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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 26 1992

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

SUBJECT: Guidance on Risk Characterization for Risk Managers and Risk Assessors

FROM: F. Henry Habicht II *FHH*
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TO: Assistant Administrators
Regional Administrators

INTRODUCTION

This memorandum provides guidance for managers and assessors on describing risk assessment results in EPA reports, presentations, and decision packages. The guidance addresses a problem that affects public perception regarding the reliability of EPA's scientific assessments and related regulatory decisions. EPA has talented scientists, and public confidence in the quality of our scientific output will be enhanced by our visible interaction with peer scientists and thorough presentation of risk assessments and underlying scientific data.

Specifically, although a great deal of careful analysis and scientific judgment goes into the development of EPA risk assessments, significant information is often omitted as the results of the assessment are passed along in the decision-making process. Often, when risk information is presented to the ultimate decision-maker and to the public, the results have been boiled down to a point estimate of risk. Such "short hand" approaches to risk assessment do not fully convey the range of information considered and used in developing the assessment. In short, informative risk characterization clarifies the scientific basis for EPA decisions, while numbers alone do not give a true picture of the assessment.

This problem is not EPA's alone. Agency contractors, industry, environmental groups, and other participants in the overall regulatory process use similar "short hand" approaches.

We must do everything we can to ensure that critical information from each stage of the risk assessment is communicated from risk assessors to their managers, from middle

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to upper management, from EPA to the public, and from others to EPA. The Risk Assessment Council considered this problem over many months and reached several conclusions: 1) We need to present a full and complete picture of risk, including a statement of confidence about data and methods used to develop the assessment; 2) we need to provide a basis for greater consistency and comparability in risk assessments across Agency programs; and 3) professional scientific judgment plays an important role in the overall statement of risk. The Council also concluded that Agency-wide guidance would be useful.

BACKGROUND

Principles emphasized during Risk Assessment Council discussions are summarized below and detailed in the attached Appendix.

Full Characterization of Risk

EPA decisions are based in part on risk assessment, a technical analysis of scientific information on existing and projected risks to human health and the environment. As practiced at EPA, the risk assessment process depends on many different kinds of scientific data (e.g., exposure, toxicity, epidemiology), all of which are used to "characterize" the expected risk to human health or the environment. Informed use of reliable scientific data from many different sources is a central feature of the risk assessment process.

Highly reliable data are available for many aspects of an assessment. However, scientific uncertainty is a fact of life for the risk assessment process as a whole. As a result, agency managers make decisions using scientific assessments that are less certain than the ideal. The issues, then, become when is scientific confidence sufficient to use the assessment for decision-making, and how should the assessment be used? In order to make these decisions, managers need to understand the strengths and the limitations of the assessment.

On this point, the guidance emphasizes that informed EPA risk assessors and managers need to be completely candid about confidence and uncertainties in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each EPA risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports and regulatory documents.

Scientists call for fully characterizing risk not to question the validity of the assessment, but to fully inform others about critical information in the assessment. The emphasis on "full" and "complete" characterization does not refer to an ideal assessment in which risk is completely defined by fully satisfactory scientific data. Rather, the concept of complete risk characterization means that information that is needed for informed evaluation and use of the assessment is carefully highlighted. Thus, even though risk characterization details limitations in an assessment, a balanced discussion of reliable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment.

This guidance is not new. Rather, it re-states, clarifies, and expands upon current risk assessment concepts and practices, and emphasizes aspects of the process that are often incompletely developed. It articulates principles that have long guided experienced risk assessors and well-informed risk managers, who recognize that risk is best described not as a classification or single number, but as a composite of information from many different sources, each with varying degrees of scientific certainty.

Comparability and Consistency

The Council's second finding, on the need for greater comparability, arose for several reasons. One was confusion -- for example, many people did not understand that a risk estimate of 10^{-6} for an "average" individual should not be compared to another 10^{-6} risk estimate for the "most exposed individual". Use of such apparently similar estimates without further explanation leads to misunderstandings about the relative significance of risks and the protectiveness of risk reduction actions. Another catalyst for change was the SAB's report, Reducing Risk: Setting Priorities and Strategies for Environmental Protection. In order to implement the SAB's recommendation that we target our efforts to achieve the greatest risk reduction, we need common measures of risk.

EPA's newly revised Exposure Assessment Guidelines provide standard descriptors of exposure and risk. Use of these terms in all Agency risk assessments will promote consistency and comparability. Use of several descriptors, rather than a single descriptor, will enable us to present a more complete picture of risk that corresponds to the range of different exposure conditions encountered by various populations exposed to most environmental chemicals.

