

## **PART II**

# **HUMAN HEALTH RISK ASSESSMENT: INHALATION**



# Chapter 5 Getting Started: Planning and Scoping the Inhalation Risk Assessment

## Table of Contents

5.1	Introduction .....	<a href="#">1</a>
5.2	Framework and Process for Air Toxics Risk Assessments .....	<a href="#">1</a>
5.2.1	Framework for Cumulative Risk Assessment .....	<a href="#">1</a>
5.2.2	General Framework for Residual Risk Assessment .....	<a href="#">3</a>
5.2.3	The Air Toxics Risk Assessment Process .....	<a href="#">3</a>
5.2.4	Overview of Inhalation Exposure Assessment .....	<a href="#">6</a>
5.2.4.1	Exposure and Exposure Assessment: What's the Difference? .....	<a href="#">6</a>
5.2.4.2	Components of an Exposure Assessment .....	<a href="#">7</a>
5.3	Planning and Scoping .....	<a href="#">8</a>
5.3.1	Why is Planning and Scoping Important? .....	<a href="#">9</a>
5.3.2	The Planning and Scoping Process .....	<a href="#">9</a>
5.3.2.1	What is the Concern? .....	<a href="#">9</a>
5.3.2.2	Who Needs to be Involved? .....	<a href="#">10</a>
5.3.2.3	What is the Scope? .....	<a href="#">12</a>
5.3.2.4	Why is There a Problem? .....	<a href="#">13</a>
5.3.2.5	How will Risk Managers Evaluate the Concern? .....	<a href="#">13</a>
5.3.2.6	Lessons Learned on Planning and Scoping .....	<a href="#">13</a>
	References .....	<a href="#">15</a>



## 5.1 Introduction

The background discussion in Part I of this manual introduced the general air toxics risk assessment process (see Exhibit 3-4). Part II describes the tools and approaches risk assessors use to evaluate human health risks associated with inhalation exposures to air toxics. Section 5.2 below describes the framework used for air toxics risk assessment, including its three phases: (1) planning, scoping, and problem formulation; (2) analysis (which includes exposure assessment and toxicity assessment); and (3) risk characterization. Part II includes nine chapters that describe these three phases in detail.

- The remainder of the current chapter describes planning and scoping (Section 5.3).
- Chapter 6 describes problem formulation.
- Because exposure assessment is generally the most labor and financially-intensive step in the analysis phase, and because it involves a variety of related (but heterogeneous activities), the discussion of exposure assessment includes five chapters:
  - Chapter 7 describes how to characterize sources and quantify emissions;
  - Chapter 8 explores the fate and transport of air toxics in the atmosphere;
  - Chapter 9 discusses air quality modeling;
  - Chapter 10 discusses monitoring; and
  - Chapter 11 discusses quantifying exposure, including exposure modeling.
- Chapter 12 describes the remainder of the analysis phase, toxicity assessment.
- Chapter 13 describes the risk characterization phase for inhalation assessments.

## 5.2 Framework and Process for Air Toxics Risk Assessments

The original risk assessment framework developed in 1983 by the NRC (see Chapter 3) has been refined based on the risk assessment experience gained by EPA and other agencies. Two descriptions of this refined framework are particularly useful for air toxics risk assessments: EPA's framework for cumulative risk assessment, and EPA's general framework for assessing residual risks.

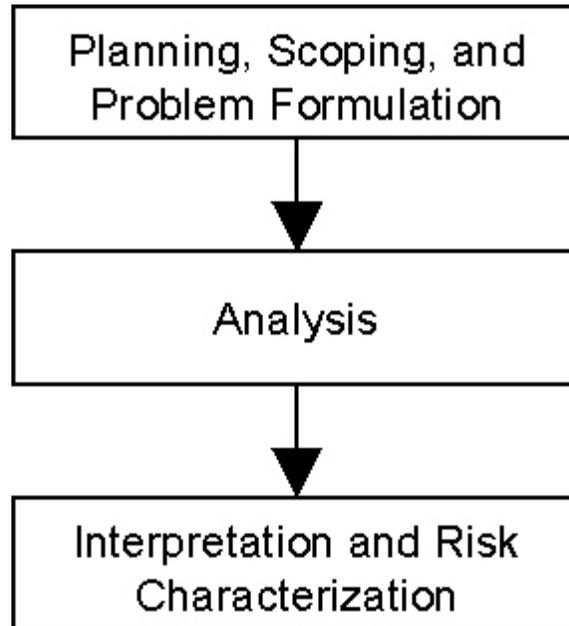
### Cumulative Risk Assessment

An analysis, characterization, and possible quantification of the combined risks to health or the environment from simultaneous exposure to multiple agents or stressors.

### 5.2.1 Framework for Cumulative Risk Assessment

EPA's *Framework for Cumulative Risk Assessment*<sup>(1)</sup> describes three main phases to a risk assessment: (1) planning, scoping, and problem formulation; (2) analysis; and (3) risk characterization (Exhibit 5-1).

