for conducting human health risk assessments and improve the utility of risk assessment in the decision-making process. The Framework addresses recommendations on risk assessment design and utility described in the National Research Council's (NRC) 2009 report, *Science and Decisions: Advancing Risk Assessment*, and those put forth in earlier NRC reports (e.g., NRC 1994). This Framework highlights the important roles of planning and scoping, as well as problem formulation, in designing a risk assessment that will serve a specific and documented purpose. In accordance with longstanding Agency policy, it also emphasizes the importance of scientific peer review, as well as public, stakeholder and community involvement.

The key elements of the process for developing a risk assessment to inform decision making are as follows:

- **Planning and scoping:** In this element, the process for conducting the risk assessment and its general scope are defined. This activity contributes to development of a sound risk assessment that serves its intended purpose. It also assists those interested in the risk assessment process in understanding the context of the risk assessment and the intended use of its results. A broad range of technical experts working as a team may be involved in this stage.

- **Problem formulation:** This analytical consideration of the issue being assessed identifies the major factors to be considered in a specific assessment, thus informing the technical approach. An important outcome of problem formulation is a conceptual model that describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed lifestage(s) and population(s), and endpoint(s) that will be addressed in the risk assessment. Based on the conceptual model, an analysis plan is developed, which describes the approach for conducting the risk assessment, including its design, methods and key inputs and intended outputs.

- **Risk Assessment**

    - **Exposure and effects assessment:** Exposure assessment, a core component of a risk assessment, will reflect the considerations identified in problem formulation. The parallel core component, effects assessment, includes hazard identification and dose-response assessment. Susceptible or more highly exposed populations may be identified in these assessments, when relevant information is available.

    - **Risk characterization:** This step of the risk assessment, in which the exposure and effects assessments are integrated, provides risk managers with risk estimates and a useful, synthesized set of conclusions about the risk. It is intended to adhere to four principles: transparency, clarity, consistency and reasonableness (TCCR).

- **Public, stakeholder and community involvement:** Input from the public is sought and considered at various stages throughout the process. Such input is essential to the Agency in fulfilling its mission to protect human health and the environment.

- **Informing decisions:** The goal of the risk assessment team is to provide a comprehensive assessment for a range of possible risk management options. The description of the decision should clarify how the risk assessment and other factors informed the decision.

The Framework reflects the NRC's recommendations on assuring that risk assessments are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way (NRC 2009). In describing these recommendations, the NRC uses the term "utility of risk assessment," among others (NRC 2009). The term "fit for purpose" used in this document is an established quality assurance principle aimed at assuring that the product is suitable for its intended purpose. The NRC's four-step risk assessment paradigm (NRC 1983) is maintained in the current Framework, but there is increased emphasis on assuring the utility of each risk assessment. The utility of risk assessment is not something that is evaluated as a separate step in the process or as a final check that occurs once the risk assessment is completed. Instead, an emphasis on the utility of the risk assessment for informing risk management decisions begins with planning and scoping and continues throughout the process.

Overall, the Framework stresses the practical nature of risk assessment; it highlights the need for analysis in support of decision making and additionally recognizes areas of overarching Agency interest, including children's environmental health and environmental justice (EJ). The Framework encourages the consideration of innovative technology and concepts in the still-developing area of sustainability in environmental decision making. The Framework supports enhanced dialogue between risk assessors and risk managers while recognizing the differences in their distinct roles.

1. Introduction

1.1 Background and History

Since EPA's inception, risk assessment has informed decisions made to protect human health and the environment from a range of threats. Over time, the scientific approaches and methods employed for these risk assessments have evolved. Risk assessments performed by the Agency inform a broad range of regulatory decisions. See Text Box 1-1. Thus, the design, objectives and specific outputs of risk assessments vary depending on the purpose and governing statute. EPA economic analyses also may assess risk to estimate the value of health benefits associated with regulatory options and actions.

Text Box 1-1. Examples of EPA Actions Informed by Risk Assessments

- Pesticide usage restrictions.
- Hazardous waste site remediation goals and approaches.
- Regulation of hazardous materials usage, storage and disposal.
- Ambient air quality standards.
- Emissions standards for hazardous air pollutants.
- Ambient Water Quality Criteria for surface waters.

The *Framework for Human Health Risk Assessment to Inform Decision Making* (Framework), presented in this document, draws on Agency experience and addresses the recommendations on risk assessment process from the National Research Council's (NRC) 2009 report, *Science and Decisions: Advancing Risk Assessment* (NRC 2009), also known as the *Silver Book*. In particular, this Framework seeks to address *Silver Book* recommendations on the design of risk assessments and opportunities for improving their utility. The Framework draws on a considerable body of additional expert advice, beginning with the NRC's 1983 report, *Risk Assessment in the Federal Government: Managing the Process* (commonly referred to as the *Red Book*), followed by the NRC's 1994 report, *Science and Judgment in Risk Assessment* (commonly referred to as the *Blue Book*), as well as incorporates principles from the Agency's extensive human health risk assessment guidance. Following publication of the *Red Book*, the Agency issued *Risk Assessment and Management: Framework for Decision Making* (USEPA 1984), which first articulated EPA's risk assessment framework. In 1984, the Agency established what is now called the Risk Assessment Forum, and in 1986, EPA formed the Risk Assessment Council, which was replaced in 1993 by the Science Policy Council (now named the Science and Technology Policy Council). Shortly after publication of the *Red Book*, EPA began issuing a series of guidelines for conducting risk assessments in a number of areas (e.g., cancer, chemical mixtures, developmental toxicity, exposure assessment, mutagenicity, neurotoxicity, reproductive toxicity) (USEPA 1986a, 1987, 2005b, 1986c, 2000e, 1991b, 1992b, 1986b, 1998b and 1996). Many of these original Agency-wide risk assessment guidelines include frameworks that have been updated over time.

In its emphasis on the planning aspects of conducting risk assessments, this Framework builds on principles of EPA's 1997 *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping*, which described an approach for integrated risk assessment and management (USEPA 1997a). The 1997 guidance was designed to help risk managers and assessors plan and document the scope of risk assessments, as well as consider appropriate (e.g., technical, advisory, stakeholder) participants and information sources to enrich the risk assessment. Additionally, the 1997 guidance augmented the Agency's 1995 *Guidance for Risk Characterization* (USEPA 1995a) by emphasizing the need for providing a transparent, clear, consistent and reasonable basis for any assessment, as well as strongly encouraging the undertaking of a formal problem formulation exercise for all risk assessments.

Prior to the *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (USEPA 1997a), the Agency published the *Framework for Ecological Risk Assessment* (USEPA 1992a) and subsequently released the *Guidelines for Ecological Risk Assessment* (USEPA 1998a), which incorporated planning and scoping into the ecological risk assessment process. In 2003, the *Framework for Cumulative Risk Assessment* (USEPA 2003b) further built on these documents in formulating a flexible structure for conducting a risk assessment to evaluate cumulative human health or ecological risk. In 2006, the Agency published *A Framework for Assessing Health Risk of Environmental Exposures to Children*, which applied this general structure (including problem formulation, analysis and risk characterization) in describing risk assessments focused on evaluating potential risks arising as a result of early life exposure (USEPA 2006b). In addition to these more general Agency documents, individual programs and offices have implemented risk assessment frameworks specific to their missions. Examples of documents with risk assessment frameworks are provided in Text Box 1-2. Finally, EPA has developed a *Risk Assessment Portal* (USEPA 2014) for the EPA website that provides basic information about environmental risk assessments and offers a comprehensive set of links to key Agency tools, policies, guidance and guidelines.

The document discusses aspects of the interaction of risk assessment and management, focusing on the utility of a risk assessment to aid in making choices among risk management options. In this context, we refer to a well-conducted, useful risk assessment, one that specifically fits its intended purpose. A risk assessment that does not support informed choices will be less useful than one that does. In addition, the risk management context (e.g., regulatory decision making) will affect the risk assessment in many ways. Statutory or regulatory requirements and restrictions, including those established by states and tribal nations, may place boundaries on risk management options. Court decisions also can affect how the U.S. Environmental Protection Agency (EPA) considers assessments of risk.

Text Box 1-2. Examples of Key EPA Documents Describing Risk Assessment Frameworks

- *Risk Assessment Guidance for Superfund (RAGS) Part A* (USEPA 1989).
- *Framework for Ecological Risk Assessment* (USEPA 1992a).
- *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (USEPA 1997a).
- *Guidelines for Ecological Risk Assessment* (USEPA 1998a).
- *Risk Characterization: Science Policy Handbook* (USEPA 2000d).
- *Framework for Cumulative Risk Assessment* (USEPA 2003b).
- "Human Health Risk Assessment: Inhalation" In *Air Toxics Risk Assessment Library*. Vol. 1. *Technical Resource Manual* (USEPA 2004c, 5-3).
- *A Framework for Assessing Health Risk of Environmental Exposures to Children* (USEPA 2006b).
- Office of Pollution Prevention and Toxics' (OPPT) *Requirements for Submitting Electronic Pre-manufacture Notices (PMNs)* (USEPA 2010d).

1.2 Scope and Purpose

The purpose of this document is to describe a process for conducting human health risk assessments that are responsive to EPA's decision-making needs. It provides an organizing structure for implementing existing and future EPA guidance on human health risk assessment. Rather than establishing new

guidance, this *Framework* compiles existing Agency policy, guidance and guidelines into a single coherent document. This document is intended to serve as a useful resource. Toward that end, text boxes throughout the document cite relevant Agency materials to which risk assessors may refer based on the needs of a particular assessment.

This Framework highlights the important role of planning and scoping in designing a risk assessment so that it serves its intended purpose, as well as the importance of scientific review and public, stakeholder and community involvement. The Framework also moves the Agency forward in the harmonization of human health and ecological risk assessment methodology. This Framework is expected to promote and increase the transparency of the human health risk assessment process at the Agency. It is consistent with EPA's *Scientific Integrity Policy* (USEPA 2012s) and follows the general principles presented in Text Box 1-3.

Text Box 1-3. General Principles of the *Framework for Human Health Risk Assessment*

- A risk assessment should be fit for its intended purpose.
- A risk assessment should state its purpose, context and scope clearly.
- Risk assessments should be based on exposure scenarios that are consistent with the purpose and context. As appropriate, they should include consideration of susceptible population groups and life stages.
- Risk assessments should follow an acceptable, overtly logical path, employing common sense and sound judgment in applying relevant guidance.
- All steps, key assumptions, limitations and decisions, as well as associated rationales, should be presented clearly.
- The role of scientific peer review should be considered.
- Public involvement should be considered.
- Risk assessments should be presented in a readily understandable and useful form for the intended audiences.

In summary, this Framework describes approaches for organizing and conducting human health risk assessments; it complements but does not replace any existing guidance or guidelines. Building on the Agency's experience and NRC recommendations, the Framework is intended to identify the critical aspects of the risk assessment process within a formal but flexible structure. The Framework is not intended to be an exhaustive reference on all relevant guidance; instead, the Framework is intended to describe the overall process clearly, giving attention to critical aspects of each component, focusing on the less technical (more process-associated) components of the process and identifying relevant references for the more technical components. It describes and discusses a series of steps and considerations important to formulating and performing a risk assessment to inform decisions. A major objective of the Framework is to improve the consistency and transparency of risk assessments while enhancing harmonization of approaches across the Agency. The Framework aims to maximize the utility of the risk assessment for informing risk management decisions, as well as ensure the most efficient use of resources by aligning the nature and/or scope of the risk assessment with the decision to be made.

1.3 Fit for Purpose

Risk assessments at EPA are performed to inform risk management decisions. Accordingly throughout the process of planning and performing the analyses, it is important to confirm that the assessment will address the information needs of the decision makers. Periodic confirmations may be part of the review steps described above or may be done as they otherwise fit within the process of the assessment. In the *Silver Book* (NRC 2009), the NRC recommended the use of a framework that "maximizes the utility of risk assessment," with a focus on assuring that risk assessments are well-tailored to the problems and decisions at hand so that they can inform the decision-making process most meaningfully. In describing this concept, the 2009 NRC report recommends development of a framework to improve the utility of risk assessment. See Text Box 1-4. With this framework document, EPA introduces the concept of "fit for purpose" to characterize risk assessments that are designed to maximize the utility of risk assessments for their intended purpose in Agency decision making. Consistent with its usage as a key principle in quality assurance programs, "fit for purpose" in this Framework refers to the development of risk assessments and associated products that are suitable and useful for their intended purpose(s), particularly for informing risk management decisions.

Text Box 1-4. Silver Book Statements on Utility

- "Risk assessment in EPA is not an end in itself but a means to develop policies that make the best use of resources to protect the health of the public and of ecosystems" (NRC 2009, 240).
- "By focusing on early and careful problem formulation and on the options for managing the problem, implementation of the framework can do much to improve the utility of risk assessment. Indeed, without such a framework, risk assessments may be addressing the wrong questions and yielding results that fail to address the needs of risk managers" (NRC 2009, 244).

In EPA's Framework described here, the utility of risk assessment is not evaluated as a separate step in the process or in a final check that occurs once the risk assessment is completed. Instead, consistent with the NRC's emphasis on consideration of risk management needs early in the process, the Agency's Framework emphasizes attention to utility throughout the process, beginning with planning and scoping, and including a specific focus on the applicability of the risk assessment for informing risk management decisions. Attention is given to this concept through focused planning and problem formulation, as well as confirmation during the process, to ensure that the informational needs for the assessment are being met by the information being generated by the assessment. The overarching questions in addressing "fit for purpose" are the following:

- Does the assessment inform choices among risk management options?
- Will the risk assessment need to be changed or expanded to discriminate between risk management options?

Questions to consider in evaluating the usefulness of the risk assessment design and its implementation include those listed below:

- Does the risk assessment design meet the objectives and does it have the attributes identified in the problem formulation step?
- Does the assessment, as implemented, meet the initial objectives, and is it consistent with the attributes identified in problem formulation? Or, if the initially identified objectives or attributes have been modified, does the assessment incorporate the modifications?

- If the assessment requires peer review, has this been done appropriately, and have the issues raised during the peer review been addressed adequately?

- How will the results of the risk assessment be communicated to the risk managers and stakeholders?

Depending on the answers to these and other questions, additional or revised analyses may be considered in the assessment that may reflect the specific risk management decision being addressed. Rather than a separate step or final check in the process once the risk assessment is completed, this emphasis on the utility of the risk assessments occurs throughout the process with the team continually mindful of the end use of the assessment.

The utility of the risk assessment is defined by the degree to which the assessment informs choices among risk management options. Related to this, it is critical that there be transparent dialogue between risk assessors and risk managers throughout the assessment process, beginning with the planning stage. It is important to note, however, that EPA maintains the conceptual distinction between risk assessment and risk management, as described in the *Red Book* (NRC 1983); the Framework does not allow for the manipulation of the risk assessment to support predetermined policy or management choices. As articulated by the NRC in the *Silver Book*, "[T]he conduct of risk assessments used to evaluate the risk-management options [is] in no way to be influenced by the preferences of risk managers" (NRC 2009, 244). For more information on the conduct of risk assessment from the *Silver Book*, see Section 2.1.

It is important to note that the uses of any risk assessment will vary with the environmental problem being assessed; statutory mandates; and limitations of data, methods, time and resources. Further as recognized in Section 5, risk assessments often are just one of a variety of factors that are considered in making a decision.

1.4 Overview of the Framework

The *Framework for Human Health Risk Assessment to Inform Decision Making* in its most basic form is illustrated in Figure 1-1. This figure reflects the main elements of the Framework and their roles in the risk assessment process in a form that encompasses the broad range of EPA risk assessment contexts. The figure conveys a path from planning and scoping to informing decisions and illustrates that the process provides opportunities for feedback along this path, which may vary among applications.

In building on the basic components identified in the *Red Book* (NRC 1983) and on processes currently employed across the Agency, this Framework takes into account key recommendations from the *Silver Book* (NRC 2009) that called for more interaction among risk assessors and risk managers during the course of a risk assessment while recognizing and keeping separate their distinctly different roles (NRC 2009). Thus, this Framework emphasizes the importance of early identification of risk management options so that risk assessment can inform choices most efficiently among such options. Risk management decisions are beyond the scope of the risk assessment proper; a risk assessment is one of the sources of information that informs the particular decision at hand. As discussed in Section 5 of this document, the risk assessment should not "make" the decision; it should characterize the estimated risk. The Framework emphasizes planning to maximize the utility of the risk assessment for informing risk management decisions.

The Framework reflects the often iterative nature of risk assessment; for example, as some scientific questions are answered, new ones may emerge that require the generation of additional data and/or analyses that better define the distribution of risk and/or address uncertainty. Throughout the process, additional knowledge may result in further refinement of the conceptual model and analysis plan.

Finally, this document recognizes a role for areas of overarching Agency interest, such as EPA's *Policy on Evaluating Health Risks to Children* (USEPA 1995b), assessment of cumulative risk (USEPA 2003b), consideration of environmental justice (EJ) (USEPA 2010b, *Interim Guidance on Considering Environmental Justice During the Development of an Action*), and the concept of sustainability in risk management decision making. Executive orders that apply to these areas are *Executive Order 13045* (Clinton 1997, *Protection of Children From Environmental Health Risks and Safety Risks*) and *Executive Order 12898* (Clinton 1994, *Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*).

