

Enclosed please find comments from TERA on the risk assessment bulletin. As per the instructions, the comments are both attached, and copied below – beneath the signature.

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Toxicology Excellence for Risk Assessment (TERA) – Comments on the Office of Management and Budget Proposed Risk Assessment Bulletin.

Summary: *TERA* supports the development of uniform federal guidance for risk assessment such as that proposed by OMB. Such guidance, when refined and finalized, will formalize the implementation of commonly used risk assessment principles, promote best practices, and improve the harmonization of risk assessments. Achieving these objectives will strengthen the scientific underpinnings of risk assessment in the federal government.

Overall, *TERA* supports the development of uniform guidance for risk assessment such as proposed by OMB. Such guidance, when refined and finalized has the opportunity to formalize the implementation of commonly used risk assessment principles, promote a series of best practices, and improve the harmonization of risk assessments. Achieving these objectives will strengthen the scientific underpinnings of risk assessment. Much of the proposal as laid out in the Supplementary Information and more briefly in the Bulletin itself is very consistent with evolving practice in risk assessment. Many of the general principles outlined relate to increased transparency, clarity, and balance in presenting scientific conclusions or enhanced communication with users of the assessments. These are well-accepted principles in current risk methods guidance, including in US EPA's Risk Characterization Guidelines (US EPA, 2000), recommendations of the Commission of Risk Assessment and Risk Management (CRARM, 1997), and the principles described by the National Academy of Sciences (NAS, 1983). We endorse these basic principles and support the proposal to promote their implementation through out the federal government.

While we generally support the guidance as proposed, a number of specific details in the Bulletin or in the Supplementary Information Section presented in the front matter may have practical implications on how risk assessments are presented in the future, and should be carefully considered. For example, a major focus in the proposal is a more complete presentation of salient uncertainties. While such a presentation is already included in many comprehensive assessments, an increased discussion of alternative risk estimates, quantitative analysis of uncertainties, and ranges of risk values will require additional detailed guidance for the risk managers on methods and implications for using such data presentations. Such guidance should include scientific methods for choosing among competing risk estimates and evaluating what may appear to be inflations in uncertainty rather than decreases in uncertainty with more information.

Few would not want to present intellectually honest assessments as suggested by the OMB guidance. However, increasing the complexity of risk assessment presentation in this way is already an issue in the context of questions we receive from site managers related to risk values presented as a range (or distribution) of values. Presentation of timely guidance and training on such issues will be essential for ensuring that implementation of the guidelines improves risk assessments, but does not slow progress in their development and use by risk managers.

In addition, potential interpretations of current methods or new requirements (at least in some risk assessment contexts) presented in the proposal need clarification before scientific comment on the intent of the language is possible. Two examples are noted here. The text on Page 20 regarding using mild effects as the basis for risk estimates needs further elucidation as many risk assessors would argue that the immediate precursor of an adverse effect could be a useful

determinant of dose-response for protection of human health. This is consistent with EPA's definition of critical effect: the first adverse effect or its known, *and immediate*, precursor (italicized words added by former EPA author for clarity). A second example is the recommendation on page 20 that data gaps and research needs should be presented along with cost and feasibility for filling these gaps. The suggestion to address cost (and implications for identifying a specific research plan) will increase the scope of at least some types of assessments. Details on how such requirements should be implemented will be needed.

While the overall goal of the Bulletin in characterizing uncertainties is laudable, the timetable suggested appears to be overly ambitious, and liable to lead to poor quality initial assessments. For example, chemical risk assessors have wrestled for years with approaches for quantitatively addressing uncertainties in noncancer assessments. While several possible approaches exist, this is an area of research that is still far from consensus. Even considering the time between the release of the draft and final OMB Bulletin, the stated timeline for assessments to comply with all aspects of the Bulletin is likely to lead to agencies applying methods that do not have the acceptance of their scientific peers. The result would be rushed or incomplete analyses without a firm scientific basis or without a basis that is generally accepted by the risk assessment community, resulting in at least a temporary decrease in the quality of assessments, rather than the intended improvements.

There are several other specific areas of unclarity where additional consideration would be useful. For example, does central tendency mean the central tendency for protection of sensitive populations, or does it mean the overall central tendency for the general population? If the latter, should agencies also consider implications to sensitive populations of exposures at the central tendency? The whole issue of methods for developing central tendency estimates is in its infancy, and adequate time to develop a scientific consensus on appropriate approaches is essential.

Overall, we endorse the objectives of the Bulletin. While we agree with the principle that uncertainty should be fully communicated, we recommend that the Bulletin make provisions for the relevant risk assessment communities to develop the methods and expertise on approaches for characterizing the uncertainty, and for agency experts to develop technical guidance for adopting the methods. A training component on use and interpretation of such data presentations to aid risk managers in the interpretation and appropriate application of risk assessments will also be important

References:

Commission on Risk Assessment and Risk Management (CRARM) (1997) Framework for Environmental Health Risk Management, Final Report Volume 1, Washington, DC.

Commission on Risk Assessment and Risk Management (CRARM) (1997) Risk Assessment and Risk Management in Regulatory Decision-Making, Final Report Volume 2, Washington, DC.

National Academy of Sciences. 1983. Risk Assessment in the Federal Government: Managing the Process, National Acadmy Press, Washington, D.C.

U.S. EPA (Environmental Protection Agency). (2000) Science policy council handbook: risk

characterization. Office of Science Policy, Office of Research and Development, Washington, DC; EPA 100-B-00-002. Available from: <<http://www.epa.gov/iris/backgr-d.htm>>.