

Chapter 13 Inhalation Risk Characterization

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13.1 Introduction

The last component of risk assessment, risk characterization, integrates the information from the exposure assessment (Chapter 11) and toxicity assessment (Chapter 12), using a combination of qualitative and quantitative information and including a discussion of uncertainty and variability.⁽¹⁾ The risk characterization and its components should be presented so that the details of the analysis are transparent, clear, consistent with EPA guidance and policy, and will generally support the conclusion that the analysis is reasonable for its intended purpose. Risk assessors aim for the risk summary and risk conclusions to be complete, informative, and useful for decision-makers. One way of accomplishing this is to make sure that major uncertainties associated with determining the nature and extent of the risk are identified and discussed.

EPA has developed several key policies about how to characterize and present risk assessment information. EPA's *Policy for Risk Characterization*⁽²⁾ specifies that a risk characterization "be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency."

The purpose of the memorandum was to ensure that risk management decisions are well-supported and well-understood, both inside the EPA and outside the Agency. The confidence in the data, science policy judgments, and the uncertainties in the database should be clearly communicated. The 1995 *Guidance for Risk Characterization* has been updated by the *Handbook for Risk Characterization*, which provides more background and approaches to presenting the risk characterization results.⁽³⁾ Risk assessors may want to become familiar with the information provided in both the policy and handbook before beginning a risk assessment.

A 1992 memorandum from EPA's Office of the Administrator provides guidance on describing risk assessment results.⁽⁴⁾ This memorandum focuses on communicating the full range of information used in developing the assessment, rather than providing only point estimates of risk to the public. The risk characterization guidance and handbook⁽³⁾ recommends presenting a full and complete picture of risk that includes: a statement of confidence about data and methods used to develop the assessment; greater consistency and comparability in risk assessment across EPA programs; and statement of the level of scientific judgment inherent in risk management decisions. Information should be presented on the range of exposures derived from exposure scenarios using multiple risk descriptors (e.g., central-tendency, high-end of individual risk, population risk, important sub-populations, if known). For risk management decisions, the risk estimates are compared to legally mandated or other risk objectives (see Part V of this Reference Manual).

Risk = f (metric of exposure, metric of toxicity)

Risk characterization combines the information from the exposure assessment and the toxicity assessment to provide a quantitative estimate of potential cancer risk and/or hazard for other adverse effects, along with a statement of confidence about the data and methods used

Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important sub-populations, if known) consistent with terminology in the *Guidance on Risk Characterization*, Agency risk assessment guidelines, and program-specific guidance.

EPA *Policy for Risk Characterization*⁽²⁾

Risks are often evaluated initially for **individuals** within the potentially exposed population. **Population risks** for the exposed population may also be estimated, which may be useful in estimating potential economic costs and benefits from risk reduction. Sensitive subpopulations should also be considered, when possible. Estimates of **incidence** also are possible (see Exhibit 13-1).

The potential risks calculated for specific inhalation exposures are typically **incremental risks**; that is, they are potential risks that are *in addition to* those risks already faced by the population under study for reasons other than exposure to air toxics (e.g., hereditary, lifestyle risks such as smoking). The risk estimates are used to answer questions concerning the general risks posed to the exposed population, the risk levels of various groups within the population, and the potential range of risks across the population (e.g., central-tendency (e.g., average) or high-end (e.g., maximum) risk for individuals within the populations of interest).

Incidence is defined by the National Cancer Institute as “The number of new cases of a disease diagnosed each year.” For example, a State’s cancer registry might report that the statewide 5-year average incidence of lung cancer (i.e., the average number of actual people that were diagnosed by a doctor over the 5 year period) is 700 new cases per 100,000 people (5-year averages are often used to provide an estimate that is more stable over time). In comparison, air toxics risk assessments provide only a theoretical estimate of the likelihood that an individual in the exposed population will contract cancer as a result of exposure over a period of time (e.g., 50 or 100 years of a facility lifetime).

Steps in an Inhalation Risk Characterization

1. Organize outputs of inhalation exposure and toxicity assessments.
2. Derive inhalation cancer risk estimates and noncancer hazard quotients for each pollutant in each pathway for each type of receptor being studied.
3. Derive cumulative inhalation cancer risk estimates and noncancer hazards for each receptor for all chemicals in a pathway and then across pathways.
4. Identify key features and assumptions of exposure and toxicity assessments.
5. Assess and characterize key uncertainties and variability associated with the assessment.
6. Consider additional relevant information (e.g., related studies).

Risk characterization should include a risk summary and risk conclusions that are complete, informative, and useful for decision-makers, and which clearly identify and discuss the major uncertainties associated with determining the nature and extent of risk. See references 2 and 3 at the end of this chapter for more information.

Estimated cancer risks and noncancer hazards are generally developed for each chemical to which people are exposed in the study area and each exposure pathway through which exposure can occur. The results are then summed in a specific way to provide total estimates of risk and hazard. The general steps involved in risk characterization are:

- Quantify risks and hazards for each chemical through each pathway for each receptor;
- Review exposure estimates and assumptions;
- Review toxicity estimates and assumptions;
- Assess uncertainties and variability; and
- Consider additional relevant information (e.g., related studies).

Exhibit 13-1. Estimates of Risk

Individual risk. Estimates of cancer risk are usually expressed as a statistical probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of one chance in 10,000 (or one additional person in 10,000) is written as 1×10^{-4} (or 1E-04). This means that for every 10,000 people that are exposed, *in the way that we have presumed*, one of those people may develop cancer over their lifetime. Likewise, a risk of one person in one million is written 1×10^{-6} (or 1E-06) and a risk of one in one hundred thousand is written 1×10^{-5} (or 1E-05).

Population Risk. Estimates of cancer risk can be expressed as the number of people in the population who may have the same risk level (e.g., 1,000,000 people in the exposed population under study may have a risk of 1×10^{-6} , 2,495 may have a risk of 1×10^{-5} , and 300 may have a risk of 1×10^{-4}).

Incidence. Estimates of cancer risk can be expressed as the incidence of cancer cases in a population. For example, the estimated incidence of cancer in a population of 500,000 individuals where the individual risk is 1×10^{-5} (based on a 100 year exposure scenario) is simply:

$$\text{Population Size} \times \frac{\text{Individual Risk}}{\text{Averaging Time}} \times \text{Exposure Duration, or}$$

$$500,000 \text{ Individuals} \times \frac{1 \times 10^{-5}}{70 \text{ Years}} \times 100 \text{ Years} = \text{up to 7 New cancer cases}$$

Note that since the individual cancer risk value is a lifetime value, it is divided by 70 years (average lifetime length) prior to multiplying by the exposure period duration (100 years). It is also important to note the assumptions in this example calculation (e.g., average population size of 500,000 individuals and individual lifetime risk value of 1×10^{-5} for the 100 year period). Given these assumptions, these possible seven new cases are the expected number of cases over the total exposure duration of 100 years. If one wanted to estimate the number of new cases per year, simply use an exposure duration of one year. In our example,

$$500,000 \text{ Individuals} \times \frac{1 \times 10^{-5}}{70 \text{ Years}} \times 1 \text{ Year} = \text{up to 0.07 new cancer cases}$$

This points out two problems with using risk estimates to derive incidence estimates. First, a fraction of a cancer case (which often results from this exercise) is not a very helpful statistic when assessing a potential air toxics problem. Second, people living in different areas with the same individual risks, but with very different exposed population sizes can end up with very different incidence rates. For example, if our population above only had 10,000 people, the incidence rate would have been predicted to be no more than 0.1 (versus seven). While the first situation indicates a higher potential population impact, the second situation nevertheless indicates identical individual risk predictions for members of the population. Both metrics are informative to the risk manager, and reflect different considerations which may have different weights in different decisions. Other ways of describing risk to an exposed population are also possible.

