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

THE ADMINISTRATOR

MAR 2 1 1995

MEMORANDUM

SUBJECT: EPA Risk Characterization Program

TO: Assistant Administrators
Associate Administrators
Regional Administrators
General Counsel
Inspector General

EPA has achieved significant pollution reduction over the past 20 years, but the challenges we face now are very different from those of the past. Many more people are aware of environmental issues today than in the past and their level of sophistication and interest in understanding these issues continues to increase. We now work with a populace which is not only interested in knowing what EPA thinks about a particular issue, but also how we come to our conclusions.

More and more key stakeholders in environmental issues want enough information to allow them to independently assess and make judgments about the significance of environmental risks and the reasonableness of our risk reduction actions. If we are to succeed and build our credibility and stature as a leader in environmental protection for the next century, EPA must be responsive and resolve to more openly and fully communicate to the public the complexities and challenges of environmental decisionmaking in the face of scientific uncertainty.

As the issues we face become more complex, people both inside and outside of EPA must better understand the basis for our decisions, as well as our confidence in the data, the science policy judgments we have made, and the uncertainty in the information base. In order to achieve this better understanding, we must improve the way in which we characterize and communicate environmental risk. We must embrace certain fundamental values

so that we may begin the process of changing the way in which we interact with each other, the public, and key stakeholders on environmental risk issues. I need your help to ensure that these values are embraced and that we change the way we do business.

First, we must adopt as values **transparency** in our decisionmaking process and **clarity** in communication with each other and the public regarding environmental risk and the uncertainties associated with our assessments of environmental risk. This means that we must fully, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions as they are made throughout the risk assessment and risk management processes. I want to be sure that key science policy issues are identified as such during the risk assessment process, that policymakers are fully aware and engaged in the selection of science policy options, and that their choices and the rationale for those choices are clearly articulated and visible in our communications about environmental risk.

I understand that some may be concerned about additional challenges and disputes. I expect that we will see more challenges, particularly at first. However, I strongly believe that making this change to a more open decisionmaking process will lead to more meaningful public participation, better information for decisionmaking, improved decisions, and more public support and respect for EPA positions and decisions. There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty. I view making this change as essential to the long term success of this Agency.

Clarity in communication also means that we will strive to help the public put environmental risk in the proper perspective when we take risk management actions. We must meet this challenge and find legitimate ways to help the public better comprehend the relative significance of environmental risks.

Second, because **transparency** in decisionmaking and **clarity** in communication will likely lead to more outside questioning of our assumptions and science policies, we must be more vigilant about ensuring that our core assumptions and science policies are **consistent** and comparable across programs, well grounded in science, and that they fall within a "zone of **reasonableness**."

While I believe that the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative. We cannot lead the fight for environmental protection into the next century unless we use common sense in all we do.

These core values of transparency, clarity, consistency, and reasonableness need to guide each of us in our day-to-day work; from the toxicologist reviewing the individual cancer study, to the exposure and risk assessors, to the risk manager, and through to the ultimate decisionmaker. I recognize that issuing this memo will not by itself result in any change. You need to believe in the importance of this change and convey your beliefs to your managers and staff through your words and actions in order for the change to occur. You also need to play an integral role in developing the implementing policies and procedures for your programs.

I am issuing the attached EPA Risk Characterization Policy and Guidance today. I view these documents as building blocks for the development of your program-specific policies and procedures. The Science Policy Council (SPC) plans to adopt the same basic approach to implementation as was used for Peer Review. That is, the Council will form an Advisory Group that will work with a broad Implementation Team made up of representatives from every Program Office and Region. Each Program Office and each Region will be asked by the Advisory Group to develop program and region-specific policies and procedures for risk characterization consistent with the values of **transparency, clarity, consistency, and reasonableness** and consistent with the attached policy and guidance.

I recognize that as you develop your Program-specific policies and procedures you are likely to need additional tools to fully implement this policy. I want you to identify these needed tools and work cooperatively with the Science Policy Council in their development. I want your draft program and region-specific policies, procedures, and implementation plans to be developed and submitted to the Advisory Group for review by no later than May 30, 1995. You will be contacted shortly by the SPC Steering Committee to obtain the names of your nominees to the Implementation Team.

