

# Chapter 26 Ecological Risk Characterization

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## 26.1 Introduction

Similar to human health risk characterization, ecological risk characterization combines information concerning exposure to chemicals with information regarding effects of chemicals to estimate risks. The major difference in ecological risk characterization is the necessity for estimating risks based on individual lines of evidence and then combining them through a process of weighing the evidence.<sup>a</sup> Another difference is that in human health assessment, we primarily consider health effects in the bodies of individual people. In ecological assessment, we consider various “health” issues that can range from actual health effects in the bodies of individual ecological receptors to something more attuned to the “health” of the ecosystem as measured by species richness and diversity. This chapter provides an overview of the approaches and methods used for ecological risk characterization. As before, additional information is provided in EPA’s *Guidelines for Ecological Risk Assessment*,<sup>(1)</sup> and readers are referred to that document for a more complete discussion of available approaches and methods.

Risk characterization is the final phase of ecological risk assessment and is the culmination of the planning and scoping, problem formulation, and analysis of predicted or observed adverse ecological effects related to the assessment endpoints. It is also based on metrics of exposure and ecosystem and receptor characteristics that are used to analyze air toxics sources, their distribution in the environment, and the extent and pattern of contact. Risk characterization is used to clarify the relationships between stressors, effects, and ecological entities, and to reach conclusions regarding the occurrence of exposure and the likelihood of anticipated effects. The results of the analysis phase are used to develop an estimate of the risk posed to the ecologically valued entities that are the focus of the assessment endpoints.<sup>(2)</sup> After estimating the risk, the risk estimate is described in the context of the significance of any adverse effects and lines of evidence supporting their likelihood. Finally, the uncertainties, assumptions, and qualifiers in the risk assessment are identified and summarized, and the conclusions are reported to risk managers.

Conclusions presented in the risk characterization should provide clear information to risk managers in order to be useful for environmental decision making. If the risks are not sufficiently defined to support a management decision, risk managers may elect to proceed with another iteration of one or more phases of the risk assessment process. Re-evaluating the conceptual model (and associated risk hypotheses) or conducting additional studies may improve the risk estimate.

Characterization of ecological risk includes risk estimation, (usually a quantitative risk estimate; see Section 26.2), risk description (Section 26.3), and documentation of results (Section 26.4).

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<sup>a</sup>Consistent with EPA’s *Guidelines for Ecological Risk Assessment*,<sup>(1)</sup> the term “lines of evidence” includes a “weight of evidence” in order to emphasize that both qualitative evaluation and quantitative weighting may be used.

## 26.2 Risk Estimation

Several general techniques are available for characterizing ecological risks associated with air toxics that persist and bioaccumulate. These are divided broadly into single-point comparisons, comparisons incorporating the entire stressor-response relationship, comparisons involving variability in exposure and/or effects, and process models. Each is described in a separate subsection below. EPA's *Guidelines for Ecological Risk Assessment*<sup>(1)</sup> provides additional discussion and examples of these techniques.

### 26.2.1 Single-Point Exposure and Effects Comparisons

The simplest approach for comparing exposure and effects estimates for air toxics ecological risk assessments is the Hazard Quotient (HQ) approach (also referred to as the "quotient method"), which is similar to that used for human noncancer health risk assessments (see Chapter 13). In this approach, modeled or measured concentrations of the chemical in each environmental medium are divided by the appropriate point estimate for ecological effects to yield a HQ for an individual chemical.

$$HQ = \frac{\text{Oral Intake}}{TRV} \quad \text{or} \quad HQ = \frac{EEC}{TRV} \quad \text{or} \quad HQ = \frac{BB}{TRV} \quad (\text{Equation 26-1})$$

where:

- HQ = hazard quotient
- Oral Intake = estimated or measured contaminant intake relevant to the oral intake-based TRV (usually expressed as mg/kg-day)
- TRV = Toxicity reference value. This may be in terms of oral intake, media concentration, or body burden. As described elsewhere, it may be a result of a single study (e.g., NOAEL) or the result of integration of multiple studies (e.g., water quality criterion).
- EEC = estimated or measured environmental media concentration at the exposure point (usually expressed as mg/L for water and mg/kg for soil and sediment)
- BB = estimated or measured body burden (usually expressed as mg/kg wet weight)

As with human health assessments, the measure of oral intake, EEC, or BB must be in the same units as the TRV to which the measure is being compared.

