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Nancy Beck  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street, N.W.  
New Executive Office Building, Room 10201  
Washington, D.C. 20503  
202-395-3093  
[OMB\\_RAbulletin@omb.eop.gov](mailto:OMB_RAbulletin@omb.eop.gov)

**SUBJECT: Comments on OMB Proposed Risk Assessment Bulletin**

Dear Dr. Beck,

Please find the enclosed comments in regards to OMB's Proposed Risk Assessment Bulletin. I submit these comments on behalf of myself, as a member of the general public, rather than on behalf of the company for which I am currently employed.

Best Regards,

A handwritten signature in cursive script that reads "Pamela Williams".

Pamela Williams, ScD.  
Principal Health Scientist  
ChemRisk  
4940 Pearl East Circle, Suite 300  
Boulder, CO 80301  
303-417-1046  
[pwilliams@chemrisk.com](mailto:pwilliams@chemrisk.com)

## Comments on OMB's Proposed Risk Assessment Bulletin

### GENERAL COMMENTS

The stated purpose of the draft OMB Bulletin is “to enhance the technical quality and objectivity of risk assessments prepared by federal agencies” (p. 3). The draft Bulletin further requires that all risk assessments meet three key attributes of “utility, objectivity, and integrity” (p. 11). Additionally, as part of the standards related to objectivity, the draft Bulletin states that a risk assessment report should have a “high degree of transparency with respect to data, assumptions, and methods” (p. 14). These are all commendable and worthwhile goals which should lead to improved and better quality agency risk assessments in the future.

Although I am fully supportive of the draft Bulletin's stated purpose and key goals, there are a number of items in the draft Bulletin that would benefit from additional clarification and explanation. Clear guidelines are necessary in order to reduce the ambiguity related to what is expected or required by the draft Bulletin, and to ensure that OMB's standards are interpreted in the same manner by different agencies. The specific comments provided below are meant to highlight some of the issues that would benefit from further consideration by OMB during its development of a final Bulletin.

### SPECIFIC COMMENTS

1. **Applicability of Uniform Standards.** On page 3, the draft Bulletin states that part of the purpose of the Bulletin is to establish “uniform, minimum standards” for federal agencies that prepare risk assessments. However, it is unclear whether or to what degree different agencies, which have diverse goals and objectives and varying time and budget constraints, should have (or will be able) to conform to “uniform” standards. Agencies should therefore have some degree of flexibility in determining which standards are feasible for them to meet, and OMB should provide clearer guidance regarding the level of flexibility agencies will have in this regard. Although the draft Bulletin specifies on page 9 that all publicly available agency risk assessments shall comply with the standards of the Bulletin “*to the extent appropriate,*” greater clarification is required throughout the Bulletin on the level of flexibility in agency compliance with the various standards. Perhaps one approach would be for OMB to require that each agency develop its own comprehensive Risk Assessment Guidelines that would best meet the specific needs of individual agencies and which would incorporate as many of the standards contained in the draft Bulletin as possible (rather than prescribing a single set of standards to apply across all agencies).
2. **Distinction Between Types of Assessments.** On pages 8-9, the draft Bulletin makes a clear distinction between “risk assessments” and “influential risk assessments” and later puts forth “general reporting standards” (p. 11-16) and “special standards” (p. 16-21) that apply to these types of assessments, respectively. However, because it is often difficult to determine *a priori* whether a risk assessment will be “influential” and because some of the standards associated with “influential risk assessments” should be applicable to all assessments (e.g., discussion of data or model uncertainties), it may not be appropriate to make a distinction between “general” and “influential” risk assessments. This distinction also seems unnecessary given the language on page 11 of the draft Bulletin, in which one

## Comments on OMB's Proposed Risk Assessment Bulletin

of the stated goals is for the level of effort expended on any risk assessment to be “commensurate with the importance of the risk assessment, taking into consideration the nature of the potential hazard, the available data, and the decision needs.” OMB should consider combining the two sets of standards into a single list that applies to all risk assessments (subject to the agency flexibility noted above) or provide further explanation about why such a distinction is necessary. If OMB decides to maintain this distinction, it would be helpful for OMB to provide, perhaps as an Appendix, example reports of what a completed “general” versus “influential” assessment would look like to lessen some of the confusion about which standards apply to each type of assessment.

3. **Examples of Assessments Covered/Not Covered by Bulletin.** On pages 9-10, the draft Bulletin provides some specific examples of risk assessments that are covered and not covered by the Bulletin. Despite these examples, which apply only to selected agencies, the coverage of the Bulletin remains largely unclear and over broad. In particular, although much of the language and many of the guidelines may make sense for agencies such as the EPA (which already follows many of the practices specified in the draft Bulletin), it is not clear whether or how these guidelines should apply to the various types of “assessments” performed by other agencies (e.g., FAA, DOD, DOE, CPSC, OSHA, etc.). OMB is strongly encouraged to provide greater clarification on this issue and present many more examples regarding what is actually covered by the Bulletin for a wide range of agencies. One approach would be for the Bulletin to contain a comprehensive table, perhaps as an Appendix, that lists all U.S. federal agencies in the first column and at least one or more examples that illustrate what is covered and not covered by the Bulletin in the second and third columns, respectively. This type of table would not only provide much clearer guidance to the various agencies (and the public), but would also likely raise a number of issues not previously considered by OMB during the course of its development (which in turn will lead to greater discussion and thought by OMB during its preparation of a final Bulletin).
4. **Completed Risk Assessments Versus Components of Risk Assessments.** On page 8, the draft Bulletin defines a “risk assessment” as any document that “could be used for risk assessment purposes,” but which might not constitute a “complete risk assessment.” This is a very confusing and not necessarily appropriate definition, however, as almost any analysis or report could eventually be used as a component of a risk assessment and many of the requirements of the Bulletin would not readily apply for these components. OMB needs to provide a more concise definition of what constitutes a “risk assessment” for purposes of the Bulletin (and set boundaries as necessary) and clearly state which standards would apply (or not apply) to various components of a risk assessment.
5. **Conflict Between Bulletin and Existing Agency Policies.** On page 14, the draft Bulletin states that all risk assessments performed by federal agencies should use “the best available data” and be based on the “weight of the available scientific evidence.” A potential significant and worthwhile outcome of this standard is the collection of new data (or disclosure of existing data) by various parties. However, the interpretation of this standard may conflict with existing federal policies, such as the EPA’s recent (January 2006) ban on the use of human testing data from any intentional dosing studies