The main elements of the Framework are discussed in the subsequent sections of this document. The concept of "fit for purpose," described in Section 1.3, is discussed throughout the document in keeping with the need for its consideration from planning through execution to ensure that assessments inform the decision-making process most meaningfully. Sections focused on the other elements are described below:

- Planning and scoping and problem formulation are detailed in Section 2 (*Initiation of the Risk Assessment Process*).
- Public, stakeholder and community involvement are addressed in Section 3 (*Public, Stakeholder and Community Involvement).*
- Exposure and effects assessment and risk characterization are discussed in Section 4 (*Risk Assessment*).
- Informing decisions is discussed in Section 5 (*Informing Decisions*).

As described in the *Silver Book* (NRC 2009), the process begins with a decision to conduct a risk assessment based on what is described as a "signal" of potential harm. Generally, this assessment would involve a set of existing or potential environmental conditions and the context may vary broadly (e.g., from consideration of a contaminated waste site to review of ambient air standards to a proposal for new chemicals to be introduced into commerce). The process outlined in the Framework initiates activities on the assessment of the risk potential of the environmental conditions.

The initial stage in conducting any EPA risk assessment focuses on carefully characterizing the task to be completed; it includes planning and scoping and problem formulation components. The planning and scoping phase involves consideration of the specific environmental issue to be addressed; the legal framework under which any action will be taken; the risk management options; and the public-, stakeholder- or community-specific issues. Specific regulatory or programmatic requirements are considered throughout the planning process. An essential question in this phase is what level of complexity is required (e.g., screening, deterministic or probabilistic risk assessment) to inform the necessary decision(s). Planning and scoping also include the identification of resources available to complete the assessment and the formation of a risk assessment team that will be capable of performing the technical analyses that may be needed. The team members may include a project manager, risk assessor and other staff with the appropriate expertise necessary to address the specific question. Based on the information developed during planning and scoping, the problem formulation then is conducted to develop a conceptual model and incorporate the information into an analysis plan. The analysis plan outlines how the exposure assessment, effects assessment (hazard and dose-response) and risk characterization components of the risk assessment will be conducted, with consideration of data quality;

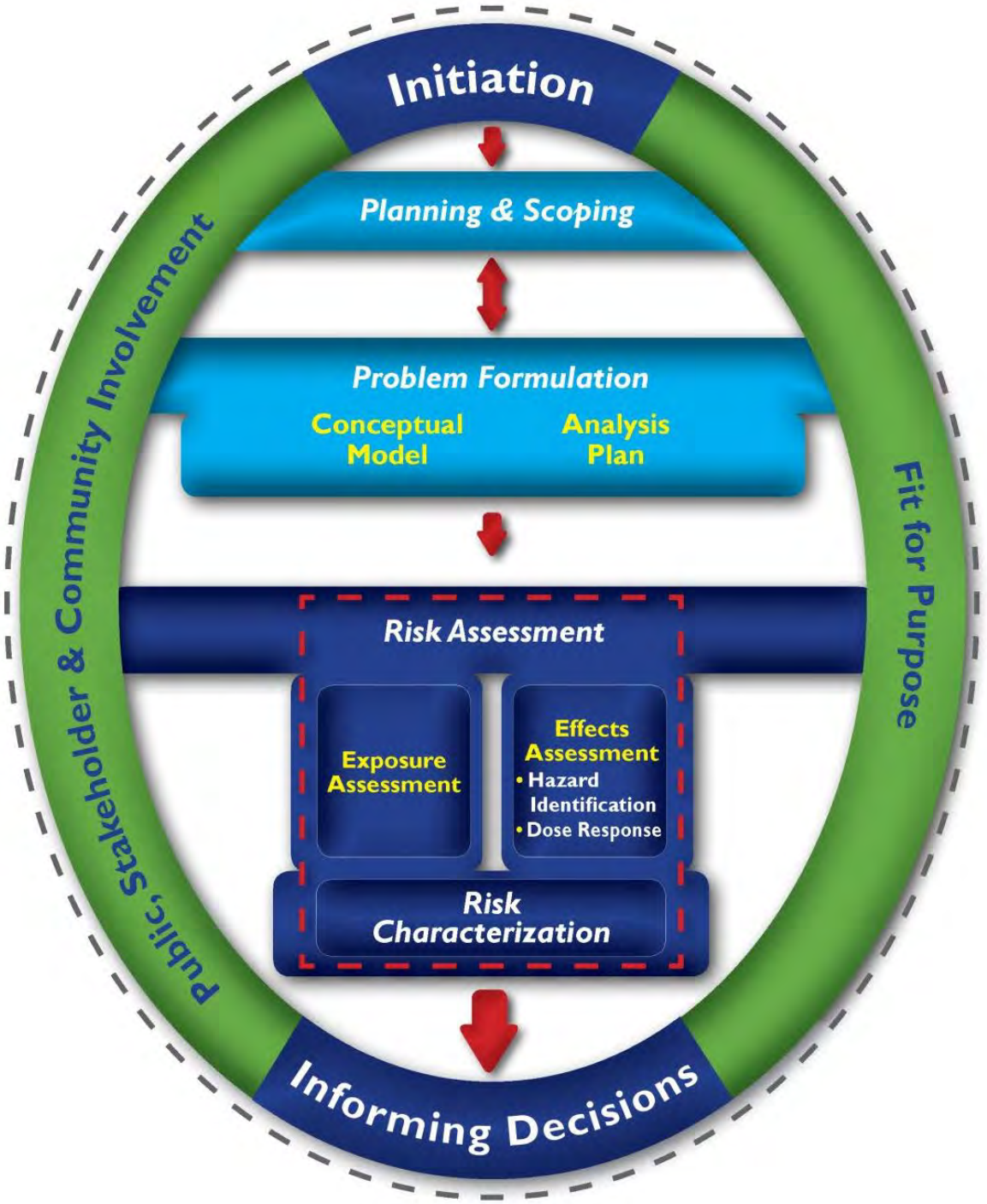


Figure 1-1. Framework for Human Health Risk Assessment to Inform Decision Making

uncertainty and variability; and public, stakeholder and community involvement for each component, as appropriate. The risk assessment then is conducted based on the analysis plan developed during problem formulation. The risk assessment phase includes developing the exposure and effects characterizations and integrating those results for presentation as part of the risk characterization. A key aspect of this Framework is an emphasis on the concept of "fit for purpose" by evaluating the applicability of the risk assessment to informing risk management decisions; these evaluations may take place at several points of the iterative risk assessment process. Focus is maintained on the information needs for the risk management decisions by asking whether the assessment is achieving its objective to inform decisions. If the answer is 'no', then the risk assessment team can make adjustments, revisit steps or develop additional information as needed.

The risk assessment or its components may be evaluated via independent peer review consistent with the Peer Review Handbook (EPA 2006e). Input may also be solicited from public, stakeholder and/or affected communities, recognizing that approaches for addressing these different audiences will vary among assessments (USEPA 2012m). Independent peer review helps to ensure the integrity and quality of the scientific and technical aspects of the risk assessment. This review may involve internal and/or external technical reviewers. Input from the public, internal and external stakeholders, and the affected community(ies) can provide insights that otherwise may not be available to risk managers, but these inputs should not compromise the integrity or quality of the scientific and technical aspects of the risk assessment.

In the decision making process, information in the risk assessment report is considered to evaluate the risk management options. This evaluation is undertaken in light of all appropriate factors and under applicable authorities. During this "Informing Decisions" phase (noted in Figure 1-1), additional analysis needs may be identified, which may lead to iteration of previous steps. This phase also generally includes development of a strategy for communicating conclusions with the public, internal and external stakeholders, and affected community(ies). In addition, plans may be made to evaluate the outcome of any actions taken.

The following example describes the current process for conducting reviews of the National Ambient Air Quality Standards (NAAQS) (USEPA 2012l, *Process of Reviewing the National Ambient Air Quality Standards*). This process includes explicit phases for planning (that includes planning and scoping and problem formulation), assessment of currently available scientific evidence (including that on hazard and dose-response relationships), risk and/or exposure assessment, and policy assessment and rulemaking. With each phase, there is consideration of the need for external peer review and/or public comment. Although each component or step in this example may not rely on precisely the same terms as those used in this Framework document, the example illustrates one manner by which EPA implements the key aspects of this Framework for a program in which risk assessment plays a role in informing regulatory decisions.

Example: Review of National Ambient Air Quality Standards

(Phases of the Framework are bolded)

EPA's current process for reviewing NAAQS has four major phases: (1) planning, (2) science assessment, (3) risk/exposure assessment, and (4) policy assessment and rulemaking. The **planning phase** of the NAAQS review process begins with a science policy workshop to identify issues and questions to frame the review. A draft Integrated Review Plan (IRP) is prepared jointly by EPA's National Center for Environmental Assessment and EPA's Office of Air Quality Planning and Standards (OAQPS). The draft IRP is made available for consultation with the Clean Air Scientific Advisory Committee (CASAC) and public comment. The final IRP is prepared in consideration of CASAC and public comments. It presents the current plan and specifies the schedule for the entire review, the process for conducting the review and the key policy-relevant science issues that will guide the review.

The second phase of the review, **science assessment**, involves the preparation of an Integrated Science Assessment (ISA), which provides a review, synthesis and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of exposure and risk assessments. The ISA provides a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review to reflect the current state of knowledge. The ISA forms the scientific foundation for the NAAQS review and is intended to provide information useful in forming judgments about the elements of the standard: air quality indicator(s), form(s), averaging time(s) and level(s).

In the third phase, **risk/exposure assessment**, EPA staff members prepare planning documents that consider the extent to which newly available scientific evidence, tools and/or methodologies warrant conducting quantitative risk and exposure assessments. If warranted, these documents outline a general plan, including scope and methods, for conducting the assessments. When an assessment is performed, one or more drafts of each risk and exposure assessment (REA) document undergoes CASAC and public review prior to completion of final REA(s). The REA provides concise presentations of methods, key results, observations and related uncertainties.

The review process ends with a **policy assessment and rulemaking** phase. The Policy Assessment is a document that provides a transparent analysis and conclusions prepared by OAQPS staff on the adequacy of the current standards and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The Policy Assessment integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the EPA Administrator. Such an evaluation of policy implications is intended to help ''bridge the gap'' between the Agency's scientific assessments, presented in the ISA and REA(s), and the judgments required of the Administrator in determining whether it is appropriate to retain or revise NAAQS. The Policy Assessment also is intended to facilitate the CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the Clean Air Act (CAA). In evaluating the adequacy of the current standards and (as appropriate) a range of alternative standards, the Policy Assessment considers the available scientific evidence and, as available, quantitative risk-based analyses, together with related limitations and uncertainties. The Policy Assessment focuses on the information that is most pertinent to evaluating the basic elements of NAAQS: indicator, averaging time, form and level. One or more drafts of a Policy Assessment are released for CASAC review and public comment prior to completion of the final Policy Assessment. Following issuance of the final Policy Assessment and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed rulemaking that communicates the Administrator's proposed decisions regarding the standards review. A draft notice undergoes interagency review involving other federal agencies prior to publication. Materials on which this decision is based, including the documents described above, are made available to the public in the regulatory docket for the review. A public comment period, during which public hearings generally are held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule, EPA develops a final rule that undergoes interagency review prior to publication to complete the rulemaking process (USEPA 2012i, National Ambient Air Quality Standards [NAAQS]).

2. Initiation of the Risk Assessment Process

The initiation of the risk assessment process occurs within a larger decision-making process. It is important that planning for the risk assessment includes consideration of the decisions that the assessment is being conducted to inform. There are multiple challenges and requirements that may arise in conducting a risk assessment. For example, an assessment conducted as part of a regulatory action may have various legal considerations, including the statute under which it is being conducted (e.g., Clean Air Act [CAA],[1] Clean Water Act [CWA][2]) and the regulatory program of which it is a part (e.g., 6-Year Review of Drinking Water Contaminants under the Safe Drinking Water Act [SDWA],[3] Pesticide Registration Review, Risk and Technology Review program). Such legal considerations may result in the selection of specific aspects of the assessment.

There also may be technical challenges in conducting an assessment. An assessor also may be faced with a lack of toxicity data for specific chemicals or routes of exposure. Information on sensitive populations may be unavailable. Information on the likelihood or timing of combined exposures to multiple chemicals may be difficult to obtain or estimate. Other challenges or considerations may be related to resources, such as the need for access to specific expertise (e.g., modeling). Time constraints associated with decision making and funding—or lack thereof—also may be an issue and should be noted in the analysis plan.

2.1 Planning and Scoping

Planning and scoping is an important first step to ensure that each risk assessment has a clear purpose and well-defined vision. It is critical to producing a sound risk assessment that serves its intended purpose. Decisions made at this stage of the process will have significant implications for later stages (NRC 2009; PCCRARM 1997a, 1997b; USEPA 1997a, 1998a, 2000d, 2002d, 2003b, 2006c). Planning and scoping is also an element of EPA's data quality objectives process. For example, EPA's guidance related to the 2001 Data Quality Act (Section 515 of the Consolidated Appropriations Act[4]) emphasizes the important role of systematic planning and attention to data quality objectives (USEPA 2006c). Text Box 2-1 provides a list of EPA references on planning and scoping. This phase may involve a team of technical

Text Box 2-1. EPA References on Planning and Scoping

- *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (USEPA 1997a)
- *Guidelines for Ecological Risk Assessment* (USEPA 1998a)
- *Risk Characterization: Science Policy Council Handbook* (USEPA 2000d)
- *Lessons Learned on Planning and Scoping for Environmental Risk Assessments* (USEPA 2002a)
- *Framework for Cumulative Risk Assessment* (USEPA 2003b)
- Human Health Risk Assessment: Inhalation (USEPA 2004c)
- *Guidance on Systematic Planning Using the Data Quality Objectives Process* (USEPA 2006c)

[1] Clean Air Act of 1963, 42 U.S.C. § 7401 et seq.

[2] Clean Water Act of 1972, 33 U.S.C. § 1251 et seq.

[3] Safe Drinking Water Act, 42 U.S.C. § 300f et seq.

[4] Consolidated Appropriations Act, Pub. L. No. 106-554, 114 Stat. 2763 (2001).

experts, such as toxicologists, environmental chemists, economists and engineers, as well as risk assessors and risk managers. In some cases, other subject matter experts may include attorneys and community outreach specialists. It also may be informed by external scientific or stakeholder input. Questions addressed in the planning and scoping step (derived from USEPA 1997a), are as follows:

- What are the overall purposes and general scope of the risk assessment? Are there legal limitations or other legal considerations? If so, what are they?

- What risk assessment products (quantitative and qualitative) are needed by management for informed decision making? What is needed for other analyses (e.g., economic analysis)?

- What resources are required, available or pending? Resources could include data or models, funding, personnel, expertise and/or coordination with other organizations.

- Who will be involved in conducting the risk assessment, and what are their roles?

- What schedule will be followed? This will include provision for timely input to the decision-making process, as well as, timely and adequate internal and independent external peer review, where appropriate.

In general, planning and scoping provides the opportunity for the risk manager(s), risk assessor(s) and others interested in the process to consider the context in which the risk assessment is being conducted and the purpose(s) for which the results will be used. The risk assessment team, in collaboration with the risk managers, also defines what is expected to be covered, considering limitations or constraints (e.g., tools, resources, timing). In this stage, risk assessors and risk managers discuss the risk management options to be considered along with any aspects of the risk assessment design for which there are policy implications.

Planning and scoping results in a common understanding of the boundaries for the risk assessment and the process for how it will be conducted. This step also recognizes the potential for the analysis plan to involve qualitative, as well as quantitative aspects. Selected examples of planning and scoping information are summarized in Text Box 2-2.

EPA and external advisors have repeatedly recognized that an important part of ensuring the usefulness of each risk assessment is the dialogue between the risk manager and the risk assessment team on the nature of the decision to be informed by the risk assessment (NRC 2009; PCCRARM 1997a and b; USEPA 1997a, 1998a, 2000d, 2002d, 2003b). This dialogue may include discussion of many topics, for example:

- Basis for the risk assessment (e.g., legal and regulatory requirements, public concern, scientific findings).

- How the information will be used (e.g., risk communication, economic analysis)

- Risk management options.

- Applicable EPA policies and Presidential Executive Orders.

- Overarching considerations (e.g., EJ, children's environmental health, cumulative risk assessment, sustainability).

- Current knowledge.

- Level of effort (e.g., resources).
- Plans for communication to risk managers, stakeholders and others.