As chronic risk will usually "drive" an ecological assessment, the HQ approach will usually be employed for chronic exposure scenarios using chronic duration TRVs. For initial screening, conservative exposure factors may be used (see Exhibit 24-2). As in human health risk assessment, an HQ greater than one indicates the potential for adverse ecological effects to occur, but does not predict their occurrence (see Chapter 13).

When ecological toxicity data for complex mixtures are unavailable, the hazard index (HI) approach<sup>b</sup> may sometimes be used in screening assessments, as scientifically appropriate, to assess potential ecological risks associated with simultaneous exposure to multiple air toxics.<sup>(1)</sup>

If the HI approach is used, the assumptions and associated limitations should be clearly documented. It may often be the case that a single chemical is responsible for the HI exceeding one, and the assessment can then focus on the HQ for that chemical. In more refined assessments, an alternative approach may be necessary.

As with human health assessments, a number of limitations restrict application of the HQ approach. While a quotient can be useful in answering whether adverse effects are likely to occur or not, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of ecological hazard. For example, it is seldom useful to say that a mitigation approach will reduce the value of a quotient from 25 to 12, since this reduction cannot, by itself, be clearly interpreted in terms of effects on an assessment endpoint. Quotients also may not be the most appropriate methods for predicting secondary effects

(e.g., bioaccumulation, loss of prey species). Finally, in most cases the quotient does not explicitly consider uncertainty, such as extrapolation from the test species to the species or community of concern. Some uncertainties, however, can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate (see Exhibit 26-1).<sup>(1)</sup>

#### State Water Quality Standards

Pursuant to Section 303 of the Clean Water Act, States have developed numerical water quality standards for the protection of aquatic ecosystems. These standards generally are considered regulatory requirements that must be met, and often are based on EPA's Ambient Water Quality Criteria (see Chapter 25). If persistent, bioaccumulative hazardous air pollutants (PB-HAPs) enter surface waters, one way to assess risk is to compare the EEC to a water quality standard using the HQ approach. State water quality standards can be accessed via EPA's national water quality standards database at <http://www.epa.gov/ost/wqs/>.

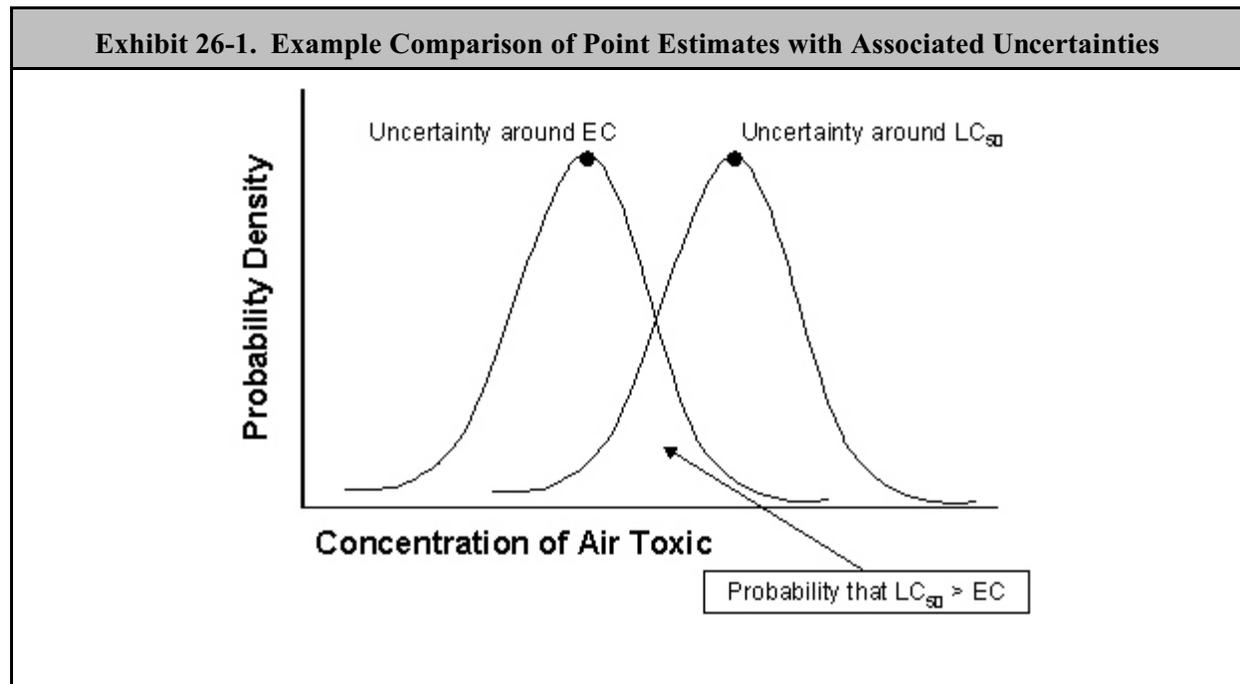
### 26.2.2 Comparisons Involving the Entire Stressor-Response Relationship