Risk estimates in screening-level (Tier 1) analyses typically are deterministic estimates based on point estimates of exposure and toxicity. Deterministic estimates are useful screening tools in a tiered analysis, but need to be qualified by transparent discussions of the nature and extent of uncertainties in the input variables and the subsequent likely impact on the ultimate risk characterization. Deterministic analyses with appropriate uncertainty characterization can be used to identify situations of low incremental risk and to focus on areas where additional analysis might improve the basis for selection of a risk management action. At higher tiers of analyses, risk assessors commonly describe exposure (and less frequently, toxicity) by probability distributions rather than by point values and propagate these distributions through the exposure assessment and risk characterization process. This type of probabilistic analysis, which may address uncertainty and variability as distinct issues, will result in an estimate of risk that is a probability distribution rather than a point value. A more detailed discussion of the assessment and presentation of uncertainty in the risk characterization process is provided in Section 13.3.4. Probabilistic uncertainty analysis is discussed in Chapter 31.

13.2 Quantification of Cancer Risk and Noncancer Hazard

Quantification of risk and hazard is the step where exposure concentrations in air are combined with applicable inhalation dose-response values. Predictive cancer risk estimates are presented separately from noncancer hazard quotients. Risks are quantified for the pathways, receptors, and exposure scenarios outlined in the conceptual site model.

Information about the distribution of exposure and risk for the population is an important component of risk characterization. Distributions are often more useful than point estimates.

However, since developing fully distributional estimates of risk is usually out of the scope of most risk assessments, assessors can provide a sense of the range of risks by developing both central tendency and high-end estimates.⁽⁵⁾

- **Central tendency** estimates are intended to give a characterization of risk for the typical individual in the population. This is usually either based on the arithmetic mean risk (average estimate) or the median risk (median estimate).
- **High-end** estimates are intended to estimate the risk that is expected to occur in the upper range of the distribution (e.g., risk above about the 90th percentile of the population distribution). For example, the maximum exposed individual (MEI) risk or maximum individual risk (MIR) might be used to estimate high-end risks.

An evaluation of the uncertainty in the risk descriptors is an important component of the uncertainty discussion in the assessment. Both quantitative and qualitative evaluations of uncertainty can be useful to users of the assessment (see Section 13.3.4 and Chapter 31).

Risk versus Hazard...What's the Difference?

Risk assessors purposefully use the term *risk* to mean the statistical probability of developing cancer over a lifetime (even if exposure only occurs over a portion of that lifetime). Noncancer “risks,” on the other hand, are not expressed as a statistical probability of developing a disease. Rather they are expressed as a simple comparison of the exposure concentration to a reference concentration associated with the observable adverse health effects. To help make this distinction, the potential harm from exposure to carcinogens is called “risk” and the potential harm from noncarcinogens is called “hazard.”

13.2.1 Cancer Risk Estimates

Estimated individual cancer risk is expressed as the upper bound probability that a person may develop cancer over the course of their lifetime as a result of the exposures under study. This predicted risk is the **incremental risk** of cancer from the exposure being analyzed that is above the risk that the individuals in the population have already (i.e., due to non-air toxics related issues). Due to the nature of the assumptions in their derivation, inhalation unit risks (IURs) are generally considered to be “plausible upper-bound” estimates of potency. As such, the calculated risks are usually a conservative estimate (i.e., the true risk may be lower).

As described above, risks may be estimated for both the central tendency (average exposure) case and for the high-end (exposure that is expected to occur in the upper range of the distribution) case. However, for both types of estimates, the same estimate of toxicity (i.e., an IUR or reference concentration [RfC]) is generally used to calculate the risk. In other words, while the estimate of exposure may be allowed to vary to derive a sense of the range of exposures in a population, *the same estimate of toxicity* is used to calculate risk for both average and high-end risks. With few exceptions, toxicity values are not currently presented as a range.

Cancer risk characterization typically is performed first for individual air toxics, then is summed over all of the air toxics to which a person may be exposed at the same time. These steps are described in separate subsections below.

13.2.1.1 Characterization of Individual Pollutant Risk

For inhalation exposures, chronic cancer risks for individual air toxics are typically estimated by multiplying the estimate of long-term exposure concentration (EC) by the corresponding IUR for each pollutant to estimate the potential incremental cancer risk for an individual:

$$\text{Risk} = \text{EC}_L \times \text{IUR} \quad (\text{Equation 13-1})$$

where:

- Risk = Cancer risk to an individual (expressed as an upper-bound risk of contracting cancer over a lifetime);
- EC_L = Estimate of long-term inhalation exposure concentration for a specific air toxic;
and
- IUR = the corresponding inhalation unit risk estimate for that air toxic.

Performing the estimate in this way provides an estimate of the probability of developing cancer over a lifetime due to the exposure in question. Because of the way this equation is written, the underlying presumption is that a person is exposed continuously to the EC_L for their full lifetime (usually assumed to be 70 years).^(a) The EC_L is an estimate of this long-term exposure even

^aEPA is currently reviewing methods for assessing cancer risk for less than lifetime exposures occurring in childhood. EPA’s Draft Document *Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens* (<http://www.epa.gov/sab/panels/sgacsrp.html>) recommends a change to the current method for strong mutagens. This document is undergoing public and Science Advisory Board review and will be completed sometime in the future with consideration of that review. EPA’s methods for air toxics assessments will be consistent with the final document.

though it is probably based on only one year's worth of monitoring data or a modeling run that covers only one year's worth of time. (As noted in Chapter 11, exposure modeling can be used, in some cases, to derive a better estimate of the amount of time people interact with contaminated air. Nevertheless, the probability of developing cancer is still averaged out over the full lifetime of the individual.)

Estimates of cancer risk are usually expressed as a statistical probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of one chance in 10,000 (or one additional person in 10,000) is written as 1×10^{-4} (or 1E-04). This means that for every 10,000 people that are exposed, *in the way that we have presumed*, one of those people may develop cancer over their lifetime. Likewise, a risk of one person in one million is written 1×10^{-6} (or 1E-06) and a risk of one in one hundred thousand is written 1×10^{-5} (or 1E-05).

Because IURs are typically upper-bound estimates, actual risks may be lower than predicted (see Chapter 12), and the true value of the risk is unknown and may be as low as zero.⁽⁵⁾ These statistical projections of hypothetical risk are intended as screening tools for risk managers and cannot make realistic predictions of biological effects. Such risk estimates also cannot be used to determine whether someone who already has cancer is ill because of a past exposure. Part VI of this volume provides an overview of the Public Health Assessment process used to evaluate whether past exposures resulted in current illness.

