



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

**AUG - 3 2006**

Dr. Ellen Mantus  
Project Director  
National Research Council  
Division on Earth and Life Sciences  
Board on Environmental Studies and Toxicology  
500 Fifth Street, NW  
Washington, DC 20001

Dear Dr. Mantus:

Enclosed with this letter are the Office of Management and Budget's (OMB's) responses to questions that the National Academies of Sciences (NAS) submitted to OMB on June 28, 2006. We hope these responses will be helpful to the National Research Council Committee as it reviews the OMB Proposed Risk Assessment Bulletin (Proposed Bulletin).

Additionally, your request to OMB asked for "copies of all comments that are submitted by federal agencies on the OMB Bulletin, if possible." At this point in time, OMB has not received any official comment letters on the Proposed Bulletin from Federal agencies that conduct risk assessments. However, staff of one agency did send us comments marked "internal deliberative." Additionally, we have received a comment letter from the Small Business Administration's (SBA's) Office of Advocacy, which is available on that office's website at [http://www.sba.gov/advo/laws/comments/omb06\\_0608.html](http://www.sba.gov/advo/laws/comments/omb06_0608.html).

If you should need further information from OMB, please contact Dr. Nancy Beck at 202-395-3258.

Sincerely,

Steven D. Aitken  
Acting Administrator  
Office of Information  
and Regulatory Affairs

Enclosure

1. Dr. Graham discussed the recent perchlorate evaluation as an example that would have benefited from this Bulletin. Does the Bulletin support using a “precursor” of an adverse effect or other mechanistic data as the basis of a risk assessment, as was recommended in the National Academies’ perchlorate review?

**OMB response:**

While the Proposed Risk Assessment Bulletin (Proposed Bulletin) does not speak to specific use of a precursor effect, there is no language in the Proposed Bulletin that precludes the use of a “precursor” of an adverse effect or other mechanistic data as the basis of a risk assessment.

Further, Section V, subsection 7 (page 20) of the preamble of the Proposed Bulletin discusses the standard for characterizing human health effects: “[I]t may be necessary for risk assessment reports to distinguish effects which are adverse from those which are non-adverse.”

Additionally, Section V, subsection 7 (page 25) of the text of the Proposed Bulletin notes the importance of describing the ramifications of the choice of effect: “Where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities.”

2. Is it correct that those submitting data and risk assessments to the government to obtain product registrations, approvals, and licenses are excluded from the requirements of the Bulletin?

**OMB response:**

The Proposed Bulletin does not apply to risk assessments performed with respect to individual agency adjudication or permit proceedings (including a registration, approval or licensing) unless the agency determines that: (i) compliance is practical and appropriate and (ii) the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings. (Proposed Bulletin, Section II, subsection 2(b), page 23). This exemption applies regardless of who generated the data and the risk assessment.

The OMB Information Quality Guidelines (67 FR 8460 Feb 22, 2002) do not cover adjudicative processes. The OMB Final Information Quality Bulletin for Peer Review (70 FR 2677 Jan 14, 2005) (Peer Review Bulletin) also includes an exemption for “individual agency adjudication or permit proceedings (including a registration, approval, licensing, site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings.” The exemption used in the Proposed Bulletin is consistent with the exemption in the Peer Review Bulletin.

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3. Will the Bulletin require further review by OMB staff of risk assessments that have been peer reviewed in accordance with established peer review procedures and standards, including publication in a reputable peer reviewed journal?

**OMB response:**

The Proposed Bulletin does not require OMB review of any risk assessment. However, under existing authorities and procedures, OMB might review a risk assessment. For example, risk assessments that are part of regulatory impact analyses might be reviewed under Executive Order 12866. Additionally, Section III, subsection 5 (page 23) states: "The agency shall follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment." Agencies should rely on the Peer Review Bulletin to determine appropriate peer review procedures.

4. Public participants in the risk assessment and rulemaking processes – industry groups, environmental groups, other governmental entities, individual scientists – often provide risk assessments for agency consideration. Will these outside assessments be held to the same standards as agency-generated assessments, that is, to the requirements in the Bulletin?

**OMB response:**

The Proposed Bulletin applies to risk assessments that are made publicly available by an agency, regardless of whether the agency conducted the risk assessment. If third-party submissions are to be used and made publicly available by Federal agencies, it is the responsibility of the Federal Government to make sure that such information meets relevant standards.

5. The 1983 NRC report *Risk Assessment in the Federal Government: Managing the Process* treats "risk assessment" as a term of art that covers four distinct analyses (hazard identification, dose-response assessment, exposure analysis, and risk characterization), each typically based on a number of separate studies and analyses. The OMB Bulletin defines "risk assessment" to apply to "any document" that "could be used for risk assessment purposes, such as an exposure or hazard assessment *that might not constitute a complete risk assessment as defined by the National Research Council.*" What is the advantage of defining risk assessment in this way?

**OMB response:**

The Proposed Bulletin used a risk assessment definition that "applies to documents that could be used for risk assessment purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment..." (Proposed Bulletin, Section I, page 8). Many of these individual documents are relied upon by Federal agencies and used in important, and often economically significant, regulatory decisions made by Federal agencies as well as other

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decision makers. The accuracy, quality, clarity, transparency, and utility of these documents could be improved by meeting, as appropriate, the quality standards outlined in the Proposed Bulletin. As we stated in the OMB Press Release accompanying the Proposed Bulletin, "Transparent and accurate risk assessments are necessary for agencies and other decision makers to make wise risk management decisions during the formation of agency rules and policy decisions."

Additionally, if these individual documents are prepared in a manner consistent with the Proposed Bulletin, this may avoid additional work when these activities are combined to create a comprehensive risk assessment document at a later point in time.

6. The Bulletin discusses the importance of risk assessors interacting with decision-makers. What safeguards will be built into the process to protect the scientific process from being framed by the decision-maker instead of the science?

**OMB response:**

In Section III, subsection 1 (page 10) of the preamble, the Proposed Bulletin sets forth an aspirational goal of an iterative dialogue between risk assessors and agency decision maker(s). This type of dialogue "will help ensure that the risk assessment serves its intended purposes and is developed in a cost-effective manner." (Proposed Bulletin, Section III, subsection 1, page 10). The standards proposed in the Proposed Bulletin are designed to ensure the quality and objectivity of the scientific process and the science.

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