If a curve relating the intensity or level of the stressor to the magnitude of response is available (for example, see Exhibit 25-1), the risk characterization can examine risks associated with many different levels of exposure. These estimates are particularly useful when the risk management decision is not based on exceeding a pre-determined reference value or regulatory standard (e.g., a state water quality standard). This approach provides a predictive ability lacking in the hazard quotient approach, and it may be used in screening level assessments or subsequent more refined risk analyses. Because the slope of the effects curve relates the magnitude of change in effects to incremental changes in exposure, the ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios can be used to compare different risk management options. Also, uncertainty can be incorporated by calculating uncertainty bounds on the stressor-response or exposure estimates. Limitations to this approach may include: lack of consideration

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<sup>b</sup>The HI approach is termed the "quotient addition approach" in EPA's *Guidelines for Ecological Risk Assessment*<sup>(1)</sup>

for secondary effects, assuming the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern; and failing to consider uncertainties such as extrapolations from tests species to the species or communities of concern.



### 26.2.3 Comparisons Involving Variability

If the exposure or stressor-response profiles describe the variability in exposure or effects, then many different risk estimates can be developed. Variability in exposure can be used to estimate risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to estimate risks to average or sensitive members of populations. As an example, exposure can vary by life-stage (e.g., exposure may be greater during spawning or migration). Likewise, effect may also vary by life-cycle (e.g., hatchlings may be more sensitive to a chemical than are adults). A major advantage of this approach is its ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios and thus provide a means for comparing different risk management options. Limitations include the increased data requirements compared with previously described techniques and the implicit assumption that the full range of variability in the exposure and effects data is adequately represented. In addition, secondary effects are not readily evaluated with this approach. This risk estimation technique would likely be used in more refined risk assessments. (A discussion of probabilistic techniques, including Monte Carlo Simulation, is provided in Chapter 31.)

### 26.2.4 Process Models

Process models are mathematical expressions that represent understanding of the mechanistic operation of a system under evaluation. They can be useful tools in both analysis and risk characterization (process models are discussed briefly in Chapter 25). A major advantage of using process models is the ability to consider “what if” scenarios and to forecast beyond the limits of observed data that constrain approaches based solely on empirical data. Process models

also can consider secondary effects, and in some cases, the combined effects of multiple stressors. Process model outputs may be point estimates, distributions, or correlations. However, since process models are only as good as the assumptions on which they are based, the outputs from these models should be interpreted with care. The lack of knowledge on basic life histories for many species, and incomplete knowledge about the structure and function of natural ecosystems are some of the many uncertainties that need to be considered. These models are complex and, are usually reserved for more refined risk assessments.

### **Risk Assessment Frontiers: Integrating Human Health and Ecological Risk Assessment**

Many tribal cultures view ecological and human health in an integrated way such that they cannot be easily separated. Similarly, there is some effort (especially in Canada) toward an integration of human health and ecological assessment, as well as decision-making, in a field known as **strategic environmental assessment**.<sup>(3)</sup> This approach has not been applied widely in the United States, and it remains to be seen how it will develop in the next few years.

The World Health Organization has published approaches to integrating human health and ecological risk assessments to improve data quality and understanding of cumulative risks for decision making.<sup>(4)</sup> This approach includes an integrated framework (modified from EPA's guidance)<sup>(1)</sup> and case studies.

EPA, in its *Framework for Cumulative Risk Assessment*,<sup>(5)</sup> offers a flexible structure for conducting and evaluating cumulative risk assessment. By "cumulative risk," EPA means "the combined risks from aggregate exposures to multiple agents or stressors." Agents or stressors may be chemicals, but they may also be biological agents or physical agents, or an activity that, directly or indirectly, alters or causes the loss of a necessity such as habitat.

## **26.3 Risk Description**

The results of the risk characterization should be documented in the **risk description**, which includes an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the significance of the observed and/or predicted effects.