**Exhibit 5-1. Three-Phase Framework for Cumulative Risk Assessment**



Source: EPA *Framework for Cumulative Risk Assessment*<sup>(1)</sup>

- In the **planning, scoping, and problem formulation phase**, a team of risk managers, risk assessors, and other stakeholders identify the problem to be assessed and establish the goals, breadth, depth, and focus of the assessment. The end products of this phase are a conceptual model and an analysis plan. The conceptual model establishes the air toxics, exposure pathways, and health and ecological effects to be evaluated. The analysis plan lays out how the elements of the conceptual model are going to be studied.
- The **analysis phase** (the elements of which are described by the analysis plan) is primarily an analytic process in which risk experts apply risk assessment approaches to evaluate the problem at hand. Specifically, the analysis plan specifies how data, modeling, or assumptions will be obtained, performed, or defined for all aspects of the exposure evaluation. Additionally, the analysis plan specifies the strategy for obtaining and considering hazard and dose-response information for these stressors and the method for combining the exposure information with the hazard and dose-response information to generate risk estimates. As the risk analysis is refined, it may be appropriate to revisit and refine the exposure, hazard, and dose-response information in an iterative fashion.
- The **risk characterization** phase integrates and interprets the results of the analysis phase and addresses the problem(s) formulated in the planning, scoping, and problem formulation phase. It describes the qualitative and/or quantitative risk assessment results and lists the important assumptions, limitations, and uncertainties associated with those results; and discusses the ultimate use of the analytic-deliberative outcomes.

## 5.2.2 General Framework for Residual Risk Assessment

EPA's *Residual Risk Report to Congress*<sup>(2)</sup> outlines a general framework for assessing residual risks to implement the requirements of CAA sections 112(f)(2) through (6). Those sections require EPA to promulgate standards beyond MACT when necessary to provide "an ample margin of safety to protect public health" and to "prevent, considering costs, energy, safety, and other relevant factors, an adverse environmental effect." EPA developed the general framework using knowledge gained from past risk assessments and guidance gained from reports such as the NRC and CRARM reports (see Chapter 3). The framework calls for an iterative, tiered assessments of the risks to humans and ecological receptors through inhalation and, where appropriate, non-inhalation exposures to HAPs.

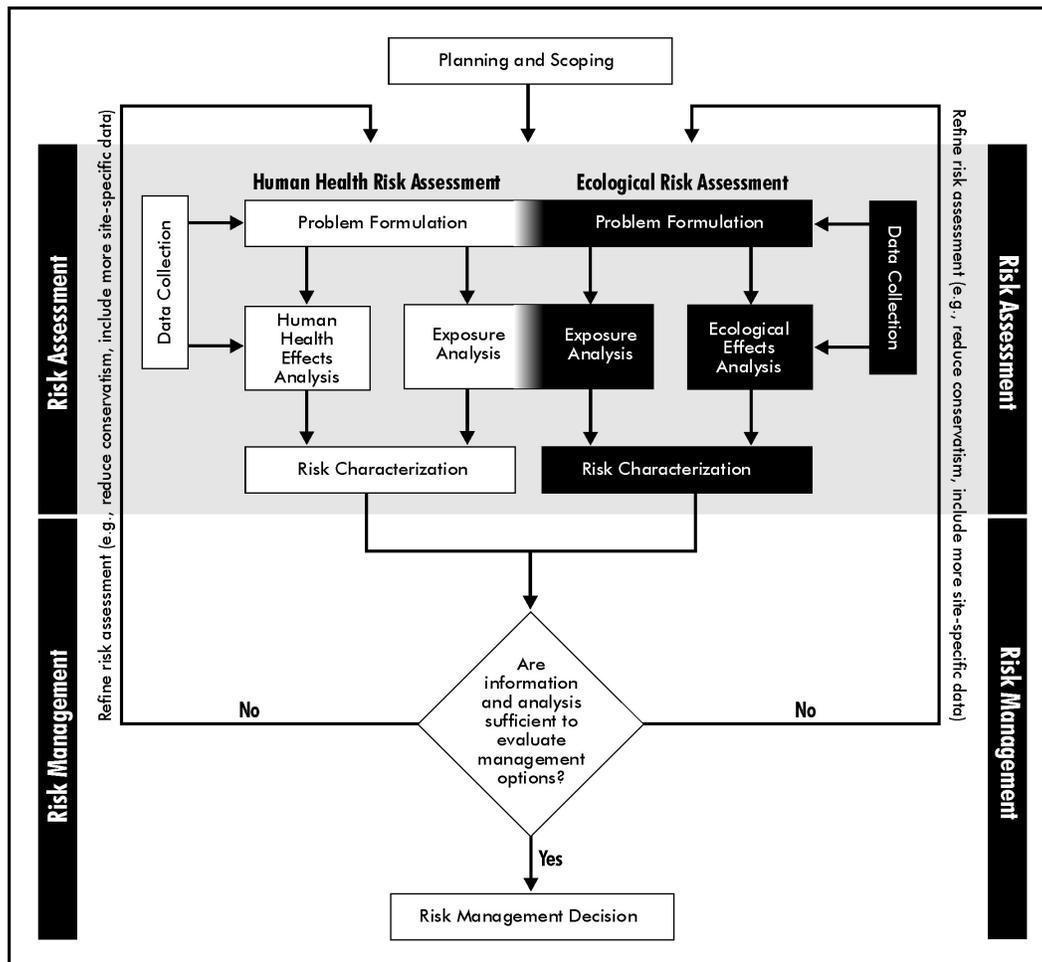
As shown in Exhibit 5-2, each human health and ecological risk assessment is organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified (this phase also includes planning and scoping activities); (2) the analysis phase, in which the toxicity of HAPs and exposures to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to determine the level of risk that may exist. The problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that some pathway of concern for humans (e.g., consumption of contaminated fish) may also be pathways of concern for ecological receptors (e.g., fish-eating wildlife). Consequently, exposure analyses for some air toxics may be designed to provide information for both ecological and human health assessments.

