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OMB and Risk Assessment

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OMB and Risk Assessment

Summary

On January 9, 2006, the Office of Management and Budget (OMB) released a proposed bulletin on risk assessment for comment by the public and peer review by the National Academy of Sciences (NAS). Risk assessment is used by federal agencies to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment. In a regulatory context, risk assessment helps agencies identify issues of potential concern (e.g., whether exposure to a given risk agent causes effects such as cancer, reproductive and genetic abnormalities, or ecosystem damage), select regulatory options, and estimate a forthcoming regulation's benefits.

The bulletin proposed to establish six general risk assessment and reporting standards (e.g., that they summarize the scope of the assessment, provide a qualitative and/or quantitative characterization of risk, be based on the best available data, explain the basis for critical assumptions, and contain an executive summary). It also proposed to establish a seventh general standard for assessments produced in relation to analysis for a rule with annual economic effects of $1 billion or more (e.g., comparison of baseline risk to alternative mitigation measures) and nine special standards for "influential" risk assessments that go beyond those general standards. The bulletin was written in a prescriptive manner, but also appeared to give agencies discretion in its implementation.

In January 2007, the NAS committee reported that the proposed bulletin was "fundamentally flawed" and should be withdrawn by OMB. Instead, the committee said that OMB should issue a bulletin that outlines goals and general principles of risk assessments that federal agencies could use to develop their own guidance. On September 19, 2007, OMB withdrew the proposed bulletin and instead issued a memorandum reiterating and reinforcing principles for risk assessment that were originally written in 1995, indicating that agencies should comply with the principles. Reaction to these principles has been generally positive, although their impact will likely depend on how they are implemented. No related legislation has been introduced in the 110th Congress.

This report will be updated when other significant developments occur.

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OMB and Risk Assessment

On January 9, 2006, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) released a proposed bulletin on risk assessment for comment by the public and for peer review by the National Academy of Sciences (NAS).[1] Public comments on the bulletin were requested by June 15, 2006. The bulletin proposed to establish general risk assessment and reporting standards, and to establish special standards for "influential" risk assessments. The bulletin applied to all agencies covered by the Paperwork Reduction Act (i.e., cabinet departments, independent agencies, and independent regulatory agencies). The legal authorities cited for the bulletin include the Information Quality Act (IQA);[2] the Regulatory Right-to-Know Act,[3] which directs OMB to "issue guidelines to agencies to standardize ... measures of costs and benefits" of federal rules; and Executive Order 12866,[4] which says OIRA is the "repository of expertise concerning regulatory issues," and requires agencies to base their decisions on the "best reasonably obtainable scientific, economic, or other information." OMB said the risk assessment bulletin builds on its IQA guidelines[5] and its peer review bulletin,[6] and is intended to be a companion document to its guidance on regulatory impact analyses (OMB Circular A-4).[7]

Although characterized as "guidance" in the document's summary, the preamble mentioned the "requirements" of the bulletin, and listed the standards with which

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[1] Office of Management and Budget, "Proposed Risk Assessment Bulletin," Jan. 9, 2006, available at [http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf].

[2] The IQA, sometimes referred to as the Data Quality Act, was enacted in December 2000 as Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554).

[3] Section 624 of the Treasury and General Government Appropriations Act, 2001, (31 U.S.C. 1105 note).

[4] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993.

[5] A copy of OMB's IQA guidelines is available at [http://www.whitehouse.gov/omb/inforeg/iqg_oct2002.pdf]. For more information , see CRS Report RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation,* by Curtis W. Copeland.

[6] A copy of OMB's peer review bulletin is available at [http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf]. For more information, see CRS Report RL32680, *Peer Review: OMB's Proposed, Revised, and Final Bulletins,* by Curtis W. Copeland and Eric A. Fischer.

[7] A copy of OMB Circular A-4 is available at [http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf].

"[e]ach agency shall" comply. However, OMB also said that the bulletin applied to all agency risk assessments "to the extent appropriate." Agency heads were authorized to waive or defer some or all of the requirements in the bulletin "where warranted by a compelling rationale." Also, under the heading of "Judicial Review," OMB said that the bulletin was "intended to improve the internal management of the Executive Branch," and "does not create any right or benefit, substantive or procedural, enforceable at law or equity, against the United States, its agencies or other entities, its officers or employees, or any other person."