Text Box 2-2. Examples of Risk Assessment Planning and Scoping at EPA

- In EPA's review of pesticide registrations, planning and scoping occurs for a series of risk assessments that are designed to address a common overarching regulatory purpose, although focused on different pesticides (USEPA 2004d, *Registration Review Update*).
- In the planning phase for reviews of National Ambient Air Quality Standards, an Integrated Review Plan is developed that describes all phases of the review, including the risk/exposure assessment. Additionally, a Risk and Exposure Assessment planning document is developed as the first step in the REA phase (e.g., planning documents for the particulate matter NAAQS review [USEPA 2011k, *Particulate Matter Standards—Documents From Current Review—Planning Documents*]).
- In EPA's residual risk review of National Emissions Standards for Hazardous Air Pollutants, the planning and scoping step encompasses a set of emissions source categories for which risk assessments are of generally similar scope and basic design, while differing in specific aspects of the sources and the chemicals emitted. A general project and methodology is described at the *Risk and Technology Review* program Web page (USEPA 2011o).
- Planning and scoping are key components of human health risk assessments conducted under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, also known as Superfund; 42 U.S.C. §9601 et seq.), and are discussed in the following guidance documents:
  - *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (USEPA 1988).
  - *Human Health: Planning and Scoping* (USEPA 2011h).
  - *Ecological: Planning and Scoping* (USEPA 2011c).

Figure 2-1 provides detail on the key elements of planning and scoping in the Framework, each of which is discussed in further detail in subsequent sections. Text Box 2-3 provides context on risk assessment from the *Silver Book* (NRC 2009). The next six subsections address the key aspects of the planning and scoping phase:

- Section 2.1.1 focuses on the need to consider the purpose and context for the risk assessment, noting that different processes may be employed depending on this context and purpose.
- Section 2.1.2 describes important overarching considerations that may affect risk management options.
- Section 2.1.3 discusses consideration of responsibilities, resources and timelines.
- Section 2.1.4 addresses planning for scientific or other reviews.
- Section 2.1.5 details public, stakeholder and community involvement.
- Section 2.1.6 discusses consideration of previous assessments.

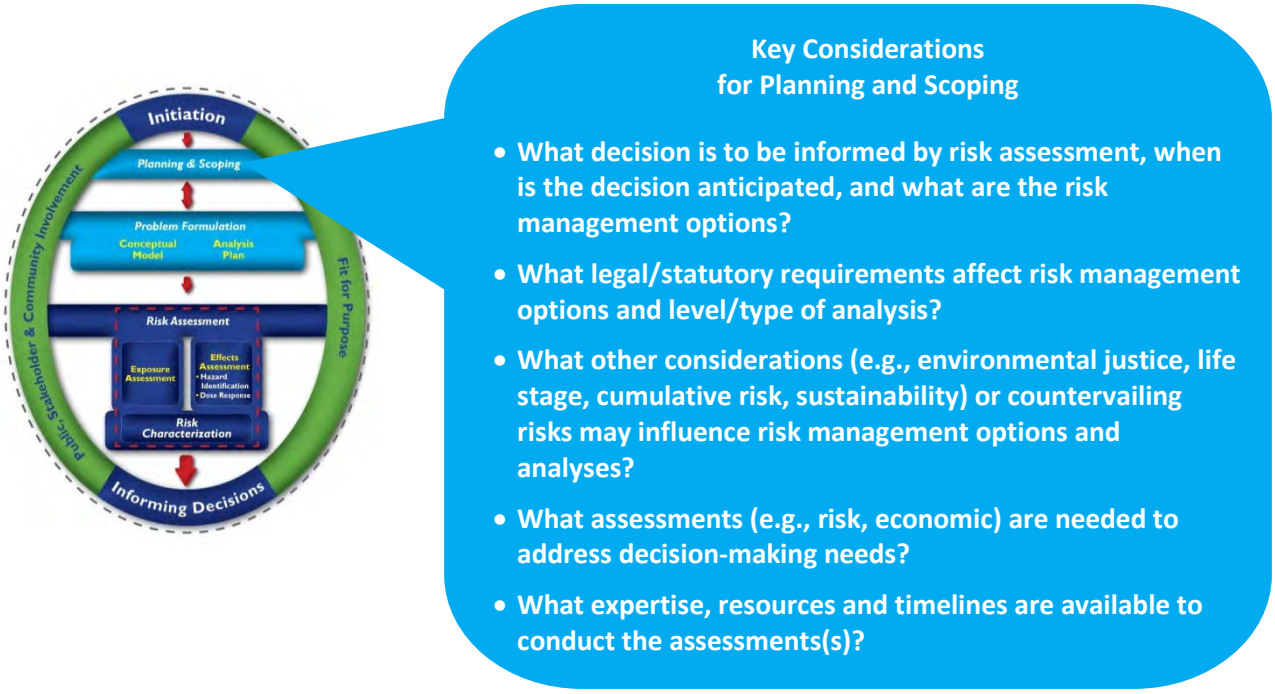


Figure 2-1. Framework for Human Health Risk Assessment to Inform Decision Making: Key Considerations for Planning and Scoping

Text Box 2-3. The Silver Book Statements on Risk Assessment and Decision Context

- "Risk assessments should not be conducted unless it is clear that they are designed to answer specific questions, and that the level of technical detail and uncertainty and variability analysis is appropriate to the decision context" (NRC 2009, 247).
- "The technical framework for risk assessment presented in the *Red Book* should remain intact but should be embedded in a broader framework in which risk assessment is used principally to help to discriminate among risk-management options" (NRC 2009, 256).

2.1.1 Context, Purpose and Scope

Each human health risk assessment is conducted within a particular context specific to regulatory or programmatic needs and responsive to environmental events or public health concerns. Many EPA risk assessments are performed to inform specific decisions that guide the development of regulatory actions. For example, risk assessments commonly inform federal regulatory actions concerning ambient air quality standards; the provision of public drinking water; and the registration of pesticides for U.S. distribution, sale and use. In other cases, such as a response to a newly identified environmental concern, careful consideration of the purpose and associated objectives, including decisions being informed is essential to the development of a risk assessment that provides information needed. It is important that planning for the risk assessment clearly states the decision to be informed and the boundaries for the assessment, detailing what will not be addressed in the risk assessment.

For risk assessments performed within a specific regulatory context, statutory language or legislative history may impose requirements or restrictions that will need to be considered in scoping the risk assessment; for example, the Food Quality Protection Act (FQPA)[5] includes directives on assessing risk that apply to pesticides in foods and water. In some regulatory contexts, a risk assessment (or some quantitative aspect of it) may be a key input into benefit-cost analyses of alternative regulatory options; these analyses may impose different or additional requirements than is the case in other regulatory contexts, where costs and quantified benefits are not considered.

As emphasized earlier, risk assessments are most useful when they are designed to answer specific questions, with a level of technical evaluation that is appropriate for the decision context ("fit for purpose"). In situations that are perceived to be particularly complex, clear articulation of the overall purpose or end use of an assessment may involve extensive interaction among the assessment team and the range of stakeholders to establish a common understanding. Such consideration recognizes that the utility of a risk assessment is a function of how well it informs the decision for which it is designed.

The planning and scoping phase includes explicit consideration of the nature of the assessment question or the hypothesis that the assessment seeks to address, with the goal of developing or clarifying the broad dimensions and elements of the assessment. In this step, the assessment and management objectives and purpose are defined clearly.

The particular purpose for which an assessment will be used and its scale (e.g., site-specific vs. regional or national) often will have significant implications for the scope, level of detail and approach of an assessment. A complete risk assessment may not be necessary when an exposure assessment or effects estimation is all that is required to inform a decision. The risk assessment scope can be defined, in a general sense, by the scale of the environmental problem being considered (e.g., local scale vs. national scale) and the regulatory context. One example is a risk assessment intended to investigate the health risks associated with a hazardous waste site that falls under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[6] The scope for this type of risk assessment may be site-specific, considering multiple receptors, multiple chemicals and multiple pathways of exposure for on- and off-site receptors (depending on the nature of the site). This will differ from the scope for a risk assessment on uses or exposure to a particular chemical, which is conducted to inform a national regulation (such as a National Primary Drinking Water Rule).

Scoping provides a foundation for the problem formulation step. Scope, in this context, refers to the proposed boundaries of the assessment (e.g., what chemical[s] and exposure pathway[s] will be addressed). The scope is considered with other factors (e.g., context, purpose, participants, timeline, resources) in developing the detailed plan for the assessment. At this step, most EPA assessment projects focus on identifying and considering information available in these areas:

- Sources of contaminants.
- Stressors, associated effects, susceptible populations and life stages.
- Exposure routes and pathways.

[5] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

[6] Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. §9601 et seq.

- Stakeholder concerns.

- Any spatial or temporal aspects of exposure (USEPA 1997a, 2001c).

Consideration of these elements during planning and scoping helps to identify missing information and potential assessment endpoints for the analysis plan. It also provides the basis for an early conceptualization of the problem being assessed and the approaches for assessment. The scoping discussion also should include regulatory context and any additional management or programmatic needs or limitations. Information considered and decisions made during the scoping step also shape the development of the conceptual model and the analysis plan (as described in Section 2.2).

At this stage, consideration of the needs of related, quantitative analyses (e.g., benefit-cost analysis or environmental impacts of associated policy decisions) can contribute to improved efficiency. Text Box 2-4 provides examples of important considerations for an economic benefits analysis. A consideration of related analyses at this stage also will help to ensure the compatibility of quantitative analyses considered in the decision-making step described in Section 5.

In the planning and scoping phase, it also is important to identify separate processes by which components of the risk assessment may be completed (e.g., development of dose-response assessment within Integrated Risk Information System [IRIS]), as well as larger processes (e.g., rulemaking that occurs within the Agency's Action Development Process) (USEPA 2011b). Furthermore, individual regulatory programs (e.g., Superfund) have a formalized process detailing the risk assessment process. These processes may have specific information requirements and timelines, and these may impose additional requirements on the risk assessment process. Depending on the nature of the risk assessment and the importance of the decisions, it may be essential to identify how the risk assessment team will interact with other program offices affected by the ultimate decision. For example, regulatory risk assessments focused on important multimedia pollutants with multiple sources for human exposure (e.g., lead) generally will involve multiple programs, particularly in cases where EPA may address the pollutant under multiple regulatory programs. In some cases, there also may be interactions with other government agencies, as well as coordination with state and tribal nations.

2.1.2 Overarching Considerations

The purpose and scope of the assessment also should be considered in the context of broad EPA priorities. The extent to which these affect the design or methods for any given risk assessment will depend on many factors, including the risk assessment purpose, scope and regulatory context. These overarching considerations, such as those described in the following subsections, may not affect all analyses; early consideration and discussion of these issues, however, can enhance the utility of the risk assessment. Thus, the potential for inclusion of analyses involving these topics is an important consideration in the planning stage for an assessment, as is the consideration of corresponding methodology. Analyses focused on such considerations may benefit from involvement of specific experts and the EPA offices that focus on them.

Overarching considerations also are often the focus for policy considerations. Accordingly, they alternatively or additionally may receive particular attention in the risk management arena, depending on the decision context. Such attention may be independent of a risk assessment. Several current examples of EPA priorities that may be important overarching considerations in human health risk assessments are described in the following subsections.

Text Box 2-4. Risk Assessment for Economic Benefits Analysis

Although risk assessment and economic analysis often are considered very separate exercises, estimates from or inputs to risk assessment sometimes may serve as inputs into the models that economists use for the benefits side of a benefit-cost analysis. Therefore, when benefit-cost analysis is needed to inform decisions, early communication between the risk assessment and benefits analysis teams, including consideration of the needs of both analyses, can contribute to efficiencies in the assessment designs. Listed below are some important considerations for benefits analyses that depending on the context for the health risk assessment may or may not otherwise be relevant.

- **Economically meaningful human health endpoints:** These are endpoints that can be linked to human well-being and for which the risks can be monetized using economic valuation methods. This may include additional outcomes or different outcomes than otherwise would be modeled in a health risk assessment. For example, benefits analysis incorporates changes in all health effects across the relevant range of exposure, not just the most sensitive. The endpoints are characterized using metrics for which there are economic valuation methods.
- **Changes in the probabilities of human health outcomes:** Although this may be part of some health risk assessments, many health risk assessments alternatively utilize measures, such as reference doses and reference concentrations, which do not inform estimates of health outcome probabilities (as noted in Chapter 5 of the *Silver Book* [NRC 2009]).
- **Expected or central estimates of risk for a given population:** Depending on the context for the risk assessment, it may rely instead on more conservative or upper-bound estimates of risk. The Science Advisory Board's (SAB) *Advisory on EPA's Superfund Benefits Analysis* highlights the issue of using conservative risk assessments in benefits analysis (Morgan and Freeman 2006), recognizing that conservative estimates of risk might differ significantly from central tendency and might lead to biased estimates of benefits.
- **A "cessation lag" to account for any time lag between reductions in exposure and health benefits:** The benefits analysis must consider the time profile of changes in exposures and resulting changes in risks. This concept is more fully described in the *Arsenic Rule Benefits Analysis: An SAB Review* (USEPA 2001a).
- **A full probabilistic distribution of risk estimates:** Not only does this possibly contribute to a better understanding of potential outcomes, but also it enables economists to incorporate risk assessment uncertainty into a broader analysis of uncertainty. Formal probabilistic assessment of uncertainty in benefits and costs is required by the Office of Management and Budget (OMB) for some regulations.

Early communication between the teams, with consideration of their needs and objectives, can help to improve the analyses performed for both purposes. For example, risk assessment estimates may be informative for benefit-cost analysis and also can contribute information and insights on how behavioral changes may affect exposure, and thus, change the risk. Additional information on economic analysis can be found in *Guidelines for Preparing Economic Analyses* (USEPA 2010a).

2.1.2.1 Children's Environmental Health Protection

Protecting children's health from environmental pollutants long has been part of EPA's mission. Children may have greater exposures to some environmental contaminants than adults; for example through increased consumption per body weight of certain foods. Furthermore, their behavior patterns, such as playing close to the ground and hand-to-mouth activity, also may increase their exposure to contaminants. In addition, they may be more vulnerable to environmental hazards because their organ systems still are developing and undergoing processes that are specifically sensitive to certain chemicals, leading to potential windows of susceptibility. Children also may differ from adults in their metabolism, detoxification and excretion of some chemicals. Accordingly, EPA's risk assessments routinely consider the potential susceptibility of children to ensure that decisions will provide protection of children's health.

EPA's *Policy on Evaluating Health Risks to Children* is intended to ensure that environmental health risks to children are considered explicitly and consistently as part of risk assessments generated during the Agency's decision-making process, including the setting of standards to protect public health and the environment (USEPA 1995b). The 1995 policy was reaffirmed by Administrator McCarthy in October 2013 (USEPA 2013c) Presidential Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks*, also requires all federal agencies to assign a high priority to addressing health and safety risks to children, coordinate research priorities on children's environmental health, and ensure that their standards take into account special risks to children (Clinton 1997).

Additionally, some public health statutes provide for the protection of sensitive populations, population groups or subpopulations. For example, the 1996 SDWA amendments use the term "subpopulation" to describe groups with unique attributes, including those defined by age or life stage. EPA recognizes that these terms, as used in such statutes, describe groups of people with common attributes, including life stage, which may make them more sensitive or susceptible to the stressor(s) being assessed. EPA emphasizes the importance of recognizing that childhood encompasses a sequence of life stages through which all members of a population pass. A life-stage approach to risk assessment considers the relevant periods of exposure in developmental life stages and subsequent outcomes that may not be expressed until later life stages (USEPA 2005b). Accordingly, using a variety of approaches, EPA's risk assessments consider and take into account the potential for differences across life stages that may affect risk. See the "life stages" entry included in USEPA 2012g. Where a statute might use the term "subpopulation," EPA recognizes this as including consideration of age groups or life stages. Text Box 2-5 highlights several guidance documents available to assist in considering children's environmental health.

Text Box 2-5. Key EPA Children's Health Guidance Documents

- *Policy on Evaluating Health Risks to Children* (USEPA 1995b and 2013c).
- *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (USEPA 2005e).
- *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (USEPA 2005a).
- *A Framework for Assessing Health Risk of Environmental Exposures to Children* (USEPA 2006b).
- *Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children* (USEPA 2006d).
- *Exposure Factors Handbook* (USEPA 2011f; includes specific sections with child-specific factors).

2.1.2.2 Cumulative Risk Assessment

In EPA's 2003 *Framework for Cumulative Risk Assessment* (USEPA 2003b), cumulative risk is defined as "the combined risks from aggregate exposures to multiple agents or stressors". Several key points are made with this definition. First, cumulative risk explicitly involves multiple agents or stressors. Second, the "agents or stressors" are not limited to chemicals; in some cases, stressors also may include biological or physical agents. In addition, stressors may include activities that directly or indirectly alter or cause the loss of a necessity or those that adversely affect health or increase susceptibility to other stressors. Third, this definition specifies that the risks from multiple agents or stressors are combined. This does not necessarily mean that the risks are added; "combining" may mean that some analysis is conducted to determine how the risks from the various agents or stressors interact. Cumulative risk assessment includes qualitative evaluation and possible quantification of the combined risks to health or the environment from multiple agents or stressors.

