REGULATORY CHECKBOOK

June 15, 2006

Steven D. Aitken
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

RE: Proposed Risk Assessment Bulletin

Dear Steve,

Attached are Regulatory Checkbook's comments on OMB's proposed risk assessment bulletin. In addition to its technical elements, these comments also address matters related to the Bulletin's statutory and Executive authorities, a strategy for OMB to finalize the guidance in a timely manner, and tools for assisting federal agencies in their efforts to smoothly incorporate the principles and practices of the proposed Bulletin into their information quality policies and practices as well as regulatory analysis.

Regulatory Checkbook is a nonprofit organization whose mission is to improve the quality of scientific and economic information used in regulatory decision making. We represent no stakeholders, and no stakeholders have vetted or approved these comments prior to their submission.

Sincerely,

Richard B. Belzer, Ph.D.
President
Belzer@RegulatoryCheckbook.org

Attachment

Regulatory Checkbook

Comments on OMB's Proposed Risk Assessment Guidance

GENERAL COMMENTS

In this section we address several overarching issues presented by OMB's proposed risk assessment guidance (Office of Management and Budget 2006; Office of Management and Budget 2006). Each of these issues is largely independent of the text.

I. STATUTORY AUTHORITIES WHICH EXIST ARE NOT MADE EXPLICIT

The text, preamble and *Federal Register* notice do not clearly state the statutory authority for this proposal. Section XI is a disclaimer commonly appended to Executive orders and similar documents that are "intended to improve the internal management of the Executive Branch" but rest entirely on the president's Article II authorities. However, OMB does not even cite these authorities as the basis for its proposal. It is as if the proposed guidance is simply "a good idea" whose merits and justifications are self-evident.

This is an oversight. OMB has authority under the federal Information Quality Act (44 U.S.C. 3516 note) to issue government-wide guidance to federal agencies for

> ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

The proposed risk assessment guidance clearly fits within this framework for the subset of federally disseminated information that is "risk assessment."

OMB also has other statutory responsibilities that it has been hard-pressed to achieve without more effective Executive branch management. In particular, under the Regulatory Right-to-Know Act (RRTK), OMB is statutorily required to annually report to Congress on the costs and benefits of federal regulation.[1] RRTK grants OMB the authority to issue guidelines to standardize measures of costs and benefits. OMB initially issued these guidelines in 2000 (Office of Management and Budget 2000) and supplanted

[1] Section 624 of the Treasury and General Government Appropriations Act, 2001, 31 U.S.C. ' 1105 note, Pub. L. 106-554, '1(a)(3) [Title VI, ' 624], Dec. 21, 2000, 114 Stat. 2763, 2763A-161.

them with Circular A-4 in 2003 (Office of Management and Budget 2003). Circular A-4 has been criticized by opponents of benefit-coat analysis as "legally unsupportable" (Steinzor 2006) even though it has been used by federal agencies, in only slightly different form, since 1990 (Office of Management and Budget 1990).

To date, OMB has issued eight reports in fulfillment of its statutory reporting responsibilities. However, none of these reports has provided valid information on the costs and benefits of regulatory actions taken by the federal government involving risk.[2] Each report has relied on risk and benefit estimates that generally do not adhere to the information quality standards OMB established in 2002 (Office of Management and Budget 2002).

One reason may be that both OMB's 2000 Guidelines implementing RRTK and Circular A-4 only *imply* that risk, cost and benefit estimates should be unbiased (i.e., "objective") but do not say so explicitly. Moreover, OMB has not yet amended its

[2] OMB has been criticized each year for relying solely on agency estimates of regulatory benefits and costs even when competing estimates were available. In its 2005 report, OMB began to address this criticism, but only indirectly by suggesting that estimates made prior to regulation ("*ex ante* estimates") could be validated by analyses of actual regulatory effects performed after regulation ("*ex post* estimates"). OMB was dismissive of the quality of *ex ante* agency estimates, but preferred to attribute quality defects to the inherent limitations of *ex ante* estimation:

> [A]n *ex ante* estimate is no more than an informed guess and, like other forms of prospective modeling, the estimates may or may not prove to be accurate, once real-world experience with the rule is accumulated and analyzed. The regulatory accounting data published in this annual Report … are based on *ex ante* estimates of benefits and costs that were prepared by Federal agencies and published in regulatory impact analyses (p. 41).

See Office of Management and Budget. (2005). "Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/2005_cb/final_2005_cb_report.pdf.

This is at best a tactical diversion from the information quality problem posed by *agency* estimation, because decision making must always depend *ex ante* estimates. But to dismissively refer to agency estimates as "no more than informed guess[es]" speaks volumes about the difficulty OMB has had securing quality improvements. The information quality problem is not limited to differences between *ex ante* and *ex post* estimation. There are significant reasons why *ex ante* estimates *produced by regulatory agencies* tend to understate costs and overstate benefits. Like other stakeholders, regulatory agencies have powerful political, bureaucratic and legal incentives to cast their work in the best possible light.

As further evidence of the diversionary nature of OMB's approach, the problem of embedded agency bias is not overcome by using *ex post* agency estimates to calibrate *ex ante* agency estimates. In its 1999 report to Congress, OMB offered an unprecedented (and not repeated) dissent from an *ex post* estimate of the benefits of the Clean Air Act produced by EPA. *See* Office of Management and Budget. (1999, January). "1998 Report to Congress on the Costs and Benefits of Federal Regulations." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/costbenefitreport1998.pdf. (Footnote 14, p. 28). A more candid discussion of this dispute can be found in Lutter, R. and R. B. Belzer (2000). "EPA Pats Itself on the Back." Regulation **23**(3): 23-28.

regulatory analysis guidance to ensure that federal risk assessments used for regulatory purposes are consistent with the IQG. Hence, portions of the proposed risk assessment Bulletin are properly justified as amendments to Circular A-4 needed to bring RRTK guidelines in conformance with the IQG. As we indicate below, the obvious way to solve this is to incorporate the overarching principles of the proposed Bulletin (i.e., transparency in process, reproducibility in method, objectivity in outcome, and honesty about ignorance) and the provisions of § IV.7 as an amendment to Circular A-4. This would solve one of the persistent criticisms that have been leveled against the proposed Bulletin – that it tries to accomplish too many different things.

II. THE PROPOSED RISK ASSESSMENT BULLETIN SUPPLEMENTS EXISTING INFORMATION QUALITY GUIDELINES

The linkage between OMB's proposed risk assessment guidance and its 2002 Information Quality Guidelines (IQG) (Office of Management and Budget 2002) is not as clear as it could be. This became transparent during discussion at the first public meeting of the NAS committee on May 22 and the subsequent Forum sponsored by the Society for Risk Analysis on May 23-24. Many (and perhaps most) NAS committee members are unfamiliar with OMB's information quality guidelines and thus see no connection between the IQG and the proposed risk assessment Bulletin. A similar knowledge deficit appears to have afflicted several (and perhaps all) non-government speakers invited by NAS and speakers invited to participate in the SRA Forum. It is not unfair to say that knowledge about risk assessment and knowledge about information quality does not overlap much. OMB needs to spend considerably more effort on education to integrate these two vital communities.

Some commentators have characterized the proposed guidance as, among other things, "the most powerful administrative fiat for changing the levels of legislatively mandated protections of public health and the environment" (Center for Progressive Regulation 2006). We have been unable to locate these provisions.[3] Mostly, the proposed guidance repeats (and in some cases mildly amplifies for the risk assessment context) provisions already included in the IQG. Although OMB has solicited wide-ranging public comment on the draft Bulletin, nothing in the draft (Office of Management and Budget 2006) or the subsequent *Federal Register* notice (Office of Management and Budget 2006) suggests that OMB is reopening issues settled in the IQG. Unfortunately, OMB sought and obtained a review by NAS (Office of Management and Budget 2006) without clearly distinguishing the new *scientific* content appropriately the subject of peer review

[3] CPR asserts that a paragraph of preamble language mentioning the concept of "acceptable risk" means OMB intends to require all federal agency risk management decisions to mimic the Toxic Substances Control Act (pp. 1, 5). The logic behind this claim is a bit elusive.

from the *policy* content which does not lie within the ambit of NAS peer review. It would help if OMB made these distinctions clearer.[4]

III. The Benefits and Costs of Improved Risk Assessment

Centralized administrative requirements and government-wide standards impose costs on federal demands agencies. This is true of procedures imposed by both the president and the Congress. The best-known presidentially imposed requirements might be Executive orders 12,291 (Reagan) and 12,866 (Clinton) governing centralized regulatory review, but many others also remain in place. Examples of Executive orders signed by President Clinton include Numbers 12,861 (50% reduction in internal Executive branch regulations), 12,873 (federal acquisition, recycling, and waste prevention), 12,875 (intergovernmental relations), 12,898 (environmental justice), 12,902 (energy efficiency and water conservation at federal facilities), 12,969 (extension of TRI reporting to federal facilities), 13,001 (greening the government), 13,011 (federal information technology), 13,031 (federal alternative fuels leadership), and 13.045 (children's environmental health).

Some opponents of benefit-cost analysis see an undercurrent of partisanship in the use of administrative directives in favor of BCA (Center for Progressive Regulation 2006; Gordon, Dingell et al. 2006). These concerns are unsupported by facts. For example, President Clinton's Executive order 12,893 established principles for federal infrastructure investments that included explicit requirements for federal agencies to perform "systematic analyses of expected benefits and costs." Section 2(b) of the Order was explicit about how this had to be done:

> (1) Benefits and costs should be quantified and monetized to the maximum extent practicable. All types of benefits and costs, both market and nonmarket, should be considered. To the extent that environmental and other nonmarket benefits and costs can be quantified, they shall be given the same weight as quantifiable market benefits and costs.
>
> (2) Benefits and costs should be measured and appropriately discounted over the full life cycle of each project. Such analysis will enable informed tradeoffs

[4] CPR also objects to OMB's use of risk assessment language found in the Safe Drinking Water Act (SDWA). *See* Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff. This language also is found in the IQG and thus is not an issue open for public comment. Still, it's worth noting that CPR's objections are not grounded in law. CPR says that the purpose of the SDWA language adopted by OMB was to enable EPA "to protect specially affected subpopulations (for example, children, the elderly, and people with immunological deficiencies)." This claim is false. SDWA directs EPA to take account of sensitive subpopulations in *setting regulatory priorities* (42 U.S.C. 300g-1(b)(1)(C)). For *setting enforceable primary drinking water standards*, however, the only risk criteria are the Administrator must determine that "the contaminant may have an adverse effect on the health of persons" (42 U.S.C. 300g-1(b)((1)A)(i)), and that "regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (42 U.S.C. 300g-1(b)((1)A)(iii).

among capital outlays, operating and maintenance costs, and nonmonetary costs borne by the public.

(3) When the amount and timing of important benefits and costs are uncertain, analyses shall recognize the uncertainty and address it through appropriate quantitative and qualitative assessments.

(4) Analyses shall compare a comprehensive set of options that include, among other things, managing demand, repairing facilities, and expanding facilities.

(5) Analyses should consider not only quantifiable measures of benefits and costs, but also qualitative measures reflecting values that are not readily quantified.

Assuming that federal agencies previously did not follow these specific procedures, the Order required them to make significant changes in their analytic procedures. The greater the deficiencies in their prior conduct the more burdensome these new requirements must have been.

Some steadfast opponents of benefit-cost analysis also oppose OMB's proposed risk assessment guidance using the highly ironic argument that OMB didn't subject the guidance to benefit-cost analysis (Center for Progressive Regulation 2006). In their view:

> the inevitable conclusion would be that the hurdles erected … will impose large costs on agencies and will delay efforts to use risk assessment to impose affirmative protections, with no countervailing benefit in terms of better protection of human health and the environment.

We concede that the guidance would impose new burdens on federal agencies, and like President Clinton's guidance on federal infrastructure investments, these burdens would be greatest for agencies whose current performance is most laggard. However, we see no evidence suggesting that the guidance would always result in delay, or that "affirmative protections" would be most susceptible to delay, or that there would be "no countervailing benefit" from better risk assessment. If performed early in the regulatory development process, better risk assessment could just as well expedite rulemaking by reducing or eliminating conflicts and controversies at the end of the process, including delays from litigation. Further, situations in which current risk assessment practice is the most deficient would seem likely to experience the greatest delays. It is not clear why only regulations offering "affirmative protections" would be unusually susceptible, unless support for them depends critically on misleading, inaccurate, or biased risk assessment. Finally, wherever agencies currently perform risk assessment in a manner that minimizes or understates risk, the likely effect of the guidance would be to increase the stringency of regulation.