Risk assessment was defined in the bulletin as a 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." In a regulatory context, risk assessment helps agencies identify issues of potential concern (e.g., whether exposure to a given risk agent causes effects such as cancer, reproductive and genetic abnormalities, or ecosystem damage), select regulatory options, and estimate a forthcoming regulation's benefits. OMB said in the bulletin that it "has a strong interest in the technical quality of agency risk assessments because these assessments play an important role in the development of public policies at the national, international, state and local levels." OMB also said that "there is general agreement that the risk assessment process can be improved, and said the purpose of the bulletin is "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards."

Background on Risk Assessment

Risk assessments, particularly quantitative assessments, date to the first half of the 20th century, but their use was accelerated by the enactment of numerous health, safety, and environmental statutes in the early 1970s. In 1983, NAS identified four steps in the risk assessment process: (1) *hazard identification* (determining whether a substance or situation could cause adverse effects), (2) *dose-response assessment* (determining the relationship between the magnitude of the exposure to a hazard and the probability and severity of adverse effects), (3) *exposure assessment* (identifying the extent to which exposure actually occurs), and (4) *risk characterization* (combining the above information into a conclusion about the nature and magnitude of the risk).[8] NAS pointed out that this four-step assessment process is separate and distinct from the decision on where to set a regulatory standard (which is termed "risk management").

In 1990, Congress mandated that a commission be formed to "make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects." In its 1997 final report, the Presidential/Congressional Commission on Risk Assessment and Risk Management said that the assessments should be guided by an understanding of the issues of

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[8] National Research Council of the National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* (Washington, DC: National Academy Press, 1983).

importance to risk management decisions and to the public's understanding of what is needed to protect public health and the environment.[9] The commission also noted, however, that risk-related controversy often "arises from what we don't know and from what risk assessments can't tell us."

Data, Assumptions, and Context. Key elements in any risk assessment are the data used in determining the level of risk associated with any given substance or situation. In many cases, though, the data needed to assess risk are lacking. For example, in 1998, the Environmental Protection Agency (EPA) reported that of 3,000 high-production-volume chemicals (those imported or produced at volumes of 1 million pounds per year), a full set of toxicity data was available for only about 200 (7%) of the chemicals, and there was no publicly available data for about 43% of the chemicals.[10] Similar data gaps exist regarding the extent to which people are exposed to chemicals. For example, in 2000, the General Accounting Office (GAO, now the Government Accountability Office) reviewed federal and state efforts to collect human exposure data on more than 1,400 naturally occurring and manmade chemicals considered by the Department of Health and Human Services (HHS), EPA, and other entities to pose a threat to human health. GAO reported that HHS and EPA surveys measured exposure of the general population for only 6% of those chemicals.[11]

Because of the lack of data, agencies must make assumptions as part of the risk assessment process. Some critics of agencies' practices believe those assumptions are unjustifiably "precautionary" (i.e., designed to ensure that risks are not underestimated) in the face of new scientific data and methods, thereby producing estimates that overstate actual risks, and that those effects are compounded when multiple precautionary assumptions are used.[12] Others, though, believe that agencies are often not precautionary enough, particularly when estimating the effects of exposures to multiple chemicals, or to account for risks to particularly vulnerable groups (e.g., children, the elderly, or the infirm).[13]

The legal context in which risk assessments are conducted plays an important role in determining what type of assessment is performed and why certain approaches are used. For example, different agencies (and often different offices within a single

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[9] Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, Final Report, Vol. 1, 1997, p. 23.

[10] U.S. Environmental Protection Agency, *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals*, April 1998.

[11] U.S. General Accounting Office, *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans*, GAO/HEHS-00-80, May 2, 2000.

[12] See, for example, John D. Graham, "The Perils of the Precautionary Principle: Lessons from the American and European Experience," speech before the Regulatory Forum, Heritage Foundation, Oct. 20, 2003, available at [http://www.whitehouse.gov/omb/inforeg/speeches/031020graham.pdf].

