PART I

BACKGROUND

Chapter 1 Introduction

Table of Contents

1.1 Introduction 1

1.2 The Special Concerns of Urban Areas 2

1.3 Promoting Localized Assessment 4

1.4 The Risk-Based Approach 4

1.5 The Purpose of this Reference Manual 5

1.6 The Layout of this Reference Manual 6

1.7 The Relationship of this Manual to Volumes 2 and 3 9

References 10

1.1 Introduction

The mission of the United States Environmental Protection Agency (EPA) is to protect human health and to safeguard the natural environment – air, water, and land – upon which life depends.[1] Following this mission, the Agency has implemented a variety of laws and programs that require and encourage the safe use and management of toxic chemicals. Many of these programs focus on understanding the consequences of releasing chemicals to the air, land, and water and working to reduce those releases when they pose too great a risk (see Glossary for definition of risk in this Reference Library). This manual describes the programs and technical tools that EPA uses to evaluate and address chemicals that are released to the air from many different types of sources, and which have the potential to harm people and the environment.

The potential impacts of chemicals released to the air depend on a number of factors, including the quantity of chemicals in the air, how the chemicals move and transform in the environment, the length of time people or the environment is exposed, and the toxic nature of the chemicals. The human health effects of exposure to air pollutants can range from no response, responses that are relatively minor and reversible (such as mild eye irritation), responses that are more serious and debilitating (such as aggravation of asthma) and, in some cases, fatal responses. Air pollution also can cause negative impacts on the environment, including distress and death in plants and animals, as well as damage to buildings and important cultural sites.

In the mid-20th century, Congress recognized the potential for air pollution to cause these kinds of problems and responded by enacting the Clean Air Act (CAA). Since that time, this Act, as amended, has provided the primary authority that EPA uses to develop programs for protecting people and the environment from the harmful effects of air pollution across the United States.

A key component of the current version of the CAA (most recently amended by the 1990 CAA Amendments) is the requirement that EPA significantly reduce emissions to the air of chemicals that are known or suspected to cause serious health problems, such as cancer or birth defects. As a starting point in this effort, the Act explicitly identifies 188 **hazardous air pollutants (HAPs)**[a] for regulation. This group of chemicals is also commonly referred to as the HAPs, **toxic air pollutants** or, simply, **air toxics**. (The CAA also covers another important group of chemicals, known as **criteria air pollutants**; these are discussed in Chapter 2.)

Many different types of sources can release air toxics. These sources include stationary facilities that release large quantities of HAPs to the air (known as **major sources**); stationary facilities that release smaller amounts of HAPs to the air (known as **area sources**); on-road and nonroad **mobile sources** (such as cars, trucks, and construction equipment) that release HAPs to the air; **indoor sources** of air toxics (such as paint and cleaning products); and **natural sources** of air toxics (such as volcanoes). Chapter 4 provides a detailed description of how EPA identifies and, in the case of anthropogenic (manmade) sources, regulates each of the various types of sources of air toxics.

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[a]Since the original Act, which listed 189 chemicals, one chemical (caprolactam) has been delisted, leaving 188 HAPs. EPA is also in the process of considering proposals to delist methyl ethyl ketone (MEK and ethylene glycol butyl ether (EGBE)). EPA has the authority to add and delete chemicals from the original list based on specified criteria [CAA Section 112(b)(3)].

1.2 The Special Concerns of Urban Areas

In urban areas, toxic air pollutants are of particular concern because people and sources of emissions are concentrated in the same geographic area. Since most people live in urban areas, this proximity leads to the potential for large numbers of people to be exposed to numerous air pollutants. While some of these urban chemical exposures tend to be fairly similar across the country (e.g., ambient air concentrations of benzene from petroleum use tend to be similar across the lower 48 states), studies also indicate that the concentrations of air toxics in many urban (and some nonurban) areas can vary significantly from one location to the next (e.g., concentrations in areas with petroleum refineries may be higher than in areas that do not have petroleum refineries). The sources of urban emissions tend to be relatively small in size but large in number, such as gas stations or mobile sources. In addition, these emissions are typically found at ground level where people are more likely to be exposed to them.

Urban air toxics also have a potential to elevate health risks among particular urban sub-populations, including children, the elderly, and persons with existing illnesses. In addition, the prevalence of minority and low-income communities in urban industrial and commercial areas, where concentrations of air toxics may be greatest, increases the likelihood of elevated exposures among these subpopulations.

