

Congress of the United States
House of Representatives
Washington, DC 20515

May 5, 2006

Dr. Ralph J. Cicerone
President
National Academy of Sciences
500 5th Street, N.W.
Washington, DC 20001

Dear President Cicerone:

We are writing in regard to the National Academy of Sciences' (NAS) agreement to review the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin (Proposed Bulletin). We are concerned that the description of NAS' review does not include important issues raised by the Proposed Bulletin. We urge NAS to define clearly the scope of its review, and either to expand the scope of its review or to articulate the issues raised by OMB's Proposed Bulletin that NAS will not address.

The Proposed Bulletin, which OMB issued on January 9, 2006, would direct agencies to comply with specified requirements when they evaluate risks to public health, safety, and the environment. OMB contracted with NAS, Contract No. 68-C-03-081, for an Ad Hoc Committee of the Board on Environmental Studies and Toxicology (Committee) to review OMB's Proposed Bulletin.

OMB's Proposed Risk Assessment Bulletin raises a number of scientific and technical issues regarding risk assessments. NAS is a logical choice to address such issues in a substantive, constructive critique of the Proposed Bulletin, given the Academy's extensive experience reviewing specific risk assessments for federal agencies and past work summarizing risk assessment techniques and best practices.

However, OMB's Proposed Bulletin also raises serious concerns about its effect on individual agencies' risk assessment practices, including whether it conflicts with statutory directives enacted by Congress. These and other important legal, policy, and budgetary questions would have to be considered in any comprehensive evaluation of OMB's Proposed Risk Assessment Bulletin.

In light of these concerns, the scope of NAS' review is very important. We are writing to inquire as to whether NAS is able and plans to address these concerns, and if not, to urge NAS to make clear in its final report the limited scope of its review. If the Committee's review does not address the full range of issues raised by the Proposed Bulletin, the NAS review cannot be considered a comprehensive review of the Proposed Bulletin.

Charge and Scope of NAS Review

OMB's charge to the NAS and the Academy's proposal produced in response to this charge are ambiguous as to the scope of the Committee's review. It is important that this ambiguity be resolved.

NAS' Plan of Action indicates the Committee will conduct a "scientific review" of the Proposed Bulletin. This suggests that the Committee will confine its review to the scientific and technical aspects of the OMB proposal. However, the specific questions to be addressed by the Committee imply that consideration will be given to issues that go beyond the scope of a scientific review.

Indeed, it appears impossible to provide a comprehensive answer to the questions without reaching beyond the scope of a scientific review. For reasons we will detail below, we believe consideration must be given to questions such as whether this guidance is necessary, and whether the imposition of a single set of rules for the performance of risk assessment across all federal agencies is appropriate.

A comprehensive review of the Proposed Bulletin must address at least the following issues:

- 1) The necessity of the Proposed Bulletin, given the risk assessment and review procedures already in place;
- 2) Potential conflicts between the Proposed Bulletin's directives and existing statutory directives;
- 3) The additional resources that would be needed for agencies to comply with the requirements of the Proposed Bulletin and the effect of these demands on agency operations; and
- 4) The potential for politicization of science created by the establishment, oversight, and enforcement of requirements for scientific and technical analyses by a White House policy office with little scientific expertise.
 - What is the precise scope of NAS' review? Will NAS address each of the issues listed above?

In addition, it is unclear whether the NAS will address the fundamental question of whether the Bulletin should be finalized, or whether the NAS will only recommend improvements to the Proposed Bulletin.

The contract and the NAS proposal describing the review appear to assume that some form of this Bulletin should be finalized and that the only open questions are those pertaining to the specific guidance contained in the Bulletin. For example, in the Purpose, the charge states:

"It is recognized that a review by NAS would be beneficial and informative as OMB moves forward *to revise and finalize the Bulletin.*" (emphasis added)

It appears that, under this charge, the Committee may offer additions to the guidance, but not consider whether the Proposed Bulletin should be withdrawn. This is emphasized in the description of the task, which states:

"The NAS shall strive to develop a consensus report *that contains advice for modifications to the Bulletin*. ... The expert panel may add *additional risk assessment issues* that they determine to be of importance." (emphasis added)

Yet, in light of the issues identified in this letter, we believe that a complete evaluation must consider whether OMB should issue a risk assessment bulletin of this kind.

- Will the Committee consider the threshold question of whether OMB should finalize and issue this Bulletin?

Consistency with Congressional Intent and Existing Law

The introduction section of OMB's proposed Risk Assessment Bulletin provides a brief description of risk assessment and some examples of the agencies that perform these analyses. The introduction also includes a description of the statutes cited as the legal basis for OMB's authority to issue the guidance. There is no mention, however, of the fact that agencies, particularly regulatory agencies, often perform risk assessments in accordance with specific statutes. We also note that the charge does not include legal expertise in the list of "Expertise Required."