Risks for cancer are generally expressed as individual risks (i.e., the risk borne by an individual in a larger exposed population). The number of people in the population who have the same risk level may also be provided (e.g., 1,000,000 people in the exposed population under study have a risk of 1×10^{-6} , 2,495 have a risk of 1×10^{-5} , and 300 have a risk of 1×10^{-4}). It is also possible to calculate the number of expected cases of cancer expected over a 70-year period by multiplying the cancer risk to an individual by the number of individuals; however, even though the calculation might yield an estimate of incidence, low predicted cancer incidence rates (even vanishingly small) do not mean that individuals within the population will not get cancer because of air toxics exposures.

13.2.1.2 Characterization of Cancer Risk from Exposure to Multiple Pollutants

People may receive exposure to multiple chemicals, rather than a single chemical, at the same time. The concurrent exposure to multiple carcinogens may occur through the same pathway or across several pathways. With a few exceptions (e.g., coke oven emissions), cancer dose-response values (e.g., IURs) are usually available only for individual compounds within a mixture.

The following equation estimates the predicted cumulative incremental individual cancer risk from multiple substances, and assumes an additive effect from simultaneous exposures to several carcinogens:

$$\text{Risk}_T = \text{Risk}_1 + \text{Risk}_2 + \dots + \text{Risk}_i \quad (\text{Equation 13-2})$$

where:

$Risk_T$ = total cumulative individual pathway-specific cancer risk (expressed as an upper-bound risk of contracting cancer over a lifetime); and
 $Risk_i$ = individual risk estimate for the i^{th} substance in the inhalation pathway.

In screening-level assessments of carcinogens for which there is an assumption of a linear dose-response, the cancer risks predicted for individual chemicals may be added to estimate cumulative cancer risk. This approach assumes that the risks associated with individual chemicals in the mixture are additive. In more refined assessments, the chemicals under assessment may be evaluated to determine whether effects from multiple chemicals are synergistic (greater than additive) or antagonistic (less than additive), although sufficient data for this evaluation are usually lacking. In those cases where IURs are available for a chemical mixture of concern, risk characterization can be conducted on the mixture using the same procedures used for a single compound. When more than one pathway is involved, the pathway specific risks are generally summed first, and then summed across pathways. This process is described in Part III of this reference manual. Note that for carcinogens being assessed based on the assumption of nonlinear dose-response, for which an RfC considering cancer as well as other effects has been derived, the hazard quotient approach will be appropriate (see Section 13.2.2).

Example Calculation to Estimate Cancer Risk (Hypothetical)

A Tier 1 modeling analysis was performed to estimate risk to the maximum exposed individual, assumed to reside at the point of maximum concentration for ABC Factory. Four HAPs were potentially of concern: benzene, dichloroethyl ether, formaldehyde, and cadmium compounds. Cancer risk estimates were obtained for each HAP by multiplying the estimated *annual average* EC by the IUR for each HAP. The resulting upper bound cancer risk estimates ranged from 2×10^{-6} (benzene, formaldehyde) to 8×10^{-4} (dichloroethyl ether). The cancer risk estimates for each HAP were summed to obtain an estimate of total inhalation cancer risk (9×10^{-4}). Note that 97 percent of the estimated total risk results from dichloroethyl ether, and that more than 99 percent results from dichloroethyl ether and cadmium compounds. In this hypothetical example, the risk assessor would need to decide which HAPs to carry to higher tiers by weighing the small proportion of risk posed by benzene and formaldehyde against the fact that these risks nevertheless exceeded one in one million.

| HAP | EC $\mu\text{g}/\text{m}^3$ | IUR $1/(\mu\text{g}/\text{m}^3)$ | Cancer Risk Estimate ^(a) | Percent of Total Risk |
|---------------------|--------------------------------|-------------------------------------|--|--------------------------|
| Benzene | 0.3 | 7.8×10^{-6} | 2×10^{-6} | < 1% |
| Dichloroethyl ether | 2.5 | 3.3×10^{-4} | 8×10^{-4} | 97 % |
| Formaldehyde | 0.2 | 1.3×10^{-4} | 2×10^{-6} | < 1 % |
| Cadmium compounds | 0.01 | 1.8×10^{-3} | 1×10^{-5} | 2 % |
| Total | | | 9×10^{-4} | |

^(a) Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

13.2.2 Noncancer Hazard Estimates

For noncancer effects (as well as carcinogens being assessed based on the assumption of nonlinear dose-response), exposure concentrations are compared to RfCs, which are estimates (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive sub-populations) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime (see Chapter 12).

13.2.2.1 Characterizing Individual Pollutant Hazard for Chronic Exposures

For inhalation exposures, noncancer hazards are estimated by dividing the estimate of the chronic inhalation EC by the RfC to yield a hazard quotient (HQ) for individual chemicals:

$$HQ = EC_C \div RfC \quad (\text{Equation 13-3})$$

where:

- HQ = the hazard quotient for an individual air toxic;
- EC_C = estimate of chronic inhalation exposure to that air toxic; and
- RfC = the corresponding reference concentration for that air toxic.

In screening inhalation risk assessments, which are routinely built around a particular year's estimate of emissions, the exposure estimate is usually based on an assumption of continuous long-term exposure using an annual average as the estimate of exposure concentration. A more refined assessment (e.g., by use of an exposure model) may generate an estimate of a more realistic exposure (e.g., by the application of an exposure model or refined emissions estimates over the longer time period).

Based on the definition of the RfC, an HQ less than or equal to one indicates that adverse noncancer effects are **not likely to occur**, and thus can be considered to have negligible hazard. Unlike cancer risks, however, HQs greater than one are not statistical probabilities of harm occurring. Instead, they are a simple statement of whether (and by how much) an exposure concentration exceeds the RfC. Moreover, the level of concern does not increase linearly or to the same extent as HQs increase above one for different chemicals because RfCs do not generally have equal accuracy or precision and are generally not based on the same severity of effect. Thus, we can only say that with exposures increasingly greater than the RfC, (i.e., HQs increasingly greater than 1), the **potential for adverse effects increases**, but we do not know by how much. An HQ of 100 does not mean that the hazard is 10 times greater than an HQ of 10. Also an HQ of 10 for one substance may not have the same meaning (in terms of hazard) as another substance resulting in the same HQ.

