

May 12, 2006

Dr. Nancy Beck
Office of Information and
Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
NEO, Room 10201
Washington, DC 20503

Dear Dr. Beck:

Thank you for providing an opportunity to comment* on the Office of Management and Budget's (OMB) proposed Risk Assessment Bulletin. The comments included below are from the U.S. Consumer Product Safety Commission (CPSC) staff.

1 *Definition*

In Section 1, the Bulletin defines risk assessment as “a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment.” This definition differs from the one put forth by the United States Council on Environmental Quality, Executive Office of the President, in the 1989 publication, Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. Additionally, the preamble recognizes that the definition in the Bulletin is very general, noting that it “applies to documents that could be used for risk assessment purposes, such as exposure or hazard assessment that might not constitute a complete risk assessment as defined by the National Research Council.”

CPSC Staff Comment

Establishing a new definition for risk assessment may be unnecessary and could be confusing for some, including scientists who use the term “risk assessment” in the manner that it has been used for many years and others who may not have a scientific background but who are familiar with the traditional usage of the term. Rather than attempting to be inclusive by redefining risk assessment, OMB could consider specifying which components of risk assessment the Bulletin will cover. By doing this, OMB could direct specific requirements for each of these components. Otherwise, the Bulletin may not adequately distinguish between the different types of documents and the unique scientific issues associated with each of them.

2. *Risk Communication/Risk Comparison*

The Bulletin includes a general requirement (Section IV, 6) that executive summaries should “place the estimates of risk in context/perspective with other risks familiar to the target audience.”

* These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily represent the views of the Commission.

CPSC Staff Comment

Comparing risks presents challenges, especially when the choice of appropriate comparisons is limited. In addition, putting comparative risk information in an executive summary, without an explanation of the context in which it was derived, could mislead the reader. Further, this type of comparison may be more appropriate in risk management documents than in risk assessment documents.

It would be useful for OMB to provide more information on how this requirement might be met. It would also be helpful if OMB would provide a list of available risk assessments that meet the Bulletin guidelines and are therefore appropriate for citation as comparable risks.

3. *Influential Risk Assessments*

In Section 1 (p. 9), the Bulletin says "Examples of "influential risk assessments" include, but are not limited to, assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels)..."

CPSC Staff Comment

This seems to suggest that all assessments that determine these reference levels are always influential risk assessments. We recognize that some estimates of reference dose, such as those published on the EPA Integrated Risk Information System (IRIS), are clearly influential. However, without an exposure assessment, a full risk assessment, or agency action, simply calculating these reference levels may not be influential. In addition, the *a priori* determination of whether a document is influential is problematic since the impact may not be easily predicted. Clarification on this point would be useful.

4. *Flexibility*

The Bulletin addresses the issue of flexibility in Section III (i.e., the scope, type, and level of effort is to be determined in each case).

CPSC Staff Comment

It is unclear whether this flexibility extends to the standards for risk assessments that are outlined in Sections IV and V. Given the large variety of types of assessments covered by the Bulletin, each with its own purpose, format, and requirements, perhaps OMB could clarify, and more explicitly address, the issue of flexibility and permissible deviations from the standards.

5. *Certification*

Section VII of the Bulletin says simply that the agency shall include a certification, as part of the risk assessment document, explaining that the agency has complied with the requirements of the Bulletin and the applicable Information Quality Guidelines.

CPSC Staff Comment

Clarification on this requirement would be useful. Is some sort of formal agency process expected? Who would do it? How would it be carried out? Additionally, would all routine reports characterizing hazard data require this type of certification?

Again, we thank you for providing the opportunity to comment on the proposed Risk Assessment Bulletin.

Sincerely,

Gregory B. Rodgers

Gregory B. Rodgers, PhD
Associate Executive Director for Economic Analysis
Directorate for Economic Analysis
4330 East West Highway
Bethesda, MD 20814
Phone 301-504-7702
fax 301-504-0109
e-mail groddgers@cpsc.gov

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