In both human health and ecological risk assessments, there is essentially a continuum of possible levels of analysis from the most basic screening approach to a highly refined, detailed assessment. The screening level or tier of analysis is designed, through the use of simplifying assumptions and conservative inputs, to identify for no further action or analysis, exposure pathways and air toxics for which risks are unlikely to be of concern. Screening tier analyses are designed to be relatively simple, inexpensive, and quick, using existing data, defined decision criteria, and models with simplifying conservative assumptions as inputs. More refined levels of analysis include the refinement of aspects of the analysis that are thought to influence risk most or may contain the greatest uncertainty. They may also allow a more quantitative analysis of uncertainty and variability. Refined analysis requires more effort, but produces results that are hopefully less uncertain and less conservative (i.e., less likely to overestimate risk).

## 5.2.3 The Air Toxics Risk Assessment Process

Building on the Cumulative and Residual Risk frameworks discussed above, the human health portions of this reference manual describe the risk assessment process for air toxics in three general phases (Exhibit 5-3; the process for ecological risk assessment is provided in Part IV). [Note that Exhibit 5-3 is consistent with both the Cumulative and Residual Risk frameworks discussed above. The benefit of Exhibit 5-3 is that it helps to better visualize the *detailed elements* that are usually performed in an air toxics risk assessment.]

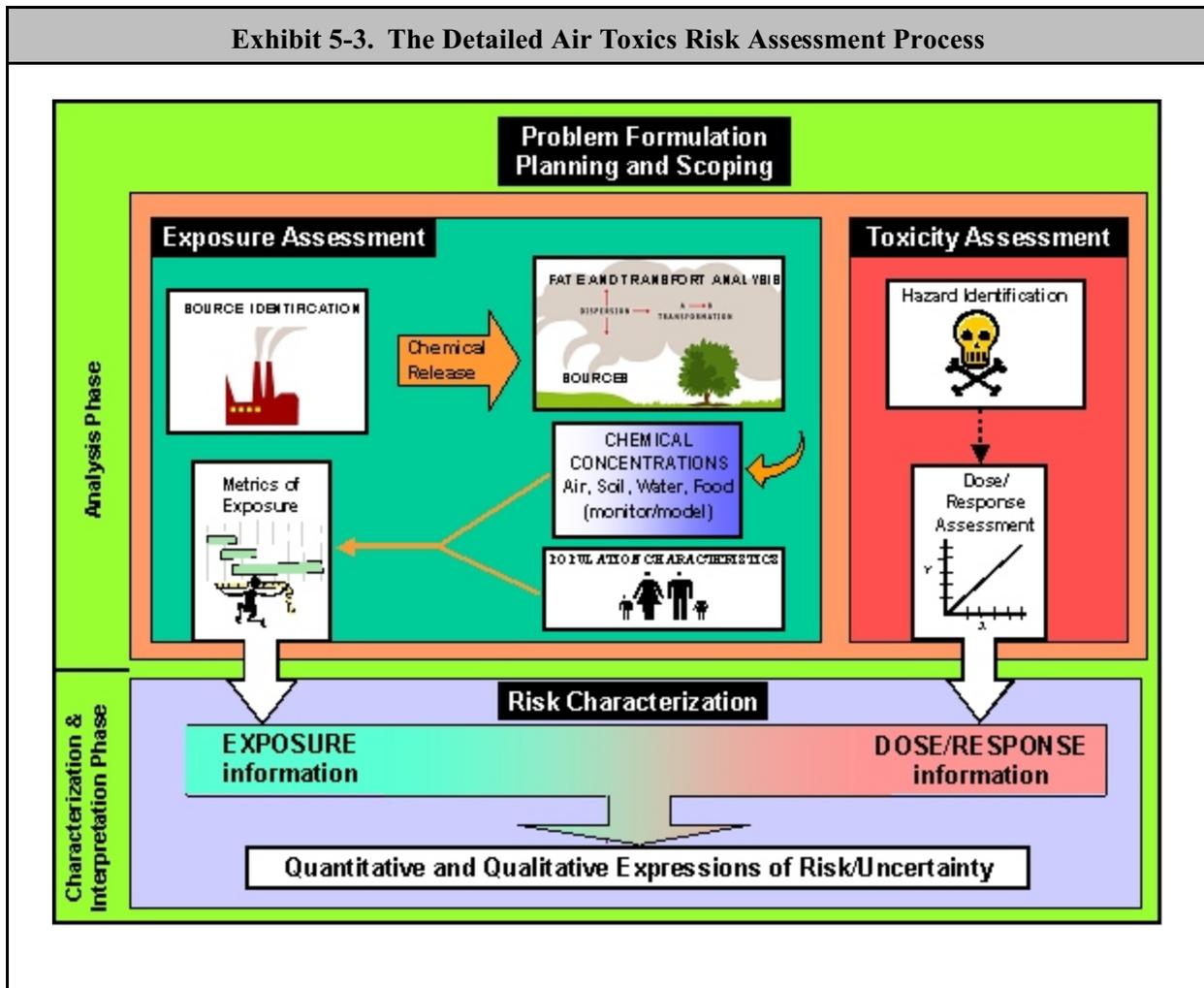
## Exhibit 5-2. General Framework for Residual Risk Assessment



Source: Modified from EPA's *Residual Risk Report to Congress*<sup>(2)</sup>

- The **planning, scoping, and problem formulation** phase is divided into two general steps: planning and scoping, and problem formulation. These two steps consist of the activities described above in the cumulative risk assessment framework. The end products of this phase are a conceptual model and an analysis plan. As shown in the Exhibit 5-3, planning, scoping, and problem formulation encompass the entire risk assessment process because stakeholders aim to understand and state the problem they want to study using the risk assessment process and plan how they are going to study the problem *before* the risk assessment is performed. They also must recognize that they may need to refine the problem statement and study methodology as new information is gained during the assessment.