Example Calculation to Estimate Chronic Noncancer Hazard (Hypothetical)

A Tier 1 modeling analysis was performed to estimate chronic noncancer hazard to the maximum exposed individual, assumed to reside at the point of maximum concentration for ABC Factory. Four HAPs were potentially of concern: benzene, dichloroethyl ether, formaldehyde, and cadmium compounds. Noncancer hazard estimates were obtained for each HAP by dividing the estimated Exposure Concentration (EC) by the Inhalation Reference Concentration (RfC) for each HAP (note that the EC is expressed in units of mg/m^3 for this analysis). The resulting Hazard quotient (HQ) estimates ranged from 1×10^{-3} (formaldehyde) to 1 (cadmium compounds). Note that no RfC was available for dichloroethyl ether. The HQs for each HAP were summed to obtain an estimate of the Hazard Index (HI) of 1. Note that cadmium compounds account for 95 percent of the HI, suggesting that the other HAPs may not need further consideration (although this determination should be made in consideration of all relevant information, including uncertainties such as confidence in the exposure concentration and uncertainty factors used to derive each RfC).

| HAP | EC mg/m^3 | RfC (mg/m^3) | HQ ^(b) | Percent of HI |
|------------------------------------|------------------------------|---------------------------------|--------------------|------------------|
| Benzene | 6×10^{-4} | 6×10^{-2} | 1×10^{-2} | 1 % |
| Dichloroethyl ether ^(a) | 5×10^{-3} | --- | --- | --- |
| Formaldehyde | 4×10^{-4} | 1×10^{-2} | 1×10^{-3} | 4 % |
| Cadmium compounds | 2×10^{-5} | 2×10^{-5} | 1 | 95 % |
| Hazard Index (HI) | | | 1 | |

^(a) note that the absence of an RfC value means that we cannot quantitatively assess a HAP.

^(b) Standard rules for rounding apply which will commonly lead to an answer of one significant figure in both risk and hazard estimates. For presentation purposes, hazard quotients (and hazard indices) and cancer risk estimates are usually reported as one significant figure.

13.2.2.2 Characterizing Multiple Pollutant Hazard for Chronic Exposures

Noncancer health effects data are usually available only for individual compounds within a mixture. In these cases, the individual HQs can be summed together to calculate a multiple-pollutant hazard index (HI):

$$\text{HI} = \text{HQ}_1 + \text{HQ}_2 + \dots + \text{HQ}_i \quad (\text{Equation 13-4})$$

where

HI = hazard index; and
HQ = hazard quotient for the i^{th} air toxic.

For screening-level assessments, a simple HI may first be calculated for all chemicals of concern within the inhalation pathway (adding hazards across pathways is discussed in Part III). If the HI is less than your decision criterion, a more refined analysis is usually not performed. Adding HQs in this fashion is based on the assumption that even when individual pollutant levels are

lower than the corresponding reference levels, some pollutants may work together such that their potential for harm is additive and the combined exposure to the group of chemicals poses greater likelihood of harm. Some groups of chemicals can also behave antagonistically, such that combined exposure poses less likelihood of harm, or synergistically, such that combined exposure poses harm in greater than additive manner. Where this type of HI exceeds the criterion of interest, a more refined analysis is warranted.

Although the HI approach encompassing all chemicals in a mixture is commonly used for a screening-level study, it is important to note that application of the HI equation to compounds that may produce different effects, or that act by different toxicological mechanisms, could overestimate the potential for effects. Consequently, it is more appropriate to calculate a separate HI for each endpoint of concern for which mechanisms of action are known to be similar.

Because the assumption of dose additivity is most appropriate for compounds that induce the same effect by similar modes of action, EPA's *Guidance for Conducting Health Risk Assessment of Chemical Mixtures and Supplementary Guidance*⁽⁶⁾ suggest subgrouping pollutant-specific HQs by toxicological similarity of the pollutants for subsequent calculations; that is, to calculate a **target-organ-specific-hazard index (TOSHI)** for each subgrouping of pollutants. This calculation allows for a more appropriate estimate of overall hazard.

Segregation of hazard indices by effect and mechanism of action can be complex and time-consuming because it is necessary to identify all the major effects and target organism for each chemical and then to classify the chemicals according to target organ(s) or mechanism of action. This analysis is not simple and a toxicologist with familiarity in developing TOSHIs is best suited to perform this function. If the segregation is not carefully done, an underestimate of true hazard could result.

Procedure for Segregation of HIs by Effect

Segregation of HIs requires identification of the major effects of each chemical, including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at an EC of 20 $\mu\text{g}/\text{m}^3$ and neurotoxicity at an EC of 50 $\mu\text{g}/\text{m}^3$). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects).

Acute HQs are developed in the same manner as chronic HQs, with the caveat that the exposure duration associated with the exposure concentration should match the exposure duration embodied in the acute toxicity value. Whereas summing chronic HQs to a total hazard index is a relatively straightforward exercise, the issues related to developing acute HI are more subtle and complex. A toxicologist familiar with acute exposure and risk analysis should be consulted to perform this process.

13.2.2.3 Characterizing Hazard for Acute Exposures

Risk assessors can derive estimates of acute noncancer hazard for each HAP by combining the applicable short-term exposure concentration (EC) and acute dose-response value (AV) for the HAP to obtain the acute Hazard Quotient (HQ) for the HAP using the following equation:

$$HQ_A = EC_{ST} \div AV$$

where:

- HQ_A = the acute hazard quotient for an individual HAP;
- EC_{ST} = estimate of short-term inhalation exposure to that HAP; and
- AV = the corresponding acute dose-response value for that HAP.

Note that ambient air concentrations are calculated for an exposure duration compatible with the acute dose-response value used.

Available acute dose-response values are more diverse than chronic values, because they were developed for different purposes and considering different exposure durations. The most effective characterization of acute risk often is to compare the maximum estimated hourly concentrations with a range of acute dose-response values from sources described in Chapter 12. If the ambient concentration is lower than all the acute benchmarks, it is generally reasonable to conclude that the potential for significant acute hazard is negligible. If the concentration exceeds some benchmarks but not others, the assessment should include a discussion of the implications for the chemical of interest, with attention to the details of both the exposure scenario and the benchmarks included in the analysis.

Acute noncancer health effects data are usually available only for individual HAPs within a mixture. In these cases, it may be possible to combine the individual acute HQs to calculate a multi-pollutant acute hazard index (HI) using the following formula:

$$HI_A = HQ_{A1} + HQ_{A2} + \dots + HQ_{Ai}$$

where

- HI_A = acute hazard index; and
- HQ_{Ai} = acute hazard quotient for the ith HAP.

Although this appears similar to the process for combining chronic HQs, the summing of acute HQs is complicated by several issues that do not pertain to chronic HQs. First, acute dose-response values have been developed for purposes that vary more widely than chronic values. Some sources of acute values define exposures at which adverse effects actually occur, while other sources develop only no-effect acute values. Second, some acute values are expressed as concentration-time matrices, while others are expressed as single concentrations for a set exposure duration. Third, some acute values may specifically consider multiple exposures, whereas others consider exposure as a one-time event. Fourth, some sources of acute values are intended to regulate workplace exposures, assuming a population of healthy workers (i.e., without children, seniors, or other sensitive individuals). Such occupational values may also consider cost and feasibility, factors that EPA considers the province of the risk manager rather than the risk assessor.

Given these differences among acute values with regard to their purposes, and the different types of acute exposure characterization that may be performed, the acute HI analysis is most informative when limited to acute values from the same source, the same level of effects, and the same duration. Analyses that mix sources, effects levels, and durations are likely to be misleading.

