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ADMINISTRATOR  
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REGULATORY AFFAIRS

MEMORANDUM FOR REGULATORY WORKING GROUP

FROM: Sally Katzen *S. Katzen*  
SUBJECT: Principles for Risk Analysis

Attached is a statement of policy on risk assessment, management and communication. The principles are designed to define risk analysis and its purposes, and to generally guide agencies as they use risk analysis in the regulatory context. They are intended to provide a general framework -- a structure stating basic principles upon which a wide consensus now exists.

The principles are aspirational rather than prescriptive. Their application requires flexibility and practical judgment. The science of risk assessment is rapidly changing and its use is a function of a number of factors -- including legal mandates and available resources -- that vary from one regulatory program to another. We therefore do not offer these principles as conclusive, complete or irrevocable; they are intended to be used as a point of departure for future efforts within individual agencies and the Executive Branch broadly.

The principles should be interpreted and applied as a whole. Particular sections should not be quoted or extracted in isolation. The principles are not intended to provide the basis for judicial review or legislation.

# **Principles for Risk Assessment, Management, and Communication**

**Regulatory Working Group  
January 12, 1995**

## **A. General Principles**

- 1. These Principles are intended to be goals for agency activities with respect to the assessment, management, and communication of environmental, health, and safety risks. Agencies should recognize that risk analysis is a tool — one of many, but nonetheless an important tool — in the regulatory tool kit. These Principles are intended to provide a general policy framework for evaluating and reducing risk, while recognizing that risk analysis is an evolving process and agencies must retain sufficient flexibility to incorporate scientific advances.**
- 2. The principles in this document are intended to be applied and interpreted in the context of statutory policies and requirements, and Administration priorities.**
- 3. As stated in Executive Order No. 12866, "In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction" [Section 1(b)(4)]. Further, in developing regulations, federal agencies should consider "...how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency" [Section 4(c)(1)(D)].**
- 4. In undertaking risk analyses, agencies should establish and maintain a clear distinction between the identification, quantification, and characterization of risks, and the selection of methods or mechanisms for managing risks. Such a distinction, however, does not mean separation. Risk management policies may induce changes in human behaviors that can alter risks (i.e., reduce,**

increase, or change their character), and these linkages must be incorporated into evaluations of the effectiveness of such policies.

5. The depth or extent of the analysis of the risks, benefits and costs associated with a decision should be commensurate with the nature and significance of the decision.

**B. Principles for Risk Assessment**

1. Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.
2. Characterizations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterizations should be broad enough to inform the range of policies to reduce risks.
3. Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.
4. Risk assessments should encompass all appropriate hazards (e.g., acute and chronic risks, including cancer and non-cancer risks, to human health and the environment). In addition to considering the full population at risk, attention should be directed to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed.
5. Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximize its use.
6. Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

**C. Principles for Risk Management**

1. In making significant risk management decisions, agencies should analyze the distribution of the risks and the benefits and costs (both direct and indirect,

both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies, including regulation, positive and negative economic incentives, and other ways to encourage behavioral changes to reduce risks (e.g., information dissemination), should be evaluated. Agencies should employ the best available scientific, economic and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and methods of data development.

2. In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).

D. Principles for Risk Communication

1. Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and "experts" in relevant disciplines, and the public.
2. Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner. To maximize public understanding and participation in risk-related decisions, agencies should:
  - a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
  - b. describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
  - c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risks; and,

- d. provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

E. Principles for Priority Setting Using Risk Analysis

1. To inform priority setting, agencies should seek to compare risks, grouping them into broad categories of concern (e.g., high, moderate, and low).
2. Agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first, accounting for relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.
3. The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organizations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.
4. Agencies should attempt to coordinate risk reduction efforts wherever feasible and appropriate.