Exhibit 5-3. The Detailed Air Toxics Risk Assessment Process



- The **analysis** phase is divided into two general steps: **exposure assessment** and **toxicity assessment** (the general process for ecological risk assessments is described in Part IV). Exposure assessment is a relatively complex process involving source identification; development of an emissions inventory; fate and transport analysis (through modeling and/or monitoring) to estimate chemical concentrations in air (and soil, food, and water for multimedia assessments); and combining information on chemical concentrations with population characteristics to obtain one or more metric(s) of exposure. Toxicity assessment includes hazard identification and dose-response assessment.
- The **risk characterization** phase integrates the information from the exposure assessment and the toxicity assessment to provide both quantitative and qualitative expressions of risk. The risk characterization also includes a thorough discussion of uncertainty associated with each of the major elements of the risk assessment.

The remainder of Parts I, II, and III of this Volume will rely on the general approach outlined in Exhibit 5-3 as a roadmap for describing the air toxics risk assessment process.

### **Risk Assessment: Is it a Linear Process?**

It may be useful to think of the risk assessment process as a set of steps that proceed in a linear fashion. But it does not always work out that way. For example, through good planning, scoping, and problem formulation (e.g., a thorough identification of sources and chemicals while developing the conceptual model), much of the preliminary exposure assessment work may be accomplished. A prior basic knowledge and discussion of toxic and chemical/physical properties of the chemicals of potential concern (COPCs) (information often developed during the toxicity and exposure assessments, respectively) may help the risk assessment team rule out certain pathways for consideration during the planning, scoping, and problem formulation phase. Of course, a good analysis plan will include mechanisms to confirm and document all these decisions, but the fact still remains that the risk assessment process is actually a combination of a variety of steps, many of which may occur simultaneously.

## **5.2.4 Overview of Inhalation Exposure Assessment**

Because exposure assessment is generally the most multifaceted and time-consuming part of an air toxics risk assessment, it cannot be discussed in a single chapter. This subsection provides an overview of exposure assessment and identifies where each step of the process is described in more detail in subsequent chapters (i.e., Chapters 6 through 11). EPA's *Guidelines for Exposure Assessment*<sup>(3)</sup> is the key reference document for the exposure assessment portion of the risk assessment, and air toxics risk assessors may want to obtain and become familiar with its contents.

Exposure assessment helps identify and evaluate a population receiving exposure to a toxic agent, and describe its composition and size, as well as the type, magnitude, frequency, route and duration of exposure. In other words, an exposure assessment is that part of the risk assessment that identifies:

- Who is potentially exposed to toxic chemicals;
- What toxics they may be exposed to; and
- How they may be exposed to those chemicals (amount, pattern, and route).

### **5.2.4.1 Exposure and Exposure Assessment: What's the Difference?**

Exposure assessment is the overall process of evaluating who receives exposure to toxic chemicals, what those chemicals are, and how the exposure occurs. Exposure, on the other hand, (according to EPA definition<sup>(1)</sup>) represents contact with a chemical at the visible external boundary of a person, including skin and openings into the body such as mouth, punctures in the skin, and nostrils. This definition of exposure does not describe the contact of a chemical with the actual exchange boundaries in the body where absorption into the bloodstream can take place, such as the linings of the lung or digestive tract. (One exception to this is chemical contact with skin or punctures in the skin; in this case, the location of the exposure and the exchange boundary are one in the same.) Other than dermal exposure, chemicals must be physically taken into the body by ingestion or inhalation (a process called **intake**) before they can contact an exchange boundary and be taken into the bloodstream (a process called **uptake**).

The term **route of exposure** is used to describe the different ways a chemical enters the body. The three main routes of exposure are **inhalation**, **ingestion**, and absorbing a chemical through the skin (**dermal**). For inhalation risk assessments, we are only concerned with the inhalation route of exposure. The dermal and ingestion routes of exposure are generally only relevant to chemicals that persist and which also may bioaccumulate (e.g., the persistent, bioaccumulative HAP (PB-HAP) compounds). Discussion of these routes of exposure is reserved for Part III.