The specific characteristics of a given cumulative risk assessment will vary depending on scientific and regulatory needs. The Office of Pesticide Programs' cumulative assessments under the FQPA and those used by the Office of Water for pesticides are conducted pursuant to the *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity*, which applies only to chemicals that share a common mechanism of action (USEPA 2002c). Other environmental statutes, such as the National Environmental Policy Act[7] and CAA (e.g., hazardous air pollutant aspects), also include various requirements for cumulative and multiple pollutant analyses. Text Box 2-6 lists resources that describe approaches to cumulative risk assessment.

2.1.2.3 Environmental Justice

EPA defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to the development, implementation and enforcement of environmental laws, regulations and policies" (USEPA 2012b). As described in *Presidential Executive Order 12898*:

> To the greatest extent practicable and permitted by law, and consistent with the principles set forth in the report on the National Performance Review, each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of the Mariana Islands (Clinton 1994).

Incorporating environmental justice considerations into EPA process for developing rules and regulations is a priority (USEPA 2010b). In the risk assessment process, the potential for disproportionate environmental and public health impacts to minority or low-income populations (e.g., inequities in environmental health and conditions) is an important consideration during the problem formulations and planning and scooping stages. EPA's *Plan EJ 2014*, the Agency outlines a strategy to understand and solve environmental and health inequalities among overburdened populations and communities that uses integrated, transdisciplinary and community-based participatory research approaches to address cumulative impacts and equity in environmental health and environmental conditions (USEPA 2011m).

[7] National Environmental Policy Act, 42 U.S.C. § 4321 et seq.

As part of EPA's Plan EJ 2014, Technical Guidance for Assessing Environmental Justice in Regulatory Analysis is being developed (EPA 2013b). Furthermore, cumulative risk assessment may have a role in EJ analyses.

Text Box 2-6. Approaches to Cumulative Risk Assessment

Cumulative risk assessments may differ in design and associated results. Examples of cumulative risk assessment at EPA include:

- The Office of Pesticide Programs' evaluation of cumulative risk according to the FQPA (USEPA 2012d).
- *Guidance for Performing Aggregate Exposure and Risk Assessments* (USEPA 1999a).
- *General Principles for Performing Aggregate Exposure and Risk Assessments* (USEPA 2001c).
- *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA 2002c).
- The Office of Air and Radiation's assessment of hazardous air pollutant risks remaining after implementation of technology-based emissions standards (USEPA 2011o, *Risk and Technology Review*).
- The Office of Environmental Justice's *Ensuring Risk Reduction in Communities With Multiple Stressors: Environmental Justice and Cumulative Risks/Impacts* (USEPA 2004a).
- Region 3's *Multi-criteria Integrated Resource Assessment (MIRA)* (USEPA 2011j).

Additionally, two NRC publications, *Science and Decisions: Advancing Risk Assessment* (NRC 2009) and *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (NRC 2008), describe approaches to consider in the practice of cumulative risk assessment. For example, *Phthalates and Cumulative Risk Assessment* discusses the advantages of focusing on physiologic consequences rather than structural or mechanistic similarity in conducting cumulative risk assessment. This approach is more directly relevant to relating chemical exposures to human diseases and disorders. *Science and Decisions* discusses the importance of considering nonchemical stressors and background processes in cumulative risk assessment.

Information on approaches for consideration of EJ in Agency actions is available at EPA's EJ *Policy & Guidance* Web page (USEPA 2012j) and in the *Interim Guidance on Considering Environmental Justice During the Development of an Action* (USEPA 2010b). For example, EPA priorities in this area include development of technical guidance and implementation plans. EPA has established the American Indian Environmental Office (AIEO) to coordinate the Agency-wide effort to strengthen public health and environmental protection in tribal lands, with a special emphasis on helping tribes administer their own environmental programs. Information on the AIEO and related activities is available at the *American Indian Environmental Office Portal* website (USEPA 2012a).

2.1.2.4 Sustainability

Sustainability is defined in *Executive Order 13514*[8] as a process "to create and maintain conditions, under which humans and nature can exist in productive harmony, that permit fulfilling the social, economic, and other requirements of present and future generations." Sustainability is based on the simple principle that everything humans need for survival and well-being depends, either directly or indirectly, on the natural environment. The concept entails consideration of how we meet society's needs of today while ensuring future generations can do the same. Sustainability is important to ensure that humans have—and will continue to have—the water, materials and resources to protect human health and the environment. EPA's efforts in the area of sustainability practices include approaches such as labeling green products, promoting green chemistry and engineering, and managing materials rather than creating waste. Text Box 2-7 includes references related to sustainability.

Text Box 2-7. Resources on Sustainability and Life Cycle Assessment

- Office of Research and Development's (ORD) *Sustainability* program (USEPA 2011t).
- National Risk Management Research Laboratory's (ORD) *Life Cycle Assessment* Web page (USEPA 2011i).
- *Sustainability and the U.S. EPA* (NRC 2011).

If the planning and scoping phase identifies this as important to decision making, analyses accompanying the risk assessment may provide the risk manager with information relevant to the sustainability of proposed risk management options. Such analyses may consider the full life cycle impacts of the agent, stressor or remedy under review, as well as the potential unintended consequences of decisions. *Sustainability and the U.S. EPA* (NRC 2011) contains a detailed discussion of how a framework for sustainability relates to risk assessment and risk management.

2.1.3 Responsibilities, Resources and Timeline

A team approach to planning risk assessments is essential (NRC 2009, USEPA 2002d). The planning and scoping process includes the initial allocation of responsibilities for members of the assessment team as well as clarification of the interactions of the risk assessment team with the risk managers and stakeholders. Transparency in planning and scoping can improve the understanding of the public and regulated community with regard to the basis for the risk assessment design, including options, limitations and approaches considered but not selected for the assessment. For some risk assessments there are precedents, templates, or guidance documents that can be used to facilitate the planning and scoping process as well as the communication of the plan (e.g., *Process for Conducting Probabilistic Risk Assessment* in the *Risk Assessment Guidance for Superfund* [USEPA 2001d]).

The composition of the risk assessment team is dependent on the nature of the problem. At a minimum, the team comprises individuals with the necessary scientific expertise. Depending on the level of complexity of a risk assessment and the context for its conduct, a multidisciplinary approach is often necessary. Some disciplines that may be pertinent include: toxicology; epidemiology; exposure science; hydrogeology; fate and transport modeling (e.g., indoor and outdoor air, surface and drinking water); computer science (including geographic information systems [GIS], data management); chemistry;

[8] Exec. Order 13514, 74 *Fed. Reg.* 52126 (October 8, 2009).

biology; various engineering fields (e.g., chemical, environmental, mechanical, industrial, civil); economics; sociology; statistics and communications. Lawyers and policy makers also may be called on to contribute to risk assessment planning and scoping. Depending on the context and process in which the risk assessment is conducted, specific expertise may be needed to develop particular tools, data or analyses. Coordination with other federal, tribal and state agencies and with other stakeholders also may be appropriate, depending on the type of assessment being conducted.

Different members of the assessment team will provide expertise for specific elements of the planning and scoping discussion. For example, the risk manager may identify the regulatory needs of the assessment, timeframes and quantity of funds available for the assessment. The site assessment team would focus on evaluation of the current and future concentrations of the contaminants in various media. An exposure assessor may help the team consider the nature, fate and transport of the contaminants; sources, routes, timing and pathways; the extent of contamination; and the availability of data, either at the national or local level. Other specialists may provide information on topics such as funding levels and sources, contractor requirements and relevant interagency agreements.

It also is important to describe or establish the resources in terms of staffing, budget and time for the assessment as part of the planning and scoping phase. These aspects need to be considered in the development of the analysis plan, as they can affect the scope and approach for the assessment. The timeline for the assessment is developed, taking into account critical legal and management timeframes, as well as any need to meet external deadlines or coordinate with the schedules of other organizations (including critical stakeholders or external review bodies). When there is extensive stakeholder involvement, it is especially important that this be reflected in the budget and schedule and understood by all participants (USEPA 2003d). Data collection activities involving human data must adhere to EPA's regulations and policies on the protection of human subjects. See EPA's Office of the Science Advisor Web page on *Ethics, Regulations, and Policies* (USEPA 2012f).

2.1.4 Opportunities for Scientific Peer Review or Other Review Steps

The need for and timing of scientific peer review or other reviews is a consideration in planning and scoping activities. Various stages in the assessment process can provide opportunities for scientific review and stakeholder involvement. For example, completion of a draft conceptual model and analysis plan or an iteration of the risk assessment may be useful points for focused discussion between the risk assessor and risk manager and/or for scientific review and public, stakeholder and community involvement. Additionally, internal review and checks for quality of the assessment are important. Other types of review also may be necessary, depending on the scope and purpose of the assessment. For example, an independent external peer review may be an important element. Also some assessments (e.g., those developed for NAAQS, pesticide registration decisions or through the IRIS program) include a public review step that often is coincident with the scientific review step.

Scientific peer review is a process used to provide a critical evaluation of a specific EPA scientific and/or technical work product. EPA has published a *Peer Review Handbook* that describes the types and extent of reviews as well as the documentation needed to fulfill EPA requirements (USEPA 2006e). It should be noted that a new edition of the Peer Review Handbook is expected to be released by the Agency in 2014. The *Peer Review Handbook* incorporates the guidance provided in the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review* (OMB 2004). The *Peer Review Handbook* makes distinctions among peer involvement, peer consultation and peer review.

Peer review is a documented process conducted to ensure that activities are technically supportable, competently performed, properly documented and consistent with established quality criteria. Peer review may be internal or external to the Agency consistent with the classification or use of the document. It is

conducted by qualified individuals or organizations that are independent of those who performed the work and who are collectively equivalent in technical expertise (i.e., peers). Peer review usually involves a one-time or limited number of interactions by the independent peer reviewers with the authors of the work product. An assessment also may benefit from other types of input (such as peer involvement and public comment) that differ from peer review (USEPA 2006e). Planning and scoping for the assessment includes discussion of whether and what types of reviews will be included in light of the context and constraints for the assessment, including schedule and resources.

As part of planning and scoping, risk assessors and/or risk managers should consider the need for and timing of peer review (USEPA 2006e).The team will need to determine whether any of the analyses or products of the assessment may need peer review and if so, what level of peer review may be required and at what stage in the process. Evaluating peer review needs early will help ensure that adequate resources are allocated. In addition, peer review considerations are an integral part of setting assessment milestones and schedules. EPA's *Peer Review Handbook* (USEPA 2006e) provides detailed guidance for determining when peer review is required and how to plan and implement a peer review. The principle underlying the Agency's peer review policy is that "all influential scientific and technical work products used in decision making will be peer reviewed" (USEPA 2006e, 30). The *Peer Review Handbook* stresses transparency in all parts of the peer review process, and EPA supports systems (e.g., the *EPA Science Inventory*, USEPA 2012e) for documentation and disclosure of peer review plans and products.

2.1.5 Public, Stakeholder and Community Involvement

The planning and scoping phase also includes consideration of opportunities for involvement and/or review by the public and specific stakeholders. EPA's public involvement policy (USEPA 2003d), a framework for implementing it (USEPA 2003c), and other references are available at EPA's *Public Involvement Policy and Related Documents* Web page (USEPA 2012m); public, stakeholder and community involvement are described at greater length in Section 3 of this Framework document. Depending on the context for the risk assessment and overarching process governing its conduct, risk assessment products also may be made available for public comment, as required or practical under specific regulatory programs. Public, stakeholder and community involvement may initiated through a formal notice of availability of the risk assessment and opportunity for public comment, and/or there may be a formal period for public comment associated with the regulatory decision that was informed by the risk assessment. Public commenters generally include a wide range of interested parties, both experts and non-experts, but they are not expected to provide the kind of independent, expert information and in-depth analyses obtained from the peer review process (USEPA 2006e). The involvement of the public, stakeholders and communities (defined in Text Box 2-8) can help

Text Box 2-8. Definitions of "Public," "Stakeholder" and "Community"

Public Involvement refers to the full range of activities that EPA uses to engage the American people in the Agency's decision-making process (USEPA 2011a).

Stakeholders are individuals or representatives from organizations or interest groups that have a strong interest in the Agency's work and policies (USEPA 2011a).

- ***Internal Stakeholders*** include EPA program offices or regions (USEPA 2007a).
- ***External Stakeholders*** include the public, affected industries, public health or environmental organizations and other government agencies (USEPA 2007a).

Community Involvement is the process of engaging in dialogue and collaboration with community members (USEPA 2011q).

ensure that the assessment process is transparent and that risk-informed decision making proceeds effectively, efficiently and credibly (NRC 2009). Such involvement also may facilitate development of sustainable solutions (NRC 2011). EPA activities may need involvement of the state and tribal environmental agencies. In Agency activities with international implications, there may be involvement of other governments or international government organizations.

The roles for stakeholders are considered during the planning and scoping phase. Deciding how and when to involve stakeholders will depend on the context for and nature of an assessment. Depending on the project, a list of critical points for stakeholder input—such as discussions of purpose, scope and approach— may be defined (USEPA 2003a).

Stakeholders may be from programs within EPA; other federal agencies; state, local and tribal governments; regulated industries; the regulated community; community members affected by an environmental release; and members of the general public. The Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM) reports (PCCRARM 1997a and b) suggest using the following questions to identify potential stakeholders:

- Who might be affected by the assessment?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who might reasonably think that they should be included?

Assessments that require short-term, low-budget efforts or preliminary screening assessments may not have the scope, time or resources for extensive public, stakeholder and community involvement. Community involvement, however, is important to many community-based or site-specific assessments; for a highly controversial, location-specific assessment, early and extensive public, stakeholder and/or community involvement can be essential to the quality and usefulness of the risk assessment and the applicability of the risk management options informed by the assessment.

The *Framework for Implementing EPA's Public Involvement Policy* (USEPA 2003c) provides general guidance for scoping a public involvement process and identifies the following seven basic steps for conducting effective public involvement:

1. Plan and budget for public involvement activities.
2. Identify the interested and affected public.
3. Consider providing technical or financial assistance to the public to facilitate involvement.
4. Provide information and outreach to the public.
5. Conduct public consultation and involvement activities.
6. Review and use input, and provide feedback to the public.
7. Evaluate public involvement activities.

2.1.6 Past Experiences and Assessments

Review of past experiences and assessments is an important part of planning and scoping because it can contribute to the development of a more robust analysis plan, as well as improve the usefulness and focus of the assessment. For example, in the review of existing national standards, consideration of previous assessments, as well as the aspects of those assessments that might cause risk estimates to change because of newly available information or tools, can inform the planning and scoping stage for a new risk assessment and predictions of what new insights the assessment might be able to provide. Furthermore, such explicit consideration of the potential value added of a new assessment may improve the efficiency of associated risk-based decision making. Valuable lessons also can be learned and information can be obtained from assessments performed for conceptually similar situations (e.g., previous analyses for a similar industry, analog or chemical).

Assessments by other agencies (federal, state, tribal and international) also may be useful to study. Understanding past risk assessment decisions and associated risk assumptions within a specific regulatory program is important to assuring the usefulness of a given risk assessment in the decision-making process. Furthermore, notable differences between the current assessment and previous assessments (e.g., new health effects evidence or technical approaches) may be important to describe in the analysis plan for the current assessment, as well as in the risk characterization.

2.2 Problem Formulation

Problem formulation is the part of the Framework that systematically identifies the major factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach. EPA's *Guidelines on Ecological Risk Assessment* defines problem formulation as the analytical phase of the assessment in which **"**the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" (USEPA 1998a, 2). Problem formulation also should define clearly the dimensions of the risk assessment, including the basis (or necessity) of the risk assessment.

Problem formulation has been detailed clearly in ecological risk assessment (USEPA 1998a), and described in Agency references that also address human health risk assessment (US USEPA 1997a, EPA 2002d, and USEPA 2003b). The formalization of problem formulation in both categories of risk assessment is a significant step in harmonizing human health and ecological risk assessment processes across the Agency's programs and key in ensuring that risk assessments are "fit for purpose" by addressing the decision-making needs of the Agency.

An important outcome of the problem formulation step is a conceptual model. Through the use of a written description and visual representation, it identifies the stressor(s), the exposed population(s) and the endpoint(s) that will be addressed in the risk assessment, as well as the relationships among them. Assessment endpoints, as well as the exposed populations, are more limited in variety in human health risk assessment than is the case in ecological risk assessment (USEPA 1998a). Many Agency regulatory programs have established specific human health risk assessment endpoints that often are linked to statutory requirements. For example, risk assessments for the Superfund and Hazardous Air Pollutant programs, among others, may include the assessment endpoint of estimating the lifetime individual cancer risk associated with the particular sources or sites assessed (Clay 1991; USEPA 1999b). Alternatively, risk assessments performed for reviews of NAAQS often focus on population risk metrics particular to the health effects evidence for the air pollutant being assessed. The analysis plan, which describes the approach for the risk assessment and how it will address the Agency's needs, is developed in light of the conceptual model, any programmatically established assessment endpoints and other planning considerations (described in Section 2.1). Additional detailed information on the conceptual model and

analysis plan are provided in the following sections, including some of the key issues that should be considered as they are developed. Figure 2-2 highlights the problem formulation steps within the Framework.

