

Regulation & Law

Government Operations

OMB Draft Bulletin Details Procedures For Agencies to Use When Assessing Risks

The White House Office of Management and Budget issued for comment Jan. 9 a draft bulletin detailing procedures agencies should use to conduct risk assessments and information that should be included.

The draft guidance, released by OMB's Office of Information and Regulatory Affairs, defines actions agencies would have to take to ensure that their risk assessments have qualities such as being objective, reproducible, and transparent--characteristics also required by Information Quality Guidance that OMB issued in 2002.

The draft technical guidance "does not encompass how federal agencies should manage or communicate risk," OIRA said in the *Proposed Risk Assessment Bulletin*. Rather, the document "addresses the development of the underlying documents that may help inform risk management and communication."

OIRA asked the National Academy of Sciences to peer-review the 26-page draft document. Public comments will be accepted through June 15, according to OIRA's announcement.

The proposed guidance would be revised in accordance with these reviews, with the goal of publishing a final bulletin in late 2006, OIRA said.

Many of the recommendations listed in OIRA's draft document are gleaned from suggestions made in reports previously issued by the National Academies and other federal advisory committees.

Many Types of Evaluations Covered

OIRA listed examples of documents and assessments covered by the draft guidance. Those examples include:

- ◆ risk values describing exposures to chemicals, pesticides, and air pollutants that the Environmental Protection Agency believes will not harm human health and which are included in the agency's Integrated Risk Information System database;

- risk assessments that EPA uses as it sets limits for ozone, particulate matter, carbon monoxide, nitrogen dioxide, sulfur oxides, and lead (National Ambient Air Quality Standards);
- tolerance values developed by the Food and Drug Administration;
- toxicological profiles developed by the Agency for Toxic Substances and Disease Registry;
- substance profiles developed by the National Toxicology Program;
- current intelligence bulletins, which review and evaluate new and emerging information about occupational hazards, and criteria documents, which are recommended occupational standards designed to limit worker exposure to a chemicals or hazardous vibrations or other type of exposure, developed by the National Institute for Occupational Safety and Health; and
- risk assessments performed as part of economically significant rulemakings.

Some Pesticide Assessments Excluded

The draft guidance also stated that certain risk assessments would not have to meet the standards contained in the draft document.

"This Bulletin does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings.... This exclusion is intended to cover, among other things, licensing, approval, and registration processes for specific product development activities," the draft document said.

Asked whether the guidance would apply to risk assessments conducted by EPA's Office of Pesticide Programs, an OMB official said, "The short answer is that 'it depends.' "

When EPA prepares a risk assessment for an entire class of pesticides (e.g., the cumulative risk assessment for organophosphates), that assessment is covered by the guidance, the OMB official said.

"However, the assessments prepared by registrants for specific products are themselves not covered because they are apart of a specific adjudication and are not agency disseminations," the OMB official said.

'Rule of Reason Should Prevail.'

"A rule of reason should prevail in the appropriate application of the standards in this Bulletin," the OIRA draft document said in a section that says different types of risk assessments can meet divergent standards.

"Agencies should take into account the importance of the risk assessment in gauging the resources, including time and money, required to meet the requirements of this Bulletin," the draft document said.

Nevertheless, "it is expected that every risk assessment shall describe the data, methods, and assumptions with a high degree of transparency; shall identify key scientific limitations and uncertainties; and shall place the risk into perspective/context with other risks familiar to the target audience," OIRA said.

However, screening level risk assessments, which are quick, worst-case analyses conducted to determine whether a particular exposure or situations might pose a concern, would not have to meet the standard of "neither minimizing nor exaggerating the nature and magnitude of risk."

Influential types of risk assessments would, however, have to meet that standard, OIRA said.

OIRA used the same definition of "influential" it used in the 2002 Information Quality Guidance. Influential means the assessment could have a "clear and substantial impact on important public policies or important private sector decisions."

The draft document described other attributes that risk assessments would have to be useful to regulatory decisions.

For example, risk assessments should examine a range of plausible risk estimates, not just the worst or best situation, the draft bulletin said, encouraging use of a "central estimate" or "expected risk."

OIRA's proposal describes many other characteristics that federal risk assessments should have and information they should contain.

For example, the objectives and scope of the analysis should be explained in an executive summary that also should contain the key findings of the analysis and the key scientific limitations and uncertainties.

Risks should "be placed in a context that is useful and relevant for the intended audience," OIRA said.

Defining 'Adverse Effect.'

Not every biological change that scientists can measure is a problem, OIRA said.

"Measuring the concentration of a chemical metabolite in a target tissue of the body is not a demonstration of an adverse effect, though it may be a valid indicator of chemical exposure," the draft documents said. "Adversity typically implies some functional impairment or [pathological] lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges."

"If an unusual or mild effect is used in making the adverse-effect determination, the assessment should describe the ramifications of the effect and its degree of adversity compared to adverse effects that are better understood and commonly used in safety assessment," OIRA continued.

The draft guidance discussed how federal agencies should respond to comments they receive about influential draft risk assessments they disseminate.

"An agency is expected to consider all of the significant comments received on a draft influential risk assessment report," the *Proposed Risk Assessment Bulletin* said. "Scientific comments shall be presumed to be significant."

"Where agencies take different positions than commenters, the agency response to comments should provide explicit rationale for why the agency has not adopted the position suggested by the commenter," OIRA's draft document said.

Praise for Draft Bulletin

Jim Tozzi, formerly a deputy director of OMB's Regulatory Review Office and now head of the industry-supported Center for Regulatory Effectiveness, described OIRA's draft guidance as "very significant and a good step forward."

The document may need some revision before being issued as final, but it does an excellent job of describing OMB's legal authority for issues such as governmentwide guidance, Tozzi said.

The draft bulletin also is important because it pulls together into a single document recommendations made in many other separate reports, he said.

The Proposed Risk Assessment Bulletin is available at
http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf 