

June 15, 2006

Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Comments on Office of Management and Budget's Proposed Risk Assessment Bulletin

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to submit written comments on OMB's Proposed Risk Assessment Bulletin. CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition and alcohol issues. CSPI is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants. We accept no government or industry funding.

We support the OMB's effort to improve the quality, objectivity, and integrity of information disseminated by the federal government by providing new technical guidance on risk assessments produced by the federal government. While it is time to standardize the risk assessment reporting, there needs to be a distinction between the requirements and the goals of the bulletin.

The elements of the bulletin that have no cost impact could be adopted as mandatory requirements. These include the general risk assessment and reporting standards that require each risk assessment to include a clear statement of the informational needs of decision makers, a clear summary of the scope, a clear description of the hazards of concern, affected entities,

exposure/event scenarios and event/consequence or dose/response used in the risk assessment. Making these elements mandatory would standardize the way that risk assessments are presented, making it easier to utilize and compare them. These elements have no real cost associated with them, only benefits.

Other elements in the proposed bulletin should not be mandated until they have been through a cost-benefit analysis to show that they would not needlessly delay health and safety regulations. This analysis should cover the benefits of each new requirement versus their costs relative to effort and resources expended by the agencies. A cost-benefit analysis is needed for numerous provisions in the proposed bulletin, especially those that require consideration of other reasonable alternative assessments; evaluation of varying alternate options; consideration of alternate mitigation measures and risk caused by such measures; and the requirements to study the risk to a population when studying individual risk.

Although it is beneficial for the OMB to strengthen the guidelines for risk assessments, we strongly urge that these elements of the bulletin not be made mandatory until the following has been evaluated:

- What is the new value of the information for regulations for each agency?
- Would the new information affect the final policy outcome?
- What is the cost of obtaining the new information in terms of delaying needed regulation?
- Are these requirements appropriate for every agency?
- Can these requirements be covered in individual agency agreements, rather than a one-size fits-all bulletin?

CSPI believes the “Standard for Reproducibility” should be a goal, not a mandate. If OMB elects to make this requirement mandatory, OMB should conduct a test of the Standard using a diverse group of existing regulations, such as those covering all-terrain vehicles, meat and poultry regulation, air and water regulation, and children’s toys before implementing the standard across the board.

To conclude, while making risk assessments more uniform is a worthy goal, the topics and complexity differ broadly from agency to agency. We question if all the information required by the bulletin is necessary to have before adopting regulations needed to protect the public. The goals of the bulletin should not be made mandatory until their impact has been fully assessed. Instead agencies should apply their Information Quality Guidelines (IQCs), negotiated with the OMB, which are specific to agency rather than the bulletin when conducting a risk assessment.

Respectfully submitted,

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