### **26.3.1 Lines of Evidence**

The development of lines of evidence provides both a process and a framework for reaching a conclusion regarding confidence in the risk estimate. Confidence in the conclusions of a risk assessment may be increased by using several lines of evidence to interpret and compare risk estimates. These lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints (e.g., hazard quotients, modeling results, or field observational studies). There are three principal categories of factors to consider when evaluating lines of evidence:

1. **Data adequacy and quality.** Data quality directly influences confidence in the results of a risk assessment and the conclusions that can be drawn from the study. Specific concerns include: whether the experimental design was appropriate for the questions being evaluated in the risk assessment; whether data quality objectives were clear and adhered to; and whether the analyses were sufficiently sensitive and robust to identify stressor-caused effects in light of natural variability of the attributes of the ecological receptors of concern.

2. **Relative uncertainty.** One major source of uncertainty comes from extrapolations (e.g., from one species to another; from one temporal scale to another; from laboratory to field effects). In general, the greater the number of extrapolations, the greater the uncertainty.
3. **Relationship to the risk hypothesis.** Finally, the relative importance of each line of evidence may be determined by how directly they relate to the risk hypothesis developed during planning and scoping. For example, lines of evidence based on a definitive mechanism rather than associations alone are likely to be relatively important.

The evaluation of lines of evidence involves more than just listing the evidence that supports or refutes the risk estimate. Each factor should be examined carefully, and its contribution in the context of the risk assessment should be evaluated. For example, data or study results are often not reported or carried through the risk assessment because they are of insufficient quality. If such data or results are eliminated from the evaluation process, however, valuable information may be lost with respect to needed improvements in methodologies or recommendations for further studies.

When lines of evidence do not point toward the same conclusion, it is important to investigate possible reasons for the disagreements. A starting point is to distinguish between true inconsistencies and those related to methodology (e.g., statistical powers of detection). For example, if a model predicts adverse effects that were not observed in the field, it is important to determine whether the model predictions were unrealistic, or the experimental design of the field study was inadequate to detect the predicted effects, or both.

### **26.3.2 Significance of the Effects**

In this step, the significance of the observed or estimated changes in the assessment endpoints is interpreted in light of the lines of evidence evaluated above. In this context, significance refers to a conclusion as to whether the observed or estimated changes are considered “adverse.” Adverse ecological effects represent changes that are undesirable because they alter valued structural or functional attributes of the ecological receptors of concern (e.g., the loss of a keystone species). This determination is difficult and is frequently based on professional judgment. The assessment of degree of adversity, along with other factors such as the economic, legal, or social consequences of the ecological change, may be considered in the risk management decision. Unless an endangered or threatened species is at issue, society is generally not concerned with the death of individual plants or animals, and therefore significance is generally assessed at the population, community, or ecosystem level(s). The following factors may be used to evaluate the degree of adversity (see also Exhibit 26-2):

- **Nature and intensity of effects.** This focuses on distinguishing adverse changes from those that are within the normal pattern of ecosystem variability or that result in little or no significant alteration of biota. For example, if survival of offspring will be affected, by what percentage will it diminish, and is that likely to have a major impact on population dynamics? It is important to consider both ecological and statistical information in evaluating the nature and intensity of effects. For example, a small change in a growth rate may not be statistically distinguishable from natural variation; however, its impact may be more significant for a population of slowly reproducing fish than for rapidly reproducing algae. When performing a more refined assessment, it is necessary to compare the potentially impacted ecosystem to a

non-impacted ecosystem (i.e., a “control” site) so there is a basis for statistical comparisons between the two systems.

#### Exhibit 26-2. Examples of Considerations for Determining Ecological Significance

- How large is the area where ecological criteria have been exceeded?
- What proportion of the habitat is affected at local, county, State, and national levels?
- Are the exposure concentrations and ecological criteria above background levels for the area of interest?
- What types of ecological impacts have been associated with this pollutant or similar pollutants in the past?
- Is the criterion or stressor-responsive curve based on high quality data (i.e., is there a high degree of confidence in the criterion)?

- **Spatial and temporal scale.** The spatial dimension encompasses both the extent and pattern of effect as well as the context of the effect within the broader ecosystem or landscape. Factors to consider include the absolute area affected, the percentage of area affected compared with a larger area of interest, and the relative importance of the affected area(s) to the ecological receptors of concern (e.g., are they critical breeding or overwintering areas?). For air toxics that persist and bioaccumulate, the temporal dimension of concern generally will be in the years to decades range, although effects in other time frames may be important in specific cases. Temporal responses for ecosystems may involve intrinsic time lags, so responses to a stressor (or risk mitigation effort) may be delayed.
- **Potential for recovery.** Recovery refers to the rate and extent of return of a population or community to some aspect of its condition prior to exposure to the stressor(s) of concern. Because ecosystems are dynamic, even under natural conditions, it is unrealistic to expect that a system will remain static at some level or return to exactly the same state that it was before it was disturbed. Thus, the “attributes” of a recovered population, community, or ecosystem should be carefully defined. In general, changes that preclude recovery or result in long recovery times are more significant than changes that allow rapid recovery. Note that different components of a community or ecosystem may recover at different rates. For example, stream chemistry may recover relatively rapidly after removal of a stressor, but re-establishment of predatory fish populations may take several years or more.

