

Below are responses developed by the U.S. Consumer Product Safety Commission's (CPSC) staff to the questions posed by the National Research Council in its scientific review of the proposed Risk Assessment Bulletin released by the Office of Management and Budget. (Note: These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily represent the view of, the Commission.)

General questions about current risk assessment practices

- Question: Please provide a brief overview of your current risk assessment practices. Specifically, do you conduct probabilistic risk assessment? Is there a common approach to both risk assessments and uncertainty analysis? How do you currently address uncertainty and variability in your agency's risk assessments?

CPSC Staff Response

In general, the CPSC staff performs risk assessments addressing a variety of hazards, including toxicity, electrical, fire and burn, and mechanical hazards. Depending on staff and agency needs, CPSC staff conducts all manner of analyses, both qualitative and quantitative. Some analyses constitute complete risk assessments, while others deal with one or more individual steps of risk assessment, e.g., hazard identification or exposure assessment.

The toxicological risk assessment practices used by the CPSC staff are described in the CPSC Chronic Hazard Guidelines (FR 57: 46626-46653, 1992). The guidelines include sections on cancer, neurotoxicity, reproductive-developmental toxicity, exposure, bioavailability, and acceptable risk. The staff uses either probabilistic methods or sensitivity analysis to assess uncertainty or variability. The approach to evaluating uncertainty and variability is determined by the analyst on a case-by-case basis, based on the purpose of the risk assessment and availability of data.

- Question: Please identify any substantial scientific or technical challenges that you may encounter when conducting risk assessments for your agency.

CPSC Staff Response

When performing toxicological risk assessments staff may encounter a variety of technical and scientific challenges, such as the lack of complete toxicity or exposure data, or the lack of methodologies to develop such data. These challenges are addressed on a case-by-case basis, and may include performing exposure assessment studies, such as migration and emissions studies, and developing novel laboratory methods. The staff also nominates chemicals for further toxicological testing by the National Toxicology Program.

Consider, for example, the CPSC staff's risk assessment of diisononyl phthalate (DINP), which is a plasticizer used in teething rings and toys made from polyvinyl chloride. CPSC convened a Chronic Hazard Advisory Panel (CHAP)* to address the toxicity and potential

* Convening a CHAP is a statutory mandate before CPSC can regulate products based on chronic toxicity of a substance, 15 U.S.C. 2077 and 2080(b).

risks from DINP, especially the human relevance of rodent tumors induced by peroxisome proliferation. Lack of exposure data for DINP in children's products led to the conduct of observational studies of children's mouthing behavior, as well as the development of methods to measure the mitigation of DINP from certain toys, and laboratory analysis of toys in the market to determine the proportion that contained DINP.

- Question: What is your current definition of risk assessment, and what types of products are covered by that definition?

CPSC Staff Response

The staff defines risk assessment following the definition of the National Research Council (1983), in which a risk assessment encompasses hazard identification, dose-response assessment, exposure assessment, and risk characterization. Depending on the agency's needs, the staff may complete one or more of these steps for a particular task, but a risk assessment generally consists of all four steps.

The definition applies to all consumer products under CPSC jurisdiction, and includes a variety of toxicological and physical hazards. However, the CPSC's Chronic Hazard Guidelines (57:46626-46653, 1992) were developed primarily to address chronic toxicity.

- Question: About how long (that is, from initiation of the risk assessment to delivery to the regulatory decision maker) does it take to produce the various types of risk assessments?

CPSC Staff Response

The length of the risk assessment process is highly variable, depending on the intended use of the assessment, *e.g.*, for screening or priority setting, or regulatory analysis; the needs of the decision maker; factors such as the availability of data and the amount, quality, and complexity of available data; and the need for public comment and peer review. The simplest assessments may be completed in a matter of days, while more involved analyses take months or years, especially if the agency must perform extensive studies to assess exposure or convene a CHAP.

Questions about OMB's definition of risk assessment and applicability

- Question: Using the definition of risk assessment described in the OMB Bulletin, are there work products that would now be considered risk assessments that were not previously considered risk assessments? If so, what are they?