Carol M. Browner

Attachments

March 1995

# POLICY FOR RISK CHARACTERIZATION

## at the U.S. Environmental Protection Agency

## INTRODUCTION

Many EPA policy decisions are based in part on the results of risk assessment, an analysis of scientific information on existing and projected risks to human health and the environment. As practiced at EPA, risk assessment makes use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology, ecology), all of which are used to "characterize" the expected risk associated with a particular agent or action 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 a fact of life for the risk assessment process, and agency managers almost always must make decisions using assessments that are not as definitive in all important areas as would be desirable. They therefore need to understand the strengths and the limitations of each assessment, and to communicate this information to all participants and the public.

This policy reaffirms the principles and guidance found in the Agency's 1992 policy (Guidance on Risk Characterization for Risk Managers and Risk Assessors, February 26, 1992). That guidance was based on EPA's risk assessment guidelines, which are products of peer review and public comment. The 1994 National Research Council (NRC) report, "Science and Judgment in Risk Assessment," addressed the Agency's approach to risk assessment, including the 1992 risk characterization policy. The NRC statement accompanying the report stated, "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the Agency must more clearly establish the scientific and policy basis for risk estimates and better describe the uncertainties in its estimates of risk."

This policy statement and associated guidance for risk characterization is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers (policy makers), from middle to upper management, and from the Agency to the public. Additionally, the policy will provide a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs. While most of the discussion and examples in this policy are drawn from health risk assessment, these values also apply to ecological risk assessment. A parallel effort by the Risk Assessment Forum to develop EPA ecological risk assessment guidelines will include guidance specific to ecological risk characterization.

## Policy Statement

Each risk assessment prepared in support of decision-making at EPA should include a risk characterization that follows the principles and reflects the values outlined in this policy. A risk characterization should 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. Further, discussion of risk in all EPA reports, presentations, decision packages, and other documents should be substantively consistent with the risk characterization. The nature of the risk characterization will depend upon the information available, the regulatory application of the risk information, and the resources (including time) available. In all cases, however, the assessment should identify and discuss all the major issues associated with determining the nature and extent of the risk and provide commentary on any constraints limiting fuller exposition.

## Key Aspects of Risk Characterization

**Bridging risk assessment and risk management.** As the interface between risk assessment and risk management, risk characterizations should be clearly presented, and separate from any risk management considerations. Risk management options should be developed using the risk characterization and should be based on consideration of all relevant factors, scientific and nonscientific.

**Discussing confidence and uncertainties.** Key scientific concepts, data and methods (e.g., use of animal or human data for extrapolating from high to low doses, use of pharmacokinetics data, exposure pathways, sampling methods, availability of chemical-specific information, quality of data) should be discussed. To ensure transparency, risk characterizations should include a statement of confidence in the assessment that identifies all major uncertainties along with comment on their influence on the assessment, consistent with the Guidance on Risk Characterization (attached).

**Presenting several types of risk information.** 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 subgroups, if known) consistent with terminology in the Guidance on Risk Characterization, Agency risk assessment guidelines, and program-specific guidance. In decision-making, risk managers should use risk information appropriate to their program legislation.

EPA conducts many types of risk assessments, including screening-level assessments of new chemicals, in-depth assessments of pollutants such as dioxin

and environmental tobacco smoke, and site-specific assessments for hazardous waste sites. An iterative approach to risk assessment, beginning with screening techniques, may be used to determine if a more comprehensive assessment is necessary. The degree to which confidence and uncertainty are addressed in a risk characterization depends largely on the scope of the assessment. In general, the scope of the risk characterization should reflect the information presented in the risk assessment and program-specific guidance. When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed.

## Risk Characterization in Context

Risk assessment is based on a series of questions that the assessor asks about scientific information that is relevant to human and/or environmental risk. Each question calls for analysis and interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem at hand, and scientific conclusions regarding the question presented. For example, health risk assessments involve the following questions:

Hazard Identification -- What is known about the capacity of an environmental agent for causing cancer or other adverse health effects in humans, laboratory animals, or wildlife species? What are the related uncertainties and science policy choices?