Professional Judgment

The call for more extensive characterization of risk has obvious limits. For example, the risk characterization includes

only the most significant data and uncertainties from the assessment (those that define and explain the main risk conclusions) so that decision-makers and the public are not overwhelmed by valid but secondary information.

The degree to which confidence and uncertainty are addressed depends largely on the scope of the assessment and available resources. When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained. For example, an emergency telephone inquiry does not require a full written risk assessment, but the caller must be told that EPA comments are based on a "back-of-the-envelope" calculation and, like other preliminary or simple calculations, cannot be regarded as a risk assessment.

GUIDANCE PRINCIPLES

Guidance principles for developing, describing, and using EPA risk assessments are set forth in the Appendix. Some of these principles focus on differences between risk assessment and risk management, with emphasis on differences in the information content of each process. Other principles describe information expected in EPA risk assessments to the extent practicable, emphasizing that discussion of both data and confidence in the data are essential features of a complete risk assessment. Comments on each principle appear in the Appendix; more detailed guidance is available in EPA's risk assessment guidelines (e.g., 51 Federal Register 33992-34054, 24 September 1986).

Like EPA's risk assessment guidelines, this guidance applies to the development, evaluation, and description of Agency risk assessments for use in regulatory decision-making. This memorandum does not give guidance on the use of completed risk assessments for risk management decisions, nor does it address the use of non-scientific considerations (e.g., economic or societal factors) that are considered along with the risk assessment in risk management and decision-making. While some aspects of this guidance focus on cancer risk assessment, the guidance applies generally to human health effects (e.g., neurotoxicity, developmental toxicity) and, with appropriate modifications, should be used in all health risk assessments. Guidance specifically for ecological risk assessment is under development.

IMPLEMENTATION

Effective immediately, it will be Agency policy for each EPA office to provide several kinds of risk assessment information in connection with new Agency reports, presentations, and decision

packages. In general, such information should be presented as carefully selected highlights from the overall assessment. In this regard, common sense regarding information needed to fully inform Agency decision-makers is the best guide for determining the information to be highlighted in decision packages and briefings.

1. Regarding the interface between risk assessment and risk management, risk assessment information must be clearly presented, separate from any non-scientific risk management considerations. Discussion of risk management options should follow, based on consideration of all relevant factors, scientific and non-scientific.
2. Regarding risk characterization, key scientific information on data and methods (e.g., use of animal or human data for extrapolating from high to low doses, use of pharmacokinetics data) must be highlighted. We also expect a statement of confidence in the assessment that identifies all major uncertainties along with comment on their influence on the assessment, consistent with guidance in the attached Appendix.
3. Regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple risk-descriptors (i.e., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with terminology in the attached Appendix and Agency guidelines.

This guidance applies to all Agency offices. It applies to assessments generated by EPA staff and to those generated by contractors for EPA's use. I believe adherence to this Agency-wide guidance will improve understanding of Agency risk assessments, lead to more informed decisions, and heighten the credibility of both assessments and decisions.

From this time forward, presentations, reports, and decision packages from all Agency offices should characterize risk and related uncertainties as described here. Please be prepared to identify and discuss with me any program-specific modifications that may be appropriate. However, we do not expect risk assessment documents that are close to completion to be rewritten. Although this is internal guidance that applies directly to assessments developed under EPA auspices, I also encourage Agency staff to use these principles as guidance in evaluating assessments submitted to EPA from other sources, and in discussing these submissions with me and with the Administrator.

This guidance is intended for both management and technical staff. Please distribute this document to those who develop or review assessments and to your managers who use them to implement Agency programs. Also, I encourage you to discuss the principles outlined here with your staff, particularly in briefings on particular assessments.

In addition, I expect that the Risk Assessment Council will endorse new guidance on Agency-wide approaches to risk characterization now being developed in the Risk Assessment Forum for EPA's risk assessment guidelines, and that the Agency and the Council will augment that guidance as needed.

The Administrator and I believe that this effort is very important. It furthers our goals of rigor and candor in the preparation, presentation, and use of EPA risk assessments. The tasks outlined above may require extra effort from you, your managers, and your technical staff, but they are critical to full implementation of these principles. We are most grateful for the hard work of your representatives on the RAC and other staff in pulling this document together. I appreciate your cooperation in this important area of science policy, and look forward to our discussions.

Attachment

cc: The Administrator |
Risk Assessment Council