[13] For a discussion of some of these assumptions, see U.S. General Accounting Office, *Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies*, GAO-01-810, Aug. 6, 2001.

agency) have different risk-related statutory mandates. Some statutes require regulatory decisions to be based solely or primarily on risk. (For example, Section 109 of the Clean Air Act requires EPA to set national ambient air quality standards that allow for an "ample margin of safety" to protect public health.) Other statutes require technology-based standards (e.g., "best available technology"), and still others require balancing the benefits of risk reduction against the costs incurred in setting risk management goals. Some statutes also place the primary responsibility for conducting risk assessments and compiling risk data for a particular chemical or source of exposure with industry, states, or localities, not federal agencies. (For example, industry petitioners have the primary responsibility to provide the data needed to support registration and tolerances from EPA for their pesticides.) Still other statutes specifically define what will be a hazard, tell the agency to take certain methodological steps, or specify an exposure scenario. However, in many cases, the statutes simply provide a general framework within which agencies make specific assumptions and methodological choices.

What OMB's Proposed Bulletin Would Have Required

OMB's proposed risk assessment bulletin would have established general risk assessment and reporting standards, as well as special standards for "influential" risk assessments. The bulletin proposed to make OIRA, in consultation with the Office of Science and Technology Policy, responsible for overseeing agency implementation of its requirements.

General Standards. With regard to the general standards, the bulletin established six risk assessment quality standards:

- that the assessments clearly state the informational needs that drive them as well as their objectives;

- that they clearly summarize the scope of the assessment (including identification of the agent, technology, or activity at issue; the hazard of concern; the affected entities; and the event-consequence or dose-response relationships for the relevant exposure ranges);

- that they provide a qualitative and, where possible, a quantitative characterization of risk (including a range of plausible estimates for quantitative measures);

- that they ensure objectivity by "neither minimizing nor exaggerating the nature and magnitude of risk;[14] using the best available data; being based on the weight of the available scientific evidence; and having a high degree of transparency regarding the data, assumptions, and methods;

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[14] OMB said this standard would not apply to "screening-level" risk assessments in which conservative, "worst case" assumptions and scenarios are used to determine whether any hazard exists. In these assessments, agencies will proceed to a more comprehensive estimate of risk only if evidence of harm is revealed.

- that they explain the basis of each critical assumption and those assumptions that affect the assessment's key findings, including an evaluation (quantitative if possible) of the effects of plausible alternative assumptions; and

- that they contain an executive summary that discloses the assessment's objectives and scope, key findings, and key scientific limitations and uncertainties.

When a risk assessment is produced in relation to regulatory analysis for a rule with annual economic effects (positive or negative) of $1 billion or more, the bulletin proposed a seventh requirement — that there be a "formal quantitative analysis of the relevant uncertainties about benefits and costs." The bulletin highlighted several "important aspects of risk assessments useful for regulatory analysis," including (1) identification of baseline risk; (2) comparison of baseline risk to alternative mitigation measures, noting any "countervailing risks" caused by those alternatives; (3) information on the timing of exposure and the onset of adverse effects, and the time between control measures and the cessation of those effects; and (4) when risk is measured quantitatively, the development of a range of plausible risk estimates, including a central estimate (e.g., a weighted average based on relative plausibility).

Special Standards for Influential Risk Assessments. The proposed bulletin defined an "influential risk assessment" as one that "the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."[15] OMB said that such assessments include those that determine the level of risk regarding health, safety, or the environment (e.g., risk assessments that support EPA's National Ambient Air Quality Standards, or economically significant rulemakings — e.g., those with a $100 million impact on the economy). In addition to the general standards delineated above, the proposed bulletin required all influential risk assessments to:

- be capable of being "substantially reproduced," which is defined in the narrative portion of the bulletin (referencing the IQA guidelines) as meaning that "independent reanalysis of the original or supporting data using the same methods would generate similar analytical results";[16]

- compare the results of the assessment to other results published on the same topic from "qualified scientific organizations" (which is undefined in the bulletin);

- highlight central estimates as well as high-end and low-end estimates of risk when such estimates are uncertain;

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[15] This is essentially the same standard that the IQA guidelines say OMB is to use to determine whether information is "influential," and OMB's peer review bulletin says that agencies are to use to determine whether information is "influential scientific information."

[16] The narrative text goes on to say that "[p]ublic access to original data is necessary to satisfy this standard."