Risk assessors commonly evaluate acute noncancer hazard using a variety of different acute values from different sources, and discuss the resulting hazard estimates considering the purpose for which each of value was developed. This kind of evaluation should only be done by an experienced toxicologist. **The significance of these HQs and HIs would need to be considered in the context of the purpose of the risk assessment and the characteristics of the dose-response values, such as their purpose, averaging time, and health endpoints.** EPA is working to provide more comprehensive guidance on what benchmarks to rely upon and plans to develop a relevant acute benchmark methodology.

13.2.3 Quantifying Risk From Background Sources

In some cases, it may be appropriate to quantify background concentrations of the air toxics of concern. For example, background concentrations may be a critical element in determining the need for further reductions of emissions from a particular source. Background concentrations are the levels of contaminants that would be present in the absence of contaminant releases from the source(s) under evaluation. Background concentrations may occur naturally in the environment or originate from other human sources (e.g., an industrial area upwind from the sources of concern).

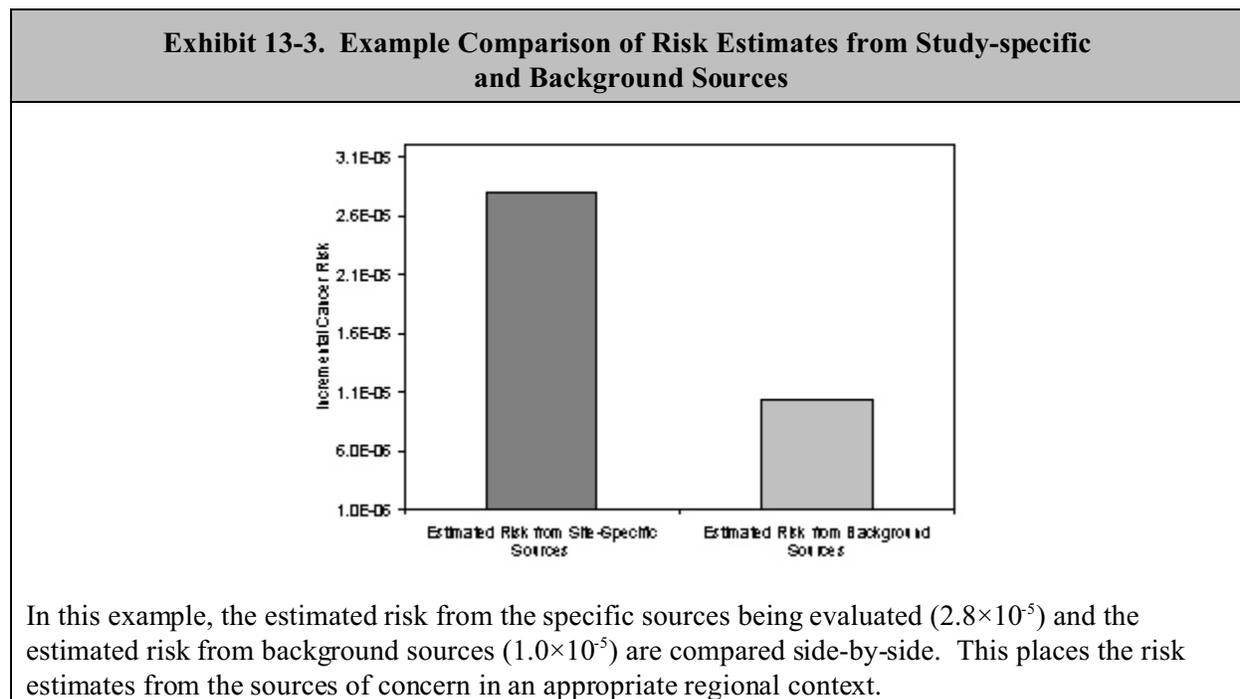
The general approach in risk assessments and risk management decisions has often been to assess the incremental risk posed by emissions from a particular source or group of sources. Various EPA programs, however, have taken specific approaches to considering background risks, some of which are summarized in EPA's *Residual Risk Report to Congress*.⁽⁷⁾

A detailed analysis of background concentrations typically would require extensive data gathering and modeling beyond that required for the incremental risk analysis. For example, numerous nearby (and possibly distant) air toxics sources of varying types would need to be characterized in sufficient detail to support release and exposure modeling. The data needs for assessment of background concentrations may differ depending on what will be done with the data. For example, if the question is simply "what is the risk to the population in a specific place," then an assessment of background may be unnecessary (monitoring data in the study area may be all that is required). On the other hand, if the question is "what is the risk and what can we do about it," then a knowledge of how much risk is contributed from both local and background sources may be necessary. If the risk is unacceptably high, but most of the risk is background in nature, there may be no appropriate risk reduction strategy (especially in regard to local sources).

Interpreting background concentrations may be difficult for anthropogenic chemicals and for chemicals formed through chemical reactions. For example, when trying to estimate background formaldehyde concentrations, it is difficult to screen out the reactive precursors which change in the study area from those that change before entering the study area. Also, if a source of nitrogen oxides (NO_x) is not present, secondary formation of formaldehyde may be slowed.

The presence of high background concentrations of anthropogenic chemicals could increase public concerns in some situations (see Part V of this reference manual for discussion of risk communication). On the other hand, knowledge of background risks could help place the air risks from a particular source or source area in better perspective.

In general, the most appropriate way to evaluate the contribution of background concentrations to the risk estimate is to simply compare the risk attributable to known or estimated (e.g., through monitoring) background concentrations in a bar chart against the risk attributable to the source(s) being evaluated (see Exhibit 13-3). Note that the study-specific risk estimate will be based on a metric of total exposure (when monitoring data are available) or incremental exposure (when modeling data are available). It generally is not appropriate to subtract background concentrations from monitored values.



13.3 Interpretation and Presentation of Inhalation Cancer Risks and Noncancer Hazards

In the final part of the risk characterization, risk assessors commonly present estimates of health risk in the context of uncertainties and limitations in the data and methodology. Exposure estimates and assumptions, toxicity estimates and assumptions, and the assessment of uncertainty are usually discussed. Additionally, information relevant to the public health context of the estimated risks is presented.

EPA's *Policy for Risk Characterization*⁽²⁾ describes a philosophy of transparency, clarity, consistency, and reasonableness (TCCR), and provides detailed approaches to achieving TCCR. Exhibit 13-4 provides an overview of EPA's TCCR principles.

| Exhibit 13-4. Transparency, Clarity, Consistency, and Reasonableness Principles | | |
|--|--|---|
| Principle | Definition | Criteria for a Good Risk Characterization |
| Transparency | Explicitness in the risk assessment process | <ul style="list-style-type: none"> • Describe assessment approach, assumptions, extrapolations, and use of models • Describe plausible alternative assumptions • Identify data gaps • Distinguish science from policy • Describe uncertainty • Describe relative strength of assessment |
| Clarity | The assessment itself is free from obscure language and is easy to understand | <ul style="list-style-type: none"> • Employ brevity • Use plain English • Avoid technical terms • Use simple tables, graphics, and equations |
| Consistency | The conclusions of the risk assessment are characterized in harmony with EPA actions | <ul style="list-style-type: none"> • Follow statutes • Follow Agency guidance • Use Agency information systems • Place assessment in context with similar risks • Define level of effort • Use review by peers |
| Reasonableness | The risk assessment is based on sound judgment | <ul style="list-style-type: none"> • Use review by peers • Use best available scientific information • Use good judgment • Use plausible alternatives |
| Source: EPA <i>Risk Characterization Guidance</i> ⁽³⁾ | | |