Considering the large number of people potentially at risk from air toxics exposures, Congress directed in the 1990 CAA amendments that elevated outdoor (also called **ambient**) concentrations of air toxics in large urban areas be substantially reduced. In response to this mandate, EPA developed an **Integrated Urban Air Toxics Strategy**. This Urban Strategy, which was published in the *Federal Register* on July 19, 1999,[2] has since become EPA's **Air Toxics Strategy (The Strategy)** and is part of the overall national effort to reduce air toxics. The Strategy attempts to address all the significant stationary, mobile, and indoor sources necessary to achieve protection of public health and the environment. The specific goals of the Strategy are to:

- Attain a 75 percent reduction in incidence of cancer attributable to exposure to HAPs emitted by stationary sources;

- Attain a substantial reduction in public health risks posed by HAP emissions from area sources; and

- Address disproportionate impacts of air toxics hazards across urban areas.

The Strategy identifies four main areas of action to help achieve these goals:

- **Develop regulations addressing sources of air toxics at the national and local levels**. Pursuant to this effort, the Agency will continue its work to develop rules that require reductions in air toxics emissions from stationary facilities (such as manufacturing plants, electric power plants, gas stations, and dry cleaners), as well as from cars, trucks, and other mobile sources and their fuels. EPA has historically developed and implemented many such standards over the years, and the Strategy indicates the need for additional standards to reduce risks in urban areas.

- **Initiate local and community-based projects to address specific multi-media pollutants (e.g., mercury) and cumulative risks within urban areas**. The CAA requires EPA to "encourage and support area-wide strategies developed by the state or local air pollution control agencies" to address air toxics in urban areas. EPA is developing tools (such as this Reference Library) and is working with communities to assess and reduce risks at the community level.

  The Strategy also recognizes the need to assess the risks from exposures to indoor air toxics and to develop non-regulatory, voluntary programs to address those risks. The Strategy also points out that air pollutants may move into other environmental media such as soil and water resulting in multimedia (i.e., more than just air) concerns. EPA is engaged in a number of activities that recognize the ability of many air toxics to deposit out of the air and bioaccumulate in biota consumed by humans and ecological receptors (e.g., deposition of mercury in watersheds, with subsequent uptake by fish).

  In risk assessment, the term "receptor" generally refers to an individual person or ecological component that is potentially exposed to a stressor (air toxic). In modeling, the term sometime refers to the location where impacts are predicted.

- **Conduct air toxics assessments to identify areas of concern, prioritize efforts to reduce risks, and track progress**. The Strategy identifies a variety of national-level assessment activities that will help EPA identify urban areas of particular concern, characterize the risks that air toxics pose, and track the progress toward meeting overall air toxics program goals. EPA is implementing the National Air Toxics Assessment (NATA) to address this goal. NATA includes:
  - Expanding air toxics monitoring;
  - Improving and periodically updating emissions inventories;
  - Assessing national- and local-scale air quality by using multimedia and exposure modeling;
  - Continuing to research the exposures to, and health effects of, toxic chemicals in ambient and indoor air; and
  - Using and improving exposure and assessment tools.

  These activities will help EPA and other stakeholders[(b)] better understand air toxics risks, as well as risk reductions associated with emissions control standards and other initiatives aimed at reducing emissions. A particularly high-profile aspect of NATA has been the national-scale assessment of 1996 emissions that produced predictions of county-level estimates of air toxics concentrations and calculated risks for a subset of HAPs that EPA believes pose most of the urban area risk. For additional information this particular analysis, see EPA's *The National-Scale Air Toxics Assessment*.[(3)] The national scale assessment of 1999 emissions is currently being performed and will be released in 2004 (see Chapter 2).

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[b]This reference manual uses the term "stakeholder" broadly to include all parties with a potential interest in a given air toxics risk assessment, including regulators, the regulated community, community partners, and individual members of the public.

- **Perform education and outreach**. Given the scientific complexity inherent in air toxics issues, EPA recognizes that the success of the overall air toxics program depends on the public's understanding of the nature of air toxics risks and the activities that can help reduce those risks. To further this understanding, EPA will support education and outreach efforts at the national level and through its state, local, and tribal (S/L/T) partners (e.g., government, industry, community). This reference manual, for example, is an outgrowth of this educational/outreach effort.

For additional information on the Integrated Urban Strategy see EPA's *Air Toxics Strategy: Overview*[4].

1.3 Promoting Localized Assessment

While substantial reductions have been achieved through federal standards, EPA is evaluating the need for additional emissions controls at the national level. However, since the mix of sources and pollutants in specific geographic areas can be quite variable, one element of an effective approach for reducing any remaining unacceptable risks is to understand the cumulative impacts at the local level, target the problem areas, and tailor risk reduction strategies to the local circumstances in those areas.