- characterize uncertainty with respect to the major findings of the assessment (e.g., by conducting a sensitivity analysis and providing a quantitative distribution of the uncertainty);

- portray results based on different effects observed and/or different studies to convey how the choice of effect and/or study influences the assessment;

- characterize (to the extent feasible) variability through a quantitative distribution, reflecting different affected population(s), time scales, geography, or other parameters relevant to the needs and objectives of the assessment;

- where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities;

- provide discussion (to the extent possible) of the "nature, difficulty, feasibility, cost and time associated with undertaking research to a report's scientific limitations and uncertainties"; and

- consider all significant comments received on a draft risk assessment report, and issue a "response to comment" document summarizing the significant comments received and the agency's responses.

Public Comments on the Proposed Bulletin

On June 22, 2006, OMB posted the comments that it had received regarding the proposed bulletin on its website.[17] Those comments varied significantly, with some suggesting ways to make the document stronger and more inclusive, whereas others suggested that OMB abandon the bulletin altogether.

For example, in its comments on the bulletin, the U.S. Chamber of Commerce said it "welcomes and applauds this undertaking by OMB to improve the risk assessments performed by federal government agencies and especially in requiring a reliable characterization of the uncertainties that impact the quality and useful information content of the assessments."[18] Although it offered several suggestions for improvement, the Chamber generally concurred with the text of the bulletin and encouraged its implementation. Perhaps most notably, the Chamber viewed the lack of judicial review as a "significant weakness" that "begs the question of what happens if agencies simply choose to ignore the directions given in the Bulletin."

Other individuals and organizations, while also supporting the issuance of the bulletin, urged OMB to go further. For example, the National Association of

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[17] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/list_rab2006.html].

[18] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/congress.pdf].

Manufacturers said exceptions to the bulletin should be "very limited" (e.g., declared public emergencies), and said the "reproducibility" standard for influential assessments should be applied to all assessments.[19] The National Federation of Small Businesses questioned the exemption for individual permitting decisions (e.g., EPA determinations regarding pesticide applications).[20] Two Members of Congress proposed deleting the phrase "to the extent appropriate" from the bulletin's scope because it suggested that compliance with its requirements was at the discretion of the agencies.[21]

On the other hand, the Center for Progressive Reform (CPR) urged OMB to "withdraw the Proposed Bulletin and abandon efforts to revise it."[22] CPR said any effort to produce government-wide, "one-size-fits-all" risk assessment requirements would only cause confusion and delay in the development of public and worker protections. The organization also questioned why OMB should be issuing risk assessment guidance at all, since it is staffed primarily with economists and budget analysts, not scientists. In particular, CPR said certain terms in the bulletin are confusing (e.g., "central" or "expected" risk), and also said that the bulletin requires information that may not exist or would be costly to obtain and may lead to the further "ossification" of the rulemaking process. Similarly, the Natural Resources Defense Council (NRDC) expressed "grave misgivings" regarding the proposed bulletin, and urged OMB to withdraw it.[23] In particular, NRDC said issuance of the document as a "bulletin" rather than as guidance and its use of directive terms (e.g., "shall") suggest that the document is mandatory, and said the exclusion of risk assessments prepared by private industry for licensing and registration requirements "protects industry assessments from scrutiny."

Other commenters raised additional issues. The American Bar Association (ABA) said the proposed bulletin is generally consistent with a 1999 ABA recommendation on risk assessment, but noted several areas for possible improvement (e.g., clarifying the amount of flexibility agencies have to deviate from the bulletin's requirements).[24] The ABA also suggested that OMB clearly describe the problems that warrant the creation of a new risk assessment bulletin, and also describe why OMB (and not the regulatory agencies) is best suited to resolve those problems. Dr. Gilbert Omenn, who chaired the Presidential/Congressional Commission on Risk Assessment and Risk Management in the 1990s, said the proposed bulletin has "worthy intentions," but also said it was "too broad" and recommended a number of improvements (e.g., deletion of the "influential" risk assessment category and its additional requirements). He also recommended greater transparency in the OMB and agency review processes, and the correction of certain "omissions" (e.g., an exclusion for research agencies).

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[19] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/nam.pdf].

[20] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/nfib.pdf].

[21] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/cec.pdf].

[22] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/cpr.pdf].

[23] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/nrdc.pdf].

[24] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/aba.pdf].