Our preliminary analysis of the OMB proposal indicates the analytical approach mandated in these guidelines represents a significant departure from approaches contained in the many statutes governing health, safety and the environment, and from statutory direction to federal agencies to protect human health, safety, and the environment.

We note that although there have been legislative proposals in several Congresses to mandate government-wide criteria for the use of risk assessment and cost-benefit analyses, these bills have never been enacted. Instead, Congress has continued to use a statute-by-statute approach to guide agencies' use of these analytical tools and to set standards for health and environmental protection in the context of discrete issues. OMB's Proposed Bulletin is in conflict with the approach taken in existing law.

The Proposed Bulletin appears to conflict with standard risk assessment practice by combining risk assessment and risk management analyses, and it appears to offer a risk management standard that differs considerably from numerous health, safety, and environmental statutes. The Proposed Bulletin also appears to require cost-benefit and comparative risk analyses to be performed in combination with risk assessments. Cost-benefit analyses are required to be done separately from risk assessments in a number of our health, safety, and environmental statutes, and requirements for comparative risk assessment represent a new analytical requirement that may be inappropriate for many of these statutes.

- Will the Committee undertake an analysis of the degree to which OMB's proposal conflicts or is inconsistent with existing laws?

Existing Agency Risk Assessment and Review Procedures

The ostensible goal of OMB's Proposed Bulletin is to improve the technical quality and objectivity of risk assessments prepared by federal agencies. To determine whether the Proposed Bulletin will achieve this goal requires much more than a technical analysis of the risk assessment procedures contained in the Proposed Bulletin. Among other things, such a determination requires an evaluation of the adequacy of the existing risk assessment

procedures used by federal agencies. It also requires an evaluation of whether the uniform requirements imposed by the Proposed Bulletin would improve current practices, either in some cases or across-the-board.

For a comprehensive review, the Committee must consider the current baseline level of the "technical quality and objectivity" of risk assessments performed by federal agencies. OMB's initiation of this Proposed Bulletin suggests there is some deficiency with current federal risk assessment practices. However, OMB did not provide any evidence of systemic deficiencies in federal agencies' current risk assessment practices. We urge the Committee to be clear in defining the baseline chosen as a basis for comparison and to evaluate carefully those baseline practices.

Agencies currently have numerous mechanisms for review of their risk assessments and other technical work products. Many agencies have one or more Science Advisory Committees made up of outside experts that review agency work. OMB currently mandates interagency reviews of risk assessments at its discretion and uses its authorities to review agency work products. Numerous NAS Committees have reviewed specific agency risk assessments – some of which are underway at this time. When analyses are incorporated into rulemaking procedures, there are opportunities for further review and public comment.

Agencies have traditionally had discretion to determine the type and scope of the risk assessments they need to undertake within the boundaries of their statutory directives and the purpose of the specific risk assessment. The imposition of a one-size-fits-all set of requirements for conducting risk assessments, such as those in this Proposed Bulletin, erodes agency discretion to determine the most appropriate level and type of analysis.

- Is the Committee going to consider all the existing procedures that agencies now use to ensure the technical quality of their risk assessments, including the current OMB review procedures, and then identify what, if any, additional benefits OMB's Proposed Bulletin would provide?
- Will the Committee consider the question of the appropriateness of a one-size-fits-all approach to risk assessment among agencies with very different missions, different scientific bases for analysis and testing, and different statutory directives?

Agency Resources and Timeliness of Agency Action

As procedures in the Proposed Bulletin are expected to require agencies to take additional steps and devote additional time and resources to conducting risk assessments, we have concerns regarding the overall effects of such resource diversions and delays.

It appears the Proposed Bulletin will create additional analytical requirements for agencies. To the extent the requirements of the Proposed Bulletin differ from existing risk assessment procedures, the agencies will be required to include additional information and analyses to comply with OMB's Proposed Bulletin. An estimate of the degree to which the requirements of the Proposed Bulletin will increase analytical burdens on the agencies will be possible only by a comparison between current agency risk assessment procedures and the requirements of the Proposed Bulletin.

The additional time required to comply with the procedures in the Bulletin also should be assessed. As we noted earlier, agencies are required to submit their work to numerous reviews

already. Agencies perform numerous analyses in the course of producing their risk assessments. They also produce cost-benefit analyses, regulatory impact analyses, small business impact analyses, and analyses on potential impacts of regulations on state and local governments. They perform these analyses in accordance with individual health, safety, and environmental statutes, as well as statutes and Executive Orders governing regulatory procedures of all agencies (e.g. the Paperwork Reduction Act, the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, E. O. 12866, etc.).

Any additional requirements for analysis and review should produce a clear and substantial public benefit. This Proposed Bulletin should not become cover for dilatory tactics by special interests. Paralysis by analysis does not serve the interest of science or public policy.