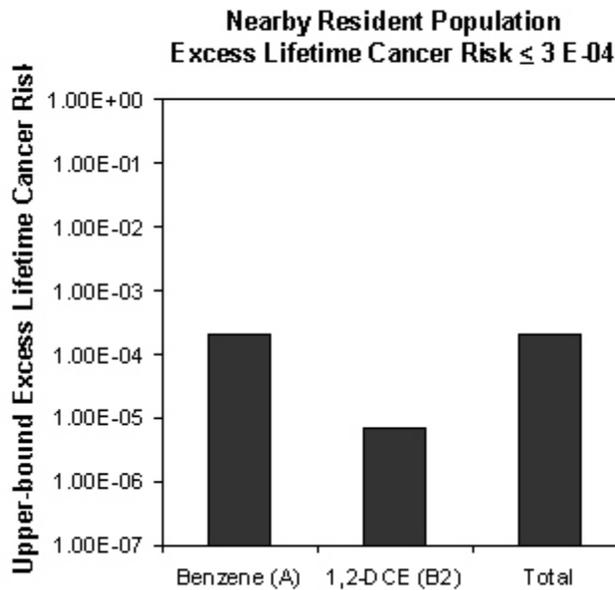
The risk characterization document should allow the risk manager, and the public, to know why risk was assessed the way it was, by clearly summarizing the available data and its analysis, uncertainties, alternative analyses, and the choices made. A good risk characterization will state the scope of the assessment, express results clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from science policy judgments. The *Policy for Risk Characterization* calls for the explanation of the choices made to be highly visible.

The goal of risk characterization is to clearly communicate the key findings and their strengths and limitations so that decision-makers can put the risk results into context with other information critical to evaluating risk management options (e.g., economics, social values, public perception, policies). The risk characterization will provide a means of placing the numerical estimates of risk and hazard in the context of what is known and what is not about the potential exposures and should include the elements listed in Exhibit 13-5. Exhibit 13-6 provides examples of graphical presentations of risk estimates.

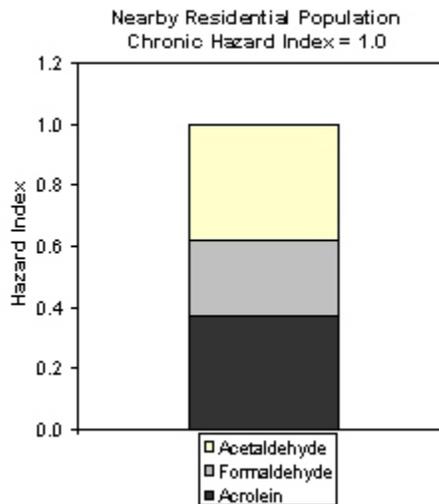
Exhibit 13-5. Elements Commonly Included in the Risk Characterization Discussion

- Agreement that the key contaminants were identified
- A discussion of modeled or measured air concentrations relative to background
- The magnitude of the estimated cancer risks and noncancer hazard indices, and a description of the types of health risks potentially present, distinguishing between known effects in humans and those found only in experimental animals
- The level of confidence in the toxicity data used to estimate risks
- A presentation of qualitative information about the toxicity of substances not included in the quantitative risk assessment
- Level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions
- The major factors driving the risks (e.g., substances, pathways)
- The major factors reducing the certainty in the results and the significance of these uncertainties (e.g., a change in the assumption for a certain parameter could increase/decrease the risk estimate).
- The exposed population characteristics
- A comparison with location-specific health studies, if available

Exhibit 13-6. Example Comparison of Risk Results for a Hypothetical Risk Assessment



The risk of developing cancer is plotted as shown. A risk of 1×10^{-4} (1 E-04) indicates a probability of one chance or less in 10,000 of an individual developing cancer. Risks of 1×10^{-5} (1 E-05) and 1×10^{-6} (1 E-06) correspond to probabilities of one chance or less in 100,000 and one million, respectively. Values in parentheses represent EPA's Weight-of-Evidence classification of the agent as a potential human carcinogen: A = human carcinogen; B2 = probable human carcinogen (with sufficient evidence in animals and inadequate or no evidence in humans).



The hazard index is equal to the sum of the hazard quotients (i.e., exposure concentration/RfC) for each chemical. It is not a probability. A hazard index ≤ 1 indicates that it is unlikely for even sensitive populations to experience adverse health effects. Thus, hazard is negligible.

13.3.1 Presenting Risk and Hazard Estimates

Risk and hazard estimates will usually be presented both to risk managers and to the public. Depending on the audience, risk characterizations can present information with different amounts of technical detail as required, although avoiding the use of technical terms generally improves clarity. Presentations may include the assumptions the risk assessment used, as well as the distribution of risks estimated for the assessment. Multiple point estimates and risk ranges could be discussed in both narrative and tabular forms. The discussion of results may include items such as:

- The range of risks estimated within specified distances from the source(s) of concern;
- An estimate of population size associated with different risk levels; and/or
- A comparison of the magnitude of the risk estimate to background risks.

Key issues and conclusions should be clearly highlighted in any summary. Exhibit 13-7 identifies several summary products that can facilitate risk communication. (See also Part V of this Reference Manual for a description of various techniques for communicating risk.)

Exhibit 13-7. Summary Products to Facilitate Risk Communication

- **Executive summary** – a summary with some technical detail, for audiences with some technical knowledge (e.g., first line managers). This executive summary may sometimes be the executive summary of the technical risk characterization itself depending on the audience.
- **Bulleted list** – a list highlighting the key issues and conclusions culled from the technical risk characterization with little or no technical detail; for audiences with little or no technical knowledge (e.g., higher-level managers, decision makers).
- **Briefing packages** – written products that describe key issues and conclusions for managers, decision makers, and other public officials.
- **Fact sheets, press releases, and public relations notices** – written products that describe key issues and conclusions for non-technical audiences (e.g., affected or interested public).
- **Slide shows, speeches, and talks** – visual presentations (perhaps accompanied by audio presentations) and transcripts of oral presentations of key issues and their context; for mostly non-technical audiences.

13.3.2 Exposure Estimates and Assumptions

For each exposure pathway evaluated in the risk assessment, check that all information needed to characterize exposure is available. For each exposure pathway evaluated, exposure estimates and assumptions should be reviewed to assure the consistency and validity of key assumptions. These assumptions may include, for example, the period of exposure and the modeling assumptions.

The risk characterization section on exposure may summarize the following exposure information:

- Estimated exposures (chronic, subchronic, and shorter-term, as appropriate); and
- Important exposure modeling assumptions, including:
 - Chemical concentration at the exposure points; and
 - Frequency and duration of exposure.