NAS Review of the Bulletin

On March 22, 2006, a committee of the Board on Environmental Issues and Toxicology within the National Academies' Division of Earth and Life Sciences began its peer review of OMB's proposed bulletin. According to the committee's website,[25] its mission was to

> determine whether the application of the proposed guidance will meet OMB's stated objective to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies." In performing its task, the committee will comment, in general terms, on how the guidance will affect the practice of risk assessment in the federal government. The committee will identify critical elements that might be missing from the guidance. The committee will also determine whether OMB appropriately incorporated recommendations from previous reports of the NRC [National Research Council] and other organizations into the proposed risk assessment guidance. In addition, the committee will assess whether there are scientific or technical circumstances that might limit applicability of the guidance.

On May 22, 2006, the committee held a public meeting on OMB's proposed risk assessment bulletin. According to press accounts, the nine federal agency officials who testified at the meeting voiced a variety of opinions about the bulletin.[26] For example, the Director of FDA's Center for Drug Evaluation and Research reportedly said that if the bulletin was made final in its then-current form, doctors and the public might not receive timely warnings about potential health risks posed by drugs and medical devices (e.g., warnings related to the use of the anti-inflammatory drug Vioxx). To illustrate, the FDA director said that of 109 safety alerts that FDA issued in 2005, 92 of them would have been considered risk assessments under the bulletin, and therefore would have been delayed by the required analyses. He and two other agency officials (from the National Institute of Environmental Health Sciences and the National Institute for Occupational Safety and Health's Risk Evaluation Branch) reportedly said that the bulletin's definition of risk assessment is so broad that many types of federal analyses could be inappropriately covered by its requirements.

On the other hand, EPA's science advisor was quoted as saying that the agency was in "pretty good shape" in terms of meeting the requirements in the proposed bulletin, but nevertheless suggested that the guidance be revised to explain how much flexibility agencies have regarding its requirements (e.g., how agencies can get waivers from the bulletin's requirements).[27] He and an official from the National Aeronautics and Space Administration also said that some aspects of the bulletin would conflict with their own agency-specific guidance documents on risk assessment, and it was not clear how those conflicts should be resolved. A representative from the Department of Defense reportedly supported the proposed

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[25] The website is at [http://www8.nationalacademies.org/cp/projectview.aspx?key=34282].

[26] Pat Phibbs, "Definition of Risk Assessment Deemed Too Broad by Several Health Agency Officials," *BNA Daily Report for Executives*, May 23, 2006, p. A-15.

[27] Ibid.

guidelines, noting that any increased cost would be justified by improvements in the resulting risk assessments.

Issuance of NAS Report. On January 11, 2007, the NAS committee issued its final report concluding that OMB's proposed risk assessment guidance was "fundamentally flawed" and should be withdrawn.[28] The committee said that it "fully supports the goal of increasing the quality and objectivity of risk assessment in the federal government," but also said that it "agrees unanimously that the OMB bulletin would not facilitate reaching this goal." Among other things, the committee said that the proposed bulletin:

- used a definition of risk assessment that was too broad and "conflicts with long-established concepts and practices";
- used a definition of "adverse effect" that was too narrow, and ignored a fundamental health goal of controlling exposures before the impairment of an organism;
- gave little attention to sensitive populations, such as children and the elderly;
- failed to explain the basis for exempting risk assessments associated with licensing and approval processes; and
- ignored the continuum of risk assessment efforts by arbitrarily using only two broad categories.

The report also criticized OMB for failing to identify the problem its guidance sought to address, and said the proposed bulletin's "most glaring omission" was the "absence of criteria and information for gauging the benefits to be achieved by implementing the bulletin (that is, a benefit-cost analysis)." In general, the NAS committee said that risk assessment "is not a monolithic process.... Thus, one size does not fit all, nor can one set of technical guidance make sense for the heterogeneous risk assessments undertaken by federal agencies."