## 26.4 Risk Characterization Report

The information on estimates of ecological risk, the overall degree of confidence in the risk estimates, lines of evidence, and the interpretation of the significance of ecological effects generally is included in a **risk assessment or risk characterization report**. Exhibit 26-3 lists the elements that generally are considered in the risk characterization report. A risk characterization report may be brief or extensive, depending on the nature of and resources available for the assessment. The report need not be overly complex or lengthy; it is most important that the information required to support the risk management decision be presented clearly and concisely. To facilitate mutual understanding, EPA policy<sup>(6)</sup> requires that risk characterizations 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.” It describes a philosophy of transparency, clarity, consistency, and reasonableness (TCCR), and

provides detailed approaches to achieving TCRR. Exhibit 26-4 provides an overview of the TCRR principles (these are the same principles listed in Chapter 13).

<b>Exhibit 26-3. Possible Risk Characterization Report Elements</b>	
<ul style="list-style-type: none"> <li>• Describe risk assessor/risk manager planning results.</li> <li>• Describe the scope of the assessment.</li> <li>• Review the conceptual model and the assessment endpoints.</li> <li>• Describe the measures of effect.</li> <li>• Discuss the major data sources and analytical procedures used.</li> <li>• Review the stressor-response and exposure profiles.</li> <li>• Assign risks to the assessment endpoints, including risk estimates and adversity evaluations.</li> <li>• Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them:               <ul style="list-style-type: none"> <li>– Discuss the degree of scientific consensus in key areas of uncertainty;</li> <li>– Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results;</li> <li>– Discuss science policy judgments or default assumptions used to bridge information gaps and the basis for these assumptions; and</li> <li>– Discuss how the elements of quantitative uncertainty analysis are embedded in the estimate of risk.</li> </ul> </li> </ul>	

<b>Exhibit 26-4. Transparency, Clarity, Consistency, and Reasonableness Principles</b>		
<b>Principle</b>	<b>Definition</b>	<b>Criteria for a Good Risk Characterization</b>
<b>Transparency</b>	Explicitness in the risk assessment process	<ul style="list-style-type: none"> <li>• Describe assessment approach, assumptions, extrapolations, and use of models</li> <li>• Describe plausible alternative assumptions</li> <li>• Identify data gaps</li> <li>• Distinguish science from policy</li> <li>• Describe uncertainty</li> <li>• Describe relative strength of assessment</li> </ul>
<b>Clarity</b>	The assessment itself is free from obscure language and is easy to understand	<ul style="list-style-type: none"> <li>• Employ brevity</li> <li>• Use plain English</li> <li>• Avoid technical terms</li> <li>• Use simple tables, graphics, and equations</li> </ul>
<b>Consistency</b>	The conclusions of the risk assessment are characterized in harmony with EPA actions	<ul style="list-style-type: none"> <li>• Follow statutes</li> <li>• Follow Agency guidance</li> <li>• Use Agency information systems</li> <li>• Place assessment in context with similar risks</li> <li>• Define level of effort</li> <li>• Use review by peers</li> </ul>
<b>Reasonableness</b>	The risk assessment is based on sound judgment	<ul style="list-style-type: none"> <li>• Use review by peers</li> <li>• Use best available scientific information</li> <li>• Use good judgment</li> <li>• Use plausible alternatives</li> </ul>

## 26.5 Evaluating Variability and Uncertainty

An important part of the Risk Characterization Report is a discussion and assessment of variability and uncertainty in all aspects of the ecological risk assessment. Note that ecological risk assessments are subject to additional sources of uncertainty and variability as compared to multipathway human health risk assessments. In addition to the uncertainties associated with multimedia modeling and sampling, the ecological risk assessment involves many decisions regarding choice of ecological receptors of concern and associated assessment and measures of effect. Some of these may be at levels of organization above individual species (e.g., communities, ecosystems), where stressor-response relationships are poorly understood. Because many different species and higher taxonomic groups may be included in the assessment, selection of many parameter values such as bioconcentration factors, dose-response values, and dietary intake is more complex and uncertain for the ecological risk assessment as compared to the human health multipathway risk assessment.

### References

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