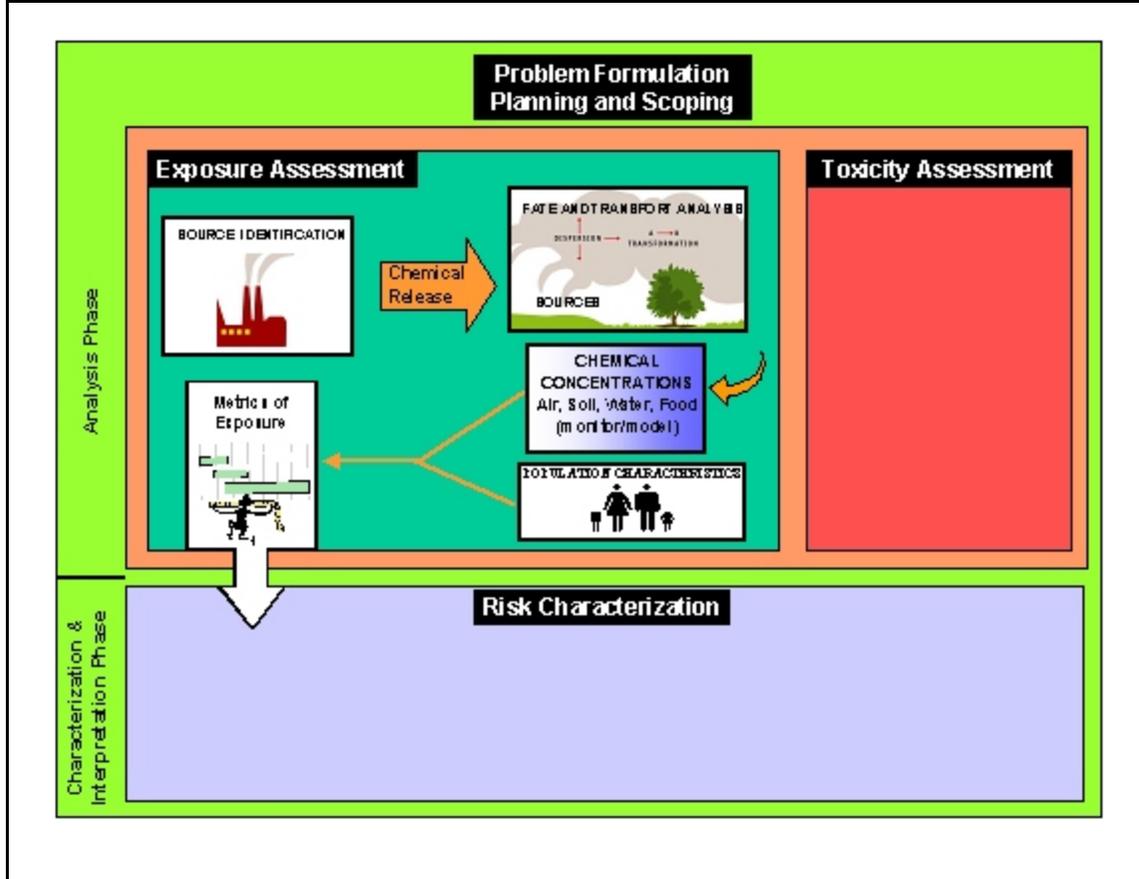
Some chemicals can cause harm in the part of the body where individuals take them in (e.g., in the respiratory system for inhaled chemicals or in the digestive tract for ingested chemicals). This is called a **portal of entry effect** because the adverse effect occurs at the place (i.e., the “portal”) where the chemical enters the body. Other chemicals have to be taken into and distributed by the circulatory system to cause a harmful effect at a point distant from their portal of entry into the body. Such effects are called **systemic effects** because they have the potential to act at points throughout the system. As a chemical moves through the body, it may be metabolized (possibly to a more toxic entity); stored in the body; and/or eliminated in urine, feces, sweat, nails/hair, or exhaled breath.

#### **5.2.4.2 Components of an Exposure Assessment**

The nature and complexity of the components within the exposure assessment are often functions of the particular risk management question (or other purpose) to be addressed. Simple screening analyses that rely on conservative default assumptions may be sufficient to rule out the need for further analyses or action. On the other hand, a more detailed exposure analysis may be needed to determine the necessity for emission controls, particularly when the application of those controls is associated with large economic consequences. Indeed, the exposure assessment raises and addresses many of the risk assessment’s difficult and critical policy questions. As illustrated in Exhibit 5-4, the exposure assessment includes the following steps:

- **Characterization of the exposure setting**, including the physical environment, scale of the study area, important sources and chemicals, and potentially exposed populations and population characteristics (e.g., demographics). Most of this information is collected and organized during the problem formulation portion of the risk assessment (see Chapter 6).
- **Identification of exposure pathways**, including sources and mechanism of release, exposure points and routes of exposure, and transport media. Again, most of this information is collected and organized during problem formulation (see Chapter 6).

Exhibit 5-4. Exposure Assessment is the Most Time-Consuming Part of Risk Assessment



- **Quantification of exposure**, including an **evaluation of uncertainty** and **preparation of documentation**. Quantification of exposure includes three general steps which are discussed in several subsequent chapters.
  - Characterization of emissions is discussed in Chapter 7.
  - Evaluation of chemical fate and transport is discussed in three chapters. Chapter 8 discusses dispersal, transport, and fate of air toxics in the atmosphere. Chapter 9 discusses air quality modeling. Chapter 10 discusses air toxics monitoring.
  - Estimation of exposure concentrations (EC) is discussed in Chapter 11, along with exposure modeling, evaluation of uncertainty, and preparation of documentation.

### 5.3 Planning and Scoping

Planning and scoping is the first step in an air toxics risk assessment (good planning and scoping is important for any scientific study). It is both a *deliberate* and *deliberative* process that identifies the problems to be assessed; identifies stakeholders in the risk assessment process; establishes the bounds (i.e., the scope) of the analysis, including elements to be included or excluded from the analysis; develops a description of the potential interrelationship between air pollutants and receptors; and articulates the overall analysis plan for the assessment. This section provides an overview of how to plan for and scope an air toxics risk assessment. The discussion focuses on four key elements of planning and scoping:

- Why is planning and scoping important?
- What is the process?
- Who should be involved?
- What are the key products?

