Methodology for Assessing Human Health-Based Risks

Judy L. Crane
Minnesota Pollution Control Agency, Water Quality Division, St. Paul, Minnesota

The purpose of this presentation is to discuss how and why human health risk assessments are conducted at contaminated sediment sites. The main components of risk assessments (i.e., site characterization, toxicity assessment, exposure assessment, and risk characterization) are described. In addition, the advantages and limitations of using a risk assessment approach, as it applies to bioaccumulative contaminants, are discussed. The variety of methods by which human health risk assessments can be conducted are described, and these methods are illustrated with examples from baseline and comparative risk assessments conducted as part of the Great Lakes National Program Office's (GLNPO) Assessment and Remediation of Contaminated Sediments (ARCS) program.

Why Use a Risk Assessment Approach?

Risk assessment provides a scientific basis by which estimates of noncarcinogenic and carcinogenic risks can be estimated at a contaminated site. These risk estimates can be used to address management questions about a site; for example, what are the baseline (i.e., current) risks to residents living in the Sheboygan River, Wisconsin, Area of Concern (AOC)? or how would risks change at the Buffalo River, New York, AOC if various remediation alternatives were implemented? A risk assessment approach can also be used for regulation and enforcement purposes, as well as for the selection of clean-up criteria.

In the United States, the triggers that initiate a risk assessment include regulatory action leading to placement on the National Priorities List or a state-equivalent list of contaminated sites. Thus, human health risk assessments are conducted at all Superfund sites. In contrast, Canada has additional trigger mechanisms for risk assessment, including real estate transactions, rezoning/redevelopment, regulatory placement on a priority list, new legislation, or regulatory orders (Golder Associates, 1993). Canadians also have the option of using a criteria-based approach instead of a risk-based approach at contaminated sites.

The primary advantages of using a risk assessment approach include the following:

- Provides a quantitative basis for comparing and prioritizing risks.
- Improves the understanding of risk.
- Acknowledges the inherent uncertainty in estimating risk.
- Estimates clear, consistent endpoints (e.g., cancer).
- Separates risk assessment from risk management.

The limitations and uncertainties associated with human health risk assessments are discussed in the following sections.

Components of Human Health Risk Assessments

The specific components of human health risk assessments are described in this section. The U.S. Environmental Protection Agency (EPA) has developed exposure and risk assessment guidance for use at Superfund sites (USEPA, 1988, 1989a, 1989b, 1991) which can be applied to other contaminated sediment sites. Refer to this guidance for detailed information about how to perform a site characterization, toxicity assessment, exposure assessment, and risk characterization for a contaminated site. A brief review of these steps is given below.

Site Characterization

Available site information is reviewed, and relevant site samples are gathered, analyzed, and evaluated for appropriate quality assurance measures in this step. Potential site-related contaminants are compared with background values. In addition, potential contaminants of concern are identified, and a set of data is developed for use in the risk assessment.

Back

Toxicity Assessment

Verified toxicity values are obtained from EPA's Integrated Risk Information System (IRIS) database. For chemicals lacking a "verified value," interim toxicity values can be obtained from EPA's Health Effects Assessment Summary Tables (HEAST) and from the literature. The reference dose (RfD) is the toxicity value used to evaluate noncarcinogenic effects (e.g., neurotoxicity, reproductive and developmental toxicity, immunotoxicty, organ-specific toxicity). The slope factor is the toxicity value used in evaluating carcinogenic effects. It quantitatively defines the relationship between dose and response. The EPA weight-of-evidence classification scheme indicates the strength of evidence that the contaminant is a human carcinogen.

Exposure Assessment

This component involves the greatest use of assumptions and professional judgment when site-specific information is lacking. The major parts of an exposure assessment include the following: characterize the physical setting, identify potentially exposed populations, identify potential exposure pathways, estimate exposure concentrations, and estimate chemical intakes. The most important exposure pathways identified at five Great Lakes AOCs included the consumption of contaminated fish and/or waterfowl (Crane, 1996). In addition, most of the carcinogenic risk was due to elevated concentrations of polychlorinated biphenyls (PCBs) in fish tissue. In the exposure assessment, it is important to identify sensitive subpopulations such as sport anglers, ethnic groups that consume a greater proportion of fish in their diet, and pregnant women who consume contaminated fish. During the past few years, the Agency for Toxic Substances and Disease Registry (ATSDR) has funded a Great Lakes Human Health Effects Research Program that will provide more exposure information about sensitive subpopulations in the Great Lakes area, as well as how fish preparation and cooking practices can reduce bioaccumulative contaminants in fish tissue.

Risk Characterization

In this step, the exposure and toxicity estimates are combined into an integrated expression of human health risk. Noncarcinogenic effects are evaluated by comparing an exposure level over a specified time period with an RfD derived from a similar exposure period. Carcinogenic effects are estimated as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen. This risk is computed using average lifetime exposure values that are multiplied by the oral slope factor for a particular chemical. Noncarcinogenic and carcinogenic risk estimates are summed separately for all chemicals in an exposure pathway (e.g., fish consumption). The risk estimates are then summed for multiple exposure pathways. This summation does not account for any synergistic or antagonistic effects that may occur among chemicals. The risk characterization also includes an evaluation of the uncertainties associated with the risk estimate. Uncertainty is reduced by using as much site-specific information as possible. Refer to USEPA (1989a), Golder Associates (1993), and Crane (1996) for additional information on evaluating uncertainties.