Estimating the benefits and costs of individual applications of the risk assessment guidance would require case-specific information. A rough idea can be gleaned however, by thinking through a simple conceptual example. Consider the case of an influential risk assessment that is intended to inform an economically significant regulation (i.e., one with effects exceeding $100 million). Spending $1 million on risk assessment – an

extraordinary sum, in most cases – would have net benefits if it provided insights sufficient to reduce regulatory cost by $1 million or increase the value of risks prevented by $1 million, or some combination thereof. Changes of this magnitude at the margin of a regulation are very easy to imagine. Indeed, the only circumstance in which "the inevitable conclusion" (in CPR's words) that OMB's guidance lacks net benefits is if agency decision makers have made up their minds and are determined to ignore it at all costs.

IV. NAS REVIEW

Some organizations publicized online their public comments on the proposed Bulletin prior to the first public meeting of the NAS committee, presumably for the twin purposes of influencing both OMB and the NAS review. The Association of American Medical Colleges expressed concern that risk communication activities of the Public Health Service and risk management decisions by the Food and Drug Administration regarding such matters as clinical trials might be impeded (Cohen 2006). AAMC apparently did not interpret the "deferral and waiver" section of the proposed guidance as sufficient (or sufficiently clear) to avoid such controversies.[5] The U.S. Chamber of Commerce commented on a wide range of issues but focused on Section XI, which would explicitly deny judicial review (Kovacs 2006). The Chamber identified this as "a significant weakness" that "beg[s] the question of what happens if agencies simply choose to ignore the directions given" in the proposed guidance. In an early press account of reaction to the proposed guidance, Natural Resources Defense Council senior scientist Jennifer Sass asserted that the proposed guidance was motivated by the Administration's desire to use faults in risk assessments to obstruct regulatory actions protecting public health, safety and the environment: "Risk assessment shouldn't be held to scientific standards, Sass says, because the field is not a science but relies on 'expert judgment, extrapolation, and leaps of faith'" (Hogue 2006).

Four Members of Congress publicized a letter to NAS President Ralph Cicerone dated May 5 challenging the legitimacy of the Academy's review and demanding that NAS make radical changes in its scope (Gordon, Dingell et al. 2006). Although this is not the first time politicians have interfered with the NAS, it is nevertheless revealing about

[5] "§VIII. Deferral and Waiver.

> "The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale. In each such instance, the agency shall include a statement in the risk assessment document that the agency is exercising a deferral or waiver as well as a brief explanation for the deferral or waiver. If the agency head defers the risk assessment requirements prior to dissemination, the risk assessment requirements shall be complied with as soon as practicable. A compelling rationale might cover health and safety risk assessments which are time-sensitive or need to be released due to an emergency situation. It is expected that a need for such a deferral would be an infrequent event. In the rare case of a time-sensitive necessary release, a complete risk assessment, which meets the standards set out in this Bulletin, should be provided to the public as soon as is practicable."

Qualitative criteria for deferrals are included in the text, but no criteria are offered for waivers.

the extent to which the practice of risk assessment has been slowly and deeply politicized over the decades since the 1983 publication of the "Red Book" (National Research Council 1983). The danger posed by the Members' letter is that it could pressure the NAS committee to expand the scope of its review into policy and political matters about which it has no special expertise or legitimacy. If it succumbed to this pressure, the committee's work product would be dismissed as politically motivated by all who disagree with the members' policy or political views. It is imperative that the NAS committee limit its review to scientific matters and resist all efforts to "solve" problems that the political branches of government are constitutionally responsible for managing.

Nevertheless, the issues raised by Gordon et al. deserve attention in OMB's public comment process. They complain that the following issues are paramount (and of course seek to encourage the NAS committee to reach certain conclusions about them:

1. Is government-wide risk assessment guidance necessary given the risk assessment and review procedures already in place?
2. Does the proposed guidance conflict with existing statutory directives?
3. What new resources will agencies need to comply with the guidance, and lacking these resources won't it just delay agency operations in a morass of "paralysis by analysis"?
4. Won't the guidance politicize science and risk assessment, given that its author is OMB?

Fortunately, these questions are easily answered.

First, effective government-wide risk assessment guidance is necessary because existing practices are highly variable in quality, both within and across agencies. The primary effect of the proposed guidance would be to improve the performance of the many departments, agencies, sub-agencies and offices that are unmistakable laggards. Those which currently lack risk assessment policies and practices will need to bring their operations "up to code." For agencies that already have established policies and procedures, the effects will be different. They will first need to assess whether these policies and procedures adhere to both OMB's and their own information quality guidelines, and correct any deficiencies they discover. Where no deficiencies are detected, they will need to ensure that they actually follow the policies and procedures they have in place.

Second, nothing in the proposed guidance conflicts with existing statutory directives because there are no existing statutory directives governing the practice of risk assessment. Gordon et al. assert that the proposed guidance "represents a significant departure from approaches contained in the many statutes governing health, safety and the environment," yet they fail to identify even a single example of a statutory conflict.

[6]Further, they assert that the proposed guidance "appears to conflict with standard risk assessment practice by combining risk assessment and risk management analyses," but they offer no supporting evidence. Perhaps what they meant to say is that the proposed guidance seeks to *remove* risk management practices from risk assessment. Finally, they express concern that benefit-cost analysis might be conducted to inform risk managers' choices and that risk assessments might suddenly become useful inputs to these analyses. Of course, benefit-cost analysis has been an institutionalized part of regulatory decision-making since Executive order 12,291 was issued in 1981, and it has been used to evaluate federal projects for decades before that (Haveman and Margolis 1970). It is a fundamental element of environmental impact assessments prepared pursuant to regulations issued decades ago by the Council on Environmental Quality implementing section 102 of the National Environmental Policy Act of 1969.

Third, the extent to which agencies will require new resources (or the reallocation of existing resources) depends on their current level of performance. There is no doubt that laggards will have to make serious changes, and these changes may initially be painful if their current practice is decades behind the state of the art. Some will suffer "paralysis by analysis" precisely because they are currently unfamiliar with risk analysis. But it is simply implausible that agencies with established, state-of-the-art risk assessment programs will need new resources. The proposed guidance would largely codify recommendations made by a plethora of blue ribbon committees empanelled by NAS and other qualified expert organizations. Agencies with established risk assessment programs would need additional resources only if they had failed to act on these many recommendations.

Fourth, concerns about potential politicization by the White House appear both overblown given the text of the proposed guidance and inconsistent with previous statements advocating strong White House leadership. The principal threads of the proposed guidance are transparency in process, reproducibility in method, objectivity in outcome, and honesty about ignorance. It is difficult to identify a reason why these values would be treasured by the White House but not by Members of Congress. While environmental groups object now to a strong White House role in supervising agency compliance with broad risk assessment principles, in 1970 they demanded that the Council on Environmental Quality play a much stronger role in forcing agencies to comply with the newly enacted National Environmental Policy Act (Council on Environmental Quality 1994-95)pp. 49-50). Rep. Dingell, a co-signatory of the Gordon et al. letter raising concern about the potential for White House interference, was NEPA's primary House sponsor and is surely well ware of this history.

[6] The likeminded Center for Progressive Regulation makes the same claim, but also offers no supporting examples of statutory conflict. *See* Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff.

Apropos the U.S. Chamber of Commerce's concern that agency compliance with the risk assessment guidance would be exempt from judicial review, NEPA most certainly was not exempt. Today, NEPA is a special practice in environmental law. There is a vast NEPA case law and no environmental law casebook is complete without covering it comprehensively. Lawsuits merely alleging that NEPA violations have occurred are sufficient to stop a federal project dead in its tracks. This does not mean NEPA is a model that risk assessment guidance should follow, and nothing in the Chamber's comment suggests that it would endorse any such thing. Indeed, the NEPA process has been widely criticized for its ossification, delay, "paralysis by analysis," and providing unending opportunities for tactical abuse. The point is that judicial review is a time-tested way to compel federal agencies to take directives seriously. If the final guidance does not include judicial review – and it is hard to see how OMB could include such language given its proposed reliance on the federal Information Quality Act as its statutory foundation – then alternative tools must be devised to create effective incentives.

V. IMPLEMENTATION

The proposed risk assessment Bulletin has generated considerable interest and debate about implementation issues. To date, this discussion has focused almost exclusively on what might be called "the missing drive train" between OMB and agencies that would be subject to its provisions. There is an additional implementation issue: how can OMB internally manage the seemingly overwhelming task of synthesizing public comments and the results of the NAS review? We address both below.

1. A process for finalizing risk assessment guidance

As indicated above, we believe that both the overarching principles for risk assessment contained in the proposed Bulletin and the elements of § IV.7 should be rewritten as a modification or amendment to Circular A-4. The overarching principles help improve the integration of OMB's information quality guidelines into regulatory analysis. The specific elements of § IV.7 apply to risk assessments used for regulatory purposes. Because Circular A-4 is the vehicle by which OMB implements its RRTK authorities, it is also the appropriate place for guidance on the use of risk assessment as an input into regulatory analysis.[7]

The overarching principles for risk assessment are policy statements that follow from the IQG and thus are not appropriate subjects for the ongoing NAS review. The NAS in general (and this ad hoc committee in particular) has neither the expertise in information quality nor any special expertise in policy-making that justifies its encroachment into authorities delegated to OMB or the president. For these reasons,

[7] Some opponents of the proposed risk assessment guidance object to the content of proposed §IV.7 on the ground that is "conflates" risk assessment with regulatory analysis. We do not agree with this argument,; nevertheless, putting these elements directly into Circular A-4 renders the argument moot.

OMB should announce its intent to meld IQG principles into Circular A-4 without waiting for the completion of the NAS review.

Specific elements of § IV.7 might well be appropriate for peer review, and a case can be made that peer review is required by RRTK.[8] However, the composition of the NAS committee precludes it from taking on this task. Not a single member of the committee is an expert in economics or regulatory analysis. Thus, OMB should subject the elements of § IV.7 to a separate and limited peer review by a different panel whose members have the necessary expertise. Because these provisions are so limited this peer review can be accomplished quickly, thereby enabling OMB to finalize amendments to Circular A-4 on a much faster schedule than if it waits another year for an NAS report that is virtually guaranteed to be uninformed on the relevant issues.

The remaining elements of the proposed Bulletin consist of (a) policy elements already put in place via OMB's information quality guidelines, (b) policy elements that apply the IQG to risk assessments as a subset of information covered by the IQG, and (c) scientific and technical details that the NAS review can properly address. The first two of these categories should not be part of the NAS review because, as stated previously, the NAS in general (and this committee in particular) lacks expertise on information quality and should not be opining on policy matters – especially policy matters that are already settled. We recommend that OMB amend its IQG to include new information quality policy elements appropriate for risk assessment. That leaves only scientific and technical issues related to risk assessment for the NAS committee to address. Conveniently, these are the issues where NAS has expertise and public legitimacy, and which are contained squarely within its Project Scope.[9]

One lesson already evident from public discussion is that the array of risk assessment issued addressed by federal agencies is amazingly broad whereas the text of the draft guidance is quite narrow. There seems to be near universal agreement from these discussions that the draft text is "too toxicological" for broad application to the

[8] "PEER REVIEW--The Director of the Office of Management and Budget shall provide for independent and external peer review of the guidelines and each accounting statement and associated report under this section. Such peer review shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.)."

[9] "The committee will conduct a scientific review of the Proposed Risk Assessment Bulletin recently released by the Office of Management and Budget (OMB). Specifically, the committee will 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 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. See http://www8.nationalacademies.org/cp/projectview.aspx?key=34282 (retrieved June 10, 2006).

entire array of federal risk assessment activities. Others object to what they assert is the draft guidance's "one size fits all" approach (Center for Progressive Regulation 2006; Gordon, Dingell et al. 2006).

We recommend a different approach that would address each of these concerns and significantly improve the quality of the final risk assessment guidance. OMB should convert its existing IQQ and the overarching principles contained in the draft risk assessment Bulletin (i.e., transparency in process, reproducibility in method, objectivity in outcome, and honesty about ignorance) into a new OMB Circular.[10] Instead of trying to force the technical details for all applications of risk assessment into a single (probably toxicological) context, with its many parochial definitions and terms of art. [11]

Separate appendices to the Circular should be crafted for each significant arena of risk assessment. To do this, OMB should identify a relatively comprehensive list of risk assessment applications and, for each, convene a public workshop to draft a working document. OMB can reasonably expect workshop participants to first master the IQG so that they all begin from the same information quality perspective. Further, OMB can (and must) reserve to itself the final authority (and responsibility) for finalizing the content of each draft appendix, publishing it for public comment, and finalizing it as soon as practicable.