More detailed discussions of the planning and scoping process can be found in the EPA guidance documents *Guidance on Cumulative Risk Assessment*<sup>(4)</sup>, *Framework for Cumulative Risk Assessment*<sup>(5)</sup>, and *Risk Assessment Guidance for Superfund (RAGS): Volume I*<sup>(6)</sup> (Chapter 2 of this RAGS document discusses the role of the risk assessor in planning and scoping).

### **5.3.1 Why is Planning and Scoping Important?**

Planning and scoping may be the most important step in the risk assessment process. Without adequate planning, most risk assessments will not succeed in providing the type of information that risk management needs to make a well-founded decision. Thorough planning and scoping is commonly conducted *before* any substantive work is done on the risk assessment. Planning and scoping is important for developing a common understanding of why the risk assessment is being conducted, the scope of the assessment, the quantity and quality of data needed to answer the assessment questions, and how risk managers will use the results. This step is also a focal point for stakeholder involvement in the risk assessment process. The specific goals of planning and scoping include:

- The approaches, including a review of the risk dimensions and technical elements that may be evaluated in the assessment;
- The relationships among potential assessment end points and risk management options;
- An analysis plan and a conceptual model (articulated in the problem formulation phase - see Chapter 6);
- The resources (for example, data or models) required or available;
- The identity of those involved and their roles (for example, technical, legal, or stakeholder advisors); and
- The schedule to be followed (including provision for timely and adequate internal, and independent, external peer review).

### **5.3.2 The Planning and Scoping Process**

The five essential steps in the planning and scoping process include (1) identifying the concern; (2) identifying who needs to be involved; (3) determining the scope of the risk assessment; (4) describing why there may be a problem (i.e., describing the presumed interrelationship among sources of risk, humans receiving the exposure, and potential health effects); and (5) determining how risk managers will evaluate the concern. Each is described in a separate subsection below.

#### **5.3.2.1 What is the Concern?**

Most risk assessments are conducted because of a regulatory requirement, a community need or concern, or some other reason. The specific concerns and the resources available to address those concerns will largely shape the risk assessment scope and methods. For example, a simple, screening-level risk assessment may be adequate to support a typical pollution permitting process

while a detailed analysis may be necessary to respond to a particular community concern (e.g., are children in a nearby school exposed to harmful levels of air toxics from all sources in the community?).

At the end of this first step, risk assessors usually identify the full breadth of the concerns of the participating stakeholders and clearly articulate which of those concerns will be the focus of the risk assessment and why. For example, in a community-level multisource analysis, some community stakeholders may be concerned about nuisance odor while others are concerned about potential cancer health risks from airborne pollutants. At the end of this step, all stakeholders should be clear that the risk assessment cannot address the odor issue but, rather, will focus on the cancer concern. This is also the time to identify other resources or means for attempting to address the non-risk related odor issue.

Stakeholders often identify a wide range of concerns in the risk assessment process that risk assessment methods may be unable to address. It is always important to acknowledge the legitimacy of stakeholder concerns and to work to clarify the limitations of the risk assessment process – especially when assessors are working to respond to community concerns. At the same time, risk assessors often assist in identifying the proper path for responding to non-risk related issues. Proceeding in this manner will help create an attitude of trust, foster buy-in of the risk assessment process and results, and avoid creating false expectations.

#### **5.3.2.2 Who Needs to be Involved?**

The key participants in the planning and scoping process include, at minimum, the risk managers who will use the results of the risk assessment and the risk assessment technical team who will perform the analysis.

- **Risk managers** are the persons or groups with the authority to make the decisions about the acceptability of risk and how an unacceptable risk may be mitigated, avoided, or reduced. For regulatory requirements (e.g., permitting, compliance), the risk manager usually is a government agency such as EPA or a S/L/T authority. For voluntary efforts, the risk manager(s) generally will include members of the potentially affected or interested parties (e.g., industry representatives, community leaders, local government).
- The **risk assessment technical team** includes those experts who will perform the activities involved in the risk assessment, including environmental scientists, modelers, chemists, toxicologists, ecologists, and engineers.

These individuals need to understand the goals of the risk assessment, how the results will be used, the amount and quality of information necessary to make key decisions, and the uncertainties associated with the inputs, risk assessment methods, and resulting risk estimates.

The specific concerns from step one may generate the need for a diverse set of individuals or groups with an interest in having the assessment done (“interested or affected parties”).<sup>(7)</sup> Each group may have a unique set of questions, concerns, and fears. It is important to design the risk assessment to address as many of these issues as possible within available time and resources. Planning and scoping begins with a dialogue among these individuals and groups; consequently, the initial planning and scoping team may need to expand over time to include additional

participants, including public officials, citizens, and industry representatives. In many cases, technical experts who live in the affected communities can be effective participants because they have both the trust of the local community and the technical skills to explain complex issues. A strong community involvement effort early in the process can help identify these concerns (see Part V of this Volume).

#### Examples of Possible Interested or Affected Parties

State governments	Affected industry
Tribal governments	Civic organizations
Local governments	Business owners
Community groups	Trade associations
Grassroots organizations	Labor unions
Environmental groups	Public health groups
Consumer rights groups	Academic institutions
Religious groups	Impacted citizens
Civil rights groups	Other federal agencies

One tool helpful in translating general goals into specific metrics is an objectives hierarchy, which is a hierarchic list starting with the overall goal of a project and moving down in levels to (component) purposes or outcomes, outputs and specific activities (see <http://www.iac.wur.nl/ppme/content.php?ID=353&IDsub=338>). A discussion of this is found in EPA's *Planning for Ecological Risk Assessment: Developing Management Objectives* (Section 3.4.2) at [http://www.epa.gov/NCEA/raf/pdfs/eco\\_objectives-sab\\_6-01.pdf](http://www.epa.gov/NCEA/raf/pdfs/eco_objectives-sab_6-01.pdf).

