POLICY FOR USE OF PROBABILISTIC ANALYSIS IN RISK ASSESSMENT

at the U.S. Environmental Protection Agency

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INTRODUCTION

The importance of adequately characterizing variability and uncertainty in risk assessments has been emphasized in several science and policy documents. These include the 1992 U.S. Environmental Protection Agency (EPA) Exposure Assessment Guidelines, the 1992 EPA Risk Assessment Council (RAC) Guidance, the 1995 EPA Policy for Risk Characterization, the EPA Proposed Guidelines for Ecological Risk Assessment, the EPA Region 3 Technical Guidance Manual on Risk Assessment, the EPA Region 8 Superfund Technical Guidance, the 1994 National Academy of Sciences "Science and Judgment in Risk Assessment," and the report by the Commission on Risk Assessment and Risk Management. As part of the implementation of the recommendations contained in these reports, the Agency is issuing guidance on the appropriate use of an application for analyzing variability and uncertainty in Agency risk assessments.

This policy and the guiding principles attached are designed to support the use of various techniques for characterizing variability and uncertainty. Further, the policy defines a set of Conditions for Acceptance. These conditions are important for ensuring good scientific practice in quantifying uncertainty and variability. In accordance with EPA's 1995 Policy for Risk Characterization, this policy also emphasizes the importance of clarity, transparency, reasonableness, and consistency in risk assessments.

There are a variety of different methods for characterizing uncertainty and variability. These methods cover a broad range of complexity from the simple comparison of discrete points to probabilistic techniques like Monte Carlo analysis. Recently, interest in using Monte Carlo analysis for risk assessment has increased. This method has the advantage of allowing the analyst to account for relationships between input variables and of providing the flexibility to investigate the effects of different modeling assumptions. Experience has shown that to benefit fully from the advantages of such probabilistic techniques as Monte Carlo analysis, certain standards of practice are to be observed. The Agency is issuing, therefore, this policy statement and associated guiding principles. While Monte Carlo analysis is the most frequently encountered probabilistic tool for analyzing variability and uncertainty in risk assessments, the intent of this policy is not to indicate that Monte Carlo analysis is the only acceptable approach for Agency risk assessments. The spirit of this policy and the Conditions for Acceptance described herein are equally applicable to other methods for analyzing variability and uncertainty.

POLICY STATEMENT

It is the policy of the U.S. Environmental Protection Agency that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments. As such, and provided that the conditions described below are met, risk assessments using Monte Carlo analysis or other probabilistic techniques will be evaluated and utilized in a manner that is consistent with other risk assessments submitted to the Agency for review or consideration. It is not the intent of this policy to recommend that probabilistic analysis be conducted for all risk assessments supporting risk management decisions. Such analysis should be a part of a tiered approach to risk assessment that progresses from simpler (e.g., deterministic) to more complex

(e.g., probabilistic) analyses as the risk management situation requires. Use of Monte Carlo or other such techniques in risk assessments shall not be cause, per se, for rejection of the risk assessment by the Agency. For human health risk assessments, the application of Monte Carlo and other probabilistic techniques has been limited to exposure assessments in the majority of cases. The current policy, Conditions for Acceptance and associated guiding principles are not intended to apply to dose response evaluations for human health risk assessment until this application of probabilistic analysis has been studied further. In the case of ecological risk assessment, however, this policy applies to all aspects including stressor and dose-response assessment.

CONDITIONS FOR ACCEPTANCE

When risk assessments using probabilistic analysis techniques (including Monte Carlo analysis) are submitted to the Agency for review and evaluation, the following conditions are to be satisfied to ensure high quality science. These conditions, related to the good scientific practices of transparency, reproducibility, and the use of sound methods, are summarized here and explained more fully in the Attachment, "Guiding Principles for Monte Carlo Analysis."

1. The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.
2. The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.
3. The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.
4. The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.
5. Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.
6. The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions are to be presented and discussed.
7. Calculations of exposures and risks using deterministic (e.g., point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening level risk assessments. Further, deterministic estimates may be used to answer scenario specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.
8. Since fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity metrics (e.g., Reference Doses, Reference Concentrations, unit cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

LEGAL EFFECT

This policy and associated guidance on probabilistic analysis techniques do not establish or affect legal rights or obligations. Rather, they confirm the Agency position that probabilistic techniques can be viable statistical tools for analyzing variability and uncertainty in some risk assessments. Further, they outline relevant Conditions for Acceptance 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 action on Agency decisions.

IMPLEMENTATION

Assistant Administrators and Regional Administrators are responsible for implementation of this policy within their organizational units. The implementation strategy is divided into immediate and follow-up activities.

Immediate Activities

To assist EPA program and regional offices with this implementation, initial guidance on the use of one probabilistic analysis tool, Monte Carlo analysis, is provided in the Attachment, "Guiding Principles for Monte Carlo Analysis" (EPA/630/R-97/001). The focus of this guidance is on Monte Carlo analysis because it is the most frequently encountered technique in human health risk assessments. Additional information may be found in the "Summary Report for the Workshop on Monte Carlo Analysis" (EPA/630/R-96/010). This report summarizes discussions held during the May 1996 Risk Assessment Forum sponsored workshop that involved leading experts in Monte Carlo analysis.

Follow-Up Activities

To prepare for the use and evaluation of probabilistic analysis methods, including Monte Carlo analysis, within the next year, EPA's Risk Assessment Forum (RAF) will develop illustrative case studies for use as guidance and training tools. Further, the RAF will organize workshops or colloquia to facilitate the development of distributions for selected exposure factors. EPA's National Center for Environmental Assessment (NCEA) will develop an Agency training course on probabilistic analysis methods, including Monte Carlo analysis for both risk assessors and risk managers which will become available during Fiscal Year (FY) 1997 or FY 1998. Also, NCEA will develop detailed technical guidance for the quantitative analysis of variability and uncertainty.

In the longer term, various Regions, Programs and the Office of Research and Development (ORD) may need to modify existing or develop new guidelines or models to facilitate use of such techniques as Monte Carlo analysis. Also, the NCEA will revise or update the Exposure Factors Handbook to include distributional information. ORD's National Exposure Research Laboratory (NERL) has formed a modeling group that may provide assessment and analysis advice to Program and Regional Offices. The issue of using probabilistic techniques, including Monte Carlo analysis in the dose response portion of human health risk assessments requires further study. NCEA will conduct research in this area and additional guidance will be provided if necessary.

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