The wisdom of this approach is self-evident for those who attended the May 23-24 SRA Forum. Because the proposed Bulletin applies broadly to the federal government (albeit only to activities related to human health, safety and the environment), Forum organizers designed it to highlight a wide range of risk assessment applications including agriculture, pesticides, pathogens, industrial chemicals, ecological resources, several forms of engineering, highway transportation, terrorism and climate change. It may be impossible to write a single set of instructions for all of these areas, never mind those left unaddressed by the Forum because of time constraints, because each has its own language, culture, and traditions, and its practitioners often have very different training. The SRA Forum also revealed that the intermingling of risk assessors from diverse areas permitted knowledge sharing and networking that ought to be made a permanent fixture of OMB's long-term implementation plans. There is no doubt that SRA, as the largest *interdisciplinary* professional society engaged in risk assessment, would be happy to organize annual meetings for this purpose.

2. Installing a "drive train" for agency implementation

[10] Previously we called for putting the elements of § IV.7 into OMB's Circular A-4. The present recommendation applies to the remaining technical provisions of the draft guidance.

[11] To provide a simple but powerful example, the term "risk" has different meanings in many of these areas. It is simply not possible (even for OMB!) to redefine key terms for all applications of risk assessment.

The proposed risk assessment guidance[12] lacks a "drive train" by which government-wide guidance issued by OMB is effectively transmitted to federal agencies. Without some kind of implementation mechanism, there is little reason to expect it to be effective.

There are three generic choices for drive trains:

- Judicial review
- Incorporation into an existing or new centralized review process managed by OMB or another entity
- Incorporation into an existing or new administrative process managed by federal agencies

We believe that each of these has conceptual advantages but serious implementation problems. For example, judicial review is not expressly authorized by either the IQA or the RRTK. Current case law concerning the IQA is very limited but so far has been unsympathetic. More importantly, it is not clear whether judicial review would be helpful. It is true that administrative reforms that lacked effective judicial review procedures (e.g., the original Regulatory Flexibility Act, the Unfunded Mandates Reform Act) did not motivate serious agency efforts at compliance. However, the record of accomplishment of judicial review is not as sterling as its advocates often claim. Under the revised Regulatory Flexibility Act, an agency's failure to perform a Regulatory Flexibility Analysis (RFA) can be a fatal error but the courts are highly deferential to RFAs, irrespective of quality, as long as agencies perform them. Effectiveness has improved largely because of a combination of the Small Business Administration's Office of Advocacy, the "SBREFA Panel" process established by the 1996 amendments, and formal collaboration between SBA Advocacy and OMB (Office of Management and Budget and U.S. Small Business Administration Office of Advocacy 2002). Without these innovations, there is little reason to believe that mere judicial review would have made much difference.

The major existing centralized review processes are the Information Collection Request process that OIRA uses to implement the PRA and regulatory review procedures authorized by Executive order 12,866. Neither of these existing procedures could be easily adapted to manage risk assessment guidance effectively.[13] The ICR process applies to data agencies propose to collect, and only a subset of those data. As currently structured, the regulatory review process occurs too late to be effective except

[12] From this point forward, we refer to the draft as a guidance document and not as a Bulletin, reflecting our view expressed above that guidance an take alternative forms beside a Bulletin.

[13] The subset of risk assessments used for regulatory purposes have always been part of centralized review under EO 12,866 and its predecessor EO 12,291.

in rare cases, even before risk assessment matters are considered. It would have to be redesigned from the ground up.

A drive train might be incorporated into agencies' own administrative procedures, but the track record for such systems is at best spotty because agencies are inherently conflicted when asked to police their own work. The most relevant of these processes is agency implementation of the IQG, and this has hardly been free of controversy. The U.S. Chamber of Commerce says that the IQA's purposes have been "negated" by the lack of judicial review. Whether this is an apt or overly strident characterization of the importance of judicial review is beside the point, which is that it is strong evidence that agencies' own administrative procedures have not overcome these inherent conflicts of interest.

Given the limitations of these generic alternatives, new approaches must be developed. We propose two such alternatives:

- A new interagency process managed by OMB

An alternative to the existing *agency* review and appeal process that is worth considering is an *interagency* review process under OMB leadership. Oftentimes, other federal agencies are well equipped to review the performance of their peers and, because of their location within the federal family, identify issues and problems that outsiders likely would not find. For such a reform to be effective, two critical thresholds must be met. First, multiple agencies must care enough about the issue at hand to devote the time, effort and resources to review and oversight. Second, OMB must have a process for resolving interagency disputes that is widely viewed as fair, consistent and predictable.

Interagency processes are notoriously opaque, and opacity conflicts with OMB's transparency standard (§ IV.4.c) and "goal" of public participation (§ III.5). Still, interagency review likely would be better than internal agency review, with its inherent conflicts of interest. Moreover, for risk assessments that for compelling reasons ought not be conducted or reviewed in public, interagency processes are probably the best that can be done.

- A new public process managed by OMB or third parties

For most risk assessments and risk assessment applications, transparency and public participation are desirable and should be secured. That cannot be accomplished through OMB's existing centralized review process under Executive order 12,866 because that review process is not (and could not be) conducted in public. The president and his advisors expect candid analysis and insight from OMB staff about the likely consequences of regulatory alternatives under consideration. Risk assessments, however, are in principle a different matter. If they are performed prior to risk characterization, there is nothing confidential about the content of risk assessments that generally warrants review in a cloistered pre-decisional environment. A public process for structuring and reviewing risk assessments to ensure that they satisfy applicable information quality standards (including scientific objectivity; see § IV.4) prior to risk characterization

would bridge the gap between OMB's ICR process (which by law is open to the public) and its centralized review process (which by custom is closed).

Some object to White House leadership on risk assessment on the ground that OMB, as an entity of the Executive Office of the President "does not approach the review of agency work products from an unbiased perspective" (Gordon, Dingell et al. 2006). A public review process would fully address those legitimate concerns. Moreover, early review of risk assessment can help agencies avoid uncertainty about OMB's expectations and prevent many of the conflicts over data and methods that routinely arise during EO 12,866 review. In short, it could expedite policymaking and rulemaking rather than engulf it in "paralysis by analysis."

The greatest problem OMB would face in implementing a public process for reviewing draft risk assessments is insufficient staff, and staff not adequately trained in appropriate sciences. For these reasons, a strong case can be made for OMB to delegate the operation of public risk assessment review to qualified third parties. This would reduce the burden on OMB staff and further insulate the review process from actual or perceived political interference.

In sum, implementation issues can be solved by creative thinking and the establishment of innovative procedures. There is no reason why OMB has to rely on conventional implementation models such as judicial review and agency self-policing. These models seem to exacerbate interest group conflict more than ameliorate it, and in any case, they have proved to be either ineffective or unpredictable.[14]

SECTION-BY-SECTION COMMENTS

I. DEFINITIONS

1. "Agency"

OMB proposes to use the statutory definition contained in the Paperwork Reduction Act (PRA, 44 USC 3501 et seq.) This definition is entirely appropriate given the federal Information Quality Act (IQA) is codified as a Policy and Procedural Guidelines note to 44 U.S.C. 3516, which is the section authorizing OMB to issue rules and regulations implementing the PRA.

Some federal agencies (and their interest group clients) can be expected to seek exemption from the risk assessment guidance. Such efforts should be resisted on both

[14] A risk assessment performed on judicial review as an enforcement tool for implementation probably would show that its results are highly unpredictable, not reproducible, and transparent (if at all) only to administrative law practitioners. Unpredictability is itself a risk, and a high degree of unpredictability makes it a dangerous choice for conflict resolution as outcomes seem to depend on a "roll of the dice" in court. NAS reviews have similar defects, as their outcomes are strongly affected by the identities of committee members, group dynamics, and even the predilections of assigned National Research Council staff. The fact that NAS reviews proceed almost entirely in secret exacerbates uncertainty, and hence risk.

policy and legal grounds. As a tool for setting priorities and understanding the likely consequences of alternative decisions, the utility of risk assessment crosses agency boundaries without restriction. As a legal matter, OMB lacks the authority to exclude agencies from the application of its rules, regulations and guidance implementing the PRA unless they are exempted by law.

2. "Risk assessment"

OMB's proposed language appears intended to encompass broad scientific and technical syntheses without reaching into policy documents. This distinction is appropriate but is hampered by the fact that agencies disseminate numerous documents that include both scientific/technical content that is covered by IQA-authorized guidelines and policy content that is not. Many complaints about the proposed guidance, including complaints voiced by federal agency representatives that it overreaches (Hogue 2006), can be attributed to agencies' routine practice of interweaving scientific/technical and policy content in ways that inhibit or prevent the public from discerning where science and technology ands and policy begins.

One way to address this dilemma is to craft a definition based on content rather than the form in which information is disseminated. This would short-circuit the ongoing but sterile argument about which document types are "in" and which are "out," and focus attention instead on the nature of the information. OMB should repeat certain definitions contained in its Information Quality Guidelines, and then define *risk assessment* in terms of the content of *government information* that is within OMB's definition of *dissemination*:

> *"Information," "government information," "information dissemination product," "dissemination," and "influential" are defined at set forth in OMB's Information Quality Guidelines.*
>
> *"Risk assessment" means the scientific and/or technical content of government information and/ore information dissemination products that assemble or synthesize such information to characterize hazard, exposure or risk to health, safety or the environment.*

Documents (and portions of documents) that are exempt from the IQG also would be exempt from the risk assessment guidance, thereby eliminating any ambiguity about whether the coverage of the risk assessment guidance is broader than the IQG. In addition, documents that contain both scientific/technical and policy content would be covered only with respect to their scientific/technical content, just as they are under the IQG.

3. "Influential risk assessment"

This term appears intended to apply the term "influential," as it is defined in Section V.9 of the IQG, to risk assessment. A neater way to accomplish this is also by reference to the IQG definitions:

> *"Influential risk assessments" mean information satisfying both the definition of "influential" in OMB's Information Quality Guidelines and the definition of "risk assessment" in Section [xx] herein.*

Securing the linkage of the risk assessment guidance to the IQG would enable federal agencies and the public to clearly understand OMB's purposes and apply them in a sensible and systematic manner. In addition, it would neutralize concerns raised by opponents who apparently believe that the standards for influential risk assessments would apply to *all* risk assessments.[15]

II. APPLICABILITY

1. "To the extent appropriate"

OMB publicly stated at the first public meeting of the NAS committee and at the subsequent SRA Forum that this language was intended to provide wide discretion. On this point both supporters and opponents of the guidance find themselves in rare agreement. Supporters expect that agencies will exercise discretion in ways that eviscerate the guidance, and opponents fear that OMB will exercise discretion in ways that paralyze federal agency activities. These concerns are intensified by the fact that the proposed guidance does not identify who would decide what is "appropriate."

OMB should replace this language with a qualitative performance standard grounded in the decision analytic framework set forth in the PRA and OMB's implementing regulations. Agencies should adhere to the overarching principles of the guidance at all times, and to specific practices when their practical utility exceeds their burden, terms that are defined by law.[16] Agencies have 25 years' experience understanding these concepts, and to the extent that the risk assessment guidance expands public understanding it will serve to improve the PRA's effectiveness.

Codified as it is within OMB's statutory rulemaking authority, the IQA confers on OMB the responsibility for overseeing agencies' achievement of statutory information quality objectives. That means OMB *may* delegate to agencies the responsibility to make *initial* determinations about the balance of practical utility and burden. However, nothing in the PRA permits OMB to delegate its decision-making authority to the agencies or abdicate its oversight role. Just as OMB has primacy in interpreting the information quality guidelines, so it must retain primacy in interpreting when elements of the risk assessment guidance apply.

---

[15] See, *e.g., Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff.:* "[T]he proposal establishes an onerous set of rules for all government-generated risk assessments while establishing absolutely no standards for agency activities typically characterized by industry-generated risk assessments."

[16] See 44 USC 3502.

Some opponents of government-wide risk assessment guidance assert that it is bad for OMB to exercise interpretative discretion because it would do so in inappropriate ways, such as by requiring all risk assessments to meet the highest standards (Center for Progressive Regulation 2006). Such claims are contradicted two important ways. First, the text of the proposed guidance says, "[t]he level of effort put into the risk assessment shall be commensurate with the importance of the risk assessment" (§ III.4). Second, the proposed text is consistent with how OMB has implemented the PRA and applied Circular A-4 (Office of Management and Budget 2003), OMB's guidance concerning the preparation of Regulatory Impact Analyses for economically significant draft regulations. No evidence has been offered suggesting that OMB has imposed equally demanding analytic standards on all RIAs, much less that it has demanded RIAs for proposed regulations that are not economically significant. Thus, these objections might be would be more persuasive if there was significant evidence that OMB had abused the much broader authority it has under the PRA and EO 12,866.