It is beneficial if planning and scoping participants understand the following six questions *before* the risk assessment begins:

- **What is the goal of the risk assessment and how will the results be used?** A risk assessment might be conducted to compare the costs of various emissions control options versus the benefits in terms of reduced risks. Some conduct risk assessments primarily for informational purposes – for example, how much do individual pollution sources contribute to total risks within a given community? Risk management goals may be risk-related (e.g., reducing risks from exposure to air toxics; reducing the incidence of a specific adverse effect such as cancer); economic (e.g., reducing risks without causing job loss or raising taxes); or related to public policy (e.g., protecting children and other sensitive populations). Generally, each risk assessment is designed to provide information that will support the identified goals.
- **What information will the risk assessors collect and what analyses will they perform on those data?** The risk assessors develop the scope of the risk assessment during planning and scoping. For example, participants may select a limited number of chemicals from all those released in an area to be analyzed throughout the risk assessment process (the chemicals of potential concern or COPC), or the assessment may focus on only a limited number of exposure pathways that may be most important. Stakeholders should understand exactly what the risk assessment is (and by extension, what it is not) going to evaluate.
- **What are the major concerns of the local community?** Significant concerns that the risk assessment does not address can result in “show stoppers” that complicate or delay the risk management decision. Clarifying what the risk assessment is not going to study, and why, before the assessment begins will help to reduce this possibility. As an example, many communities express concerns about perceived disease clusters. All stakeholders need to understand that the risk assessment process is not used to evaluate disease clusters or establish cause-effect relationships between air pollution and existing cases of disease. However, stakeholders often raise this concern, and it is imperative that the planning and

scoping team acknowledge these concerns and direct them to the appropriate resources. Given the prevalence of this concern in areas with air toxics concerns, this Volume includes a lengthy discussion in Part VI of this Volume on options for addressing such issues.

- **What are the roles and responsibilities of each participant?** Stakeholders often address many administrative issues during planning and scoping, including who will lead the risk assessment, who will perform each of the various tasks, who will pay for it, and when the participants need the results.
- **What are the available resources and schedules?** Time and money are always limited; therefore, the planning and scoping process will almost certainly involve trade-offs between the amount and quality of information participants desire and the time and monetary resources available to obtain and analyze the information. Participants often choose to determine critical milestones and institute a clear, yet reasonably flexible, schedule to keep the assessment on track.
- **What documentation and other products are required?** Regulatory requirements often include specific types of information in specific formats. In a community-level analysis, stakeholders may want specific information such as maps indicating estimated levels of air pollutants in different parts of the community. Thus, documentation requirements are meant to provide transparency throughout the risk assessment process, from the initiation of the planning and scoping step to the presentation of the final product. Participants are urged to document all important decisions, goals, discussions, schedules, resource allocations, roles and responsibilities, data quality objectives. Participants also may document the analytical approach such that anyone may follow the methodology of the risk assessment.

Finally, risk assessors, risk managers, and all other stakeholders generally recognize the sensitivity of their roles throughout the risk assessment process. Specifically, there must be no direct or indirect actions on the part of any stakeholder to influence the outcome of the science-based analysis. Even the appearance of such activity can severely undermine trust in the risk assessment as a valid analysis tool.

### **5.3.2.3 What is the Scope?**

The risk assessment scope helps determine how comprehensive the analysis will be. The scope of a risk assessment may be narrow or broad, depending on the specific risk management goals. For example, a relatively broad goal such as “reducing risks from exposure to air toxics” may require a relatively broad risk assessment that examine many types of sources (e.g., stationary, mobile) and dozens of specific air toxics. In contrast, a more narrow goal such as “reducing the potential cancer risk in the community” may result in a risk assessment that focuses more narrowly on only those air toxics that contribute to cancer. Geography (e.g., political boundaries), demographics (e.g., focusing on a subset of exposed populations), legal requirements (e.g., statutes or regulations), or methodological or data limitations can all narrow the scope. Most importantly, time and money will almost always limit the scope of the risk assessment.

Participants can determine scope by listing and answering critical **assessment questions** such as:

- What specific sources are to be included?
- What specific air toxics are to be included?
- What are the physical boundaries of the study area?
- What are the temporal constraints of the study?
- What potential exposure pathways will be evaluated?
- What potentially exposed populations will be assessed?
- What types of health risks will be evaluated?

The details of scope (e.g., what sources are to be included, what potential pathways will be included) are developed during the problem formulation stage (see Chapter 6).

The goal of the scoping process is to produce a clear understanding of what the risk assessment should and should not include and why. For example, if available data or methods make it impossible to assess a potential exposure pathway, the planning and scoping team may need to re-evaluate the goals and expectations of the risk assessment process.

#### **5.3.2.4 Why is There a Problem?**

The **problem statement** often summarizes the end result of the scoping process, describing the specific concerns that the risk assessment will address. Problem statements often also include statements about how the risk assessors will evaluate these concerns. The problem statement is commonly as specific as possible and may also include explicit statements of what will not be assessed in the risk assessment.

