

June 7, 2006

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St., NW
New Executive Office Building, Room 10201
Washington, DC 20503

RE: OMB Proposed Risk Assessment Bulletin – Request for Comments

Dear Dr. Beck,

The Office of Management and Budget has requested comments in response to its Proposed Risk Assessment Bulletin, by which it seeks to improve the quality and objectivity of the Federal Government risk assessment process. This effort by OMB to further advance risk assessment as a tool to guide decision making at the Federal level is welcome and we are pleased to submit comments regarding the proposed Bulletin.

BIGMAP, a research center at Iowa State University, is dedicated to providing an objective voice for assessing and communicating risks for sound public policy and regulatory decision-making. The goals of BIGMAP are to conduct expert analysis of risk/benefit assessments and mitigation alternatives, to encourage science-based public debate of field confined biogenic production in crop systems, and to communicate the results of these activities to key regulatory and public policy stakeholders.

Continued strengthening of the science-based process of risk assessment to inform decisions is laudable. We are supportive of the intent of the bulletin, particularly as it relates to the stated goal of enhancing the technical quality and objectivity of risk assessments prepared by federal agencies. We are therefore glad for the opportunity to help strengthen the bulletin and our comments pertain to areas where further clarification would ensure that the stated goals are met.

Problem formulation

We are encouraged that OMB recognizes the importance of problem formulation in clarifying the purpose of the assessment in advance of the analytical work. Section III-1 of the introduction outlines several goals related to problem formulation, including the need for an iterative dialogue with decision makers, and a recognition that clarifying the intended objectives of the assessment can help ensure it meets its intended purpose. However, the bulletin itself contains only a brief mention of this step, with no guidance on its implementation. The critical importance of problem formulation often has been overlooked as risk managers and assessors

have undertaken risk assessments. The problem formulation should identify effective choices of options and outcomes, properly delineate scope for the risk assessment, and culminate in a clear conceptual path and analysis plan for the subsequent assessment. We suggest that OMB emphasize this point further and make this area of the bulletin more robust.

Definition of risk assessment

The bulletin broadens the definition of ‘risk assessment’ to include documents not normally included, such as those that assess hazard potential. This is a step backwards in the evolution and communication of concepts of risk and the risk assessment process. As described in *Science and Judgment* (NAS, 1994), “risk assessment entails the evaluation of information on hazardous properties ..., on the extent of ... exposure ..., and on characterization of the resulting risk.” OMB should not deviate from this notion of risk as the joint characterization of hazard *and* exposure, and should be explicit that risk is the likelihood of an adverse consequence to be manifested under realistic conditions. Identification of hazard potential provides a rationale for the conduct of a risk assessment, but it should not be construed as evidence of risk *per se*; therefore, OMB should clarify the distinction of hazard and risk by providing a more rigorous definition of risk. Hazard relates to intrinsic properties of a substance or action that can inflict damage or harm; hazard potential implies the existence of some threat which may or may not be manifested as a risk.

In its attempt to increase quality standards in documents released by federal agencies, OMB should not redefine risk assessment, and should recognize that frameworks and processes currently in use have been in development within the federal government for over four decades and have well-served decision makers and society. If the OMB wishes to extend these guidelines to other documents that may influence or support the risk assessment process, it should explicitly indicate this, but should not reinvent or confound the definition of risk assessment in doing so.

Areas of intended use

OMB should clarify the areas of intended use of the bulletin. The document outlines certain specific areas where it does not apply, such as in agency adjudications and permit proceedings, but does not indicate explicitly where its use *is* intended, although it appears to be aimed at risk assessments conducted for the purpose of new rule making or new regulations. A definition of ‘regulatory analysis’ would further help to clarify its intended use. Furthermore, a clearer identification of agency activities that do fall under the purview of this bulletin would make it easier to anticipate problems that could arise during its implementation, and ensure that these are resolved prior to when the bulletin takes effect.

The fact that risk assessments relating to permits, inspections and agency adjudications are excluded is curious. Federal agencies devote significant time, resources and expertise to these activities and these assessments have broad implications for human and environmental safety. OMB should provide justification as to why these activities are not held to the same high standards as other risk assessments produced by the federal government and available to the public. OMB should also explicitly outline how to determine whether a risk assessment is ‘scientifically or technically novel’ and therefore does not fall under the exemption. Confusion as to whether or not the bulletin is applicable to these types of agency activities could result in unnecessary delay in agency regulatory decisions.

The bulletin outlines additional requirements to be followed when a risk assessment is considered ‘influential’. More specific guidance should be provided on how to make this

determination, particularly when the bulletin could be interpreted to exclude certain assessments. For example, does this bulletin exclude risk assessments relating to permits, inspections and adjudications even when those risk assessments would be considered 'influential'?

Bulletin vs. introduction

We suggest that OMB formalize the relationship between the bulletin and the introduction. The proposed bulletin is a short (4-page) document, which is preceded by a lengthy (22-page) introduction that serves to clarify and contextualize the intent of the bulletin. However, it is not stated whether the information in the introduction is meant only to be explanatory or whether its content is also prescriptive. There are sections of the bulletin whose interpretation or applicability would be unclear without the accompanying introduction. OMB should explicitly incorporate the introduction into the bulletin, perhaps as a preamble or an annex, and distinguish between portions that set mandatory guidelines and portions that are simply meant to provide additional information.

Additionally, OMB should outline to what extent the bulletin is enforceable, who is responsible for ensuring that it is followed – both at OMB and at the agency performing the assessment – and what are the consequences of not following it. OMB should design appropriate measures to ensure that the high standards set for risk assessment are complied with across the federal government, and should take care that the language of the bulletin, in trying to be widely applicable, does not inadvertently create loopholes for its enforcement.

Respectfully submitted,

Jeffrey D. Wolt, Ph.D.
Professor of Agronomy and Risk Analyst
jdwolt@iastate.edu
(to whom correspondence should be addressed)

Saharah Moon Chapotin, Ph.D.
Research Associate