

United States Senate

May 14, 2007

The Honorable Robert Portman, Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Portman:

We are writing to express our strong concern about the Office of Management and Budget's (OMB) proposed Risk Assessment bulletin, which proposes new technical guidance for the risk assessment protocol across federal agencies. Although we agree with the OMB's stated goal "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies," we and others – including the National Academy of Science – believe that the guidelines proposed by the bulletin would have the opposite effect if put into practice.

Therefore, we request that the Office of Management and Budget follow the recent NRC recommendation that OMB withdraw the proposed risk assessment bulletin. The NRC expert committee, convened at OMB's request, reported "that the potential for negative impacts on the practice of risk assessment in the federal government, although varied and uncertain to some extent, would be very high if the currently proposed bulletin were implemented." The NRC committee further concluded that "the OMB bulletin is fundamentally flawed and recommends that it be withdrawn."

The NRC committee found a host of problems with the OMB guidance which could result in actions that "are clearly contrary to prior [NRC] guidance....," which include:

- **OMB did not perform a baseline study of risk assessment practices.** Without an understanding of current risk assessment practices and capabilities, it is difficult to judge what changes are necessary to improve the risk assessment process.
- **A one-size-fits-all approach won't work.** Federal agencies assess an array of dangers, including: disease outbreaks; chemical, radioactive, and biological agents; defective products; natural disasters; and vulnerable infrastructure. Due to this diversity of issues and technical considerations, the NAS warns that a one-size-fits-all guidance will not increase the quality of risk assessments in the federal government.
- **The new definition of "risk assessment" is too broad.** The proposed bulletin defines risk assessment as a document. This could include many documents that are

not considered risk assessments by the standard definition, which treats risk assessment as a process.


- **New guidance gives little attention to sensitive populations.** The proposed guidance emphasizes the use of central or expected estimates of risk. However, public health practice often strives to protect the *most vulnerable* in the population, including children and the elderly. Using the mean or central estimate would not accomplish that goal unless it reflected the mean response of the distribution of vulnerable or susceptible individuals.”
- **The definition of “adverse effect” may be too restrictive to prevent harmful exposures.** The definition of “adverse effect” in the proposed bulletin is limited to clinically apparent effects. However, a goal of public health is to control exposures before the occurrence of functional impairment.
- **Non-risk factors should not be included in the risk assessment.** The proposed guidance separates risk assessments into “normal” and “influential” categories based on non-risk factors, such as the expected economic or political consequences of a proposed regulatory action. This directly conflicts with past recommendations by the NRC and other expert organizations to establish clear distinctions between assessment of risk and consideration of risk management alternatives.
- **The costs of implementing the guidance would be substantial.** Though the OMB did not complete a cost-benefit analysis of implementing the bulletin, the NRC suggests that implementing the bulletin would require substantial additional staff time. In addition, the guidelines would add to the timeline of existing risk assessments and likely require the application of risk assessments to documents that do not customarily require assessments.

In summary, the proposed guidance appears to increase the burden of risk assessments, inject political considerations into the risk assessment process, and make it more difficult to issue regulations to protect our citizens. Finalizing the proposed OMB guidance would impede federal agencies’ ability to develop public health and environmental protections, promote public safety, encourage good business practices, improve consumer protections, and efficiently use taxpayer funds.

Sincerely,



JEFF BINGAMAN
U.S. Senator



JOSEPH I. LIEBERMAN
U.S. Senator