CPSC Staff Response

Using the definition in the OMB Bulletin, almost every work product prepared by the CPSC staff could be considered a risk assessment. This would include:

- Injury or fatality reports;
- The agency budget, which employs "risk-based" decision making;
- Product Safety Assessments—short-turnaround assessments of specific products;
- Toxicity reviews; and

- Routine testing of products, such as toys and fireworks, for compliance with standards.

Work products from the CPSC's Directorate for Epidemiology might especially be affected by the expanded definition of risk assessment contained in the Bulletin. For the most part, these work products provide information on injuries and fatalities associated with consumer products and, under the Bulletin's definitions, would be considered either risk assessments or work products that contain data that are used in risk assessments. Examples include hazard sketches (estimates of the number of product-related injuries and descriptions of injury scenarios), estimates of consumer product-related injuries and deaths as part of Product Safety Assessments, and analyses supporting Commission briefing packages that are associated with regulatory activities.

Some of these work products contain estimates of risk in the form of injuries or deaths per unit exposure. Exposure may be defined as products in use or per unit population possibly subdivided by age group. Exposure-based analyses are more commonly found in staff work products where there are a large number of injuries or deaths. They are less common when there are relatively few casualties and/or valid exposure measures are not available. In those cases, it is likely that most readers would conclude that the risk is small regardless of the exposure measure selected.

Questions about type of risk assessment (tiered structure)

- Question: In your agency, is there currently a clear demarcation between risk assessments used for regulatory analysis and those not used for regulatory analysis? Is this clear at the outset of the risk assessment?

CPSC Staff Response

There is no clear demarcation between risk assessments used for regulatory analysis and those not used for regulatory analysis. Moreover, the importance to the agency of a specific risk assessment is not necessarily determined only by whether it is used to support a regulation. For example, in the staff risk assessment of DINP in children's products, it was determined that the risk was low and no regulations were pursued. Nonetheless, it was important to perform the best risk assessment possible to be reasonably certain that the products (soft plastic toys) were not hazardous.

The intended use of a staff risk assessment is usually clear at the outset, *e.g.*, responding to public petitions, evaluating the impact of a regulation, or supporting the development of voluntary standards. In the event that staff objectives or agency needs change during the process, adjustments are made.

- Question: In your agency, is there currently a clear demarcation between “influential risk assessment” used for regulatory purposes and other risk assessments used for regulatory purposes? Is this clear at the outset of the risk assessment?

CPSC Staff Response

There is currently no clear demarcation between “influential risk assessments” and other risk assessments used for regulatory purposes. Additionally, staff believes that the *a priori* determination of whether a risk assessment is influential is problematic since the impact of the action may not be easily predicted. For example, a determination that something is an “influential risk assessment” may depend upon both the magnitude of the risk and the eventual scope of the regulatory action.

Because of the practical difficulties in distinguishing between influential and non-influential risk analyses at the outset of a project, and because of the additional resources that would be required to prepare influential risk assessments, it would be useful for OMB to provide clarification on how agencies should make this determination.

Questions about impact of the Bulletin on agency risk assessment practices

- Question: If applicable, please specify provisions in the Bulletin that can be expected to have a substantial positive effect on the quality, conduct, and use of risk assessments undertaken by your agency.

CPSC Staff Response

It is unclear whether the provisions of the Bulletin will have a substantial positive effect. As a matter of routine, the CPSC staff strives to perform risk assessments that are scientifically defensible and of the highest quality by using the CPSC’s Chronic Hazard Guidelines that clearly define how risk assessments should be performed and by having significant CPSC staff risk assessments peer-reviewed in accordance with OMB guidelines. The staff believes that it appropriately applies the best practices in risk assessment consistent with agency needs and resources.

- Question: If applicable, please specify provisions in the Bulletin that can be expected to have a substantial negative effect on the quality, conduct, and use of risk assessments undertaken by your agency.