Dose-Response Assessment -- What is known about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or epidemiology studies providing data for the assessment? What are the related uncertainties and science policy choices?

Exposure Assessment -- What is known about the principal paths, patterns, and magnitudes of human or wildlife exposure and numbers of persons or wildlife species likely to be exposed? What are the related uncertainties and science policy choices?

Corresponding principles and questions for ecological risk assessment are being discussed as part of the effort to develop ecological risk guidelines.

Risk characterization is the summarizing step of risk assessment. The risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative and useful for decisionmakers.

Risk characterizations should clearly highlight both the confidence and the uncertainty associated with the risk assessment. For example, 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. In essence, a risk characterization conveys the assessor's judgment as to the nature and existence of (or lack of) human health or ecological risks. Even though a risk characterization describes limitations in an assessment, a balanced discussion of reasonable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment.

"Risk characterization" is not synonymous with "risk communication." This risk characterization policy addresses the interface between risk assessment and risk management. Risk communication, in contrast, emphasizes the process of exchanging information and opinion with the public – including individuals, groups, and other institutions. The development of a risk assessment may involve risk communication. For example, in the case of site-specific assessments for hazardous waste sites, discussions with the public may influence the exposure pathways included in the risk assessment. While the final risk assessment document (including the risk characterization) is available to the public, the risk communication process may be better served by separate risk information documents designed for particular audiences.

## Promoting Clarity, Comparability and Consistency

There are several reasons that the Agency should strive for greater clarity, consistency and comparability in risk assessments. One reason is to minimize confusion. For example, many people have not understood that a risk estimate of one in a million for an "average" individual is not comparable to another one in a million 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.

EPA's 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 EPA to present a fuller picture of risk that corresponds to the range of different exposure conditions encountered by various individuals and populations exposed to most environmental chemicals.

## Legal Effect

This policy statement and associated guidance on risk characterization do not establish or affect legal rights or obligations. Rather, they confirm the importance of risk characterization as a component of risk assessment, outline relevant principles, and identify factors Agency staff should consider in implementing the policy.

The policy and associated guidance do not stand alone; nor do they establish a binding norm that is finally determinative of the issues addressed. Except where otherwise provided by law, the Agency's decision on conducting a risk assessment in any particular case is within the Agency's discretion. Variations in the application of the policy and associated guidance, therefore, are not a legitimate basis for delaying or complicating action on Agency decisions.

## Applicability

Except where otherwise provided by law and subject to the limitations on the policy's legal effect discussed above, this policy applies to risk assessments prepared by EPA and to risk assessments prepared by others that are used in support of EPA decisions.

EPA will consider the principles in this policy in evaluating assessments submitted to EPA to complement or challenge Agency assessments. Adherence to this Agency-wide policy will improve understanding of Agency risk assessments, lead to more informed decisions, and heighten the credibility of both assessments and decisions.

## Implementation

Assistant Administrators and Regional Administrators are responsible for implementation of this policy within their organizational units. The Science Policy Council (SPC) is organizing Agency-wide implementation activities. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, working with external groups on risk characterization issues and methods, and developing recommendations for revisions of the policy and guidance, as necessary.

Each Program and Regional office will develop office-specific policies and procedures for risk characterization that are consistent with this policy and the associated guidance. Each Program and Regional office will designate a risk manager or risk assessor as the office representative to the Agency-wide Implementa-

tion Team, which will coordinate development of office-specific policies and procedures and other implementation activities. The SPC will also designate a small cross-Agency Advisory Group that will serve as the liaison between the SPC and the Implementation Team.

In ensuring coordination and consistency among EPA offices, the Implementation Team will take into account statutory and court deadlines, resource implications, and existing Agency and program-specific guidance on risk assessment. The group will work closely with staff throughout Headquarters and Regional offices to promote development of risk characterizations that present a full and complete picture of risk that meets the needs of the risk managers.

APPROVED: Carol M. Browner DATE: MAR 2 1 1995

Carol M. Browner, Administrator