2. "Available to the public"

The proposed language would apply to all risk assessment subject to public disclosure under the Freedom of Information Act (FOIA). It appears to be borrowed from Section I.4 of OMB's proposed Bulletin on Good Guidance Practices (GGP).[17] Because OMB stated no supporting statutory authority in its draft GGP, it appears to be founded primarily on the regulatory oversight authority of Executive order 12,866. That connection is a sensible one in part because the Executive order explicitly covers all *regulatory actions*, a term broadly defined to include "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation" (§ 3(e)).

As stated elsewhere in the proposed GGP and its preamble, the line between rules of general applicability, which are covered by provisions of the Administrative Procedure Act (5 USC § 553 and 554) and guidance documents (which are not covered) can be a fine one. But there is no obvious connection between the APA and EO 12,866 on the one hand, and FOIA on the other. Moreover, OMB has no statutory authority to implement FOIA or oversee its implementation. Hence, in our public comments on the proposed GGP we objected to the FOIA linkage and recommended that it be removed.[18]

[17] "The term "available to the public" means made available to the public by the agency or required to be disclosed under the Freedom of Information Act, 5 U.S.C. § 552."

[18] "OMB has proposed a definition of 'guidance document' that is at once overly broad and inappropriately narrow, and which does not home in on the most important issues at stake. The proposed definition in § I(2) would cover any document 'prepared by an agency and available to the public to describe the agency's interpretation of or policy on a regulatory or technical issue,' with the only exception being documents issued pursuant to the APA. The phrase 'available to the public' is defined to mean either disseminated by the agency or involuntarily disclosed pursuant to the Freedom of Information Act (FOIA).

In its proposed risk assessment guidance, OMB presents the same FOIA linkage and its case for doing so is even weaker. OMB's information quality guidelines, the antecedent for the proposed risk assessment guidance, explicitly mentions FOIA but only for exempting FOIA disclosures from IQA coverage:

> 'Dissemination' does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law.[19]

We see no legal justification for extending the applicability of risk assessment guidance to documents not disseminated by an agency but reachable under FOIA. We can imagine a policy justification for the FOIA standard if there is evidence that agency employees are circumventing the IQG by discreetly inviting FOIA petitions for the purpose of disclosing documents that do not adhere to applicable information quality standards. We are aware of no evidence presented, by OMB or others, to suggest that this is happening, and even if it were happening, it is not clear that this is an appropriate or workable remedy.

3. Exemptions

The proposed guidance would exempt "inspections relating to health, safety, or environment," "individual agency adjudications or permit proceedings," "individual product label[s] … if the individual product label is required by law to be approved by a Federal agency prior to use." The latter two of these exemptions apparently are controversial. Some opponents have asserted that the "agency adjudication" exemption frees industry from having to meet the high standards that agencies would have to meet (Center for Progressive Regulation 2006), but at least one industry trade association supporting the guidance agrees that adjudications ought to be covered (Hogue 2006).[20] In

---

"We expect that many commenters will strenuously object to the extraordinary breadth of this definition, especially when combined with the cross-reference to FOIA. Neither regulated entities nor the general public can be at all certain what documents are reachable via FOIA, and agency regulatory personnel also may not know because FOIA law itself has become rather complicated. Even without the FOIA cross-reference, the number of agency documents that could be construed as 'describ[ing] an agency's interpretation' of a policy or regulation is difficult to gauge." See Regulatory Checkbook. (2006). "Letter to John D. Graham, Administrator, Office of Information and Regulatory Affairs." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/good_guid/c-reg_checkbk.pdf.

[19] See §V.8, Office of Management and Budget (2002). "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." Federal Register **67**(36): 8452-8460.

[20] Adjudications would be covered if an agency determined that "compliance … is practical and appropriate" and "the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings." Because this language is discretionary

oral remarks at the first public meeting of the NAS committee on May 22, Judith Graham of the American Chemistry Council specifically stated that her organization was likely to oppose the exemption. Thus, the "double standard for industry" may be imaginary.

OMB's aversion to including adjudications is a persistent cultural inheritance from Executive order 12,291. OIRA does not review regulatory actions that involve individual persons or firms for the good reason that doing so would place it in the middle of highly sensitive decisions and vulnerable to pressure to intervene on their behalf. Perhaps reflexively, OMB extended this exemption to its Information Quality Guidelines[21] and now to risk assessments as well.

A practical reason for extending the adjudication exemption to risk assessment is that adjudications are exempt from the definition of dissemination in the IQG. It is not obvious how they could be included within a subcategory of information that is disseminated when they are outside of the definition of dissemination.[22]

We propose a compromise that retains the adjudicatory exemption in the IQG but provides a way out of it in cases where the exemption ought not to apply. In particular, we suggest that OMB add language that overrides the exclusion in any case where a party to the adjudication prefers that the risk assessment guidance be applied:

> *Suggested language:*
>
> *The exclusion in § ___ above shall not apply if the licensee, permittee or registrant formally requests that the agency adhere to the provisions of this guidance.*

If opponents of the risk assessment guidance believe that they, too, ought to have the ability to "force" adherence to the guidance, suitable language can be crafted to extend the same rights to any interested party with standing to participate in the administrative proceeding.

III. GOALS

1. Distinguishing goals, objectives, standards and performance measures

It is fully appropriate that OMB should want to establish goals that are highly aspirational (and possibly even inspirational). Normally, goals serve that purpose and are reinforced by objectives, each of which is consistent with some aspect of a goal.

---

to the agencies, it is superfluous: agencies need no authority from OMB to apply OMB's guidance anywhere they please.

[21] See §V.8, Office of Management and Budget (2002). "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." Federal Register **67**(36): 8452-8460.

[22] As noted earlier, OMB's definition of applicability extends to materials covered by FOIA. Thus, there is evidence that OMB is capable of putting square pegs in round holes when it wants to.

Standards can be articulated in design or performance, the latter being desirable when flexibility and discretion are desired. Performance measures set milestones for evaluating whether progress toward goals is being met. The proposed guidance lacks this systematic management approach. It consists of goals and standards, the latter being a hybrid weighted toward design, and no performance measures at all.

This is odd for an agency that has pioneered numerous program evaluation tools, most notably OMB's current Program Analysis Rating Tool (PART). On its PART website, OMB describes the process as follows:

> The PART was developed to assess and improve program performance so that the Federal government can achieve better results. A PART review helps identify a program's strengths and weaknesses to inform funding and management decisions aimed at making the program more effective. The PART therefore looks at all factors that affect and reflect program performance including program purpose and design; performance measurement, evaluations, and strategic planning; program management; and program results. Because the PART includes a consistent series of analytical questions, it allows programs to show improvements over time, and allows comparisons between similar programs (Office of Management and Budget 2006).

OMB applies PART throughout the federal government, except that programs under OMB's own management are excluded.

Before finalizing government-wide risk assessment guidance, it probably would be helpful (and perhaps inspiring to agencies uninterested in adhering to government-wide risk assessment guidance) if OMB applied the discipline of PART.

2. Are OMB's stated goals worthy?

Oftentimes goals are both aspirational and demanding. That is not true for the proposed risk assessment guidance. The goals proposed in § III are platitudinous and uninspiring. Some are truisms while others are processes; none are genuine goals. An "iterative dialogue" (§ III.1) is exclusively procedural; products thereof should not be "goals" in their own right unless OMB's goal is pure process. Saying that the "scope and content" of a risk assessment are determined by its "the objectives" and "best professional judgment" (§ III.2) means we are confronted by a truism. It is also a truism that the "type of risk assessment" depends on "the nature of the potential hazard" and "decision needs," but false that it depends also on "the available data" (§ III.3); as OMB states elsewhere in the previous subsection, "the benefits and costs of acquiring additional information" matter a lot. Granted, the "importance of the risk assessment" (presumably meaning the stakes) and the "level of effort" are positively correlated (§ III.4), but it is hard to see how this truism constitutes a *goal*. If it truly is a *goal* that agencies "shall follow appropriate procedures for peer review and public participation," what does it say about the quality of procedures agencies currently follow?

We can easily think of goals that are aspirational, demanding, and worth the effort to accomplish.

Suggested language:

- *Substance: Risk assessments shall be transparent, reproducible and objective, meaning neutral with respect to alternative policy choices and free of embedded policy judgments that are the province of policy makers, risk managers and the public.*
- *Timeliness: Risk assessments shall be performed, peer reviewed, and open to genuine public participation except where there is compelling public interest in confidentiality or secrecy.*
- *Utility: Risk assessments shall be designed and prepared to inform the design and analysis of multiple policy alternatives and to aid in decision-making, not to rationalize or support prescribed or pre-determined alternatives, policies, programs or preferences.*

Goals such as these provide clarity of purpose consistent with OMB's stated mission under the IQA and its other authorities. They can inspire and focus the work of thousands of risk assessment theoreticians and practitioners, who will generate the tools and products federal agencies need to fulfill their statutory responsibilities more effectively and efficiently. Some will object that these goals are too difficult, or in some cases infeasible given the peculiarities of certain risk problems. These objections are narrow-minded, unimaginative, defeatist, and in some cases transparently obstructionist.

IV. GENERAL RISK ASSESSMENT AND REPORTING STANDARDS

Section IV applies to all risk assessments, so it is vital that it be limited to fundamental principles where universal application is reasonable. The content of this section appears to be guilty of being "too toxicological" and needs to be rewritten to apply to risk assessment more generally. In addition, this section also intermingles important issues of clarity and transparency that truly ought to apply to all risk assessments with matters best implemented elsewhere (§ IV.7) and some issues that require careful, nuanced treatment to ensure that they remain neutral with respect to risk management preferences that do not belong in analytic work products (i.e., risk characterization).

1. Clarity and transparency (§IV.1-2)

Risk assessments often have conflicting or opaque objectives, or their stated purposes may be one thing but their actual purpose is another. For example, an assessment of risks from consuming raw shellfish is immaterial to the risks from consuming cooked shellfish. Clarity about what objectives the risk assessment *is not* intended to address may be as important as clarity about what was intended. To reduce ambiguity, OMB should direct agencies to be clear about both intended and unintended uses.

OMB says that agencies shall clearly state "the informational needs of decision makers" in risk assessments (§ IV.1), but it does not insist on clarity about who these decision makers are (or are not). Without clarity on this vital point, agencies may assume that decision makers are always government officials. Yet federal agencies perform risk assessments for many different audiences, often within the same risk assessment, and one of these audiences may be the general public.

OMB says that agencies shall clearly state "the scope of the assessment" including various descriptions about risk agents, hazards of concern, those affected, relevant scenarios, and dose-response relationships. It is not clear that these attributes fully define scope, and there is reasonable concern that it is "too toxicological." A potentially useful alternative approach is to direct agencies to describe *what, who, when, where,* and *how*. This is especially important because § IV applies to *all* risk assessments, and the use of a less technical descriptive model would be especially helpful to agencies just beginning to practice risk assessment. Along these lines, it is imperative that risk assessments clearly state what aspects of risk they are intend and do not intend to address.

Suggested language:

- *Risk assessments shall clearly describe, in language understood by the governmental risk manager and/or the affected public:*
    - *What risk is addressed by the risk assessment, and what closely related risks are not*
    - *Who is affected by the risk, and who is not*
    - *When is the risk pertinent or applicable, and when is it not*
    - *Where is the risk manifest, and where is it not*
    - *What activities, circumstances or events lead to or prevent the realization of the risk*
    - *The purposes for which the assessment is intended, and closely related purposes for which it is not*
    - *The benefits (including improved accuracy) and costs (including delay) of obtaining specific additional information prior to performing the assessment*

2. Scientific objectivity (§ IV.4.a and c)

Scientific objectivity (§IV.4.a and c) is already an element of OMB's information quality guidelines (§V.3 in (Office of Management and Budget 2002)) and thus is not a new concept. What is new is OMB's clarification of substantive objectivity to mean, "neither minimizing nor exaggerating the nature and magnitude of risks." A complementary formulation of the concept of objectivity is *policy-neutrality*. A risk assessment is *policy-neutral* if it contains no embedded biases that materially favor or disfavor particular policy alternatives that might be devised for risk management

alternatives. Policy-neutrality is not a concept to be proved; rather, it is a null hypothesis that can be disproved with evidence, in this case, evidence that an embedded bias is present that materially favors or disfavors a particular policy alternative.

Opponents of the draft risk assessment guidance allege that objectivity is [expand based on CPR]. It is difficult to give credence to this view because it necessarily implies that bias in risk assessment is both desirable and necessary to protect public health. Advocates of biased risk assessment do not address the extent to which bias varies across risk assessments or the resource misallocation that inevitably results because some risk assessments are more biased than others are. Nor do they confront the perverse "incentives that are created when purposeful bias is welcomed and endorsed. This incentivizes a "race to the top" of the risk ladder, in which craftiness and deceit are rewarded over scientific merit.