#### **Example Problem Statement**

Air toxics emissions may be causing increased long-term inhalation health risk (both cancer and noncancer concerns) to people in the immediate vicinity of Acme Refining Company. A modeling risk assessment will be performed to evaluate potential long-term human health impacts of inhalation exposures to all air toxics emitted by the facility. Inhalation risks for populations within 50 km of the Acme property boundary will be assessed under residential exposure conditions. Non-inhalation pathways will not be assessed for either human or ecological receptors.

#### **5.3.2.5 How will Risk Managers Evaluate the Concern?**

The risk assessments are most often designed to provide input to risk managers to help inform the decisions they must make. Part of the planning and scoping process is developing an understanding of the types of information needed by the risk managers and the level of uncertainty in that information that can be tolerated. It does not make sense to conduct an expensive risk assessment if the eventual results will not be helpful to decision makers.

#### **5.3.2.6 Lessons Learned on Planning and Scoping**

EPA's Science Policy Council has evaluated the planning and scoping process, particularly as it relates to cumulative risk assessments (<http://www.epa.gov/osp/spc/2cumrisk.htm>). From an assessment of five case studies, a working group identified the following lessons learned.<sup>(8)</sup>

- Early and extensive involvement of the risk manager (decision maker) helped focus the process toward a tangible product.
- Purporting that planning and scoping will be quick and easy is likely to be counterproductive; it is a lot more work than people assume. However, it ultimately saves time by helping to organize everyone's thinking and usually results in a better quality assessment.
- Stakeholder engagement is essential at the beginning, because their patience is directly proportional to their sense of influence in the process. They have been helpful in identifying important public health endpoints that were not initially considered by EPA in the process of developing a conceptual model.
- Conceptual models are helpful in demonstrating how one program relates to other regulatory activities as well as the relationship between stressors and effects beyond traditional regulatory paradigms.
- Debate over terminology and brainstorming sessions are necessary to reach a consensus. A clear set of definitions aids this process.
- The planning and scoping process cannot be prescriptive, because the context of each situation is different. Planning and scoping is particularly valuable when the assessment will be complex, controversial, or precedential. At this time, planning and scoping usually precede cumulative risk assessments.
- Clear objectives, resource commitments, and estimated schedules from management will drive the approach and level of detail that can be considered.
- Explaining uncertainty to stakeholders is critical despite a hesitancy to reveal all that is known and not known about chemical risks. While revealing these uncertainties may lead to criticism and political ramifications, it can also develop a sense of trust, credibility, and support for the decision making process.

It should also be noted that the entire planning and scoping (and risk assessment process) is inherently iterative in nature. As the analysis proceeds and participants learn more about the study area, participants may find the initial assumptions in the conceptual model inadequate and they will need to modify the conceptual model (and, thus, the analysis plan). For example, suppose a conceptual model was developed that assumed a chemical was released from a facility that is generally thought to deposit quickly from the air, is highly persistent, and has a large bioaccumulation potential, thus requiring a multipathway analysis. Once the emissions inventory is verified, it is found that this chemical is actually not used or produced by facility, rendering the multipathway analysis moot for this chemical. (Multipathway analysis may still be needed for other chemicals in the emissions.)

When such changes are required in the conceptual model and analysis plan, all key stakeholders may be apprised of the change and ideally agree to any alterations in the goals of the overall assessment. The initial goal of "no surprises at the end of the assessment" is still maintained in light of evolving information.

## References

1. U.S. Environmental Protection Agency. 2003. *Framework for Cumulative Risk Assessment*. Risk Assessment Forum, Washington, DC 20460, May 2003, EPA/630/P02/001F. Available at <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=54944>.
2. U.S. Environmental Protection Agency. 1999. *Residual Risk Report to Congress*. Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711, March 1999, EPA/453/R99/001. Available at [http://www.epa.gov/ttncaaa1/t3/reports/risk\\_rep.pdf](http://www.epa.gov/ttncaaa1/t3/reports/risk_rep.pdf).
3. U.S. Environmental Protection Agency. 1992. *Guidelines for Exposure Assessment*. *Federal Register* 57:22888-22938, May 29, 1992. Available at <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=15263>.
4. U.S. Environmental Protection Agency. 1997. *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* Science Policy Council, Washington, D.C. Available at: <http://www.epa.gov/osp/spc/cumrisk2.htm>.
5. U.S. Environmental Protection Agency. 2003. *Framework for Cumulative Risk Assessment*. Risk Assessment Forum, Washington, D.C. 2003. EPA/630/P02/001F. Available at: <http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=54944>.
6. U.S. Environmental Protection Agency. 2001. *Risk Assessment Guidance for Superfund (RAGS): Volume I - Human Health Evaluation Manual (Part D, Standardized Planning, Reporting and Review of Superfund Risk Assessments) Final*. Office of Emergency and Remedial Response, Washington, D.C. Available at: <http://www.epa.gov/superfund/programs/risk/ragsd/index.htm>.
7. U.S. Environmental Protection Agency. 1999. *Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual. Supplement to Part A, Community Involvement in Superfund Risk Assessments*. Office of Solid Waste and Emergency Response, Washington, D.C. EPA/540/R98/042/PB99/963303.
8. U.S. Environmental Protection Agency. 2002. *Lessons Learned on Planning and Scoping for Environmental Risk Assessments*. Science Policy Council, Washington, D.C. Available at: <http://www.epa.gov/osp/spc/handbook.pdf>.