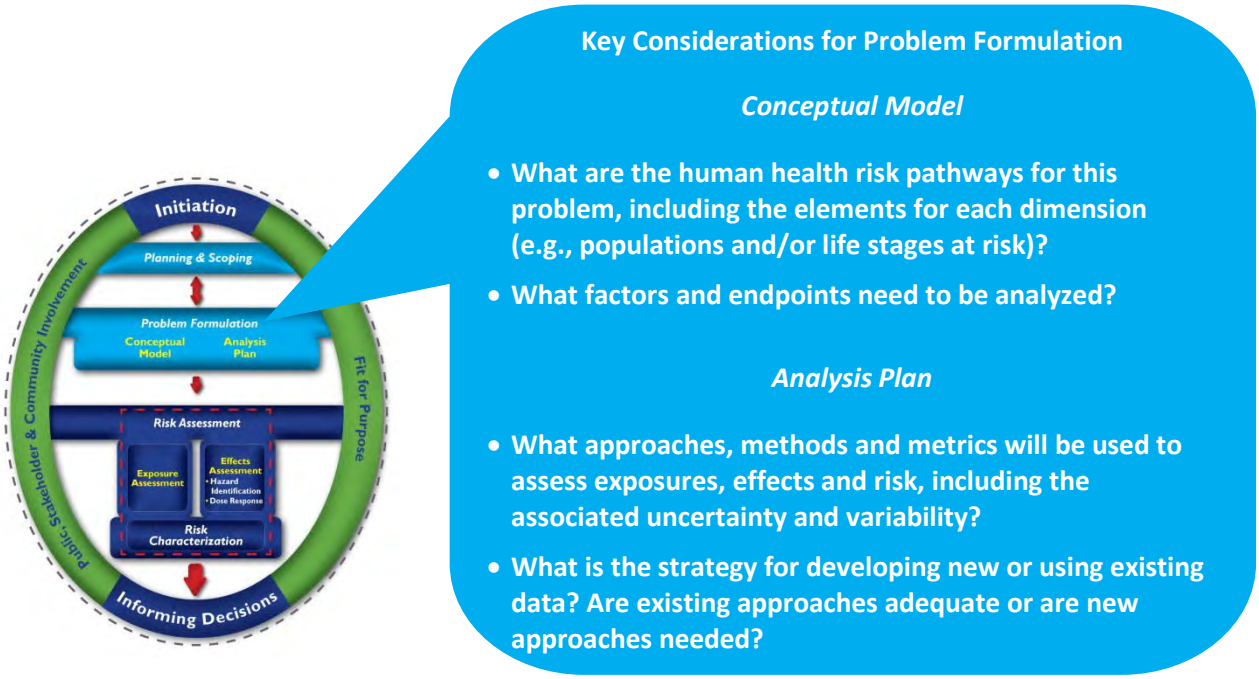


Figure 2-2. Framework for Human Health Risk Assessment to Inform Decision Making: Key Questions and Considerations for Problem Formulation

2.2.1 Conceptual Model

A conceptual model includes a written description and a visual representation of actual or predicted relationships between humans (populations or population segments) and the chemicals or other stressors to which they may be exposed. The conceptual model is a scientific or technical work product that can include the following:

- The rationale for selecting the sources, stressors, exposure pathways, receptors, exposed populations, endpoints or risk metrics, including effects.
- The basis for the model development.
- The scientific implications of additional data gathering.

The complexity of the conceptual model depends on the complexity of the problem. This may be related to the number of stressors, exposure pathways or assessment endpoints; the nature of effects; and/or the characteristics of the exposed populations or life stages. Generally, the conceptual model identifies factors and endpoints that will be analyzed in the risk assessment. It also addresses those aspects that might not be analyzed in the risk assessment, the recognition of which sometimes is important in the overall decision-making process. For example, although a risk assessment for a particular stressor may focus on exposure pathways or media relevant to the regulatory decision being faced (e.g., ingestion of drinking

water), the conceptual model also will describe the role of other pathways (e.g., consumption of fish), thus ensuring appropriate characterization of and context for the assessment results.

A conceptual model can provide documentation of decisions for future reference during risk assessment and can be useful in characterizing and communicating the risk management decision. The conceptual model is valuable as a risk communication tool within EPA and in the Agency's interactions with the public.

A general conceptual model (visually represented in Figure 2-3) defines the key elements for the problem to be assessed and shows pathways and routes of exposure between the stressors and effects (endpoints) for human receptors. The visual representation of the conceptual model is a diagram that may include the following types of elements:

- Source(s) of stressors of interest in the environment (e.g., releases from a leaking storage tank, waste material poured on the ground).

- Types of stressor(s), including physical, chemical and biological stressors.

- Exposure pathways, including fate and transport processes by which stressors move from the original point of release through the environment (e.g., a chemical in soil might penetrate down into groundwater or might volatilize into air) and the interaction(s) through which populations or individuals are exposed (e.g., ingestion of contaminated water, inhalation of chemicals in air, dermal contact with contaminated soil).

- Receptors, which may be groups of individuals or populations identified by common characteristics (e.g., the general population, local residents near the site of concern, adult workers, recreational visitors, particular populations with unique exposures and/or susceptibilities to stressors), including life stages (e.g., infants or women of childbearing age).

- Types of endpoints to be considered (e.g., cancer, asthma, IQ decrement, developmental effects).

- Risk metrics (e.g., cases of disease or disease incidence, hazard quotient, magnitude of effect, margin of exposure).

Conceptual models are used to plan the risk assessment and associated data collection activities, and they may be periodically revised as data become available. Conceptual models consist of two principal components: (1) a set of risk hypotheses that describe predicted relationships among stressor, exposure and health endpoints and/or responses, along with the rationale for their selection; and (2) a diagram that illustrates the relationships presented in the risk hypotheses. Examples of conceptual models from various EPA risk assessments are provided in Text Box 2-9 and Text Box 2-10 identifies EPA resources with more information about conceptual models.

Figure 2-4 presents a diagram illustrating a detailed conceptual model of multiple exposure pathways and receptors potentially affected by multiple sources of chemical stressors; this model was designed by EPA Region 8 for the analysis of Superfund sites contaminated with polychlorinated biphenyls (PCBs) (USEPA 2012p).

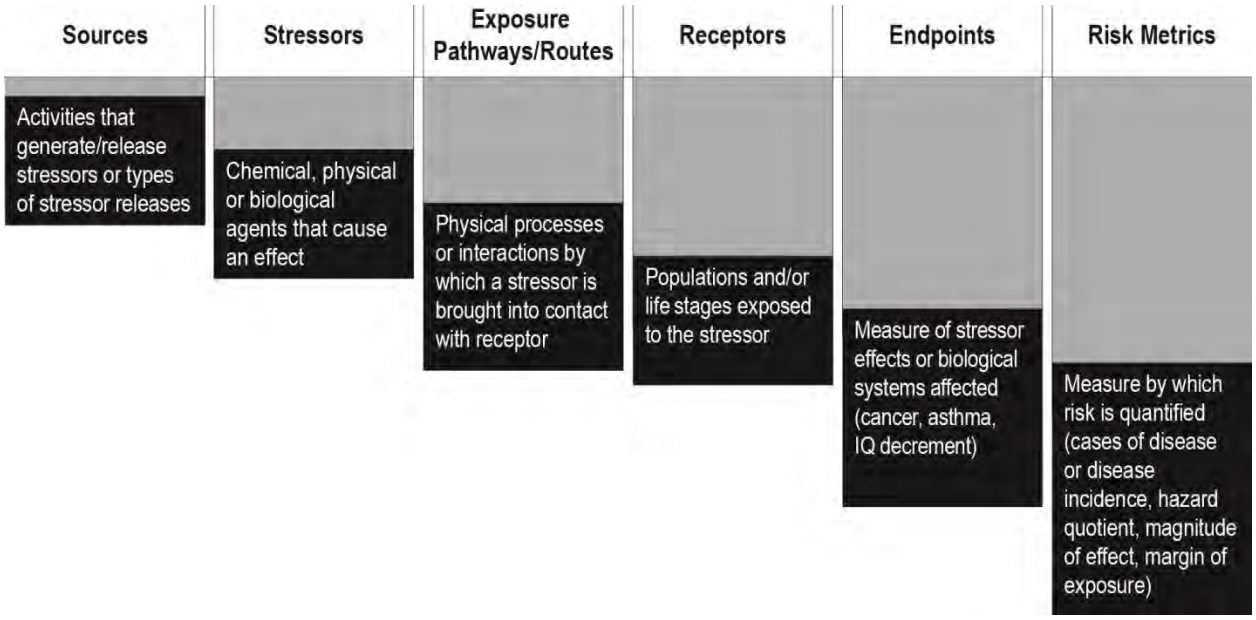


Figure 2-3. Example of a Generalized Conceptual Model With Examples of Possible Dimensions and Linkages

Source: Adapted from USEPA 2002d, 2003b.

Text Box 2-9. Examples of Conceptual Models in EPA Risk Assessments

- Conceptual model to inform lead NAAQS risk assessment (USEPA 2007b, 2-1 to 2-19).
- Case study on concentrated animal feeding operations (USEPA 2002a, Appendix B).
- Re-registration of pentachlorophenol (USEPA 2002e, Appendix C).

Text Box 2-10. EPA Resources on Conceptual Models

- *Ecological Risk Assessment Guidelines* (USEPA 1998a, 40–41).
- *Lessons Learned on Planning and Scoping for Environmental Risk Assessments* (USEPA 2002a, 5–6).
- *Risk Characterization: Science Policy Council Handbook* (USEPA 2000d, 29–30, B-21, B-23).
- *Framework for Cumulative Risk Assessment* (USEPA 2003b, 25–27).
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (USEPA 2006b, 3-5 to 3-9).

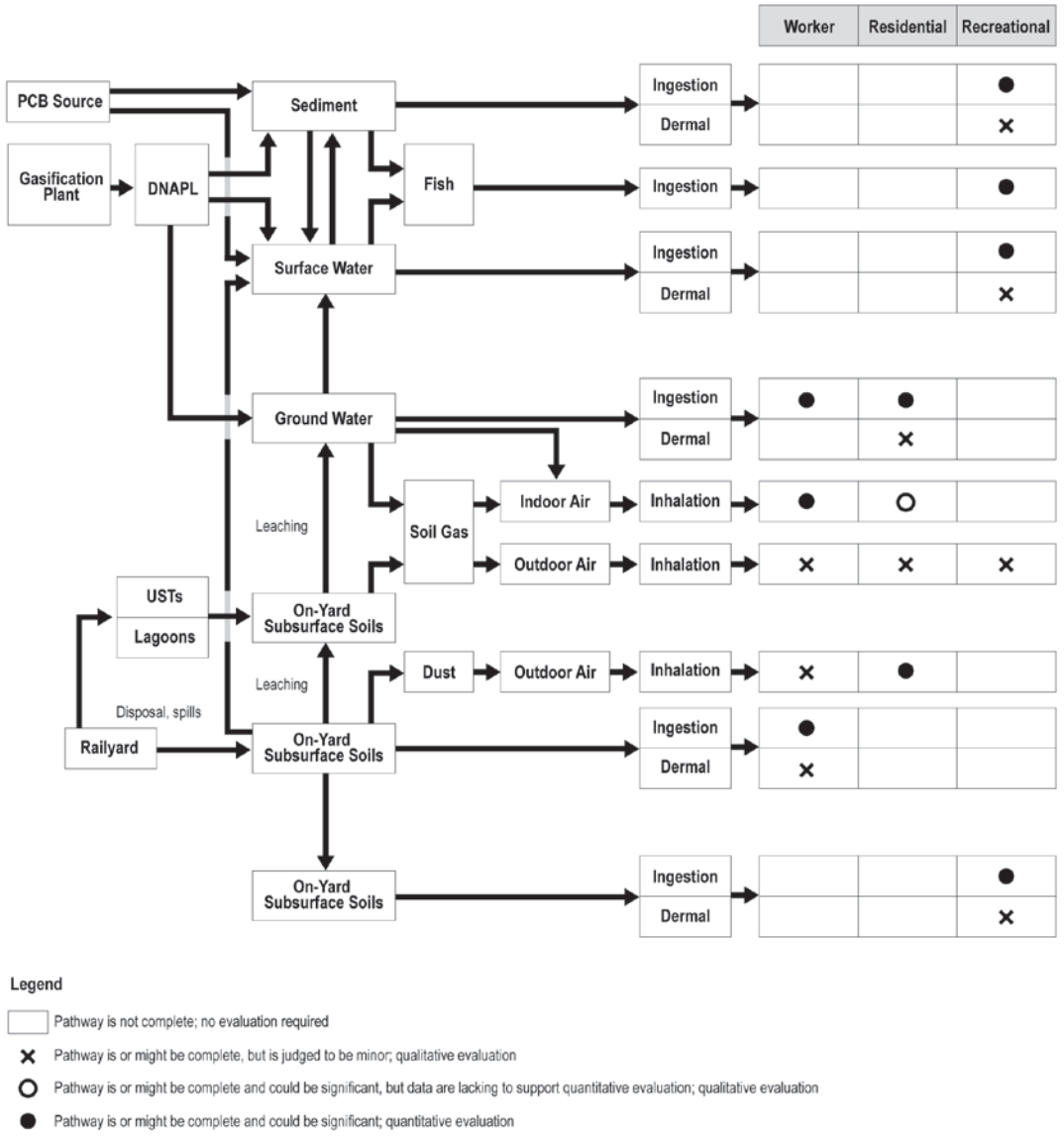


Figure 2-4. Example Conceptual Model of Exposure Pathways for Multiple Receptors to Multiple Stressors for Superfund Site Assessment

Note: PCBs = polychlorinated biphenyls; DNAPL = dense non-aqueous phase liquid; USTs = Underground Storage Tanks.

Source: Region 8's *Site Conceptual Model* (USEPA 2012p).

2.2.2 Analysis Plan

The analysis plan is the final stage of problem formulation (USEPA 1989, 2000e, 2002d, 2003b). It is developed with attention to the conceptual model and the Agency's needs for the risk assessment. The analysis plan describes intentions for the assessment, which may have been developed during the planning and scoping process and it provides details on technical aspects of the risk assessment. In some cases, it will specify a phased or tiered risk assessment approach to facilitate management needs; scientific review (such as external peer review); and/or public, stakeholder and community involvement.

During analysis planning, hypotheses about the relationships described in the conceptual model are evaluated to determine how they will be assessed using available and new data. Although the conceptual model may identify a larger set of pathways and relationships, the analysis plan focuses on the pathways and relationships that will be pursued in the risk assessment analyses. The rationale for selecting or omitting pathways and relationships is incorporated into the plan, as is acknowledgement of data gaps and uncertainties. The analysis plan also may include a consideration of how the level of confidence (or precision) needed for the management decision compares with that expected from available analytical approaches; this comparison determines data needs and evaluates which analytic approach is best. When new data are needed, the feasibility of obtaining them is evaluated. The analysis plan is most useful when it contains explicit statements of how measures were selected, what the measures were intended to evaluate and which analyses they support.

The analysis plan may include these components:

- The assessment design and rationale for selecting specific pathways to include in the risk assessment.

- A description of the data, information, methods and models to be used in the analyses (including uncertainty analyses), as well as intended outputs (e.g., risk metrics).

- The associated data gaps and limitations.

Also described is the extent or aspects of the assessment that are qualitative rather than quantitative. Analysis plans may be brief or extensive, depending on the assessment and its level of complexity. For assessments that are performed for some purposes (e.g., EPA's new chemical assessments [USEPA 2013a] under the Toxic Substances Control Act [TSCA][9]), a standard analysis plan is established for the set of assessments to be conducted for the same purpose and regulatory context. The type or design of analyses to be conducted is influenced by statutory requirements or programmatic objectives, data availability, risk management options, available resources, and the purpose and scope of assessment. Thus, risk assessment designs will vary, and variations will be reflected in the development of the plan. For example, EPA performs risk assessments that range from deterministic, scenario-based assessments to more complex, probabilistic, population-modeling analyses. Assessments may be screening-level or more robust, depending on various factors, including the resources available for the assessment. Furthermore, the organization of the analysis plan may vary with the purpose and context for the assessment.

In all cases, the analysis plan addresses the quality of data to be used; assessments of exposure, hazard and dose-response; and risk analyses, including analyses of uncertainty and variability. These areas are described in the subsections below.

[9] Toxic Substances Control Act of 1976, 15 U.S.C. § 2601–2692.

2.2.2.1 Data Quality Planning

In developing and implementing the analysis plan, several aspects of the data and information to be used in the assessment are evaluated, including the following (USEPA 2003b):

- **Soundness.** The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable and consistent with the intended application.
- **Applicability and utility.** The extent to which the information is relevant for the intended use.
- **Clarity and completeness.** The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.
- **Uncertainty and variability.** The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.
- **Evaluation and review.** The extent of independent verification, validation and peer review of the information, procedures, measures, methods or models.

Evaluation of data quality requires context. Depending on how and for what purpose the data will be used, the same data may be acceptable in one situation and unacceptable in another. *EPA's Quality System for Environmental Data and Technology* (USEPA 2011e) ensures that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use. A critical aspect of this system involves the use of data quality objectives for the development of new data and evaluation of existing data. Aspects of a risk assessment for which data quality may be important to consider in the analysis plan include:

- The collection, evaluation and use of environmental data, including the distributions of contaminants, as well as sources of variability, tolerance for potential decision errors and/or precision requirements (USEPA 2011e).
- Development, evaluation and use of computer or mathematical models, including evaluation of uncertainty and variability (USEPA 2009a).
- Use of secondary data collected for purposes other than the planned assessment.

Analysis plans also consider data quality guidance specific to the program for which the assessment is being conducted. Information disseminated by the Agency also follows EPA's information quality guidelines (USEPA 2002b). Some key data quality resources are given in Text Box 2-11.

Text Box 2-9. Data Quality Resources

- *EPA Requirements for Quality Assurance Project Plans* (USEPA 2001b).
- *EPA's Quality System for Environmental Data and Technology* (USEPA 2011e).
- *Superfund Quality Assurance/Quality Control* (USEPA 2011s).
- *Resources for Planning New Data Collections* (USEPA 2011n).

2.2.2.2 *Exposure Assessment Planning*

Text Box 2-10. EPA Exposure Assessment Resources for Human Health

- *Guidelines for Exposure Assessment* (USEPA 1992b).
- *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (USEPA 2005a).
- *A Framework for Assessing Health Risk of Environmental Exposures to Children* (USEPA 2006b).
- *Highlights of the Exposure Factors Handbook* (USEPA 2011g).
- *Exposure Factors Handbook* (USEPA 2011f).

The analysis plan describes the approach (quantitative or qualitative) to be employed for characterizing exposure in the risk assessment. See Text Box 2-12 for EPA resources on how to conduct exposure assessments. The exposure assessment component of the analysis plan is developed by drawing on the information, considerations and decisions represented by the conceptual model for human health (as described in Section 2.2.1). Accordingly, the analysis plan describes the exposure assessment elements specified in the conceptual model, including the relevant routes and pathways, frequency and duration of exposures, populations and life stages, and assessment metrics. The analysis plan also defines the methods, models and information or data that will be used, as well as the environmental conditions or scenarios (e.g., conditions associated with alternative standards or cleanup levels for environmental contaminants or different uses for a pesticide). Key limitations, assumptions and uncertainties associated with the tools and approaches are recognized in the analysis plan.

The analysis plan also identifies the approach for describing exposure variability. For example, the approach might specify a deterministic, scenario-based assessment to provide point estimates for a particular population (e.g., long-term residents or high-end consumers of a particular food such as fish) or life stage (e.g., very young children). In contrast, a more complex, probabilistic population modeling assessment might provide a distribution of estimates for the specific population assessed; an example would be children living in three specific urban areas under environmental conditions associated with a current standard or food consumption pattern (e.g., for specific age groups based on dietary survey information). The rationale for the selected approach is described in the analysis plan, as well as the extent to which estimates will be developed for the central and upper percentiles of the population being assessed. Furthermore, the analysis plan generally delineates the approaches for assessing uncertainty and variability in the exposure estimates.

2.2.2.3 *Effects Assessment Planning: Hazard Identification and Dose-Response Analysis*

The effects assessment is composed of hazard identification and dose-response analysis. The analysis plan specifies the strategy for characterizing hazard and dose-response relationships for the stressors being assessed. For example, the strategy may include use of publicly available hazard identification and dose-response assessments that already have been prepared (in accordance with Agency guidance and methods), such as those in EPA's IRIS database. Alternatively, the strategy may specify a different approach for characterizing the hazard of the identified stressors and describing the dose- or concentration-response relationship that will be used in the risk assessment. A range of factors that stem from the chemical-specific information available, as well as from logistical considerations for the assessment, may influence the extent to which the effects assessment may include qualitative aspects and quantitative analyses.

EPA has established a variety of guidance documents for the hazard identification and dose-response components of risk assessment (Text Box 2-13). These documents address the evaluation of particular

Text Box 2-11. EPA Resources on Hazard Identification and Dose-Response Assessment

- *Guidelines for the Health Risk Assessment of Chemical Mixtures* and *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA 1986a, 2000e).
- *Guidelines for Developmental Toxicity Risk Assessment* (USEPA 1991b).
- *Methods for Derivation of Inhalation Reference Concentrations (RfCs) and Application of Inhalation Dosimetry* (USEPA 1994).
- *Guidelines for Reproductive Toxicity Risk Assessment* (USEPA 1996).
- *Guidelines for Neurotoxicity Risk Assessment* (USEPA 1998b).
- *A Review of the Reference Dose and Reference Concentration Processes* (USEPA 2002f).
- *Guidelines for Carcinogen Risk Assessment* (USEPA 2005b).
- *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (USEPA 2005e).
- *A Framework for Assessing Health Risk of Environmental Exposures to Children* (USEPA 2006b).

types of toxicity, dose-response assessment and endpoint selection; the consideration of information on mode of action (MOA) or pathways of toxicity; the role of toxicokinetic information; and factors influencing sensitivity and susceptibility (e.g., nutrition, life stage, exposure characteristics, disease state). Rather than describing in detail the steps in effects assessment, the analysis plan may instead reference these guidance documents or other relevant published sources

2.2.2.4 Risk Characterization Planning

The analysis plan identifies and describes the strategy or approach for combining exposure information with hazard and dose-response information to generate risk estimates or other measures for characterizing health risk. The approaches may vary widely depending on considerations described above for the planning and scoping phase, such as the following: the purpose and context for the assessment, available information, available resources, and timeline. Risk analyses might range from deterministic, scenario-based assessment to a probabilistic, population-modeling assessment. These approaches may yield estimates for general population risk or for specific, defined groups within the general population. For estimates of individual risk, calculations can consider central tendency and/or the upper end of the risk distribution. The upper end of the distribution used for risk characterization may vary depending on the needs of the assessment (e.g., the 90th, 95th or 99th percentiles) (USEPA 1992b).

As stated above, assessments may be screening-level or more robust, depending on the purpose and availability of data. Decisions on the type or design of the assessment are influenced by statutory requirements or programmatic objectives, data or resource availability and limitations, and the purpose and/or scope of the assessment. Types of metrics that might be considered for the assessment include:

- Incidence of specific health outcomes.
- Risk of specific health outcomes.
- Occurrences of exposures above health-based benchmarks or comparison points.

- Potential for occurrence of exposure above health-based benchmarks.
- Margins of exposure between a point of departure for an effect and a measured or estimated environmental level.
- Hazard quotients (i.e., measured or estimated exposure levels divided by a reference value) for specific exposure scenarios.

In defining the analyses to be performed the plan also describes the associated limitations, assumptions and plans for the assessment of uncertainty and variability. EPA resources for risk analysis are described in Text Box 2-14.

Text Box 2-12. Risk Analyses Resources

- Risk assessment guidance for EPA's Superfund Program (Clay 1991; USEPA 1989, 1991a, 1991c, 2001d, 2001e, 2004f, 2009b).
- *Risk Characterization: Science Policy Council Handbook* (USEPA 2000d).
- *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA 2000b).
- *Framework for Cumulative Risk Assessment* (USEPA 2003b).
- *Air Toxics Risk Assessment Reference Library* (USEPA 2004b, 2004g, 2006a, 2007c).

2.2.2.5 Uncertainty and Variability Planning

Drawing from EPA guidance and experience, the analysis plan describes how uncertainty and variability will be characterized in the risk assessment. The complexity of the approaches will be influenced by considerations identified earlier in the planning phase, including the purpose and context for the assessment, as well as the timeline and resources. Planning for this stage of the assessment also will consider how elements of an uncertainty/variability evaluation can inform different parts of the assessment approach, improving the overall plan as well as the utility of the final product. The analysis plan may consider the value of obtaining additional data or information to reduce areas of uncertainty. More information about uncertainty and variability can be found in Text Box 2-15.

Text Box 2-13. Definitions of Uncertainty and Variability

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. Although numerous schemes for classifying uncertainty have been proposed, most focus on two broad categories: parameter uncertainty and model uncertainty. Descriptions of both areas are found in *Risk Assessment Principles and Practices* (USEPA 2004e).

Variability refers to inherent natural variation, diversity and heterogeneity across time and/or space or among individuals within a population. Although we can describe and understand variability in the world or a particular system better than uncertainty, it is unavoidable and cannot be reduced (USEPA 2010e).

Resources for Characterizing Uncertainty/Variability

- *Guiding Principles for Monte Carlo Analysis* (USEPA 1997b).
- *Risk Characterization: Science Policy Council Handbook* (USEPA 2000d).
- *Process for Conducting Probabilistic Risk Assessment.* Part A of Vol. 3 of *Risk Assessment Guidance for Superfund* (USEPA 2001d).
- *Risk Assessment Principles and Practices* (USEPA 2004e).
- *A Framework for Assessing Health Risk of Environmental Exposures to Children* (USEPA 2006b).
- *Guidance Document on Characterizing and Communicating Uncertainty in Exposure Assessment* (WHO 2008).

3. Public, Stakeholder and Community Involvement

As discussed in Section 2.1 *Planning and Scoping*, public, stakeholder and community involvement are key elements of the Framework. The level of public, stakeholder and community involvement varies depending on the activity and program requirements. Figure 3-1 highlights key questions and considerations for stakeholder involvement. As indicated in the figure, public, stakeholder and community involvement are considered early and may be considered often in the risk assessment and decision-making process. Although the single term "public" could be used to include the full range of external stakeholders, including community members, all three terms are specifically included in recognition of the differences in what each term may convey to different readers and in recognition of the unique roles played by internal stakeholders. See Section 2.1.5.

Figure 3-1. Framework for Human Health Risk Assessment to Inform Decision Making: Key Questions and Considerations for Public, Stakeholder and Community Involvement

Public participation is an essential aspect of EPA's process for making decisions to achieve the Agency's mission of protecting human health and the environment. It provides EPA with the opportunity to obtain and consider a range of views on the issue being assessed, as well as on management options. Effective public involvement (including key stakeholders and/or communities) can enhance the deliberative process and improve the content of the Agency's decisions (USEPA 2003d); it is consistent with sustainability principles. A critical feature of the Framework is the involvement of the public, stakeholders and communities at key points in the process. The timing, frequency and level of community involvement will depend on a number of factors, including regulatory requirements, the nature of the decision and community interest.

As discussed in Section 2.1.5, public involvement may begin when individuals and organizations seek information from EPA about a topic or issue or when the public receives information from EPA because the Agency identifies them as a potentially affected party. EPA's outreach activities serve and engage these individuals and organizations (USEPA 2003d).

Each decision or action by the Agency may call for a different level of public involvement, and certain members of the public, stakeholders or communities may need to be involved at different steps in the risk assessment process. EPA's *Public Involvement Policy* (USEPA 2003d, 1) states that "EPA staff and managers should seek input reflecting all points of view and should carefully consider this input when

making decisions." In addition, the policy states that "EPA should not accept any recommendation or proposal without careful, critical examination" (USEPA 2003d, 1).

The overall goal of public involvement is to provide opportunities for people to contribute at every point along the progression of the decision-making process. Individuals and groups decide for themselves whether, when and how to participate. It is recognized that not everyone who is interested in the situation being assessed chooses to be an active participant in providing input (e.g., facts, data, opinions) to policy or regulatory decisions of the Agency. The information provided through the public involvement process is considered by the Agency's officials in the decision-making process.

3.1 Audiences for the Risk Assessment

If properly planned and executed, the technical risk characterization itself will be consistent with the level of detail and complexity of the assessment conducted. The information presented, however, may vary by regulatory and audience needs. Co-regulators such as states and tribal nations also are audiences for the risk assessments; these groups may prefer a high level of technical detail in communication of an assessment. Several statutes and executive orders affect the development of regulatory rules and other EPA decisions and may define specific activities for public, stakeholder and community involvement. In addition, several programs have developed specific guidance on public involvement—variously termed public, stakeholder and community involvement (Dalton and Harter 2009). These guidance documents are listed in Text Box 3-1.

3.1.1 Stakeholders

The appropriate stakeholder involvement process will depend on the specifics of the situation. Stakeholder involvement processes are highly adaptive and can be modified to take changing circumstances into account. Additional details are found in *Better Decisions Through Consultation and Collaboration* (Dalton and Harter 2009).

Staff and management of EPA offices are important internal stakeholders in the process of drafting rules, policies, permits or plans. The planning process considers inclusion of internal stakeholders in establishing the project. Three key considerations are to include stakeholders early, obtain "buy-in" along the way and keep stakeholders engaged.

Communication with stakeholders outside the Agency may vary depending on regulatory requirements. For example, regulatory and non-regulatory activities in the Office of Chemical Safety and Pollution Prevention provide mechanisms to interact with stakeholders while EPA is developing the assessments. During the review of pre-manufacture notices (PMNs) for new substances, the EPA Program Manager or other Agency personnel may contact the submitter for additional information if EPA identifies concerns or needs clarification of the technical information provided in the PMN. Rules issued under TSCA Section 5 (i.e., Significant New Use Rules) and Section 6 (e.g., formaldehyde) provide a notice and comment period in the *Federal Register* that allows public involvement in the Office of Pollution Prevention and Toxics' (OPPT) rulemaking actions (e.g., *Proposed Significant New Use Rule for Multi-walled Carbon Nanotubes* [USEPA 2010c] and *Formaldehyde Emissions From Pressed Wood Products* [USEPA 2008]). Public meetings are scheduled in different parts of the United States to increase public involvement in the rulemaking process. Under the High Production Volume (HPV) Challenge Program, OPPT posts notice of and links to data summaries and test plans for HPV chemicals (USEPA 2012o) and provides a 120-day public comment period. The Office of Pesticide Programs provides multiple opportunities for public comment and involvement in its registration review program, including at the opening of the process for a chemical on the Preliminary Work Plan, on the draft risk assessment and on the proposed regulatory actions.

Text Box 3-1. Resources for Public Involvement Efforts, Tools and Policies

Public Involvement

- *The Model Plan for Public Participation* (USEPA 2000c).
- *EPA Public Involvement* website (USEPA 2011d).
- *Pesticide Program Dialogue Committee*. This Committee provides a forum for a diverse group of stakeholders to provide feedback to the pesticide program on various pesticide regulatory, policy and program implementation issues (USEPA 2011l).

Community Involvement

- *Superfund Community Involvement Plans* (USEPA 2002g).
- *EPA's Superfund Community Involvement Handbook* (USEPA 2005d).
- *Superfund Community Involvement Publications* Web page (USEPA 2011r).

Risk Communication

- *Seven Cardinal Rules of Risk Communication* (Covello and Allen 1988; USEPA 1988).
- *Risk Communication.* Vol. 4 of *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* (USEPA 1995c).
- *Lessons Learned About Designing, Developing, and Disseminating Environmental Information Products* (USEPA 2000a).
- *Risk Communication in Action: The Risk Communication Workbook* (USEPA 2007d).
- *Risk Communication in Action: The Tools of Message Mapping* (USEPA 2007e).

Sustainability

- *Sustainability and the U.S. EPA* (NRC 2011).

Another example of stakeholder involvement is the IRIS process (USEPA 2012k), which provides multiple opportunities for stakeholder participation. The process includes a call for nominations that allows stakeholders to suggest chemicals for assessment through the IRIS Program. Nominations include a description of why the chemical(s) should be considered for assessment. Multiple opportunities for review and comment occur during the development of health hazard assessments. For example, the IRIS process includes a step that provides for review by other offices within EPA (Agency review) and two opportunities for interagency science consultation and discussion, enabling other federal agencies to comment on the assessment. Finally, during the period of public review and comment, any interested member of the public may comment on the assessment; there also is a public listening session in which any stakeholder or member of the public has the opportunity to speak about the assessment.

3.1.2 Community

Community involvement may be a component of the stakeholder involvement process, particularly in cases in which the issue assessed relates to a specific location (e.g., decisions regarding contaminated waste sites or facilities with environmental releases). Community involvement is the process of engaging in dialogue and collaboration with community members who may be affected directly by the risk assessment. For example, in the Superfund Program, the goal of community involvement is to advocate

and strengthen early and meaningful community participation during the investigation, while conducting the risk assessment and during the decision-making process. For additional information see the *EPA Public Involvement* website, USEPA 2011d and USEPA 2011q.

3.2 Communication

Successful communication begins early in the risk assessment process—during planning and scoping and problem formulation – see Section 2.1.5 — and has a pivotal role throughout the process. As the *Silver Book* (NRC 2009, 250) points out, "[C]ommunication among those involved in the policy and technical evaluations are [sic] difficult to achieve, but they are necessary for success." Communication of risk may be challenging as a result of the complexity of the information being conveyed, the inherent uncertainty in risk estimates and the varying needs of the audiences (e.g., scientists, risk managers, various stakeholders, the media, and the general public). The *Silver Book* (NRC 2009, 66) recognized this issue, stating that "… the critical final process in risk assessment is ultimately communication."