Opponents also claim that objectivity in risk assessment will lead to less aggressive risk management. This hypothesis can be tested empirically. In theory, however, one would expect this outcome only if public support for risk management is dependent on the misinformation that is communicated through purposeful bias. Conversely, public support for risk management would *increase* to the extent that risk assessment is purposefully biased to understate or minimize risk.

There is probably no way to remove politics and policy completely from risk assessment. Nevertheless, OMB is undoubtedly right to establish the principle that *purposeful* bias, in any direction, is incompatible with the broad purposes of the IQA.[23] Purposeful bias undermines the value and legitimacy of risk assessment as tool for informed decision-making.

3. Weight of evidence judgments (§ IV.4.b)

Weight of evidence determinations are listed as an objectivity attribute, but almost certainly does not belong there. It is surely true that both positive and negative studies should be accounted for "in light of each study's technical quality," but there is no objective way of "giving weight" to them. Perhaps OMB included this provision here because of experience with (possibly few) low-quality positive studies trumping (possibly many) high-quality negative studies. In any case, the absence of a verifiable way of

[23] It is also inconsistent with benefit-cost analysis, both as a descriptive tool and a normative guide to decision making. Descriptively, exaggerating risk leads to upwardly biased estimates of baseline conditions and the benefits or costs of regulatory intervention. Understating risk leads to downward biases. Both mislead decision makers, whether they be government officials or individual actors. Normatively, net benefits cannot be maximized if risk estimates are biased. Opponents of normative benefit-cost decision making frequently allege the opposite – that rigorously applied, benefit-cost analysis yields less (and less stringent) regulation. This can only be true if risk is systematically exaggerated such that regulations would systematically fail net benefit tests if risk was estimated without bias. This would imply that conventional risk assessment methods are not policy-neutral; that the purposeful exaggeration of risk is a quintessential element of a policy strategy; and that policy neutrality poses a grave threat to the continued success of that strategy..

assigning weights objectively should exclude weighting procedures from any list of objectivity criteria.

Weight-of-evidence judgments are inherently subjective. Where they are verifiably grounded on *scientific* judgment, they have an important role to play in risk assessment. Scientific uncertainty will always be present, and risk managers are better off if they are informed by the subjective *scientific* judgment of experts. However, subjective judgment that is grounded in *policy* is not an appropriate component of risk assessment. It must be excluded, and fully and transparently described elsewhere such as in risk characterization.

4. Risk characterization (§ IV.3)

Precisely because risk characterization often requires judgment, OMB should be exceedingly careful about what directives it establishes here (§ IV.3). This is especially important because the use of judgment may be perceived as inherently at war with objectivity (§ IV.4). Unless these principles are carefully and unambiguously reconciled, agencies will not know which provision is controlling in any given risk assessment.

Risk characterizations must be objective as far as scientific knowledge can be applied; the question is what to do beyond that horizon where subjectivity reigns. OMB should direct agencies to ensure that subjective characterizations of risk are grounded in *scientific* judgment alone. *Policy* judgment does not belong anywhere within a risk assessment, for that is the exclusive province of risk managers. To be concrete about this, characterizing a particular chemical as a "likely human carcinogen" is a scientific statement that must be grounded in both biological science ("human carcinogen") and probability ("likely"). If biological science and probability do not support it, then no such statement should appear in a risk characterization. It is up to risk managers to decide whether to act *as if* the chemical in question is a likely human carcinogen. That would be a statement about risk policy and not a characterization of risk, and it ought to be clearly distinguished as such.

OMB's proposed language asking for a "range of plausible risk estimates" does not provide a sufficient solution to this problem. Not all estimates are equally likely, and each estimate should be accompanied by the best available scientific information about likelihood. These likelihood statements could be highly precise (e.g., in metric units with multiple significant figures), minimally precise (e.g., in metric units with a single significant figure), or perhaps not at all precise (e.g., in semi-quantitative language such as "extremely likely," "highly likely," "likely," "unlikely," "highly unlikely," or "extremely unlikely"). To adhere to the substantive objectivity standard in the IQG, agencies must be directed to use semi-quantitative probability statements in ways that are consistent with how such terms are understood by the target audience. Thus, if the public understands "likely" to mean, say, a probability exceeding 50% but not greater than 80%, then this term must not be used to describe risks whose likelihoods are above or below this range. Using a term such as "likely" to characterize a risk scientists believe to be rare violates both the substantive and presentational aspects of objectivity.

Some federal agencies already have well established practices for characterizing risks semi-quantitatively. For example, the National Weather (NWS) characterizes the probability of precipitation (PoP) as "slight chance" (20%), "chance" (30-50%), and "likely" (60-70%) (National Weather Service 2006).[24] We have not researched the question whether the public's understanding of these terms matches that of NWS, but the assignments are intuitively plausible and, more importantly, they are clearly articulated. OMB should encourage these practices because they are consistent with presentational objectivity (i.e., full disclosure of what an agency means when it uses certain terms) and substantive objectivity (i.e., convergence between an agency's use of a term with what the public understands it to mean).

Suggested language:

- *Risk characterizations shall be based on science, and adhere to the objectivity standard in §__ as far as a consensus about scientific knowledge exists. When risk characterizations go beyond scientific knowledge, they may be subjective insofar as they capture scientific judgment. However, risk characterizations shall not be materially influenced by policy judgments, which are the sole province of risk managers (where statutory authority for governmental risk management exists) or the public.*
- *Weight-of-evidence determinations shall be strictly based on science and scientific judgment; fully and completely disclosed and reproducible; and internally consistent.*

5. Assumptions (§ IV.5)

It is true that assumptions cannot be avoided in risk assessment, but OMB's proposed guidance concerning how to manage their use is insufficient. It calls only for sensitivity analysis without regard for whether assumptions are consistent with the objectivity standard in § IV.4. In addition, OMB offers no guidance concerning what alternative assumptions are "reasonable."

The provisions of § IV must be internally consistent. Therefore, OMB should explicitly require default assumptions to satisfy the objectivity standard in IV.4. OMB should permit agencies to perform sensitivity analyses on alternative assumptions of interest and evaluate "their implications for the key findings of the assessment." Each alternative assumption must satisfy the presentational objectivity standard in the IQG—i.e., it must be described objectively and impartially.

Suggested language:

- *Assumptions critical for the risk assessment generally shall adhere to the objectivity standard in §__. Where this is infeasible because no objective value is*

[24] No semi-quantitative terms apparently are used when PoP is less than 20% or greater than 80%.

available, critical assumptions must be based on scientific judgment as provided for in § __ on risk characterization. Critical assumptions shall not be based on policy judgment, because policy judgments are the sole province of risk managers.

- *Agencies are encouraged to evaluate the implications of alternative assumptions of interest. All such assumptions must be described objectively and impartially in accordance with the standard for presentational objectivity in OMB's Information Quality Guidelines.*

6. Executive summaries (§ IV.6.a—c)

OMB is correct to direct agencies to include an executive summary with every risk assessment. This should not be overly burdensome because agencies always must devise ways of synthesizing risk assessments, especially for non-technical audiences. Paragraphs (a) through (c) appear to be designed to ensure that executive summaries are materially complete insofar as they cover all the important aspects of the risk assessment.[25] What is missing from OMB's proposed language is a requirement that executive summaries be accurate. It is vital that executive summaries, however abbreviated they have to be, are accurate as well as materially complete. Except for risk assessment wonks, few others will ever read beyond the executive summary.

Suggested language:

- *Risk assessments shall include an executive summary that includes all material elements as required elsewhere in this section; and is objective in presentation.*

7. Comparative risk assessment (§ IV.6.d)

Section V.3.a of OMB's Information Quality Guidelines established the principle that objectivity in presentation requires information be "presented in an accurate, clear, complete, and unbiased manner," and said "[t]his involves whether the information is presented within a proper context." Section IV.6.d of the proposed risk assessment Bulletin reiterates and expands upon this information quality principle by stating that, in the case of risk assessments, proper context includes information about "other risks familiar to the target audience."

Some have alleged that this paragraph encourages agencies to make bizarre risk comparisons. While this possibility always exists, it seems likely that such risk comparisons would not be "accurate, clear, complete, and unbiased," and thus they would violate the presentational objectivity standard. The absence of useful and informative risk comparisons seems much more likely to inhibit or undermine understanding, especially for non-technical audiences. In any case, useful and informative risk comparisons belong in the body of risk assessments and not just in the executive summary.

[25] § IV.6.d does not belong in the subsection on executive summaries; see Section **Error! Reference source not found.** *supra*.

Suggested language:

- *Risk assessments shall include sufficient information to place the results into a useful and informative context consistent with the standard for presentational objectivity.*

8. Risk assessments used for regulatory analysis (§ IV.7)

In Section V.1 of our comments (p. 9), we recommended that OMB strip this subsection from the guidance and incorporate its elements as an amendment to Circular A-4 (Office of Management and Budget 2003), OMB's guidance governing Regulatory Impact Analysis. Our comments here concern the content of what OMB ought to include in this amendment. Even though it was issued 18 months *after* OMB's Information Quality Guidelines (Office of Management and Budget 2002), Circular A-4 contains only hortatory text about the IQG[26] and unhelpful instruction to get help elsewhere.[27] It needs a thorough updating to capture the IQG.

Several of the specific provisions in § IV.7 of the proposed guidance have direct parallels in Circular A-4, and thus are not new.[28] For example, Circular A-4 includes language related to the establishment of baselines (*e.g.*, pp. 15-16); the identification and evaluation of alternatives (*e.g.*, pp. 16-17); accounting for timing of exposures, control measures, and the subsequent reduction or cessation of risk (*e.g.*, pp. 18, 27, 31, and 34-36); the estimation of risk distributions (*e.g.*, pp. 8, 14, 18, 40-42, and 45); countervailing risks (pp. 26), and, where distributions cannot be derived, the need for expected values of risk (*e.g.*, pp. 40, 42, and 45).

Population risk (§ IV.7.d) also is an integral and essential element of regulatory analysis. Social benefits from regulation cannot be validly estimated using individual risk estimates, even if they satisfy the objectivity standard for identifiable persons. All of Circular A-4 concerns population risk, so its presence in proposed risk assessment guidance is unremarkable.

This proposal for the reporting of "risk ranges" is a refinement on Circular A-4. In Circular A-4, agencies are directed to "address the ranges of probabilities, types of health risks and specific populations affected" (p. 28) and "a range of plausible values for the time lag" between exposure and disease. In the face of scientific uncertainty, agencies are

[26] "Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's 'Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies'" (p. 17, internal reference omitted).

[27] "The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality" (p. 43).

[28] Others apparently seek to use the proposed risk assessment guidance to reopen these settled issues. For example, CPR accuses OMB of "conflating" risk assessment with regulatory analysis. *See* Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff. Incorporating the material from §IV.7 into Circular A-4 renders the argument moot.

encouraged to present "results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur" (p. 39).

> Some activists for regulation object to "risk ranges" on implementation grounds:
>
> Regulatory programs simply cannot function with vague ranges of risks. The nature of rules is definiteness; they are not useful otherwise. As an analogy, states impose speed limits (50, 65, etc.) rather than giving drivers a range of possible speeds (40-70).

See (Center for Progressive Regulation 2006), p. 5. The analogy is an odd one, in part because highway speed limits are hated by drivers and wantonly disobeyed. In addition, it is incorrect that variable speed limits do not exist. Variable speed limits (including both minimum and maximum speeds) are becoming increasingly popular strategies for "managing" traffic risks. The clear value of ranges to regulated entities is that it gives them control parameters within which they can be assured of regulatory compliance.

Nevertheless, we agree that OMB's proposed language needs certain adjustments. For example, risk ranges without valid probabilities attached to values within them have limited utility for regulatory analysis. All that can be done is generate alternative estimates of baseline risk, benefits and costs. By themselves, ranges do not add significant information that decision makers can use to decide whether to take action, much less what action to take. Perhaps more importantly, they detract from developing valid risk distributions.

