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REPORT
IN BRIEF

Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget

The White House Office of Management and Budget issued a draft bulletin in January of 2006 seeking to improve the quality of federal agencies' risk assessments by setting new standards for their conduct. OMB asked the National Research Council to review the bulletin, and one year later, an NRC panel of experts determined it had technical shortcomings and recommended that it be withdrawn.

Risk assessments are often used by the federal government to estimate the risk posed to the public by exposure to a chemical or the potential failure of a bridge or other engineered structure. Government agencies use risk assessments in setting safeguards for the workplace, consumers, human health and the environment.

Last January, the White House Office of Management and Budget (OMB) sought to improve federal risk assessments by issuing a draft bulletin prescribing stricter standards for developing them, including a revised definition of risk assessment and new requirements for analyzing risks and describing what is uncertain about them. At the request of OMB, the National Research Council evaluated the draft bulletin and supports its overall goal of improving the quality of risk assessments.

However, after careful review, the National Research Council report concluded the OMB draft bulletin omits key topics such as risks to ecosystems, risks posed by engineered structures, and impacts on sensitive populations--factors which limit its relevance. The National Research Council also found that OMB had not studied agencies like the Food & Drug Administration and the Environmental Protection Agency (EPA) to evaluate their risk assessment proficiency before recommending new methods and standards. OMB also did not evaluate the impact of the bulletin's mandates on agency staffing, resources and the additional time it would require to complete risk assessments.

Based on this and other concerns, the National Research Council concluded in its report *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and*



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Budget that the bulletin is “fundamentally flawed” from a scientific and technical standpoint and should be withdrawn. Instead, if OMB elects to move forward, the National Research Council encourages OMB to articulate broad principles and goals but allow the agencies to develop their own technical guidance to suit their unique missions and legal mandates.

Problems with the OMB bulletin include an overly broad definition of risk assessment which stands in conflict with long-established concepts and practices, and an overly narrow definition of adverse health effects—one that considers only clinically apparent effects to be adverse, ignoring other biological changes that can lead to health problems.

The National Research Council report also criticizes the bulletin for focusing mainly on human health risk assessments while neglecting assessments of technology and engineered structures like dams or air-traffic control systems. A number of federal agencies, including the National Aeronautics and Space Administration (NASA) and the Department of Transportation routinely conduct risk assessments for engineered systems.

The majority of examples the proposed OMB risk assessment bulletin presents apply to the biologi-

cal impact of environmental contaminants on people, an area which is regulated by EPA. EPA officials generally develop risk assessments by relying on studies of test animals exposed to chemicals. On occasion, studies of people exposed in the workplace or other contexts allows EPA scientists to use research on human health in risk assessments as well. These agency risk assessments are then used to set regulations that protect people and ecosystems from potentially dangerous levels of toxic exposure.

The National Research Council was also asked if the proposed OMB bulletin was consistent with past National Research Council expert reports on risk assessment and in particular, how analysts can incorporate what is unknown into their conclusions about risk. In general, the National Research Council found that while many of the OMB bulletin’s requirements are somewhat consistent with past National Research Council recommendations, OMB omitted key topics and extended its standards beyond what can currently be justified by the available science.

After the January 11th release of the National Research Council report, OMB stated it will withdraw the current version of the bulletin.

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This brief was prepared by the National Research Council based on the committee’s report. For more information, contact the Board on Environmental Studies and Toxicology at (202) 334-3060 or visit <http://nationalacademies.org/best>. Copies of *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.

