SECTION 1. RISK ASSESSMENT - RISK MANAGEMENT INTERFACE

Recognizing that for many people the term risk assessment has wide meaning, the National Research Council's 1983 report on risk assessment in the federal government (hereafter "NRC report" distinguished between risk assessment and risk management.

> Broader uses of the term [risk assessment] than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions -- <u>functions that we assign to risk management</u> (emphasis added). (1)

In 1984, EPA endorsed these distinctions between risk assessment and risk management for Agency use (2), and later relied on them in developing risk assessment guidelines 3).

This distinction suggests that EPA participants in the process can be grouped into two main categories, each with somewhat different responsibilities, based on their roles with respect to risk assessment and risk management

> <u>Risk Assessment</u>
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> One group <u>generates</u> the risk assessment by collecting, analyzing, and synthesizing scientific data to produce the hazard identification, dose-response, and exposure assessment portion of the risk assessment and to characterize risk. This group relies in part on Agency risk assessment guidelines to address science policy issues and scientific uncertainties.
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> Generally, this group includes scientists and statisticians in the Office of Research and Development, the Office of Pesticides and Toxic Substances and other program offices, the Carcinogen Risk Assessment Verification Endeavor (CRAVE), and the RfD/RfC Workgroups.

Others use analyses produced by the first group to generate site- or media-specific exposure assessments and risk characterizations for use in regulation development. These assessors rely on existing databases (e.g., IRIS, ORD Health Assessment Documents, CRAVE and RfD/RfC Workgroup documents) to develop regulations and evaluate alternatives.

Generally, this group includes scientists and analysts in program offices, regional offices, and the Office of Research and Development.

Risk Management

A third group integrates the risk characterization with other non-scientific considerations specified in applicable statutes to make and justify regulatory decisions.

Generally, this group includes Agency managers and decision-makers.

Each group has different responsibilities for observing the distinction between risk assessment and risk management. At the same time, the risk assessment process involves regular interaction between each of the groups, with overlapping responsibilities at various stages in the overall process

The guidance to follow outlines principles specific for those who generate, review, use, and integrate risk assessments for decision-making.

1. Risk assessors and risk managers should be sensitive to distinctions between risk assessment and risk management.

The major participants in the risk assessment process have shared responsibilities. Where responsibilities differ, it is important that participants confine themselves to tasks in their areas of responsibility and not inadvertently obscure differences between risk assessment and risk management.

Shared responsibilities of assessors and managers include initial decisions regarding the planning and conduct of an assessment, discussions as the assessment develops, decisions regarding new data needed to complete an assessment and to address significant uncertainties. At critical junctures in the assessment, such consultations shape the nature of, and schedule the assessment.

For the generators of the assessment, distinguishing between risk assessment and risk management means that scientific information is selected, evaluated, and presented without considering non-scientific factors including how the scientific analysis might influence the regulatory decision. Assessors are charged with (1) generating a credible, objective, realistic, and balanced analysis; (2) presenting information on hazard, dose-response, exposure and risk; and (3) explaining confidence in each assessment by clearly delineating uncertainties and assumptions along with the impacts of these factors (e.g., confidence limits, use of conservative/non-conservative assumptions) on the overall assessment. They do not make decisions on the acceptability of any risk level for protecting

public health or selecting procedures for reducing risks.

For users of the assessment and for decision-makers who integrate these assessments into regulatory decisions, the distinction between risk assessment and risk management means refraining from influencing the risk description through consideration of non-scientific factors -- e.g., the regulatory outcome -- and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or serve political purposes. Such management considerations are often legitimate considerations for the overall regulatory decision (see next principle), but they have no role in estimating or describing risk.

However, decision-makers establish policy directions that determine the overall nature and tone of Agency risk assessments and, as appropriate, provide policy guidance on difficult and controversial risk assessment issues. Matters such as risk assessment priorities, degree of conservatism, and acceptability of particular risk levels are reserved for decision-makers who are charged with making decisions regarding protection of public health.

2. The risk assessment product, that is, the risk characterization, is only one of several kinds of information used for regulatory decision-making.

Risk characterization, the last step in risk assessment, is the starting point for risk management considerations and the foundation for regulatory decision-making, but it is only one of several important components in such decisions. Each of the environmental laws administered by EPA calls for consideration of non-scientific factors at various stages in the regulatory process. As authorized by different statutes, decision-makers evaluate technical feasibility (e.g., treatability, detection limits), economic, social, political, and legal factors as part of the analysis of whether or not to regulate and, if so, to what extent. Thus, regulatory decisions are usually based on a combination of the technical analysis used to develop the risk assessment and information from other fields

For this reason, risk assessors and managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment. That is, the analysis of the overall regulatory problem may not be the same as the picture presented by the risk analysis alone. For example, a pesticide risk assessment may describe moderate risk to some populations but, if the agricultural benefits of its use are important for the nation's food supply, the product may be allowed to remain on the market with certain restrictions on use to reduce possible exposure. Similarly, assessment efforts may produce an RfD for a particular chemical, but other

considerations may result in a regulatory level that is more or less protective than the RfD itself.

For decision-makers, this means that societal considerations (e.g., costs, benefits) that, along with the risk assessment, shape the regulatory decision should be described as fully as the scientific information set forth in the risk characterization. Information on data sources and analyses, their strengths and limitations, confidence in the assessment, uncertainties, and alternative analyses are as important here as they are for the scientific components of the regulatory decision. Decision-makers should be able to expect, for example, the same level of rigor from the economic analysis as they receive from the risk analysis

Decision-makers are not "captives of the numbers." On the contrary, the quantitative and qualitative risk characterization is only one of many important factors that must be considered in reaching the final decision -- a difficult and distinctly different task from risk assessment per se. Risk management decisions involve numerous assumptions and uncertainties regarding technology, economics and social factors, which need to be explicitly identified for the decision-makers and the public