To encourage reductions of air toxics emissions at the local community level, EPA Headquarters and Regional Offices are working collaboratively with S/L/T and community partners. This team effort has focused on education/information exchanges, identification and assessment of pollution prevention and control options, and promotion of voluntary measures and innovative solutions to assess and address community air pollution problems.

While EPA has the authority to issue standards to address certain air toxics risks, in many cases these risks may be more appropriately and more effectively addressed at the S/L/T level, rather than at the federal level. Specifically, S/L/T air agencies may wish to address issues that are of concern on a state-wide, area-wide, community-wide, or individual neighborhood basis, and for areas in the immediate vicinities of specific air toxics sources. Some S/L/T governments are already addressing some of these issues; others are just beginning to develop their own programs.

1.4 The Risk-Based Approach

While there are several methodologies to assess potential health impacts of air toxics on populations at the local level, the risk-based approach is perhaps the most effective.

The methodology described here, called **risk assessment,** is the process for evaluating:

- The sources of air toxics released to the environment;
- How the released chemicals move and change in the environment;
- Who may be exposed to the chemicals and at what levels;
- How exposures may occur;
- The toxic effects of the chemicals in question and how potent; and
- How likely it is that the potentially exposed people will experience harm because of the exposures.

This manual also discusses the ecological risk assessment process, which assesses the impact of air toxics on ecological receptors such as aquatic organisms and terrestrial mammals.

This kind of information can be extremely helpful to decision makers as they try to balance the competing concerns of protecting public health, fostering economic development, and evaluating issues of fairness and equity, among others. Specifically, risk assessment can provide:

- A predictive estimate of the potential health risks posed by air toxics, which may help determine the need for action;
- A basis for determining the levels of chemicals that can be released to the air without posing unacceptable risks to public health and the environment;
- A basis for comparing potential health impacts of various pollution reduction alternatives;
- A consistent process for evaluating and documenting threats to public health and the environment from toxic air pollution; and
- A basis for comparing risks from various exposure scenarios (e.g., the risk from breathing contaminated air compared to the risk from eating contaminated food).

Performing an air toxics risk assessment is often challenging. Risk assessments can be resource and time-intensive, depending on the specific questions being asked and the level of detail needed for informed decision making. Risk assessments usually require input from a number of scientists and engineers with a variety of skills (e.g., chemistry, toxicology, statistics, modeling, meteorology, monitoring). Decision makers may also need to acquire new skills in order to understand and use the risk assessment results. Finally, although they are based on science, risk assessments often rely on the best judgment of the analysts in the face of various uncertainties.

There has not been, up to this point, a unified and comprehensive reference manual on the methods and tools that are currently available to perform air toxics risk assessments *per se*. This document is EPA's attempt to fill that void.

1.5 The Purpose of this Reference Manual

The primary purpose of this reference manual (Volume 1) is to provide, in one single place, descriptions of the major methods and technical tools that are commonly used to perform air toxics risk assessments. Specifically, the manual attempts to cover all the common basic technical approaches that are used to evaluate: how people in a particular place (e.g., a city or neighborhood) may be exposed; what chemicals they may be exposed to and at what levels; how toxic those chemicals are; and how likely it is that the exposures may result in adverse health outcomes. Topics include uncertainty and variability, basic toxicology and dose-response relationships, air toxics monitoring and modeling, emissions inventory development, and risk characterization. This manual also discusses approaches for using the results of a risk assessment in the risk management decision-making process. Links to more detailed references on each subject are presented, along with EPA contacts. Additionally, EPA's Fate, Exposure, and Risk Analysis (FERA) web site (www.epa.gov/ttn/fera) provides up-to-date tools for air toxics risk assessment, including computer models, databases, and other information used by EPA and others for air pollutant human exposure modeling, multimedia modeling, and risk.

To provide readers with a broad perspective on the potential impacts of air toxics (in addition to information on the risk assessment process), this manual also includes a discussion of a

complementary process called a **public health assessment** (PHA). One of the objectives of a PHA is to evaluate whether existing cases of illness in a community may possibly have resulted from past exposures to particular toxins (based on epidemiological principles). This process is routinely carried out at Superfund sites by the Agency for Toxic Substances and Disease Registry (ATSDR) in addition to EPA's Superfund risk assessment process. PHAs often involve the use of capabilities beyond those required for risk assessment, including medical skills. S/L/T air agencies generally will not perform such assessments themselves; however, because questions about current or past illnesses and deaths in communities often arise during the risk assessment process, information about the PHA process is offered to help S/L/T air agencies and other stakeholders understand the rudiments of the process and whom to contact for more information and help.

