

**Comments on Office of Management and Budget's Proposed Risk
Assessment Bulletin**
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The Proposed Risk Assessment Bulletin put forth by OMB is a document covering a wide range of risk assessments performed for a variety of purposes. These risk assessments are in many cases governed by different statutory authorities, which can lead to different methodologies. The Bulletin cites several of these purposes (setting priorities, informing risk management decisions, informing benefit-cost analyses, and informing the public), as well as methodologies (actuarial/epidemiological analysis, dose-response modeling, and failure analysis).

One of the challenges of such a wide-ranging Bulletin is to ensure that it is sensible for all of the situations it would cover. While the Bulletin allows for a certain degree of flexibility, such as for screening risk assessments, this flexibility is quite limited. Based on the comments that the National Research Council received during its May 22, 2006 hearing, there is a clear potential for this Bulletin, if implemented, to cause significant harm. An example was cited in this hearing by the Food and Drug Administration (FDA) regarding whether it could inform the public about an adverse effect from a drug before it could, through a formal risk assessment, define the relationship between dose and outcomes. Presumably this situation would be covered under the Bulletin's provision that it is a health and safety risk assessment that is time-sensitive or needs to be released due to an emergency situation. However, the fact that the FDA raised this issue implies that they are either unclear of the applicability of the exemption, are concerned that this would not be an infrequent event as is required by the Bulletin, are concerned about having the resources to perform a complete risk assessment after the fact, and/or some other substantial adverse consequence.

In addition, there is a potential for some of the requirements of the Bulletin to be onerous in terms of the effort required to properly implement them, while providing little value in terms of affecting final decisions. I have performed hundreds of risk assessments of hazardous waste sites, all of which have contained uncertainty analyses, but of which only one or two have affected site management decisions. This is because the risk managers have no criteria for utilizing these analyses. What is to prevent the same thing from happening with the implementation of this Bulletin?

The proper way to rectify these concerns would be to subject this Bulletin to the same type of risk assessment that it requires. This risk assessment would be in the form of a benefit-cost analysis, examining exactly how different agencies would implement the Bulletin in different situations. The outcome would compare the potential benefits from improving the risk analyses to the costs, e.g., the necessity for increased resources to

perform the risk assessments, delays in beneficial rules, etc. The value of the risk assessment would come not only from the results, but also from the experience of implementing the Bulletin. That experience would likely expose many of the pitfalls that it may contain.

It is true that such a risk assessment is not required prior to Bulletin implementation. However, this Bulletin will have an influence on risk assessments on par or exceeding many of the studies/regulations/activities that will be subject to this Bulletin. If the requirements of the Bulletin are of substantial benefit, then subjecting the Bulletin to its requirements will accrue a similar benefit.