Risk Assessment Methodologies

Given the risk assessment framework described above, human health risk assessments can vary in their complexity and scope. Risk assessments can be conducted in a qualitative, semi-quantitative, or quantitative way. The level of detail and cost associated with conducting a risk assessment increase as more quantitative results are needed. The human health risk assessments conducted for the ARCS program (Crane, 1996) were done in a semi-quantitative way because uncertainty was expressed in a qualitative way and quantitative risk estimates were estimated. Semi-quantitative risk assessments compose the greatest proportion of risk assessments conducted in the United States.

Semi-quantitative risk assessments are conducted using a deterministic approach (see Table 1). In this approach, a single number is used from each parameter set to calculate a single value of risk. Quantitative risk assessments are conducted using a stochastic approach (see Table 1), whereby a distribution of values for each parameter set is used in the risk calculation and a distribution of risk is produced. Some jurisdictions, such as British Columbia, are starting to require quantitative risk assessments at some contaminated sediment/soil sites.

Human health risk assessments conducted for the Superfund Program include baseline conditions and future land use exposure scenarios. Future land uses do not need to be considered if the management questions for the non-Superfund site are concerned only with current risk conditions to the public. Comparative risk assessments can be conducted to assess the risk, relative to the baseline risk, that would result from the implementation of various sediment remedial alternatives. The ARCS Risk Assessment and Modeling Workgroup developed a comparative risk assessment framework to integrate the results from baseline risk assessments, field data, and mass balance modeling to provide estimates of the potential impact of remedial actions on human health, aquatic life, and wildlife (USEPA, 1993). A demonstration of this approach was conducted for the Buffalo River, New York, AOC (Crane, 1995).

Problems with Current Risk Assessment Practice

Risk assessment is an evolving science and is not without its limitations. Some of the major problems associated with human health risk assessments include the following:

- Use of arbitrary exposure scenarios.
- Excessive credence to the carcinogen classification.

Table 1. Components of deterministic and stochastic risk assessments (Golder Associates, 1993).

Deterministic	Stochastic
Low degree of public interest	High degree of public interest
Relatively low degree of site-specific uncertainty	Relatively high degree of site-specific uncertainty
Deterministic result is far from action level	Deterministic result is close to action level
Small-scale project (scope, budget, schedule)	Large-scale project (scope, budget, schedule)
Routine application	Non-routine application
Large number of potential contaminants and/or pathways (rapid screening or triggering tool)	Small number of potential contaminants and/or pathways
Initial model development	Model refinement
	Quantification of uncertainty
	Detailed value-of-information analysis (project planning)

- Excessive reliance on findings from animal cancer tests.
- Lack of toxicity data for many components/metabolites of bioaccumulative contaminants (e.g., PCB congeners, some PCB Aroclors, polynuclear aromatic hydrocarbons).
- Lack of a quantitative level of risk that is universally acceptable or unacceptable.
- Poor assessment of noncarcinogenic health effects.
- Uncertainty of risk estimate may be poorly characterized.
- Risks may not be communicated well to the public.
- Environmental inequity not always considered for low-income and minority populations.

Despite the above limitations, risk assessment has been demonstrated as an effective way to prioritize how scarce funding sources should be spent to provide the most benefit to human and ecological health. EPA has adopted a risk assessment approach, as has the Minnesota Pollution Control Agency, for determining priorities and shaping regulatory planning/policy making. As the scientific and policy issues associated with conducting and communicating human health risk assessments are strengthened, the public will benefit from this increased level of confidence in risk estimates.

References

Crane, J.L. 1995. *Comparative human health and wildlife risk assessment: Buffalo River, New York, Area of Concern.* EPA 905-R-95-008. U.S. Environmental Protection Agency, Great Lakes National Program Office, Chicago, IL.

Crane, J.L. 1996. Carcinogenic human health risks associated with consuming contaminated fish from five Great Lakes Areas of Concern. *J. Great Lakes Res.* 22:653-668.

Golder Associates. 1993. *Quantitative human health risk assessment. Phase 1 - Review of methods and framework recommendation.* Prepared for Ministry of Environment, Lands and Parks, Victoria, BC, by Golder Associates, Burnaby, BC.

USEPA. 1988. *Superfund exposure assessment manual.* EPA/540/1-88/001. U.S. Environmental Protection Agency, Office of Remedial Response, Washington, DC.

USEPA. 1989a. *Risk assessment guidance for superfund: Human health evaluation manual part A.* Interim final. OSWER Directive 9285.7-01a. U. S. Environmental Protection Agency, Washington, DC.

USEPA. 1989b. *Exposure factors handbook.* EPA/600/8-89/043. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, Washington, DC.

USEPA. 1991. *Risk assessment guidance for Superfund. Volume I: Human health evaluation manual. Supplemental guidance: "Standard default exposure factors."* Interim final (March 25, 1991). OSWER Directive 9285.6-03. U.S. Environmental Protection Agency, Washington, DC.

USEPA. 1993. *Risk assessment and modeling overview document.* EPA 905-R93-007. U.S. Environmental Protection Agency, Great Lakes National Program Office, Chicago, IL.

Next