## Comments on OMB's Proposed Risk Assessment Bulletin

that involve pregnant women or children for pesticides or other substances that EPA regulates. It is unclear how the Bulletin would apply in such instances where data are available for use in a risk assessment, but which are precluded from such use by existing (or future) agency policies. OMB needs to clarify what will or should happen if any of the standards presented in the Bulletin conflict with a particular agency's current or future policies or regulations.

6. **Use of Expert Judgment.** On pages 17-18, the draft Bulletin discusses the reliance on “qualified experts” and “professional judgment” to help assessors establish risk estimates and address data and model uncertainties. However, it is unclear to what extent or for which aspects of a risk assessment OMB believes that the use of professional or expert judgment would be acceptable (or not acceptable). OMB should also clarify whether the reliance on professional or expert judgment will need to be based on formal “expert elicitation” methods or whether more informal approaches (e.g., informal meetings or interviews) will be considered acceptable for filling data gaps and addressing uncertainties in risk assessments.
7. **Age Considerations or Groupings.** On page 19, the draft Bulletin states that the characterization of variability in risk assessments should reflect the different affected population (e.g., children or elderly). However, nowhere in the Bulletin is there a discussion or requirement regarding more precise child-specific age or behavioral-related considerations or groupings when evaluating toxic endpoints, exposures, or risks (e.g., nursing and non-nursing infants and various age groupings within the category of “children”). Given the significant advances that have been made over the last few years in regards to a better understanding about the exposure profiles and key windows of vulnerability or susceptibility among different age groups, OMB is strongly encouraged to review the most recent literature on this topic and add language to the Bulletin that addresses this topic, as appropriate.
8. **Application of Bulletin.** On page 1, the draft Bulletin specifies that it provides new technical guidance on risk assessments “produced by the federal government.” OMB should consider extending the coverage of the Bulletin to apply to all risk assessments that are prepared on behalf of or are submitted to the agencies by outside parties, which are subsequently adopted or used by the agencies (but which are not necessarily produced by the agency itself). Although the draft Bulletin specifies on page 8 that it addresses quality standards for risk assessments “disseminated by federal agencies,” OMB should clarify whether this applies to risk assessments not necessarily generated or produced by the agency itself. Additionally, on page 22, the draft Bulletin indicates that it applies to risk assessments disseminated 12 months following publication of the final Bulletin (or after 6 months for draft risk assessments). However, because the Bulletin requires that baseline risks and prior assessments be considered during the preparation of agency risk assessments, OMB should consider extending the coverage of the Bulletin to apply to previously conducted risk assessments that have not been updated (with some lead in time for re-evaluation of prior risk assessments). This would help ensure that all agency risk assessments (past and future) are based on the same set of criteria and would help facilitate more appropriate comparisons among historical and current assessments.

## Comments on OMB's Proposed Risk Assessment Bulletin

9. **Evaluation and Enforcement of Bulletin.** On page 21, the draft Bulletin suggests that agencies should routinely evaluate and perhaps revisit their risk assessments as new information becomes available, and on page 16, the Bulletin states that some risk assessments should consider “countervailing risks.” However, nowhere in the Bulletin is there any discussion about how or when the Bulletin itself will be evaluated or whether potential unintended consequences of the Bulletin have been or will be considered by OMB. Additionally, on page 22, the draft Bulletin states that agencies should submit a “certification” as part of their risk assessment documents. However, there is no discussion about how the required standards in the Bulletin will be evaluated or enforced or what the consequences of noncompliance with these standards will be. OMB needs to provide further clarification regarding how the Bulletin will be evaluated and enforced.
  
10. **Risk Comparisons.** On pages 9 and 15, the draft Bulletin states that all risk assessments “shall place the risk in perspective/context with other risks familiar to the target audience.” However, in alignment with the comments provided in #4 above, it is unclear whether risk comparisons could (or should) be required for all types of assessments, particularly for components of a risk assessment (rather than a complete risk assessment). Additionally, in alignment with the comments provided in #8 above, it is unclear whether comparable comparisons can really be made if prior assessments do not meet the same criteria or standards as those of the assessment produced in accordance with the Bulletin. OMB should provide additional clarification regarding when and how risk comparisons should be made in regards to agency risk assessments and the degree of flexibility agencies will have in determining when such comparisons are necessary or feasible.