Instead of finalizing the proposed bulletin, the NAS committee recommended that OMB issue a bulletin that outlines goals and general principles of risk assessments that would enhance the quality, efficiency, and consistency of such studies. Federal agencies could then be required to develop their own risk assessment guidance, which would be peer reviewed and contain procedures for ensuring compliance. The committee said that the agencies or expert panels appointed by the agencies should develop these detailed guidance documents,

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[28] National Academies of Science, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*, Jan. 11, 2007, as cited in Pat Phibbs-Rizzuto, "Draft OMB Guidance 'Fundamentally Flawed,' National Academies Panel Says in Report," *Daily Report for Executives*, Jan. 12, 2007. As of January 16, 2007, the NAS report was not available to the public, but a pre-publication executive summary was available at [http://books.nap.edu/openbook.php?record_id=11811&page=11].

because therein "lies the depth of expertise to address the issues relevant to their specific types of risk assessments."

In response to the NAS committee report, OMB reportedly said that it would not issue the proposed bulletin in final form, and was considering what further steps to take. Possible future actions reportedly include the development of a new proposed bulletin (similar to how OMB responded to adverse comments on its peer review bulletin), the issuance of a new final bulletin, or some other action.

Updated Principles for Risk Assessment

On September 19, 2007, Susan E. Dudley, Administrator of OIRA, and Sharon L. Hays, Associate Director and Deputy Director for Science in the Office of Science and Technology Policy, jointly issued a memorandum for the heads of executive departments and agencies entitled "Updated Principles for Risk Analysis."[29] The memorandum indicated that the proposed risk assessment bulletin would not be issued in final form. Instead, the memorandum reinforced general principles for risk analysis that were issued in 1995,[30] reiterating the text of the principles and referencing more recent guidance where appropriate. For example, the memorandum noted that the 1996 amendments to the Safe Drinking Water Act (SDWA) had established certain standards for risk assessments and risk characterizations pursuant to the act, and that agencies had adopted or adapted these standards as part of their Information Quality Act guidelines. It also referenced requirements in OMB Circular A-4 regarding accepted practices for regulatory analysis, and a 2007 OMB bulletin on good guidance practices.[31]

Reaction to the risk memorandum has been generally positive. Sally Katzen of the George Mason University School of Law, who was OIRA Administrator during the Clinton Administration and who issued the 1995 principles, said the memorandum was "responsive to the NAS critique."[32] Similarly, Rena Steinzor of the University of Maryland School of Law and the Center for Progressive Regulation said the memorandum indicated that OMB had "backed down" from its earlier position and was "not anything close" to what OMB had set out to do.[33] Representatives from the National Association of Manufacturers and the American Chemistry Council were generally supportive of the memorandum. A representative from OMB Watch, however, expressed concern that the memorandum is an attempt to "bootstrap more recent OMB policies onto the 1995 principles." Jim Tozzi, a

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[29] To view a copy of this memorandum, see [http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf].

[30] To view a copy of these principles, see [http://www.whitehouse.gov/omb/inforeg/regpol/jan1995_risk_analysis_principles.pdf].

[31] U.S. Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," 72 *Federal Register* 3432, Jan. 25, 2007, available at [http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf].

[32] Ralph Lindeman, "Mild Response Greets New OMB Memo To Reinforce Risk Assessments Principles," *BNA Daily Report for Executives*, Sept. 28, 2007, p. A-42.

[33] Ibid.

former OIRA official who currently heads the Center for Regulatory Effectiveness, said it was significant that OMB indicated that it would enforce the aspirational goals in the 1995 policy statement.[34]

Concluding Observations

The NAS committee's conclusion in its January 2007 report that OMB's proposed risk assessment bulletin was "fundamentally flawed" appears to have had a major effect on the principles of risk assessment that OMB issued in September 2007. As some observers have noted, however, much depends on how aggressively OMB chooses to implement those principles. General statements that agencies should use the "best reasonably obtainable scientific information to assess risks," and that those analyses should be based on the "best available scientific methodologies, information, data, and weight of the available scientific evidence" can be broadly interpreted and benign, or can be used to stop agency rulemaking.

The NAS committee also pointed out that OMB had not clearly established a need for government-wide requirements, and had not included any information on the expected costs and benefits of their implementation. To establish need, the NAS committee implicitly suggested the establishment of a baseline of each agency's risk assessment proficiency, "including the extent to which generally satisfactory and high-quality risk assessments are produced or how some agencies fall short of the specified standards." To date, OMB has not developed such a baseline or established what "problem" in agencies' risk assessments the new policy statement is intended to correct. No related legislation has been introduced in the 110th Congress.

[34] Ibid.