> *Suggested language:*

- *To the maximum extent practicable, risks shall be presented as distributions for the affected population or relevant subpopulations. Risk distributions are the best inputs for regulatory analysis. The components of a risk distribution include both an exposure distribution and a probability distribution for hazard.*
- *If multiple point estimates but not a risk distribution can be derived, point estimates shall include the expected value. For any value above or below the expected value, a value equidistant from the expected value in the opposite direction shall be derived.*
- *If only a single point estimate can be derived, that point estimate shall be the expected value.*

In any case, objections now being raised to ranges are not germane to the draft risk assessment guidance. We see little, if anything, in § IV.7 of the proposed risk assessment guidance that significantly expands upon what is already required by Circular A-4. It is inappropriate for opponents of regulatory analysis to try to use the proposed risk assessment guidance as a back-door tactic for reopening Circular A-4 and the long-settled technical issues it summarizes. Indeed, most (if not all) of these technical issues have been settled for at least 15 years. For example, OMB established its first formal guidance

on the subject of expected values and risk distributions in 1990 (Office of Management and Budget 1990)"

> Whenever parameter estimates are uncertain, for either benefits or costs, expected-value estimates should be presented. Hypothetical best-case or worst-case estimates may be presented as alternatives for sensitivity analysis. Where possible, information about the probability distribution of the parameter estimate should be presented (p. 658)

V. SPECIAL STANDARDS FOR INFLUENTIAL RISK ASSESSMENTS[29]

Section V applies to "influential" risk assessments, where the term "influential risk assessment" is defined based on definitions contained in OMB's 2002 Information Quality Guidelines. A risk assessment is influential if "the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." This threshold is ambiguous, but both agencies and the public have almost four years' experience with it. Unless a compelling argument can be presented otherwise, it is better to retain an existing term of art with which there is experience than invent a new one.

1. "Capable of being substantially reproduced" (§ V.1)

This language follows directly from the procedural test of reproducibility in § V.10 of OMB's 2002 Information Quality Guidelines. It is a reasonable and appropriate standard for influential information in general, and certainly for risk assessments. In any case, it is not a new requirement: even without risk assessment guidance, influential risk assessments remain subject to the requirements of IQG § V.10. It is inappropriate for OMB to use proposed risk assessment guidance to reopen this issue.[30]

2. Comparisons across qualified scientific organizations (§ V.2)

OMB's intent here is unclear, and the preamble offers no illumination. Moreover, important elements of the text are not defined, including: (a) what constitutes a "qualified scientific organization" and who makes this determination? (b) does "published" have the same meaning as "dissemination" in OMB's Information Quality Guidelines, or does it refer only to risk assessments that have peer reviewed? and (c) how close must a topic be to be "the same," especially given the likelihood of significant differences in analytic scope?

---

[29] We understand any risk assessment that would be subject to proposed § IV.7 is an "influential risk assessment." Our comments in this section primarily apply to all types of influential risk assessments, whether or not they are used for regulatory purposes.

[30] Some opponents have raised this issue as if it new. *See* Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff.

We see the value of risk comparisons here just as in § IV.6.d. However, we believe OMB should avoid creating ambiguous new terms of art, and distinguish only on matters of performance.

Suggested language:

- *Each influential risk assessments shall compare results with the results of other risk assessments dealing with the same agent, technology or activity.*
- *All such comparisons shall distinguish between results obtained using procedures that adhere to these guidelines and results obtain using procedures that do not.*

3. Central, high-, and low-end estimates of risk (§ V.3)

Ideally, risk assessments should describe as best as possible the entire risk distribution instead of isolated points within the distribution. Besides being more revealing and useful for decision makers, risk distributions would moot tiresome arguments about which values to "highlight."

OMB states in its preamble explaining this subsection:

> When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks. Influential risk assessments should characterize uncertainty by highlighting central estimates as well high-end and low-end estimates of risk. The practice of highlighting only high-end or only low-end estimates of risk is discouraged. " (p. 17).

This explanation provides helpful insight into OMB's intent, but unfortunately, it also generates confusion. First, single estimates of risk are misleading even when no uncertainty exists. Risk would vary in accordance with numerous parameters such as exposure intensity and duration even in a world free of uncertainty. Because people have different realizations of these many parameters, there is only probably one point estimate of risk that applies to each individual. All other point estimates are misleading if we have enough information to determine where in the risk distribution a person is located. Thus, the problem with point estimates is not they provide a "false sense of precision" but rather that they provide a false sense of accuracy.[31]

A range of plausible risk estimates clearly is superior to a single point estimate because it conveys more information. Whether it conveys more *objective* information depends on the range, and how it describes relative degrees of "plausibility." If all values

[31] Accuracy is commonly mistaken for precision, and vice versa. Precision generally refers to the number of legitimate significant digits in an estimate. Accuracy concerns whether any of these significant digits are correct.

within the range are characterized as equally plausible, chances are the range is not "more objective."

The issue presented here is what federal agencies should estimate and disseminate. The answer is that they should estimate the entire risk distribution whenever they can. Where they cannot, they should provide an appropriate central tendency estimate and symmetric point estimates. In section IV.8 above, we proposed alternative language relevant to this point, which we repeat below:

Suggested language:

- *To the maximum extent practicable, risks shall be presented as distributions for the affected population or relevant subpopulations. Risk distributions are the best inputs for regulatory analysis. The components of a risk distribution include both an exposure distribution and a probability distribution for hazard.*
- *If multiple point estimates but not a risk distribution can be derived, point estimates shall include the expected value. For any value above or below the expected value, a value equidistant from the expected value in the opposite direction shall be derived.*
- *If only a single point estimate can be derived, that point estimate shall be the expected value.*

The purpose of this language is to help federal agencies break the habit of estimating risk selectively, tactically or strategically, in ways that are decidedly not objective or policy-neutral. This has been conventional practice for decades in certain agencies (Office of Management and Budget 1990), but only recently was it officially acknowledged (U.S. Environmental Protection Agency 2004).[32]

Others have expressed contrary views, claiming that OMB's directive that agencies *estimate* central tendencies for risk compels agencies to *manage* risk based on central tendencies (Center for Progressive Regulation 2006). For "small" risks, we happen to be highly sympathetic to such a policy.[33] We see nothing in OMB's proposed

[32] "[S]ince EPA is a health and environmental protective agency, EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks" (p. 13). This policy violates the objectivity standard because it is purposefully asymmetric with respect to error and uncertainty, and policy considerations are explicitly incorporated into what should be a scientific process. Later it is asserted that "[a]pparent inconsistencies in risk assessment practices across EPA can stem from differences in statutory language" (p. 14), but no statutory language related to risk *assessment* is actually cited in support of the claim.

[33] In this context, a "small" risk is one for which an individual's willingness to pay to avoid it is a negligible fraction of income or wealth. For example, there is extensive empirical evidence that individuals are willing to pay less than $10 to avoid an incremental mortality risks as small as one-in-one million (10^{-6}). If this were amortized over a working lifetime (e.g. 40 years), using a 3% real interest rate, the monthly payment would be four cents. Mortality risk would have to be more than 100 times greater (i.e., 10^{-4}) for the monthly payment to equal 39 cents, the current USPS postage rate for first class letters.

guidance that could reasonably lead to this conclusion. As the lawyers affiliated with CPR know, any command by OMB to supplant a statutory risk management rule would be illegal.

4. Confusion between central tendency and bias (§ V.3 and elsewhere)

Central tendency risk estimates are important for several reasons. For example, in the absence of more complete information about the risk distribution, the central tendency of risk is the best point estimate for benefit-cost analysis. All other point estimates yield biased estimates of benefits and costs. Similarly, if nothing else is known the central tendency is the best predictor of average risk in the population. Still, it is *not* an unbiased estimate of individual risk.

In principle, a risk distribution (and any value within it) can be estimated in an unbiased manner. Unbiased estimators of uncertain quantities are highly prized in statistics, and among them the unbiased estimator whose sampling distribution has the smallest variance is considered "best" (Kennedy 1985). Thus, it is possible to derive best unbiased estimators of the central tendency for risk, but also any other value such as the 90^{th} or 95^{th} percentile. To comply with the substantive objectivity standard in OMB's Information Quality Guidelines, an agency's estimate of the n^{th} percentile of a risk distribution must be an unbiased estimate of the n^{th} percentile. Furthermore, the presentational objectivity standard requires that estimates of the n^{th} percentile of a risk distribution must be clearly and accurately *represented* as the n^{th} percentile, and not as some other value such as the 50^{th} percentile (the median) or the mean, or left undisclosed just what it is.[34]

The additional presentational objectivity problem OMB confronts here is that even the best unbiased estimate of the n^{th} percentile is inherently misleading if it is far from the central tendency and other risk estimates are not provided. For example, reporting only the 95^{th} percentile is likely to lead 19 of 20 people in the affected population to incorrectly think that they experience risk at this level. Similarly, reporting only the 50^{th} and 95^{th} percentiles induces people to forget all about the undisclosed lower half of the risk distribution.

OMB's approach – to invite "high-end and low-end estimates" to accompany central tendency estimates – is fine as far as it goes. We believe, however, that the language provided in Sec V.3 above is a clearer and cleaner approach.

5. Characterizing uncertainty; multiple effects and multiple studies (§§ V.4-5)

[34] It is theoretically possible that the mean and 95^{th} percentile will be the same. This is a special and extreme case. It is inappropriate to defend 95^{th} percentiles *as if they are the mean* just because such concordance is feasible.

This is almost certainly the most salient, and most challenging, provision in Section V because it directly takes on the problem of model uncertainty with respect to the hazard component of risk. For many risk assessments, model uncertainty with respect to hazard is huge, both in absolute terms and relative to all other sources of uncertainty. In cases where credible science suggests that risk is subject to an exposure threshold, or alternatively, there is little credible science supporting the assumption that no threshold exists, the amount of potential model uncertainty with respect to hazard could be infinite. If exposure stays below the threshold, then risk should be zero.

Plausible models ought to be examined, but all models are not equally plausible. For that reason, § V.4.a calls for alternative models to be weighted in a transparent and reproducible manner based on *scientific* judgment of their relative likelihood.[35] The exclusion of *policy* judgment, which is implied by OMB's text, should be made explicit. Policy judgment always belongs to government risk managers (where government is statutorily authorized to decide) or to the public.

The subject of a risk assessment may be an agent, technology or activity that has different effects under different circumstances, including different exposure scenarios. A common practice is to draw absolute inferences (e.g., Chemical X causes Effect Y in humans) based on limited data (e.g., effects observed in a rodent species at the maximally tolerated dose). This dose may be irrelevant to humans; or Chemical X could cause Effect Z in humans at a much lower dose; or no effect at all at a still lower dose. OMB's proposed text begins the process of reforming risk assessment so that agencies estimate risk based on well-defined conditions. This will supplant misleading absolute statements about risk with conditional statements that are more accurate and objective.

The choice of study as the foundation for a risk assessment can significantly affect the outcome of a risk assessment, and in some cases, determine it outright. Choosing a study for nonscientific reasons (e.g., because it leads to precautionary or anti-precautionary risk estimates) violates the objectivity standard in OMB's Information Quality Guidelines. When studies vary significantly in their implications about risk, it is a powerful indication of widespread uncertainty. It is imperative that the uncertainty analysis performed pursuant to § V.4 captures this source of uncertainty.

Eliciting subjective scientific judgment is a complex and difficult task, so it must be undertaken with great care. First, it is imperative that only scientific judgment be elicited and that policy judgment be excluded. Scientists have no special gift for policy judgment, which does not belong in the scientific and technical assessment of risk. Moreover, they are not legitimately empowered to exercise policy judgment when asked for their scientific views. To minimize the likelihood that policy judgment intrudes, agencies should be strongly encouraged to take aggressive, affirmative steps to insulate

[35] Some have asserted that the draft text would permit (or even require) all models to be weighted equally [[cite CPR]].. A plain reading of the text shows this is false. It would occur only in the theoretical case in which scientific judgment concludes that all plausible models are equally likely.

policy considerations from the elicitation of scientific judgment. Because no specific set of tools is demonstrably superior, OMB should set high performance standard and encourage agencies to be innovative.

Because they deal with different aspects of the same concern, §§ V.4-5 ought to be combined in a systematic manner. We suggest alternative language:

Suggested language:

- *With respect to each significant component of the risk model, including but not necessarily limited to exposure and hazard, all influential risk assessments shall*
    - *include a clear, accurate and unbiased characterization of uncertainty with respect to each significant component*
    - *provide a quantitative distribution of each material source of uncertainty where it is feasible to do so, and a sensitivity analysis otherwise*
    - *report conditional risk estimates that depend on the realization of material sources of uncertainty, not absolute risk estimates that ignore uncertainty*
- *When the outcome of a risk assessment is materially affected by the choice of study, all influential risk assessments shall*
    - *Objectively estimate, to the extent feasible, the likelihood that each alternative study is the scientifically best indicator of risk*
    - *Where objective estimation methods are infeasible, subjectively estimate the likelihood that each alternative study is the scientifically best indicator of risk, taking care to include only scientific judgment and not policy judgment*
    - *Objectively (or if infeasible, utilizing subjective judgment) weight the alternative studies for use in risk assessment, taking care to include to include only scientific judgment and not policy judgment*
- *For the purposes of this section:*
    - *Quantitative or semi-quantitative methods may be utilized depending on the level of precision that is feasible*
    - *Weights assigned to alternative studies must be explicitly revealed and internally consistent for each expert whose judgment is obtained*
    - *Agencies must make every reasonable effort to deter or prevent strategic behavior among experts in the elicitation of scientific judgment, and document these efforts clearly, completely and accurately. Agencies are strongly encouraged to take aggressive, affirmative steps to fully insulate policy considerations from the elicitation of scientific judgment*

6. Variability

Capturing population variability has become relatively easy over the past several years, as numerous research projects have been performed to estimate many relevant exposure parameters. To is credit, EPA has published exposure factor handbooks that summarize most of the relevant scientific literature (U.S. Environmental Protection Agency 1989; U.S. Environmental Protection Agency 1997; U.S. Environmental Protection Agency 2002).