We are also concerned about the potential for this Proposed Bulletin to increase significantly the costs to the covered agencies. Agencies have limited staff and budgets. OMB has supplied no cost estimates for this proposal, and it appears unlikely that any additional resources would be provided to agencies to fulfill their obligations under the Proposed Bulletin.

- Will the Committee assess the potential for and effects of increased costs and increased time to produce agency work products?

OMB's Role and Influence on Science and the Rulemaking Process

We assume the Committee will need to obtain information from the various federal agencies regarding their current risk assessment practices and whether OMB's proposal directs them to perform risk assessments in a manner that is not compatible with their needs, that is burdensome, or that is contrary to their statutory responsibilities.

If so, we have serious reservations about the level of candor the Committee will hear given that it will be asking agencies to offer opinions and information that might directly conflict with a policy proposal from the White House. We note this is not a problem unique to any individual Administration. The nature of the relationship between the Office of Management and Budget and federal agencies does not foster candid evaluations by career agency employees of the policies proposed by the Administration.

For example, *Inside EPA* recently reported that Dr. Nancy Beck, one of the principal OMB authors of this Proposed Bulletin, is now on detail to the Office of the Science Advisor, Dr. George Gray, at the Environmental Protection Agency (EPA). This example illustrates our concern. This Office will play a key role in providing agency comments about the Proposed Bulletin. Dr. Gray, a recent political appointee to EPA, a former colleague of Dr. John Graham, and Dr. Graham's co-author on a number of articles on risk assessment (one of which is cited by OMB in the footnotes in the Proposed Bulletin) is a proponent of the approach outlined in this Proposed Bulletin. Dr. Gray's agreement to have one of the authors of the Proposed Bulletin from OMB on detail to his office during the time period when the comments are being prepared does not give us confidence that the comments provided by EPA will reflect the concerns of EPA career practitioners of risk assessment.

The task of maintaining objectivity and delineating the boundary between science and policy is a difficult one. It is important to have safeguards to protect the integrity of scientific and technical information from political interference. We have concerns that barriers between science and politics would be eroded by involvement of a White House policy office in the establishment and

enforcement of criteria for the production of risk assessments and other scientific and technical work products by federal agencies.

Congress authorized federal agencies to implement statutes in specific areas of public health, safety, and environmental protection. OMB review is not required by any of these statutes. Technical expertise resides within the agencies, not within the Executive Office of the President. Agency actions are required by law to include public processes to ensure transparency. OMB has no such mandate, and its influence over agency actions is significant but poorly understood and documented.¹

A review that seeks to determine whether OMB's Proposed Bulletin would increase objectivity of risk assessments must consider the fact that the Executive Office of the President, of which OMB is a part, is first and foremost a policy office dedicated to implementing the policies of the President's Administration. As the Government Accountability Office (GAO) found in its 2003 report, "The Office of Information and Regulatory Analysis (OIRA) is part of the Executive Office of the President, and the President is OIRA's chief client."² OMB does not approach the review of agency work products from an unbiased perspective.

- Will the Committee address the question of whether it is feasible and desirable to have risk assessment requirements issued, overseen, and enforced by a policy office with little scientific expertise and no public accountability?

Conclusion

At times, risk assessment can be a useful tool to assist the government in decision-making. It is intended, however, to be a decision support tool, a means to the end of implementing laws ensuring public health, a safe workplace, a clean environment, functioning ecosystems, and robust engineered structures, among others. Agency cost and time to implement the Proposed Bulletin's requirements must be considered in light of the goals and requirements Congress has set in these areas. The Proposed Bulletin is not in the public interest if it results in undue delay in achieving the goals Congress established in our laws for public health, environmental, and workplace safety.

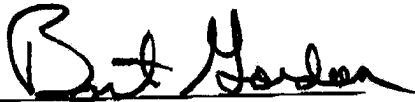
We value the expertise the NAS brings to policy deliberations. The Committee's findings regarding the OMB Proposed Risk Assessment Bulletin will carry great weight in this policy debate. We urge the Committee to be as clear as possible about the scope of its deliberations and the specific issues its review will and will not encompass.

¹ "Our review documented OIRA's direct influence with regard to more than two dozen rules in which it suggested significant changes that were ultimately adopted by the rulemaking agencies. OIRA's presence in the rulemaking process may also have a subtler, more indirect effect on agencies' decision making—discouraging them from submitting rules that OIRA is unlikely to find acceptable and encouraging them to make the case for the regulations that they do submit more carefully. However, the OIRA regulatory review process is not well understood or documented, and the effect that OIRA's reviews have on individual rules is not always easy to determine." P.110. General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp.


² General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp. (page 110)

Thank you for your consideration and attention to these important issues.

Sincerely,



BART GORDON
Ranking Member
Committee on Science



JOHN D. DINGELL
Ranking Member
Committee on Energy and Commerce



HENRY A. WAXMAN
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