1.6 The Layout of this Reference Manual

This reference manual is divided into six Parts, each of which are divided further into three or more chapters. Chapters are numbered consecutively. A number of Appendices provide more detailed reference materials.

- **Part I (Background)** provides a general introduction to air toxics risk assessment and is divided into four chapters.
  - Chapter 1 (this chapter) provides an introduction to the manual.
  - Chapter 2 begins with an overview of the CAA as well as major regulations, programs, and initiatives that relate to air toxics risk reduction.
  - Chapter 3 provides an overview of risk assessment and the risk-based decision making framework, including an introduction to tiered approaches to risk assessment.
  - Chapter 4 identifies the set of chemical pollutants that are the focus of this manual and describes the general categories of air toxics sources and the primary emissions inventories (which contain information on the nature and magnitude of emissions released from various sources).

- **Part II (Human Health Risk Assessment: Inhalation)** provides a discussion of the methods and tools used to evaluate risks to human health via the inhalation pathway. It is divided into nine chapters.
  - Chapter 5 provides an overview of the inhalation risk assessment process, discusses the initial planning and scoping process that needs to be completed before the risk assessment begins, and describes the **exposure assessment**, which will usually comprise the bulk of the effort for most air toxics risk assessments.
  - Chapter 6 describes the problem formulation phase which results in the development of the conceptual model and analysis plan for the risk assessment.
  - Chapter 7 describes how to develop an emissions inventory for the risk assessment.
  - Chapter 8 discusses the factors that affect the movement and, in some cases, chemical transformation of chemicals in the atmosphere following release (i.e., the fate and transport of chemicals in the atmosphere).
  - Chapter 9 provides an overview of the use of computer modeling to predict the movement, fate, and transport of air toxics in the atmosphere. It also describes the major computer models that are commonly used for this purpose.
  - Chapter 10 provides an overview of monitoring methods that are commonly used to measure ambient concentrations of air toxics in the atmosphere.

- Chapter 11 provides information for estimating exposure concentrations for inhalation analyses, including exposure modeling.
- Chapter 12 provides an overview of **toxicity assessment** for air toxics.
- Chapter 13 provides information for completing the **risk characterization**, including uncertainty analysis and how to present the results of the risk assessment.

- **Part III (Human Health Risk Assessment: Multipathway)** provides a discussion of the methods and tools used to evaluate risks to human health when air toxics that are highly persistent or bioaccumulative are present in emissions. The focus of the multipathway risk assessment is to evaluate the potential exposures associated with ingesting soil, food, and water that has become contaminated with these chemicals after deposition from the atmosphere to surfaces, such as soils and surface waters. This Part is divided into nine chapters.
  - Chapter 14 provides an overview of the multipathway risk assessment process, discusses the initial planning and scoping process that needs to be completed before the risk assessment begins, and describes the multipathway **exposure assessment**.
  - Chapter 15 describes problem formulation for the multipathway risk assessment.
  - Chapter 16 describes how to develop an emissions inventory for the multipathway risk assessment.
  - Chapter 17 discusses the factors that affect the movement and, in some cases, chemical transformation of air toxics in soil, water, sediment, and biota.
  - Chapter 18 provides an overview of the computer modeling used to predict the movement, fate, and transport of toxics in soil, water, sediment, and biota and describes the major multimedia computer models commonly used by risk assessors.
  - Chapter 19 provides an overview of monitoring methods used to measure ambient concentrations of air toxics in soil, water, sediment, and biota.
  - Chapter 20 provides a summary of the process and assumptions used to estimate chemical intake rates – the key measure of exposure used to assess ingestion risks – including exposure modeling.
  - Chapter 21 provides an overview of the toxicity assessment for air toxics that are persistent and which may also have a high potential to bioaccumulate in food chains.
  - Chapter 22 provides information on how to complete the risk characterization for the multipathway risk assessment, including uncertainty analysis and how to present the results of the risk assessment.

- **Part IV (Ecological Risk Assessment)** provides an overview of the methods and tools used to evaluate risks to ecological receptors (e.g., birds, mammals, plants, and ecological communities) due to exposure to air toxics. This Part is divided into four chapters.
  - Chapter 23 provides an overview of the ecological risk assessment process and discusses the initial planning and scoping process that needs to be completed before the risk assessment begins.
  - Chapter 24 provides information on characterizing exposure for the ecological risk assessment.
  - Chapter 25 provides information on characterizing ecological effects, including development of the stressor-response profile.
  - Chapter 26 provides information on how to complete the risk characterization for the ecological risk assessment, including the analysis of uncertainty, and how to present the results of the ecological risk assessment.