Despite this rich source of information, risk assessments commonly do not include exposure distributions derived from these (or other) references. Even when they utilize these resources, risk assessors often use only selected values. OMB's proposed language does not ask agencies to push the state of the art, but instead only to take advantage of information already available.

7. The definition of "adverse effects"

OMB is correct to include language within the proposed guidance dealing with the definition of "adverse effects" because this has become a critical issue in risk assessment. One obvious example is the case of perchlorate, which former OIRA Administrator John Graham used as an illustration in his May 22 presentation to the NAS committee. At the same time, the perchlorate example clearly shows that OMB's proposed language would stimulate rather than reduce conflict in risk assessment, and not incidentally, is technically inappropriate.

In its 2002 external peer review draft toxicological profile of perchlorate, EPA did not clearly identify an adverse effect (U.S. Environmental Protection Agency Office of Research and Development National Center for Environmental Assessment 2002). Numerous endpoints were discussed as "potential adverse effects" and "levels of concern for adverse effects," but EPA ultimately settled on defining a "key event" instead. In EPA's current lexicon, a "key event" is a highly ambiguous term of art. In the draft perchlorate risk assessment, EPA said:

> The key event is defined as an empirically observable precursor step that is a necessary element of the mode of action or is a marker for such an element (p. 7-4).

Apparently, a "key event" can be any precursor so long as it is observable, or it can be an observable marker for a precursor.

The breadth of nonscientific interpretative discretion implied by this definition is nothing short of stunning. As a practical matter, anything that qualifies as a "key event" can be treated *as if it is equivalent to* an adverse effect. In its draft perchlorate risk assessment, this is exactly what EPA did:

> Competitive inhibition of iodide uptake at the [sodium iodide symporter] by perchlorate is the key event leading to both potential neurodevelopmental and neoplastic sequelae (p. E-8).

This drained the concept of adversity of all scientific meaning, which is magnified by the ambiguous adjective *potential* prior to the list of distant effects plausibly defined as adverse. Eaton and Klaassen (Eaton and Klaassen 2001) point out that adversity lies at one end of a continuum of effects in which knowledge about the context is essential:

> The spectrum of undesired effects of chemicals is broad. Some effects are deleterious and others are not. In therapeutics, for example, each drug produces a number of effects, but usually only one effect is associated with the primary objective of the therapy; all the other effects are referred to as *undesirable* or *side effects* of that drug for that therapeutic indication. However, some of these side effects may be desired for another therapeutic indication… Some effects of drugs are never desirable and are always deleterious to the well-being of humans. These are referred to as the *adverse, deleterious,* or *toxic* effects of the drug (p. 15, italics in original).

Only effects that are "never desirable" are *adverse, deleterious, or* toxic.

This should have excluded iodide uptake inhibition from consideration as an adverse effect in the perchlorate risk assessment. Although it no longer is the drug of choice, potassium perchlorate was long used for the therapeutic purpose of inhibiting iodide uptake inhibition, most notably in patients with Graves' disease. Thus, the "key event" construct is tactically necessary to make iodide uptake inhibition *implicitly* adverse. If it did not have this construct to rely upon, EPA's draft perchlorate risk assessment would fall apart.

And that is exactly what happened. The NAS committee expressly charged with reviewing the scientific data and EPA's draft risk assessment rejected every significant element in the Agency's risk model, save one: the committee supported EPA's *key event* construct (National Research Council 2005). The most plausible explanation for this is, having decided to go beyond its charge to derive its own reference dose, the committee (like EPA) needed the non-scientific discretion provided by the *key event* construct. There is hardly any question that the committee did not adhere to OMB's proposed risk assessment guidance. Indeed, it did not adhere to even the most fundamental principles of OMB's 2002 information quality guidelines or, for that matter, any previously known risk assessment method. The committee derived a recommended reference dose using a No Observed Effect Level as the point of departure (instead of a No Observed Adverse Effect Level), then divided that value by 10. (The resulting value is less 1/570th of the NOAEL identified by the NAS committee.) [36]

[36] At a congressional briefing, Graham is reported to have claimed the absence of a probability analysis or quantitative uncertainty analysis is all that separated the NAS committee's risk assessment from the proposed OMB risk assessment guidelines. The lack of an uncertainty analysis was a minor issue. The NAS risk assessment failed the proposed risk assessment guidance because it was scientifically opaque and transparently driven by a combination of precautionary policy considerations and politics.

The perchlorate case also shows why OMB's proposed text would not solve the problem of how to define adverse effects. OMB would delegate this critical task to "the best available scientific information generally accepted in the relevant clinical and toxicological communities." OMB does not consider the possibility that there will be disagreements within or across these communities, such as among toxicologists or between toxicologists and clinicians. (The perchlorate case had both.) Nor does OMB even contemplate the near certainty that policy considerations affect what is "generally accepted" within any of these communities. (All scientific communities have values.) Finally, it is disturbing to imagine that the values of the people the government is established to serve should be subordinated to the values of scientific elites.

Economics provides an objective way to define adversity contingent only on the policy judgment that the values of individuals who bear risk, and benefit from actions taken to reduce risk, ought to be the basis for risk assessment: willingness-to-pay (WTP). This policy judgment has long been an established principle at OMB; it is codified throughout Circular A-4, where individual preferences are presumed to rule.

Suggested language:

- *The determination of which effects are beneficial or adverse shall be based on willingness-to-pay*
    - *An effect that individuals are willing to pay to experience is beneficial*
    - *An effect that individuals are willing to pay to avoid is adverse*
    - *The magnitude of willingness-to-pay is the appropriate measure of the severity of an adverse effect or the amount of benefit derived*
    - *For a specific individual, an effect may be beneficial or adverse depending on the context or circumstances, but it may not be both beneficial and adverse in the same context or circumstance for the same individual*
    - *Across individuals, an effect may be simultaneously beneficial to some and adverse to others*
- *Identified effects must be identified and defined clearly, accurately, and in an unbiased manner; they should be ratified by experts in the underlying mechanism which converts the agent, technology or activity into risk*
- *The estimated or approximated magnitude of willingness to pay must be demonstrated to be substantial before a risk assessment is justified; speculative or suggestive evidence that willingness to pay is substantial is insufficient*

The first set of bullets outlines the WTP framework for application in the risk assessment context. The second and third major bullets are is intended to ensure that risk assessments focus on serious concerns and not be distracted by trivial or speculative matters.

If the WTP definition had been applied to perchlorate, there is little question that iodide uptake inhibition would not have been construed as an adverse effect by EPA. It is

transient, fully reversible, and goes unnoticed. It is experienced routinely just by eating a normal diet (Belzer, Bruce et al. 2004). Possibly no one fully informed about it would be willing to pay anything to avoid it. The NAS committee that reviewed perchlorate probably would not have derived a reference dose that is $1/10^{th}$ of the NOEL. Most importantly, EPA would not have adopted the NAS risk assessment by reference because the NAS risk assessment does not satisfy applicable information quality standards.

Fluoride provides another recent and helpful example showing why the WTP framework is sensible and desirable, and superior to OMB's proposed reliance on the expertise of toxicological and clinical communities. Fluoride is known to be an effective preventative for dental caries. The ingestion of excess fluoride, however, causes enamel fluorosis. "Whether to consider enamel fluorosis … an adverse effect has been the subject of debate for decades" (National Research Council 2006) (p. 87). Clinicians have been hesitant to call fluorosis an adverse effect, probably because in their judgment the value of avoiding dental caries exceeds the costs of tooth discoloration. Even severe enamel fluorosis is often termed an "adverse *cosmetic* effect" (see, e.g., pp. 104,106), suggesting that this concession is made grudgingly.

This "scientific" debate would have ended long ago if adversity had been defined by WTP. Individuals are willing to pay substantial amounts for cosmetic dentistry to repair or disguise enamel fluorosis; there are dental associations whose primary focus is cosmetic repair and improvement; and several national personal care companies market over the counter remedies. This is ample evidence, based on revealed preference, of the value of avoiding enamel fluorosis. If the purpose of risk assessment is to assess risk – and not to justify public policy decisions based on other grounds – then WTP provides as close to a policy-neutral way to define adversity.

Absent an objective criterion for adversity such as WTP, risk assessment will continue to be plagued by policy-driven efforts to use apply risk assessment to *nonadverse* effects (Center for Progressive Regulation 2006). If ever there was a strategy that is likely to waste analytic resources on trivial matters, and thereby engender "paralysis by analysis," this is it. For those whose objectives are the most stringent regulatory standards possible, irrespective of both cost and risk, scientifically objective risk assessment is a deeply threatening enterprise.

8. Value of information (§V.8)

We commend OMB for explicitly addressing the question of how much new information is worth obtaining before performing (or updating) a risk analysis. This occurs constantly in practice, for no risk assessment can be performed in a state of total ignorance and no risk assessment ever produced was based on perfect information. A tradeoff always must be made between waiting to obtain more information on the one hand, and completing a risk assessment now based on available information. At best, these decisions appear to be made based largely on intuition rather than analysis. OMB is wise to use this guidance to begin rationalizing this process.

We believe that OMB should be bolder on this point. Rather than asking agencies to "provide discussions" about numerous criteria related to the value of information, it should provide a true VOI framework for agencies to apply. We prefer the decision analytic framework pioneered long ago by Raiffa (Raiffa 1970) and others, and for which a vast literature now exists.

Suggested language:

- *All influential risk assessment shall include a section analyzing, quantitatively to the extent possible, the value of obtaining additional information, utilizing the established principles and practices of decision analysis*
- *Value-of-information analysis shall*
    - *identify gaps in scientific knowledge*
    - *distinguish critical from non-critical knowledge gaps by assessing the extent to which having the information would have a material effect on the results of the risk assessment, free of all policy considerations*
- *For knowledge gaps determined to be critical, value-of-information analysis shall*
    - *estimate the change in risk assessment outputs that could result from obtaining and using specific new information*
    - *estimate the value to the public expected to result if important public and private decisions were informed by a risk assessment utilizing specific new information*
    - *estimate the lost value to the public expected to result from delays associated with obtaining and utilizing the specific new information*

9. *Responding to public comments (§ V.9)*

We are second to no one in our belief that agencies ought to be responsive to scientifically relevant public comments on draft risk assessments. Moreover, we believe that the evaluation of the merits of public comments addressing the scientific content of agency risk assessments ought to be required elements of any agency-sponsored external peer review of a draft risk assessment. This latter process is not standard practice, although it is now encouraged by OMB (Office of Management & Budget 2005) and specifically included in the NAS review of OMB's draft peer review Bulletin (Office of Management and Budget 2006). Conventional agency practice has been to exclude public comments from external peer review irrespective of their scientific content or relevance (U.S. Environmental Protection Agency Science Policy Council 2000), but the policy

directing that practice appears have been changed somewhat in response to OMB's guidance (U.S. Environmental Protection Agency Science Policy Council 2006).[37]

The value of response-to-comment documents remains limited, however. They tend to be defensive exercises rather than opportunities for agencies to make take advantage of external expertise and insight. We are aware of no systematic study of the effectiveness of response-to-comment requirements, but our experience has been that they are not very useful. Given this history, an additional instruction to agencies seems in order.

Suggested language:

- *Analyze and respond to all comments received on a draft risk assessment that materially affect its results or outcome, providing this analysis in a response-to-comment document attached to the draft risk assessment*
- *Include in the response-to-comment document analysis and responses to all comments made by external peer reviewers, including public comments identified by such reviewers as being material to the risk assessment*

VI. UPDATES

OMB's proposed language calling on agencies to update existing risk assessments is unlikely to have any demonstrable effect. It confers complete discretion on the agencies themselves to determine if new information is sufficient to warrant revision. There is ample evidence that this approach cannot succeed. As just one example, in 2001 EPA surveyed a limited number of internal and external users of its Integrated Risk Information System and identified dozens of chemicals believed to be overdue for updating (U.S. Environmental Protection Agency 2003). Little progress has been made since then.

OMB has similar experience with "look-back" provisions. Executive orders 12,291 and 12,866 both contain such provisions exhorting agencies to review existing regulations to ensure that they are still needed. The number of regulations reviewed pursuant to these provisions is small.