Other items that could be addressed in the risk characterization summary of the exposure assessment include:

- The most significant sources of environmental exposure:
 - Data on sources of exposure from different media (when multimedia analyses are performed);
 - Estimates of the relative contribution of different sources of exposure; and
 - Identification of the most significant environmental pathways for exposure (when multimedia analyses are performed);
- Descriptions of the populations that were assessed, including the general population, highly exposed groups, and highly susceptible groups;
- Description of the basis for the exposure assessment, including any monitoring, modeling, or other analyses of exposure distributions (e.g., probabilistic techniques – see Part VII of this Reference Manual); and
- Key descriptors of exposure:
 - Description and illustration of the (range of) exposures to: “average” individuals, “high-end” individuals, the general population, and special subpopulations such as children and the elderly;
 - Description of how the central tendency estimate was developed, including the factors and/or methods used in developing this estimate;
 - Description of how the high-end estimate was developed;
 - Description of how population estimates of risk were developed; and
 - Description of how any incidence calculations were performed.

13.3.3 Toxicity Estimates and Assumptions

During the risk characterization step, the risk assessor usually reviews whether all toxicity information needed to characterize risk is available. The risk characterization section on toxicity often summarizes the following information:

- IURs for all carcinogenic chemicals;
- Discussion of weight of evidence and classifications for all carcinogenic chemicals;
- Type of human cancer for Class A carcinogens;
- Chronic and subchronic dose-response values and shorter-term (acute) dose-response values (if appropriate) for all chemicals (including carcinogens and developmental toxicants);
- Critical effect associated with each dose-response value;

- Discussion of uncertainties, uncertainty factors, and modifying factors used in deriving each dose-response value and degree of confidence in dose-response values;
- Whether the dose-response values are expressed as absorbed or administered doses (applies primarily to ingestion exposures - See Chapter 22);
- Pharmacokinetic data that may affect the extrapolation from animals to humans for dose-response values; and
- Uncertainties in any route-to-route extrapolation.

13.3.4 Assessment and Presentation of Uncertainty in Risk Characterization

The risk estimates used in air toxics risk assessments usually are not fully probabilistic estimates of risk but conditional estimates given a considerable number of assumptions about exposure and toxicity. Air toxics risk assessments make use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology), all of which are used to characterize the expected risk in a particular environmental context. Informed use of reliable scientific information from many different sources is a central feature of the risk assessment process. Reliable information may or may not be available for many aspects of a risk assessment. Scientific uncertainty is inherent in the risk assessment process, and risk managers almost always must make decisions using assessments that are not as definitive in all important areas as would be desirable. Risk assessments also incorporate a variety of professional and science policy judgements (e.g., which models to use, where to locate monitors, which toxicity studies to use as the basis of developing dose-response values). Risk managers therefore need to understand the strengths and the limitations of each assessment, and to communicate this information to all participants and the public.⁽²⁾ A critical part of the risk characterization process, therefore, is an evaluation of the assumptions and uncertainties inherent in the risk assessment in order to place the risk estimates in proper perspective.

One of the key purposes of uncertainty analysis is to provide an understanding of where the estimate of exposure, dose, or risk is likely to fall within the range of possible values. Often this is expressed as a subjective confidence interval within which there is a high probability that the estimate will fall. A related analysis, termed “sensitivity analysis” or “analysis of uncertainty importance,” is often performed to identify the relative contribution of the uncertainty in a given parameter value (e.g., emission rate, ingestion rate) or model component to the total uncertainty in the exposure or risk estimate.⁽⁸⁾ Often this is used either to identify which parameter values should be varied to provide high-end vs. central-tendency risk estimates, or to identify parameter values where additional data collection (or modeling effort) can increase the confidence in the resulting risk estimate.

The Presidential/Congressional Commission on Risk Assessment and Risk Management (CRARM) recommends that risk assessors respect the objective scientific basis of risks and procedures for making inferences in the absence of adequate data.⁽⁹⁾ Risk assessors should provide risk managers and other stakeholders with plausible conclusions about risk that can be made on the basis of the available information, along with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.

The risk characterization typically should address the following:

- Considering the hazard and the exposure, what is the nature and likelihood of the health risk?
- Which individuals or groups are at risk? Are some people more likely to be at risk than others?
- How severe are the anticipated adverse impacts or effects?
- Are the effects reversible?
- What scientific evidence supports the conclusions about risk? How strong is the evidence?
- What is uncertain about the nature or magnitude of the risk?
- What is the range of informed views about the nature and probability of the risk?
- How confident are the risk analysts about their predictions of risk?
- What other sources cause the same type of effects or risks?
- What contribution does the particular source make to the overall risk of this kind of effect in the affected community? To the overall health of the community?
- How is the risk distributed in relation to other risks to the community?
- Does the risk have impacts besides those on health or the environment, such as social or cultural consequences?
- The level of detail considered in a risk assessment and included in a risk characterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.

Risk characterizations should include sufficient information to enable:

- Risk managers to make a useful risk management decision, and
- Stakeholders to understand the importance and context of that decision.

13.3.4.1 Practical Approaches to Uncertainty Assessment

There are numerous sources of uncertainties in air toxics risk assessments, and each merits consideration. The degree to which these sources of uncertainty need to be quantified, and the amount of uncertainty that is acceptable, varies considerably on a study-specific basis. For a screening-level (Tier 1) analysis, a high degree of uncertainty is often acceptable, provided that conservative assumptions are used to bias potential error toward protecting human health. The use of conservative assumptions is intended to result in a situation where the risk assessor is confident that the risk estimate is unlikely to be *greater* than the point estimate of risk. In other words, the point estimate of risk is expected to be at the high-end of the range of possible values. The uncertainty characterization for a Tier 1 analysis commonly is limited to a qualitative discussion of the major sources of uncertainty and their potential impact on the risk estimate. At higher tiers of analysis, sensitivity analysis to quantify the impact of varying input parameter values (or model

Sources of Uncertainty

- **Scenario uncertainty.** Information to fully define exposure or risk is missing or incomplete
- **Model uncertainty.** Algorithms or assumptions used in models may not adequately represent reality
- **Parameter uncertainty.** Values for model parameters cannot be estimated precisely
- **Decision-rule uncertainty.** Policy and other choices made during the risk assessment may influence risk estimates

algorithms) on the risk estimate, or more complete quantitative uncertainty analysis, commonly are performed to more fully describe the range of possible or plausible values.