- **Part V (Risk-Based Decision Making)** discusses the process by which the information from the risk assessment can be used to inform risk management decisions and two important aspects of that process. This Part is divided into three chapters.
  - Chapter 27 provides an overview of the risk management process, including the types of decisions that may need to be made and how the risk assessment informs the decision-making process.
  - Chapter 28 provides an overview of the importance of stakeholder involvement in the risk assessment and management process and provides information for developing and implementing a stakeholder involvement plan.
  - Chapter 29 provides information for developing and implementing a risk communication strategy for helping members of the community and the media understand the risk assessment results and how they are being used in the decision-making process.

- **Part VI (Special Topics)** provides an overview of three tools or procedures that may be used as part of performing or reporting a risk assessment.
  - Chapter 30 provides an overview of the process by which public health agencies may evaluate the public health implications posed by the emissions from air toxic sources in a community. The public health assessment, if performed, is a complementary process to risk assessment.
  - Chapter 31 discusses probabilistic risk assessment, which is aimed at describing risks as a distribution (or range) of potential outcomes.
  - Chapter 32 provides an overview of the use of Geographical Information System (GIS) tools in the process of conducting risk assessments and reporting results.

- The **Glossary** defines key terms and acronyms.

- **Appendix A** provides a listing of all HAPs along with their status as a Toxics Release Inventory (TRI) chemical, a Section 112(k) high priority urban toxic, and a Mobile Source Air Toxic.

- **Appendix B** provides a guide to the agencies and organizations that oversee air toxics regulations.

- **Appendix C** provides recommended dose-response values for cancer and noncancer effects for all HAPs.

- **Appendix D** presents the decision process by which the persistent, bioaccumulative HAP compounds (PB-HAPs) were selected.

- **Appendix E** provides an overview of all CAA designated air toxics Source Categories, including the most common HAPs in emissions, typical industries, and applicable maximum achievable control technology (MACT) standards.

- **Appendix F** provides a list of all of the specific pollutants and compound groups included in the 1999 National Emissions Inventory (NEI) along with their Chemical Abstract Services (CAS) numbers.

- **Appendix G** provides an overview of meteorology as it relates to the movement of air toxics in the atmosphere. This appendix also provides information on sources of meteorological data for modeling air toxics dispersal and transport.

- **Appendix H** discusses the process of evaluating and reducing a monitoring data set (e.g., air, water, soil sample results) into a grouping of data that are useable for exposure evaluation.

- **Appendix I** provides a general overview of how a reduced monitoring data set (developed by the methods in Appendix H) may be used to estimate exposure concentrations.

- **Appendix J** provides an overview of available air toxics monitoring methods.

- **Appendix K** provides the equations for calculating the concentrations of PB-HAPs in non-air media (e.g., soil, food, water).

1.7 The Relationship of this Manual to Volumes 2 and 3

This manual is the first volume of a three-volume set. **Volume 1: Technical Resource Manual** discusses the overall air toxics risk assessment process and the basic technical tools needed to perform these analyses. The manual addresses both human health and ecological analyses. It also provides a basic overview of the process of managing and communicating risk assessment results. Other evaluations (such as the public health assessment process) are described to give risk assessors, risk managers, and other stakeholders a more holistic understanding of the many issues that may come into play when evaluating the potential impact of air toxics on human health and the environment.

Volume 2: Facility-Specific Assessment builds on the technical tools described in Volume 1 by providing an example set of tools and procedures that may be used for source-specific or facility-specific risk assessments, including tiered approaches to source- or facility-specific risk analysis.

Volume 3: Community-Level Assessment builds on the information presented in Volume 1 to describe to communities how they can evaluate and reduce air toxics risks at the local level. The volume will include information on screening level and more detailed analytical approaches, how to balance the need for assessment versus the need for action, and how to identify and prioritize risk reduction options and measure success. Since community concerns and issues are often not related solely to air toxics, the document will also present readily available information on additional multimedia risk factors that may affect communities and strategies to reduce those risks. The document will provide additional, focused information on stakeholder involvement, communicating information in a community-based setting, and resources and methodologies that may play a role in the overall process. Note that EPA's Office of Pollution Prevention and Toxics has also developed a "Community Air Screening How To Manual" that will be available in 2004 and will be discussed in Volume 3 (Volume 3 will be available in late 2004).

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