



Risky Business: Sullyng Science With Politics Yet Again

RECKLESS DISREGARD

*How the New OMB Risk Memo Ignores
the Recommendations of the National Academies*

After a scathing rebuke by the National Academies' National Research Council (NRC), the Bush White House withdrew a draft one-size-fits-all policy for risk assessments. OMB's response claims to respect the NRC's recommendations but actually adds new burdens to risk assessments and sends signals that evince a reckless disregard of the expert counsel of the NRC.

What OMB is requiring in the new risk memo . . .¹

. . . was rejected by the National Academies.²

Subjecting scientific risk assessments to political OMB review . . .

- "Agencies should refer to OMB's Final Bulletin for Agency Good Guidance Practices, as well as the Peer Review Bulletin, for updated guidance regarding best practices for increasing public access and public comment concerning guidance documents and influential scientific information." (13)
- The "good guidance practices" bulletin, a supplement to Executive Order 13,422, requires review and approval by senior political appointees and OMB of "significant guidance documents," a broadly-defined universe of materials that, according to the new risk memo, now includes major risk assessments.

. . . would allow industry-biased politics to trump scientific expertise and unnecessarily delay agencies.

- "Specifically, the committee is concerned that to the extent that the implementation of the technical aspects of risk assessment will be overseen by OMB and not by the peer-review process or by agency technical managers, scientific issues may be superseded by policy considerations." (99-100)
- "More important, additional time would be added if, in addition to the peer review process, OMB were to review anew the work product even where there is an existing well-done peer review." (99)

Subjecting risk assessment to industry challenge . . .

- Declares that influential risk assessments are subject to new "good guidance practices," which require *Federal Register* notice, comment period for industry to challenge the risk assessment, and execution of a full response-to-comments document for "economically significant guidance." (13)
- Repeatedly invokes OMB guidelines pursuant to the so-called "Information Quality Act," an eleventh-hour appropriations rider requiring the establishment of processes for the public to file challenges to agency information.

. . . will politicize and delay risk assessments.

- "There is also concern that the call for peer review, with the call for public participation, in the bulletin goes beyond previously stated requirements" (99) by "calling for a response to comment package for all influential risk assessments [which] would affect the timeliness of the reports without adding improvements in the scientific quality" (99 n.32).
- "[R]equiring a federal agency to provide a rationale for why its position is preferable to positions proposed by commenters is likely to expend excessive resources and might result in less time to devote to agency risk assessments, thus affecting the quality and output of agency products." (69)
- "The committee is therefore troubled by OMB's repeated references to the Information Quality Act (IQA) and its invocation as the legal authority for OMB to issue this bulletin, that suggest that challenges to a particular risk assessment — and almost every risk assessment is open to challenge on one ground or another — will be handled through the process designed for the IQA, a process that is more a legal or policy process than a scientific one." (99)

Requiring risk assessors to consider risk *management* concerns . . .

- Bootstrapping the IQA Guidelines, Peer Review Guidelines, and “Good Guidance Practices” order/bulletin requires risk assessors to comply with commands based on an evaluation of how the assessment will have consequences for risk management, both by policymakers and by voluntary private sector actors (including the cost to industry of modifying its own behavior or complying with a regulation that could possibly be promulgated at some future date in response to the risk assessment).

Requiring risk assessments to focus on risk *ranges* rather than point estimates and to emphasize central or expected risk values . . .

- “Due to the inherent uncertainties associated with estimates of risk, presentation of a single estimate may be misleading and provide a false sense of precision. Expert panels agree that when a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.” (6-7)
- Stresses that IQA Guidelines, which are bootstrapped to govern influential risk assessments, “direct the agencies to . . . specify, to the extent practicable . . . the expected risk or central estimate of risk for the specific populations [affected and] each appropriate upper-bound or lower-bound estimate of risk.” (6)

. . . violates the fundamental principle of distinguishing between risk *assessment* and risk *management* and will unreasonably delay needed risk assessments.

- “Whether an analysis constitutes an ‘influential risk assessment’ may not be clear at the outset. Moreover, this standard’s focus on economic impacts imposes risk management concerns on risk assessment. Arbitrarily separating risk assessments into two broad categories (influential and noninfluential) ignores the continuum of risk assessment efforts.” (66)
- “A slightly different problem arises from the bulletin’s requirement that risk assessments used for regulatory analysis include a variety of evaluations of alternative mitigation measures. Although risk assessors contribute information for use in risk management, this standard goes well beyond the job description of the scientist or technical person assessing the risk onto the path of risk management Not only will these requirements be resource-intensive and time-consuming, but the committee is also concerned that if they were incorporated at the primary stage of the risk assessment process (for example, identifying a hazard and determining the extent of the risk), risk assessors will be greatly delayed in doing their work.” (101)

. . . threatens the quality of risk assessments.

- “The standard does not provide clear guidance on how such a range is to be defined. As a result, it may produce confusion that could erode the quality of risk assessment.” (62)
- “The term *plausible risk estimate* is undefined in the bulletin. If a distribution is substantially skewed or bimodal, identifying a single estimate considered a ‘plausible’ estimate of the distribution is not meaningful. In that case, a ‘central’ estimate will not reasonably represent the distribution. When distributions reflect variability, the ambiguous term *plausible* appears to be at odds with the fundamental orientation of public-health practice and prevention, especially when the applicable laws seek to protect the most vulnerable in the population: infants, children, the elderly, and those with illnesses or predispositions to illness. Using a mean or central estimate to identify the most ‘plausible’ individual would undermine public- health goals.” (62-63)
- “The bulletin’s discussion of central and expected estimates and uncertainty is confused and prevents useful application of the standard. It is misleading to suggest as the bulletin does that ‘central’ and ‘expected’ estimates are synonymous.... [W]ithout proper definitions and context, use of the range or ‘central estimate’ will be misleading.... It is not in decision-makers’ or society’s interest to treat fundamentally different predictions as quantities that can be ‘averaged.’” (67)

¹ See Office of Info. & Reg. Affs., OMB, *Updated Principles for Risk Analysis* (OMB Memo. No. M-07-24, Sept. 19, 2007), available at <<http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>>. Subsequently cited parenthetically.

² Board on Env'tl. Studs. & Toxicology, Nat'l Research Council, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* (National Academies P, 2007). Subsequently cited parenthetically, with citations in original removed but all other emendations noted.