Practical approaches to the assessment and presentation of the principal sources of uncertainty in risk assessments are summarized below.⁽¹⁰⁾

Characterize Scenario Uncertainty. There are uncertainties associated with the estimate of the magnitude and extent of chemical exposure or toxicity, the spatial and temporal aggregation of chemical concentrations to calculate the exposure concentration used in the risk characterization, the completeness of the analysis (e.g., important exposure pathways may not have been evaluated), and the manner in which the exposed population and/or exposure scenario were specified for the analysis. Ideally, the key scenario uncertainties have been discussed during planning, scoping, and problem formulation, and the analysis plan has been developed to address these uncertainties. A limited sensitivity analysis (e.g., on key assumptions associated with exposure) may indicate the magnitude of uncertainty associated with specific aspects of the scenario. At a minimum, the analysis of uncertainty should identify the key scenario uncertainties and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Characterize Model Uncertainty. There are uncertainties associated with the selection of scientific models; these include dose-response models, models of environmental fate and transport, and exposure models. There is always some doubt as to how well an exposure model or its mathematical expression approximates the true relationships between site-specific environmental conditions. Ideally one would like to use a fully validated model that accounts for all the known complexities in the parameter interrelationships for each assessment. Often, however, only partially validated models are available. As a consequence, it is important to identify key model assumptions (e.g., linearity, homogeneity, steady-state conditions, equilibrium) and their potential impact on the risk estimates. In the absence of field data for model validation, the risk assessor could perform a limited sensitivity analysis (i.e., vary assumptions about functional relationships) to indicate the magnitude of uncertainty that might be associated with model form. At a minimum, the analysis of uncertainty should list key model assumptions and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Characterize Model Uncertainties

- List/summarize key model assumptions
- Indicate the potential impact of each assumption on the exposure and risk estimate
 - Direction
 - Magnitude

Characterize Parameter Uncertainty. During the course of a risk assessment, numerous parameter values are included in the calculations of chemical fate and transport and human intake. Significant data gaps might have required that certain parameter values be assumed for the risk assessment. For example, no information on the time spent outdoors may be available for a specific population, and a national average may be used instead. Even if data on the parameter of interest are available, they will be uncertain because the parameter estimates are derived from a sample of the potentially exposed population. A first step in characterizing parameter value uncertainty is to identify the key parameters influencing the risk estimate. This usually can be accomplished by expert opinion or by an explicit sensitivity analysis. In a

sensitivity analysis, the values of parameters suspected of driving the risk estimates are varied, and the degree to which changes in the input variables result in changes in the risk estimates are summarized and compared. It may be possible to reduce parameter uncertainty in the most sensitive parameters by additional, selective data gathering.

Characterize Decision-Rule Uncertainty. There are uncertainties associated with policy and other choices made during the risk assessment. For example, the exposure assessment might have evaluated an exposure duration (e.g., a subchronic exposure) for which no appropriate dose-response value was available. Uncertainty would be associated with the choice of value to use in the hazard characterization (e.g., an acute versus chronic value). In this situation, it might be possible to assess hazard twice, once with the acute value, and once with the chronic value, to may indicate the magnitude of uncertainty associated with this decision. At a minimum, the analysis of uncertainty should identify the key decision-rule uncertainties and indicate the potential impact of each on the direction and magnitude of the risk estimate.

Tracking Uncertainty. Ideally, one would like to quantitatively carry through the risk assessment the uncertainty associated with each parameter in order to characterize the uncertainty associated with the final risk estimates. However, this process can be highly complex and resource intensive and the more practical approach for air toxics risk assessments may be to describe qualitatively how the uncertainties might be propagated through the risk analysis. Three different approaches to tracking uncertainty are described below:

- *Qualitative Approach.* This approach involves developing a quantitative or qualitative description of the uncertainty for each parameter and indicating the possible influence of these uncertainties on the final risk estimates given knowledge of the models used.
- *Semi-Quantitative Approach.* This approach involves: (1) using available data to describe the potential range of values that the parameters might assume; (2) performing sensitivity analysis to identify the parameters with the most impact on the risk estimate; and (3) performing sensitivity analysis to compute the range of exposure or risk estimates that result from combinations of minimum and maximum values for some parameters and mid-range values for others.
- *Quantitative Approach.* Probabilistic techniques such as Monte Carlo simulation analysis can explicitly characterize the extent of uncertainty and variability in risk assessment, especially in the exposure assessment step. Using these techniques, important variables in the exposure assessment, as well as in the other parts of the risk assessment, are specified as distributions (rather than as single values) according to what can be expressed about their underlying variability and/or uncertainty. Values are sampled repeatedly from these distributions and combined in the analysis to provide a range of possible outcomes. While this technique can offer a useful summary of complex information, it must be noted that the analysis is only as certain as the underlying data (and assumed forms of the distribution of data values in the population). It is important that the risk assessor clearly expresses individual modeled variables in a way that is consistent with the best information available. Highly quantitative statistical uncertainty analysis is usually not practical or necessary for most air toxics risk assessments. The general quantitative approach to propagating or tracking uncertainty through probabilistic modeling is described in Chapter 31.

13.3.4.2 Presentation of Uncertainty Assessment

The final discussion of the risk characterization results must place the numerical estimates of risk in the context of the uncertainties inherent in the analysis.⁽²⁾ The discussion should include:

- Level of confidence in the quantitative toxicity information used to estimate risks;
- Presentation of qualitative information on the toxicity of substances not included in the quantitative assessment;
- Level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions;
- Major factors reducing certainty in the results and the significance of these uncertainties (e.g., adding individual risk estimates for several substances or across multiple exposure pathways); and
- Possible graphical presentation of key parameter and risk uncertainties.

13.3.5 Additional Information

Other studies relevant to the risk assessment being performed may be available, such as community health studies or previous risk assessments. For example, the Agency for Toxic Substances and Diseases Registry (ATSDR) may conduct public health assessments, health consultations, and other activities resulting in evaluations, assessments, and recommendations on specific public health issues related to actual or potential human exposure to hazardous materials (see Chapter 30). ATSDR's recommendations may include additional hazard characterization or risk reduction activities. In addition, these activities can initiate other activities within ATSDR such as exposure investigations, health studies, and health education.

If health or exposure studies have been identified and evaluated as adequate, the study findings may be incorporated into the risk characterization to strengthen the conclusions of the risk assessment. In general, a qualitative comparison of the results of available studies will usually be sufficient.

Additional References Related to Uncertainty Analysis

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Information Quality Guidelines

The U.S. Office of Management and Budget (OMB) has directed all federal agencies to develop information quality guidelines for risk-related and other information; EPA has developed draft guidelines pursuant to the OMB directive. While these guidelines do not apply to S/L/T governments, they provide useful principles for developing and communicating the information developed for the risk characterization.

The OMB guidelines denote four substantive qualifiers for information disseminated by federal agencies. **Quality** is defined as the encompassing term, of which utility, objectivity, and integrity are the constituents. **Utility** refers to the usefulness of the information to the intended users. **Objectivity** focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. **Integrity** refers to security – the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

The guidelines provide some basic principles for agencies to consider when developing their own guidelines, including:

- Guidelines should be flexible enough to address all communication media and variety of scope and importance of information products.
- Some agency information may need to meet higher or more specific expectations for objectivity, utility, and integrity.
- Ensuring and maximizing quality, objectivity, utility, and integrity comes at a cost, so agencies should consider using a cost-benefit approach.
- Agencies should adopt a common-sense approach that builds on existing processes and procedures. It is important that agency guidelines do not impose unnecessary administrative burdens.

EPA developed draft information quality guidelines in response to the OMB directive (www.epa.gov/oei/qualityguidelines). EPA's guidelines include two components of particular relevance to air toxics risk management: (1) guidelines to ensure and maximize the quality of "influential" information; and (2) guidelines to ensure and maximize the quality of "influential" scientific risk assessment information.

Source: Office of Management and Budget. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. 67 *Federal Register* 36:8451. February 22, 2002 (www.whitehouse.gov/omb/fedreg/reproducible.html).

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