Risk communication begins with understanding the risk characterization portion of the risk assessment. Risk characterization is an integral part of a risk assessment and summarizes the key findings, as well as the strengths and weaknesses of the assessment, for risk managers and others. Although it provides information that may be useful for communicating with the public, risk characterization is not synonymous with risk communication.

Risk communication includes the process of providing information to the public—including individuals, groups and other institutions—about levels of health or environmental risk. Risk communication is used for such things as information and education, behavior change and protective action, disaster warnings and emergency information, and joint problem solving. Although the final risk assessment documentation (including the risk characterization) can be used to communicate with the public, the risk communication process often is better served by a separate set of documents designed for particular audiences.

Risk communication tools are written, verbal or visual statements containing information about risk. These tools put a particular risk in context, possibly adding comparisons with other risks, and often include advice about risk reduction behavior. Risk communications also can encourage a dialogue between the sender and receiver of the message (USEPA 2007d). In general, the communication tools should be concise and provide adequate information for the user, although not at the level of detail provided in the risk characterization. In addition, care is required to assure that the risk information is consistent with the data provided in the risk characterization and includes risk assessment results, the strengths and limitations of the analysis, and how they will be used by risk managers.

Risk communication documents should be designed to consider the intended audience for the information. For example, risk managers generally prefer not to receive the depth of detail found in the technical risk characterization. The usual products prepared for risk managers from the risk characterization provide a summary and can take various forms depending on specific needs (e.g., executive summary, bulleted list of key issues and conclusions, briefing packages) (USEPA 2000d). Risk characterization products prepared for the public, stakeholders and communities can come in many forms. Generally, these communication pieces carry forward the key issues and describe conclusions in a lay person's context rather than a technical one (e.g., that of a scientific presentation or paper); this can include plain language definitions, translations into appropriate languages, use of graphics as appropriate to convey information, and so on. Communication products are developed to meet the needs of the intended audience and may include products such as fact sheets for interested members of the public, press releases, slide shows, public relations notices, decision documents, and speeches and talks (USEPA 2000d). Text Box 3-1 identifies resources helpful in developing a risk communication plan for various audiences.

4. Risk Assessment

Risk assessments conducted for EPA range from relatively simple to complex, depending on factors that include the needs of the risk management decision being made and the availability of relevant data. Consistent with Agency policies and guidance, the analyses that contribute to a risk assessment may range from those based on default assumptions to more refined analyses that include site-specific information and quantitative uncertainty assessment (USEPA 1992b, 2005b, 2011f). Planning and scoping identifies the level of assessment appropriate for the needs of the risk manager and the role that risk information plays in the decision. Information gathered during planning and scoping is used during problem formulation to develop a conceptual model and analysis plan. The assessment step builds on the conceptual model and implements the analysis plan. As information is developed and preliminary conclusions are drawn, it is not uncommon to revisit data needs or revise the conceptual model and analysis plan.

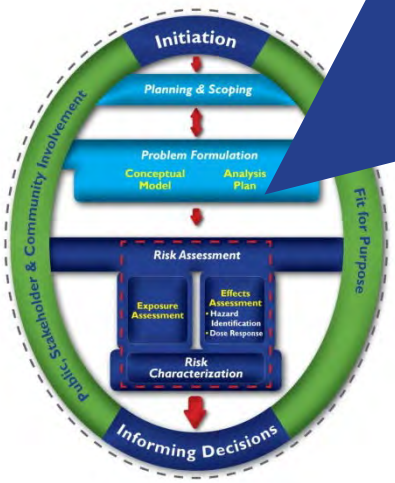
EPA has issued guidance on all four steps of the risk assessment paradigm (i.e., exposure assessment, effects characterization, which includes hazard identification and dose-response assessment, and risk characterization); these publications are highlighted in Section 2. The steps in risk assessment often are performed together, in an integrative fashion, rather than as a linear, sequential process. This Framework document focuses on the context, utility and planning for the risk assessment itself; therefore, it does not provide detail on the conduct of the steps.

EPA risk assessments may focus on individual risk metrics or may include population-level and/or life stage-specific assessments to inform characterization of risk. Different categories of assessments may be conducted by the Agency depending on the specific types of regulatory or programmatic decisions the assessment is intended to inform. The Agency's *Risk Assessment Portal* (USEPA 2012n) provides basic information about environmental risk assessments and offers a comprehensive set of links to key EPA tools, guidance and guidelines.

Figure 4-1 highlights the assessment phase in the Framework, detailing several cross-cutting areas for consideration in exposure or effects characterization. The risk assessor might consider available data on metabolism; modeling; MOA; toxicity; cumulative risk (exposure and/or effects); the susceptibility of individuals based on factors such as life stage, genetics and gender; specific population groups, including socio-economic considerations; uncertainty and variability; and other factors relevant to the characterization of risk. The landscape of risk assessment is changing, with new advances in molecular biology, computational toxicology and risk assessment methodology. The areas of consideration noted in Figure 4-1 are meant to be illustrative of today's practices rather than definitive or comprehensive, and they are likely to change as the science of risk assessment advances.

4.1 Exposure Assessment

Exposure assessment is one of the primary components of risk assessment; it describes how humans come into contact with hazards. The approaches employed for this component may vary across risk assessments to reflect considerations described in the conceptual model and analysis plan, as well as regulatory needs. The *Guidelines for Exposure Assessment* provides principles, concepts and methods used by EPA in evaluating exposures (USEPA 1992b). The use of exposure science has been instrumental in forecasting, preventing and mitigating exposures that lead to adverse human health outcomes. It addresses the intensity and duration of human contact with different types of stressors (e.g., chemical, physical, biological) and their fate in living systems, including vulnerable populations and susceptible life stages (NRC 2012).



Exposure Assessment

- **How and to what range of concentrations/doses are populations/life stages of interest exposed?**
- **How do risk management options affect existing/resulting conditions of exposure?**

Effects Assessment

- **Hazard ID: What adverse endpoints are associated with agents or stressors of concern? Are there data to identify susceptible populations or support a MOA for the agent or stressor?**
- **Dose-Response Assessment: What is the relationship between exposure/dose and the likelihood of each endpoint at the exposure range of interest? How does MOA and other relevant information affect choices of low-dose extrapolation?**

Risk Characterization

- **What is the nature and magnitude of risk for existing conditions and for options?**
- **What are the sources and magnitude of uncertainty and variability in all steps of the risk assessment?**

Figure 4-1. Framework for Human Health Risk Assessment to Inform Decision Making: Key Questions and Considerations for Assessment

Exposure is characterized, quantitatively or qualitatively, for relevant routes and pathways, frequency and duration, and populations and life stages. The specific type of exposure estimation needed and the level of complexity employed for this component of the assessment will vary depending on the assessment purpose, legal authority and other factors considered in the planning and scoping step. For example, this step may involve collection of new data, implementation of simple or complex exposure models or data analysis. A key aspect of all exposure assessments is the consideration of the potential existence of susceptible or more highly exposed populations, life stages or groups. Based on considerations and decisions in the conceptual model, quantitative exposure assessments may include the development of estimates specific to these populations or life stages. The available toxicokinetic information also may be characterized and internal doses calculated. EPA's exposure factors handbook provides a compendium of exposure factors for a number of parameters for adults and children, including such metrics as ingestion of soil, time spent in residence, surveys of fish ingestion, ingestion of homegrown products and inhalation rates (USEPA 2011f). Some key elements of exposure characterizations are listed in Text Box 4-1.

Text Box 4-1. Key Elements of an Exposure Assessment

- Assess sources, pathways and routes of exposure and determine approach for consideration of multiple pathways, as relevant.
- Investigate patterns of exposure (e.g., frequency and duration).
- Assess populations and life stages (e.g., the general population or highly exposed, vulnerable, or susceptible groups) and determine bases for inclusion.
- Consider the rationale for the analysis approach, including any monitoring or modeling needs.
- Consider variability in exposures and appropriate exposure distributions (e.g., the use of Monte Carlo or kriging).
- Establish descriptors of exposure, generally including estimates for "average" and "high-end" exposures, as well as susceptible populations or life stages.
- Determine data and methods used in developing the exposure estimates.

Source: Adapted from EPA's *Guidance for Risk Characterization* (USEPA 1995a) and *Guidelines for Exposure Assessment* (USEPA 1992b).

4.2 Effects Assessment

In human health risk assessment, the characterization of effects includes hazard identification and dose-response assessment. The approaches employed for these components, including, for example, the level of detail and complexity of quantitative aspects may vary across different risk assessments and will reflect considerations described in the conceptual model and analysis plan.

4.2.1 Hazard Identification

Hazard identification is the process of identifying the type of hazard to human health (e.g., cancer, birth defects) posed by the exposure of interest for a given risk assessment. Hazard identification for most Agency risk assessments focuses on chemical agents. Chemical agents are a subset of all stressors (e.g., chemical, biological, social or physical) (USEPA 2003b). In the case of chemical agents, the process examines the available scientific data for a given chemical (or group of chemicals) and often develops a characterization of hazard. This step requires identification, evaluation and synthesis of information to describe the health effects of individual chemicals or chemical mixtures. Studies evaluated may include human clinical or epidemiological studies, *in vivo* or *in vitro* laboratory animal studies, or mechanistic or kinetic studies in a variety of test systems. In recent years, risk assessors have begun to consider additional types of data during hazard identification, for example, those from computational toxicology (quantitative structure-activity relationships, high-throughput assays) and genomic response assays. Other data types may be identified in the future. Key aspects of hazard identification include consideration of available information on toxicokinetics (i.e., how the body absorbs, distributes, metabolizes and eliminates chemicals) and toxicodynamics (i.e., the effects that chemicals have on the body), as well as potential MOAs (or toxicity pathways) related to the health effects identified. Text Box 4-2 describes some contexts in which the MOA or the adverse outcome pathway[10] is considered.

[10] Adverse Outcome Pathway: A description of plausible causal linkages that illustrates how a chemical interaction with a biological system at the molecular level causes biological effects at the subcellular, cellular, tissue, organ and whole animal levels of observation (Ankley et al. 2010).

Text Box 4-2. Example of a Consideration for Effects Characterization: Mode of Action

The *Guidelines for Carcinogen Risk Assessment* (USEPA 2005b) emphasizes the important contribution that understanding a chemical's MOA[A] makes to informed risk assessment decisions. These can include:

- Relevance of data (e.g., animal, *in vitro*, *in silico*) for human health risk assessment.
- Harmonization of risk assessments for various health endpoints.
- Conditions under which an agent is likely to cause cancer (or some other health endpoint).
- Choice of low dose extrapolation (e.g., linear or nonlinear).
- In cancer assessments, applicability of default age-dependent adjustment factors (ADAFs) for early lifestage exposure.

The carcinogen guidelines and supplemental guidance (USEPA 2005b, 2005e) include a framework for assessing available data to determine whether a hypothesized MOA is likely to be involved in induction of a specific tumor type. This framework also is useful for assessment of other health endpoints. For an example of application of the MOA framework to reproductive effects, see the Office of Pesticide Program's work on the pesticide cacodylic acid (USEPA 2005c, 2012c).

Although the scientific community historically has focused on understanding how chemicals cause biological effects, the use of detailed information on MOA in human health risk assessment has been increasing as methods are refined and more reliable information is generated. Recognizing the critical role in risk-based decision making of understanding how a chemical causes effects, *Toxicity Testing in the 21st Century* (NRC 2007) proposed that the next generation of toxicology studies be designed to focus on "toxicity pathways."[B] These are normal biological pathways that respond to chemicals or other stressors depending on the magnitude of the insult (dose, timing, duration and frequency of perturbation). For example, at low exposures, some systems will remain within their homeostatic limits, while at higher levels of stress, adaptive biologic responses may occur, the adversity of which may depend on the physiological characteristics of those exposed; that is, groups of sensitive individuals may respond adversely, whereas others may not. At still greater magnitude of stress, the adaptive capacity may be overwhelmed for all groups, increasing the likelihood of adverse effects. These and similar concepts may provide approaches for applying greater scientific understanding of what a chemical does in causing an effect. This knowledge in turn will support improved human health risk assessments.

The availability of data for these types of detailed assessments varies widely across chemicals. Accordingly, EPA and the NRC continue to support the use of default methods and procedures to complete a risk assessment when data are lacking.

[A]**MOA:** The sequence of key events and cellular and biochemical events (measurable parameters), starting with the interaction of an agent with the target cell or tissue, through functional and anatomical changes, resulting in cancer or other adverse health effects (Boobis et al. 2008, USEPA 2005b). MOA differs from mechanism in that the latter implies a more detailed understanding of the molecular basis of the toxic effect (Seed et al. 2005).

[B]**Toxicity Pathways:** Cellular response pathways that, when sufficiently perturbed, are expected to result in adverse health effects (NRC 2007).

In hazard identification, the strengths and limitations of the data and information used to support the weight of evidence are described, including areas for which data may be unavailable (data gaps). In situations where a quantitative risk assessment is to be performed, a particular study or group of studies may be identified for use in dose-response assessment.

Hazard identification may be focused on health risks of exposure to specific individual chemicals or identification of groups of chemicals with common MOAs (e.g., pesticides). In some cases, the specific chemicals are identified by statute (e.g., the CAA hazardous air pollutants). Thus, the chemical exposures to be evaluated in the risk assessment may vary across programs, depending on the legal authorities under which the assessment is conducted. In all cases, the conceptual model and analysis plan will specify the extent, content and limits of the hazard identification.

4.2.2 Dose-Response Assessment

In this component of effects characterization, the relationship between the exposure or dose of a contaminant and the occurrence of particular health effects or outcomes is assessed. Drawing from the conceptual model and analysis plan, the dose-response assessment (USEPA 2012q) may be developed using a combination of data, science policy decisions and models. For example, the response assessed might be incidence of some endpoint or health outcome (e.g., cancer incidence, incidence of a critical effect, hospital admission for a specific outcome, death) or it might describe the magnitude of a response (e.g., magnitude of IQ loss). The assessment also may include the derivation of an established metric, such as EPA's reference doses and reference concentrations (USEPA 2002f).

In documentation of the dose-response assessment, aspects of the full database, particularly the key studies, are described along with their strengths and weaknesses, including the potential impact of those weaknesses on the reliability of the overall assessment. Toxicokinetic information also is described; in data-rich situations, measured or modeled target tissue dose may be used in the dose-response calculations. In some cases, multiple chemicals may be included in a single dose-response assessment, with decisions made about the grouping of chemicals, as well as the means by which the chemicals will be combined (e.g., common MOA, common toxic effect, estimation of cancer potency factors, specific data for chemical mixtures, likelihood of simultaneous exposure). Decisions on these issues are specific to the individual risk assessment and may be influenced by the information gathered during problem formulation. Details of EPA practices and policies related to dose-response assessment can be found in the various guidance documents noted in Section 2 of this document and at EPA's risk assessment *Guidance & Tools* Web page (USEPA 2012h), as well as in documents particular to specific assessment contexts.

4.3 Risk Characterization

Risk characterization is the final, integrative step of risk assessment. This step integrates exposure assessment and effects assessment into quantitative and qualitative estimates of risk for the evaluated population(s) (USEPA 2011p). EPA has incorporated advice on scope and necessity of appropriate risk characterization into its guidance; see, for example NRC 1994 and NRC 1996. The Agency's *Risk Characterization: Science Policy Council Handbook* (USEPA 2000d) describes risk characterization as the step that "integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about the risk that is complete, informative, and useful for decision makers" (USEPA 2000d, 10).

A good risk characterization will restate the scope of the assessment, express results clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate

scientific conclusions from policy judgments (USEPA 2011p). EPA's risk characterization policy calls for conducting risk characterizations in a manner that is consistent with the following principles:

- **Transparency:** The characterization should fully and explicitly disclose the risk assessment methods, default assumptions, logic, rationale, extrapolations, uncertainties, and overall strength of each step in the assessment.

- **Clarity:** The products from the risk assessment should be readily understood by readers who were involved and not involved in the specific risk assessment process. Documents should be concise, be free of jargon, and use understandable tables, graphs and equations as needed.

- **Consistency:** The risk assessment should be conducted and presented in a manner that is consistent with EPA policy, and consistent with other risk characterizations of similar scope prepared across programs within EPA.

- **Reasonableness:** The risk assessment should be based on sound judgment, with methods and assumptions consistent with the current state-of-the-science and conveyed in a manner that is complete, balanced and informative.

These four principles—Transparency, Clarity, Consistency and Reasonableness—are referred to collectively as TCCR (USEPA 2012r). To achieve TCCR in a risk characterization, the same principles need to have been applied in all of the prior steps in the risk assessment that lead up to the risk characterization.

A risk characterization conveys the nature and presence or absence of risks in quantitative and qualitative terms. It describes information on how the risks were assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. If numerical estimates of effects or exposure are not available, qualitative estimates may be used to characterize risk.