If OMB is serious that existing risk assessments get updated, it must create the incentives that permit it to happen. The most likely way this will happen is if OMB puts

[37] The list of materials to be delivered to external peer reviewers now includes: "For highly influential scientific assessments, copies of significant public comments on scientific issues." See § 3.5.2 (#4).. it remains up to the agency to decide which public comments are "significant." This is a small subset of *influential risk assessments*, consisting of those that could have a potential impact of more than $500 million in any year, or are novel, controversial, or precedent setting. See § III.1, U.S. Office of Management and Budget (2005). "Final Information Quality Bulletin for Peer Review." Federal Register **70**(10): 2664-2667.

in place a mechanism by which third parties can update existing risk assessments. If an updated risk assessment adhere to the provisions of the OMB's risk assessment guidance, and OMB's Information Quality Guidelines, and OMB's guidelines on peer review, the revised risk assessment should earn a rebuttable presumption that it is superior to the existing risk assessment it is intended to replace. The language for such an incentive-based system is easy to craft.

Suggested language:

- *Existing risk assessments shall be presumed to be potentially deficient if they do not comply with all applicable provisions of*
    - *this guidance*
    - *OMB's Information Quality Guidelines*
    - *OMB's guidance on peer review, including elements related to public participation*
- *If a third party prepares an update of an existing risk assessment that was prepared by that agency, it shall be eligible to supplant the existing risk assessment provided that the updated risk assessment complies with all applicable provisions of*
    - *this guidance*
    - *OMB's Information Quality Guidelines*
    - *OMB's guidance on peer review, including elements related to public participation*
- *If a third party submits to the agency that authored the original risk assessment an updated risk assessment meeting these requirements, using that agency's error correction procedures established pursuant to OMB's Information Quality Guidelines, the updated risk assessment is entitled to a rebuttable presumption that*
    - *it is superior in quality to the original risk assessment*
    - *it should be added without prejudice to the applicable file of risk assessments used or disseminated by the agency*
    - *the original risk assessment should be withdrawn*
- *The presumption that the original risk assessment should be withdrawn may be rebutted by a persuasive showing that the original risk assessment satisfies the standard of objectivity set forth inn this guidance*

VII. CERTIFICATION

A requirement for certification by high-level agency officials serves at least two purposes. First, it can make high-level officials more aware of risk assessments generally

so that they understand the role of risk assessment in decision making. Second, it can increase the likelihood that risk assessments serve their primary internal purpose – i.e., ensuring that decision makers are informed prior to making decisions.

VIII. DEFERRAL AND WAIVER

Provisions such as these clearly are necessary to ensure that the guidance does not encumber decision making during emergencies or other situations in which adherence to these guidelines is impractical. However, OMB should tighten the language to ensure that the exercise of deferral or waiver authorities is transparent. Non-transparent exercise should be limited to cases where the compelling rationale is inappropriate to disclose publicly, such as when it is classified.

IX. JUDICIAL REVIEW

The proposed text clearly states that there would be judicial review of agency compliance. The U.S. Chamber of Commerce has argued that judicial review is essential for a risk assessment guidance to be effective, and say that the text must be changed to explicitly permit it (Kovacs 2006). Others, who just as passionately oppose judicial review, acknowledge what the proposed text says but worry that a future court might rule that agency decisions under the IQA are reviewable and then give this guidance force despite the disclaimer, apparently in part because they are afraid that Congress would like the courts to have a significant role (Center for Progressive Regulation 2006).[38]

We believe that judicial review would not be as significant as its proponents hope or its opponents fear. Proponents' expectations seem to reflect a triumph of hope over experience. There are few examples in which courts, despite their lack of scientific expertise, smartly adjudicated highly complex matters related to risk assessment. The most the courts probably could do is discipline an agency for failing to perform risk assessment at all, or for doing so poor a job of it that low quality is self-evident even to non-experts. For their part, opponents of judicial review seem to have extraordinarily little confidence in the technical ability of the same federal regulatory agencies whose subject matter expertise they say is beyond question. They appear to be deeply afraid that courts would be able to discern frank scientific error and unwilling to let it pass. In short, they seem to be concerned that industry could use the IQA and its implementing guidelines to undermine federal regulation as well as environmental activists have used NEPA to undermine federal projects.

[38] "The courts are still considering whether requests for correction are judicially reviewable. If they are [sic], then the Proposed Bulletin will become an overpowering tool for threatening agencies with litigation if they do not dot every 'i' and cross every 't' of its extensive requirements. Even if the courts do not find decisions made under the Act to be judicially reviewable, the Chamber of Commerce has announced that it will seek a congressional amendment to that effect. And even if the Act is ultimately determined not to provide a vehicle for court review, the prospect of answering interminable requests for correction will provide ample incentive for agencies to comply with its burdensome and unnecessary conditions" (p. 8, internal references omitted).

Enforcement of IQA-related administrative reforms, including risk assessment guidance, is a complex matter that likely cannot be solved through any one "magic bullet." It is an interesting – and vexing – problem, and one that calls for some creative thinking. Our objective ought to be to establish a system in which all stakeholders' have incentives to act in responsible ways. How to get there continues to be the most elusive guidance document that has never been written.

REFERENCES

Belzer, R. B., G. M. Bruce, et al. (2004). Using Comparative Exposure Analysis to Validate Low-Dose Human Health Risk Assessment: The Case of Perchlorate. Comparative Risk Assessment and Environmental Decision Making. I. Linkov and A. Bakr Ramadan, Kluwer**:** 57-74.

Center for Progressive Regulation (2006). OMB Risk Assessment Bulletin: A Power Grab. CPR Quarterly News. **II:** 1ff.

Cohen, J. J. (2006, March 10). "Letter to Nancy Beck, Office of Information and Regulatory Affairs." from http://www.aamc.org/advocacy/library/research/corres/2006/031006.pdf.

Council on Environmental Quality (1994-95). Environmental Quaility; The Twenty-fifth Anniversary Report of the Council on Environmental Quality. Council on Environmental Quality. Washington, D.C.**:** 526.

Eaton, D. L. and C. D. Klaassen (2001). Principles of Toxicology. Casarett and Doull's Toxiclogy: The Basic Science of Poisons. C. D. Klaassen. New York, McGraw-Hill. **Chapter 2:** 11-34.

Gordon, B., J. D. Dingell, et al. (2006, May 5). "Letter to Ralph J. Cicerone, President, National Academy of Sciences." Retrieved June 10, 2006, from http://sciencedems.house.gov/Media/File/ForReleases/natacad_riskeval_05may06.pdf.

Haveman, R. H. and J. Margolis (1970). Public Expenditures and Policy Analysis. Markham Economics Series. J. Margolis. Chicago, Markham**:** 596.

Hogue, C. (2006). "Assessing Risk: White House Proposes Government-wide Benchmarks to Evaluate Numerous Risks." Chemical & Engineering News **84**(2): 6.

Hogue, C. (2006). "Guidelines for Assessing Risk; White House Proposal Could Impede Broad Range of Government Activities, Agency Representatives Warn." Chemical & Engineering News **84**(23): 45-48.

Kennedy, P. (1985). A Guide to Econometrics. Cambridge, Mass., MIT Press.

Kovacs, W. L. (2006, May 18). "Letter to Nancy Beck, Office of Information and Regulatory Affairs, Office of Management and Budget." from http://www.uschamber.com/press/releases/2006/May/06-84.htm (press release), http://www.uschamber.com/NR/rdonlyres/e2welcezxthvj6agcin2qmjhzlti3olwwowtljghhrsj3moinxizwnugaxm5pbaobtggod4as6blrnlxfao7so4tfpf/051006wscommentsombriskassessmentbulletinpart1.pdf (text), http://www.uschamber.com/NR/rdonlyres/ewqaqg2sssz552x7r3padfcxadwn4cp2o5vtvm4hhjmq4xxdqmajwogzpks7ob5zkfhlnkeqjctwcxp4c4lh2yp6tgh/051006wsc

ommentsombriskassessmentbulletinpart2.pdf (SUPPLEMENTARY INFORMATION).

Lutter, R. and R. B. Belzer (2000). "EPA Pats Itself on the Back." Regulation **23**(3): 23-28.

National Research Council (1983). Risk Assessment in the Federal Government: Managing the Process. Washington, D.C., National Academy Press.

National Research Council (2005). Health Implications of Perchlorate Ingestion. Washington, D.C., National Academy Press.

National Research Council (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. Washington, D.C., National Academy Press.

National Weather Service. (2006). "Weather Terms and Warning/Advisory Criteria." Retrieved June 10, 2006, from http://www.crh.noaa.gov/lot/severe/wxterms.php#pp.

Office of Management & Budget (2005). "Final Information Quality Bulletin for Peer Review." Federal Register **70**(10): 2664-2677.

Office of Management and Budget (1990). Current Regulatory Issues in Risk Assessment and Risk Management. Regulatory Program of the United States, April 1, 1990 -- March 31, 1991. Washington, DC, Office of Management and Budget**:** 13-26.

Office of Management and Budget (1990). Regulatory Impact Analysis Guidance (Appendix V) Regulatory Program of the United States Government, April 1, 1990 -- March 31, 1991. Washington, DC, Office of Management and Budget**:** 653-666.

Office of Management and Budget (1990). Regulatory Impact Analysis Guidance: Discussion of Comments. Regulatory Program of the United States, April 1, 1990 -- March 31, 1991. Washington, DC, Office of Management and Budget.

Office of Management and Budget. (1999, January). "1998 Report to Congress on the Costs and Benefits of Federal Regulations." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/costbenefitreport1998.pdf.

Office of Management and Budget. (2000, March 22). "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/memoranda/m00-08.pdf.

Office of Management and Budget (2002). "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." Federal Register **67**(36): 8452-8460.

Office of Management and Budget. (2003). "Circular A-4: Regulatory Analysis." Retrieved June 10, 2006, from http://www.whitehouse.gov/OMB/circulars/a004/a-4.pdf.

Office of Management and Budget. (2005). "Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/2005_cb/final_2005_cb_report.pdf.

Office of Management and Budget. (2006, January 9). "Press Release: OMB Requests Peer Review of Proposed Risk Assessment Bulletin." from http://www.whitehouse.gov/omb/pubpress/2006/2006-01.pdf.

Office of Management and Budget. (2006). "Program Assessment Rating Tool (PART)." from http://www.whitehouse.gov/omb/part/.

Office of Management and Budget. (2006, January 9). "Proposed Risk Assessment Bulletin." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.

Office of Management and Budget (2006). "Proposed Risk Assessment Bulletin; Notice of proposed Bulletin and request for comments." Federal Register **71**(10).

Office of Management and Budget and U.S. Small Business Administration Office of Advocacy. (2002, March 19). "Memorandum of Understanding Between the Office of Advocacy, U.S. Small Business Administration and the Office of Information and Regulatory Affairs, Office of Management and Budget." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/oira.pdf.

Raiffa, H. (1970). Decision Analysis. Reading, Mass., Addison-Wesley.

Regulatory Checkbook. (2006). "Letter to John D. Graham, Administrator, Office of Information and Regulatory Affairs." Retrieved June 10, 2006, from http://www.whitehouse.gov/omb/inforeg/good_guid/c-reg_checkbk.pdf.

Steinzor, R. (2006). The John Graham Legacy: Weaker Safeguards and a Cozier Relationship with Industry. CPR Quarterly News. **2:** 2-3.

U.S. Environmental Protection Agency (1989). Exposure Factors Handbook, U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency (1997). Exposure Factors Handbook. U.S Environmental Protection Agency.

U.S. Environmental Protection Agency (2002). Child-Specific Exposure Factors Handbook. U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency (2003). Needs Assessment for U.S. EPA's Integrated Risk Information System.

U.S. Environmental Protection Agency (2004). An Examination of EPA Risk Assessment Practices and Principles**:** 193.

U.S. Environmental Protection Agency Office of Research and Development National Center for Environmental Assessment (2002). Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (NCEA-1-05-3), External Review Draft. Washington, D.C.:, U.S. EPA, Office of Research and Development.

U.S. Environmental Protection Agency Science Policy Council. (2000). "Peer Review Handbook." 2nd ed. Retrieved August 30, 2005, from http://www.epa.gov/osa/spc/pdfs/prhandbk.pdf.

U.S. Environmental Protection Agency Science Policy Council. (2006). "Peer Review Handbook." 3rd ed. Retrieved June 13, 2006, from http://www.epa.gov/peerreview/pdfs/Peer%20Review%20HandbookMay06.pdf.

U.S. Office of Management and Budget (2005). "Final Information Quality Bulletin for Peer Review." Federal Register **70**(10): 2664-2667.