CPSC Staff Response

The staff believes a number of provisions in the Bulletin could have a negative effect on the quality, conduct, and use of risk assessments undertaken by the CPSC. Several examples follow.

1. While many of the proposed requirements seem reasonable, meeting the standards could come at significant cost in terms of time and other resources. For example, while the proposed Bulletin addresses the need to consider resources in *Section III: Goals*, it is

not clear that the flexibility implied in this section is reflected in the language elsewhere in the Bulletin. CPSC staff believes that lack of flexibility would result in unnecessarily applying requirements that will not actually improve assessments in all cases (*i.e.*, a one size fits all approach is likely not possible or desirable). Further, staff expects that during the process of planning a risk assessment, there will be discussions about which Bulletin standards will be applicable. Such discussions will be *a priori*, *i.e.*, before the risk assessment has been conducted. Because the applicability of Bulletin standards is ultimately made on the basis of the risk findings and potential regulatory action, it is entirely possible that the standards chosen at the design stage and those required subsequently based on the findings (or potential regulatory action implied by the findings) may be different. This can have serious resource implications.

2. The Bulletin's 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" could have three negative effects. First, staff resources will be needed for the analysis of other risk assessments to determine (a) comparability and (b) validity of the analysis. In some cases, the comparable risk may be in areas outside the expertise of CPSC staff and outside assistance may be necessary. Second, we expect that there will be challenges to the selection of comparable risks, especially when the choice of appropriate comparisons is limited. Third, putting comparative risk information in an Executive Summary, without an explanation of the context in which it was derived, could mislead the reader.

If this requirement is implemented, it would be useful for OMB to provide more information on how this requirement might be met.

3. The requirement to revise each risk assessment as new information becomes available could have a negative impact. CPSC staff agrees that some risk assessments remain a source of information years after they are conducted, and such important assessments should be updated as information becomes available. However, many CPSC risk assessments are conducted for specific purposes, *e.g.*, preliminary assessments conducted to support decisions on the disposition of petitions, and may never again be used for informational or regulatory purposes. While the proposed Bulletin states that resources should be considered in meeting this requirement, CPSC staff believes that the flexibility implied in this statement would not necessarily be realized and that scarce resources would be spent on inconsequential, outdated, assessments.

4. Section VII of the Bulletin says 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. This requirement needs clarification since the method of certification, which is unspecified in the Bulletin, could have resource implications.

- Question: If your agency followed the procedures described in the Bulletin, would it affect the time course for production of the risk assessment (that is, the time required from initiation of the risk assessment to delivery to the regulatory decision maker)? If so, please explain why?

CPSC Staff Response

CPSC staff believes that the effect of the proposed Bulletin on the time course of a risk assessment would in part depend on the level of flexibility afforded the assessor. If, for example, the Bulletin requires certain steps that the assessor previously might have determined to be unnecessary, then the time course might be lengthened significantly. This would be especially applicable to many routine work products, such as screening level risk assessments and other tasks not normally considered risk assessments.

- Question: One of the Bulletin's reporting standards states the need to be scientifically objective by "giving weight to both positive and negative studies in light of each study's technical quality." Please give an example of how this would be implemented by your agency or department.

CPSC Staff Response

This issue is addressed in the Chronic Hazard Guidelines. CPSC staff considers "all of the available data" in performing risk assessments.

- Question: Does your agency use risk assessments conducted by external groups? Would it be helpful to you if risk assessments submitted to your agency by external groups, such as consultants and private industry, met the requirements proposed in the OMB Bulletin?

CPSC Staff Response

The CPSC issued Chronic Hazard Guidelines in 1992, in part, to guide manufacturers in complying with the requirements of the Federal Hazardous Substances Act. CPSC staff generally does not use risk assessments performed by outside groups, but sometimes it will consider an external risk assessment if it is applicable and if it provides information that the staff does not have. To the extent that such externally-derived assessments would then be used by staff in performing its work, the staff believes that it would be appropriate that such assessors follow accepted risk assessment practices, including the CPSC Chronic Hazard Guidelines, as well as other requirements of the federal government.