In describing the nature and magnitude of risk for the assessed environmental condition, the risk characterization describes the universe of people who may be affected, including sensitive and/or susceptible life stages or populations. As indicated in EPA's risk characterization policy, EPA risk assessments generally address or provide descriptions of individual risk (including central tendency and high end portions of risk distribution), population risk, and important population subgroups, such as highly exposed or highly susceptible groups (Browner 1995; USEPA 2000d; USEPA, 1995b). Specific life stages and/or populations (e.g., potentially at-risk groups) are first considered in the planning and scoping phases and may be evaluated explicitly in the risk assessment. Text Box 4-3 presents details on characterizing cancer risk from early life exposures. Additionally, in consideration of highly exposed or susceptible life stages and/or populations, risk characterizations generally present multiple risk descriptors (e.g., high-end and central-tendency) and may include risk descriptors (e.g., maximum exposed individual, reasonable maximum exposure, central-tendency) that are specific to underlying legislative requirements (e.g., CAA, CERCLA, CWA) (USEPA 1995a).

In risk characterization, information about uncertainty and variability (defined in Text Box 2-15) from each step of the risk assessment (e.g., use of default parameters, choice of models and data used for quantitative analysis) is integrated into an overall discussion and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA uses several techniques to ensure that risk is not underestimated with data are lacking. EPA may characterize uncertainty using a qualitative assessment of the overall strength and limitations of the data used in the assessment. To estimate the effect of data uncertainty on modeled pollutant impacts, various modeling tools may be employed. Even the quantification of uncertainty and variability in probabilistic risk assessments itself includes an element of additional uncertainty. It is important that the level and type of uncertainty analysis be commensurate

Text Box 4-3. Characterizing Cancer Risk from Early-Life Exposure

When assessing cancer risk resulting from early-life exposures, the risk assessor considers life-stage differences in both exposure and dose-response relationships. The *Guidelines for Carcinogen Risk Assessment* (USEPA 2005b) and EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (USEPA 2005e), provide guidance in this regard. The preferred approach is the calculation of life-stage specific slope factors and use of life-stage specific exposure information when this is supported by data. In the absence of sufficient data, age-dependent adjustment factors (ADAFs) in dose-response relationships (i.e., adjustments to slope factors based on age groups) are combined with age-specific exposure estimates when assessing cancer risks for chemicals determined to act through a mutagenic MOA. This integrative approach is used to assess total lifetime risk resulting from lifetime or less-than-lifetime exposure during a specific portion of a lifetime.

with the decision to be made. In some cases, highly detailed quantitative uncertainty analyses might not be warranted, whereas they might be useful for others.

Communicating the results of probabilistic risk assessment requires particular attention. Probabilistic risk assessments provide range and likelihood estimates for one or more aspects of hazard, exposure or risk, rather than a single point estimate (USEPA 2010e; Zartarian et al. 2005). A goal of probabilistic risk assessment is the quantitative characterization of the uncertainty and variability in estimates of hazard, exposure or risk (USEPA 1997b). Risk assessors are responsible for sharing information on probabilistic results so that risk managers have a clear understanding of quantitative assessments of uncertainty and variability and how this information will affect the risk management decision. Clear communication between the risk assessment team and the decision maker is essential in aiding the decision maker's understanding and use of the results from the probabilistic risk assessment.

Areas of uncertainty that may make an appreciable difference in the assessment results or conclusions are highlighted in the risk characterization. For example, the risk characterization document includes a discussion of any issues associated with the data quality (e.g., reliability and availability) that may impact the calculated risks or other metrics. This may include explicit discussions of the evaluation process and description of issues that may impact the reliability or utility of the endpoints identified for use. A key question addressed in the risk characterization is whether the risk assessment outcome would change significantly if data were interpreted differently or if different models were used. This kind of uncertainty is difficult or impossible to characterize probabilistically. It is essential, however, to describe uncertainty and variability so that the impact will not be overlooked or misinterpreted. It may be useful to revisit the analysis plan if the uncertainty/variability analysis determines that gathering additional information will have a substantive impact on reducing uncertainty in the assessment.

4.4 Characterizing the Risks for Risk Managers

It is the role of the risk assessor to provide a transparent description of all aspects of the risk assessment (e.g., default assumptions, data selected, policy choices) to make clear the range of plausible risk associated with each risk management option. Clear communication between the risk assessors and risk managers is vital to assuring that risk information is conveyed appropriately.

Whatever approach is used to estimate risk, it is important to be clear in describing the range of possible risks (including central tendency and high end portions of the risk distribution), as well as important subgroups such as highly exposed or highly susceptible groups. For example, the extent to which the

assessment may underestimate or overestimate risk for some populations should be highlighted to inform the decision making appropriately. As discussed in Section 4.3, these uncertainties may be characterized quantitatively (e.g., using probabilistic methods) or qualitatively (e.g., describing how the results would change if the data were interpreted differently). The risk assessment characterizes the nature and magnitude of risk and who is at risk under different risk management options (including a *status quo* option).

5. Informing Decisions

EPA uses risk assessment as a key source of scientific information for evaluating risks and related outcomes associated with possible risk management options, and ultimately, informing the process of making sound decisions about managing risks to human health and the environment. As noted in Section 4.3, risk assessments that are well-planned and focused will be most useful and informative for decision making.

EPA makes many types of decisions that cover a wide range of environmental issues and pollutants. Each of these decisions is made in the context of a combination of statutes, precedents and stakeholders. The statutes establish legal requirements that generally describe the protection that EPA regulations must achieve, and in so doing, also may specify aspects of the risk assessment. Statutes also may identify other factors to inform the regulatory decision, such as consideration of best available control technologies, cost and benefit considerations, and so forth. Accordingly, how risk assessment informs decision making may be affected by such statutory or regulatory requirements and restrictions.

The informational needs, identified as part of planning and scoping, and are updated and refined throughout the assessment process to ensure that the risk assessment is fit-for-purpose. Much of this information will be in the risk characterization and is based on transparency in conducting and explaining the risk assessment combined with clarity, consistency and reasonableness in the preparation of the risk description (USEPA 2000d). The science supporting the risk assessment conclusions, as well as consideration of variability, susceptibilities and uncertainties, informs decisions among the risk management options presented in the risk assessment.

In addition to consideration of the risk assessment, some statutes also may require consideration of other assessments, such as benefit-cost analysis, which may draw upon the risk assessment in whole or in part. Addressing these considerations when scientific assessments are integrated into a comprehensive analysis requires collaboration among the risk assessors, economists and other analysts.

As recognized above, risk assessment is one of many considerations that inform Agency decisions. Other considerations may include:

- **Laws and Regulatory Requirements:** legal mandates, flexibility and constraints.
- **Economic Analyses:** costs, benefits and impacts of potential actions.
- **Sustainability:** life cycle, multimedia and long-term impacts.
- **Technological Considerations:** feasibility, impact and range of risk management options.
- **Political Considerations:** interactions with different branches and levels of government, as well as the citizens that they represent.
- **Public and Social Considerations:** susceptible population groups and life stages, nonchemical stressors and cumulative risk assessment considerations.

Some of these considerations are independent of the risk assessment, though the analysis of some may be informed by the risk assessment.

Some key questions and considerations for the informing decisions step of the process are shown in Figure 5-1.

Figure 5-1. Framework for Human Health Risk Assessment to Inform Decision Making: Key Questions and Considerations for Informing Decisions

In this step of the process, the goal of the risk assessment team ultimately is to paint as complete a picture as possible regarding risk for a range of possible management options. The description of the risk management decision should clarify how the risk assessment and other factors informed the decision.

6. Summary

The *Framework for Human Health Risk Assessment to Inform Decision Making* lays out a Framework for conducting human health risk assessments in support of decision making at EPA. It focuses on the planning and scoping and problem formulation steps, drawing on NRC (2009) and other advisory groups, and EPA experience. For example, the Framework addresses recommendations in the *Silver Book* (NRC 2009) on assuring the utility of risk assessment, which the Framework terms as being fit for purpose. See Text Box 6-1. As indicated in the Framework diagram, Figure 6-1, the NRC's 1983 four-step risk assessment paradigm is maintained, but there is increased emphasis on interaction between risk assessors and risk managers in planning the assessment to maximize utility. Emphasis on utility is maintained throughout the process, beginning with planning and scoping and continuing through the evaluation of the applicability of the risk assessment in informing decisions.

The Framework highlights the practical nature of risk assessment. For example, although the Agency is committed to advancing risk assessment science, assessments are not academic exercises. Instead, they are intended to support decision making for the protection of human health. Application of the Framework, with its emphasis on problem formulation and the utility of the risk assessment, ultimately will result in better, more transparent choices among risk management options. This Framework builds on Agency guidelines, policies and guidance and is directed at improving risk assessment products but does not overturn or in any way change existing science policy decisions.

EPA programs routinely apply components of this Framework, as evidenced by the examples cited in the preceding sections. It is expected, however, that this document will facilitate the formal recognition of these components in Agency risk assessment activities. The Framework's explicit recognition of the roles for planning and scoping; public, stakeholder and community involvement; and consideration of utility will assist in the development of risk assessments focused on informing decisions. Furthermore, "institutionalization" of this *Framework for Human Health Risk Assessment to Inform Decision Making* will contribute transparency to the Agency's risk assessment process and a level of consistency across assessments, media and programs, as well as between human health and ecological outcomes.

Text Box 6-1. The Silver Book Recommendations for a Human Health Risk Assessment Framework

- The technical framework for risk assessment presented in the *Red Book* should remain intact but should be embedded in a broader framework in which risk assessment is used principally to help to discriminate among risk-management options (NRC 2009, 256).
- The framework for risk-based decision making (Figure 6-1) should have as its core elements a problem-formulation and scoping phase in which the available risk-management options are identified, a planning and assessment phase in which risk-assessment tools are used to determine risks under existing conditions and with proposed options, and a management phase in which risk information and other factors are integrated to inform choices among options (NRC 2009, 256).
- EPA should phase in the use of the framework with a series of demonstration projects that apply the framework and that determine the degree to which the approach meets the needs of Agency risk managers, and how risk-management conclusions differ as a result of the revised orientation (NRC 2009, 256).

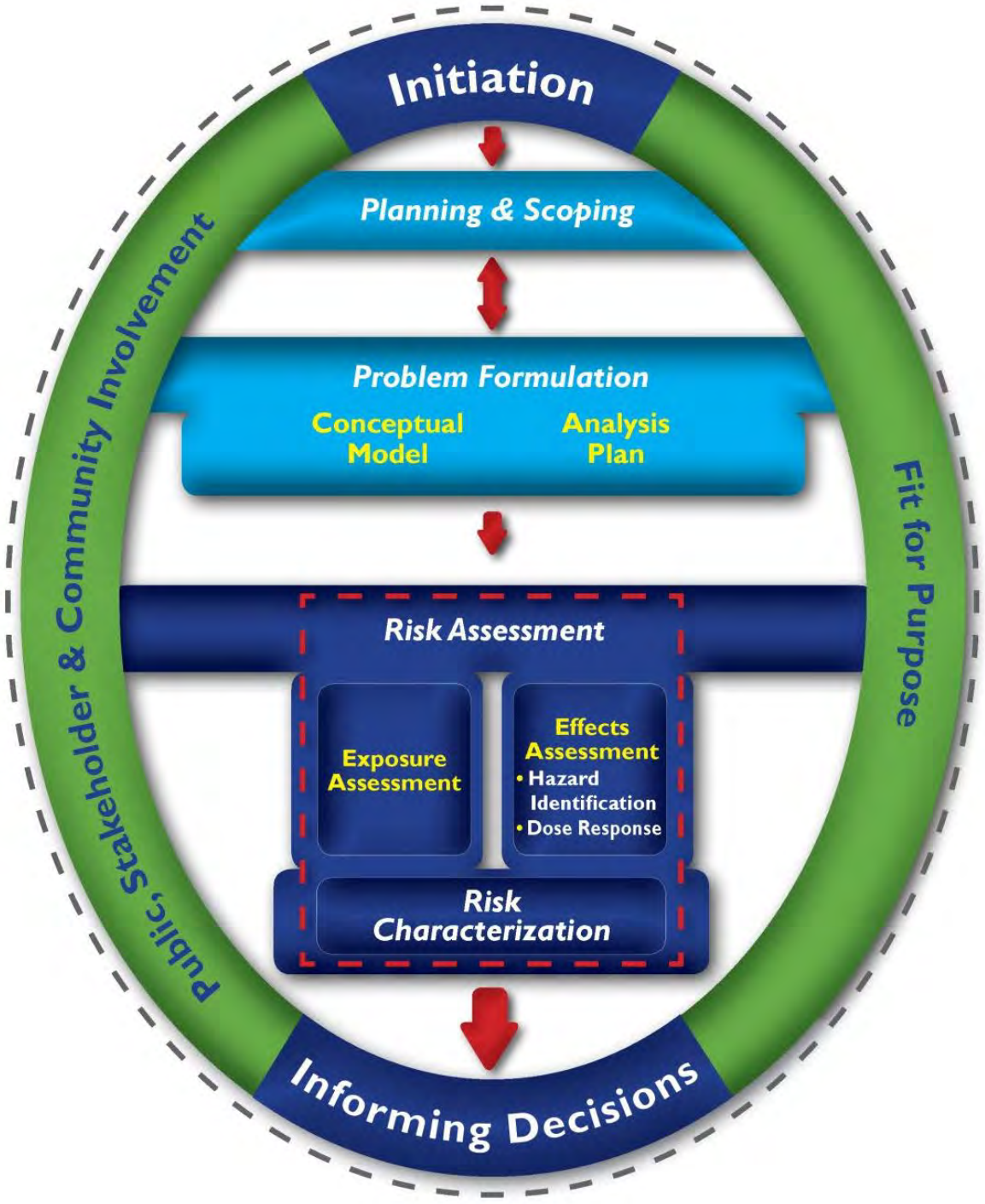


Figure 6-1. Framework for Human Health Risk Assessment to Inform Decision Making

The Framework is intended to be flexible. The structure will accommodate advances in the technology and science. These might include development of life cycle analyses and use of data from high throughput assays (i.e., those that generate data much more rapidly and for many more chemicals than the standard toxicological assays of the 20th century). The Framework structure is sufficiently adaptable to encompass evolving changes in Agency direction, developing needs and new or revised legislative mandates.

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Appendix I. Examples of EPA Program-Specific Resources and Guidance on Risk Assessment Activities

EPA Risk Assessment Portal

- A useful source of information on Agency risk assessment terms and guidance documents for readers of this Framework is EPA's *Risk Assessment Portal* (USEPA 2012n). http://www.epa.gov/risk/

Air Toxics Program (Office of Air Quality Planning and Standards [OAQPS])

- *Air Toxics Risk Assessment Reference Library.* Developed for conducting air toxics analyses at the facility- and community-scale. The library provides information on the fundamental principles of risk-based assessment for air toxics and how to apply those principles in different settings, as well as strategies for reducing risk at the local level.
    - *Volume 1: Technical Resource Manual* (http://www.epa.gov/ttn/fera/risk_atra_vol1.html).
    - *Volume 2: Facility-Specific Assessment* (http://www.epa.gov/ttn/fera/risk_atra_vol2.html).
    - *Volume 3: Community-Scale Assessment* (http://www.epa.gov/ttn/fera/risk_atra_vol3.html).
- *Residual Risk: Report to Congress* (http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf).

Hazardous Waste Program (Office of Solid Waste and Emergency Response [OSWER])

- *RCRA Public Participation Manual* (http://www.epa.gov/wastes/hazard/tsd/permit/pubpart/manual.htm).

National Ambient Air Quality Standards Program (NAAQS) (OAQPS)

- *Process of Reviewing the National Ambient Air Quality Standards.* Process for NAAQS reviews, including the role of risk assessment (http://www.epa.gov/ttn/naaqs/review.html).
- *Risk Assessment and Modeling—Criteria Air Pollutant Risk Assessment*. Recent NAAQS risk assessments (http://www.epa.gov/ttn/fera/risk_criteria.html).
- *National Ambient Air Quality Standards.* Current documents for NAAQS reviews (http://www.epa.gov/ttn/naaqs/).

Pesticides Program (Office of Pesticide Programs)

- *Science Policy Issues and Guidance Documents* (http://www.epa.gov/oppfead1/trac/science/).
- *Models and Databases* (http://www.epa.gov/pesticides/science/models_db.htm).
- *Public Participation Process for Registration Actions* (http://www.epa.gov/pesticides/regulating/public-participation-process.html).

Safe Drinking Water Program (Office of Water)

- *Public Access to Information & Public Involvement.* Public Access Information for the Safe Drinking Water Act (SDWA) (http://water.epa.gov/lawsregs/guidance/sdwa/upload/2009_08_28_sdwa_fs_30ann_publicinvolve_web.pdf).

Superfund Program (OSWER)

- *Superfund Risk Assessment.* Risk assessment resources and guidance (http://www.epa.gov/oswer/riskassessment/risk_superfund.htm).

- *Risk Assessment Guidance for Superfund: Volume 1— Human Health Evaluation Manual. Supplement to Part A: Community Involvement in Superfund Risk Assessments* (http://www.epa.gov/oswer/riskassessment/ragsa/pdf/ci_ra.pdf).

- *Community Involvement Guidance and Publications.* Guidance and publications for EPA's Superfund program (http://www.epa.gov/superfund/community/involvement.htm).