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AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

Public Comment on OMB Draft Risk Assessment Bulletin

Gilbert S. Omenn, M.D., Ph.D. [*]

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[*] Dr. Omenn is a professor of internal medicine, human genetics, computational biology, and public health at the University of Michigan.

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Executive Summary

The OIRA draft Risk Assessment Bulletin has worthy intentions and has stimulated useful review and discussion. Most previous major documents in the development of the risk assessment field have been cited and used appropriately. In general, the formulation is too broad. The Revision should clarify the place of risk assessment as distinguished from hazard identification and from risk management. The category of "influential risk assessment" is unnecessary and confusing, and should be deleted. A single set of six standards would suffice, without the additional nine special standards for "influential risk assessments". Greater transparency within the EOP is desirable to give this process credibility and meet one of the explicit aims of the Bulletin. Finally, several omissions should be addressed: proactive engagement of stakeholders, public health context, deceptive use of quantitation, exclusion for research agencies, interagency steering committee, and symmetry of risk assessment guidance for manufacturers as well as regulatory agencies.

Public Comment on OMB Draft Risk Assessment Bulletin

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1. Introduction

This Bulletin has a worthy intent: to enhance the named attributes of quality--objectivity, utility, and transparency--of risk assessments prepared by or for the federal agencies.

There is a supportive objective of improving quantitative components of risk assessments, including methods of characterizing and estimating what the National Research Council report, "Science and Judgment in Risk Assessment" (1994), differentiated as variability and uncertainty. Nevertheless, the Bulletin makes clear the primary importance of the qualitative or narrative characterization of risk, starting with the nature, significance, and reversibility of the potential adverse effects from exposure scenarios, as recommended by the OSTP (Calkins et al, 1980) (Figure 1) and the National Research Council (NRC, 1983, "The Red Book").

The Bulletin recognizes and emphasizes the fact that many agencies have responsibilities for a variety of particular risk scenarios, clearly justifying the interest of OIRA/OMB and of OSTP in providing guidance and periodic oversight, though perhaps not in case-by-case management.

Examples are described. However, consistency in what is presented and meaningful evaluation of lessons learned from these case studies and value-added from the risk assessments would enhance this important element of the Bulletin. Moreover, major examples—like the air-only analysis of the addition of MTBE to gasoline and the protracted Corps of Engineers analyses of risks and risk management for levees—would be informative.

The Bulletin appropriately cites many major reports from the development of risk assessment concepts and methods, especially a series of National Research Council reports, most from the Board on Environmental Studies and Toxicology (including years 1988-1991 when I was chair). The Bulletin also draws extensively upon the reports of the Presidential/Congressional Commission on Risk Assessment and Risk Management (1994-1997, see www.riskworld.com/reports/1997; hereinafter, "The Risk Commission"). The Bulletin should recognize early work from EPA and FDA (see Alberts, 1994; Anderson, 1983).

Finally, OIRA has shown respect for the Public Comment process and enhanced its depth through cooperation with the National Academy of Sciences, among others, to hold well-planned workshops, as in this case and in the preceding case of the Peer Review Guidelines.

2. Key Concepts from the Risk Commission

The Framework for Risk Management presented by the Risk Commission and utilized by multiple agencies in the United States and around the world is shown in Figure 2.

The special features of this framework, as shown in the hexagon of six steps, are two:

a) The requirement to put a "new problem" into public health (or ecological) context before launching into technical aspects of risk assessment.

"Context" at the more technical level means moving beyond analysis and regulation of one chemical, one environmental medium (air, water, soil, food), one health (cancer, birth defects, …) at a time to a comprehensive analysis. For each agent (a chemical, for example), it is necessary to describe and analyze the sources and pathways of exposure, the often multiple health effects, and the variation in susceptibility within exposed populations; then it is necessary to describe and analyze other causes of the same adverse effects; and finally to address aspects of environmental justice, different perceptions of risks, cultural practices influencing exposures, and statutory requirements.

b) The central feature of proactively and broadly engaging stakeholders, so that their questions, their perceptions, their sometimes substantial information, and their often practical risk management/risk reduction suggestions can inform the whole risk assessment/risk management/risk communication process.

The Commission addressed many cross-agency issues, as directed in its mandate in the 1990 Clean Air Act Amendments, and then addressed various agency-specific and program-specific issues. The cross-agency topics were: risk assessment science and models; risk-management framework; communicating uncertainty; peer review; inter-and intra-agency consistency; "bright lines"; sensitive subpopulations; ecological risk assessment; comparative risk assessment; economic analysis; and judicial review. The work was all presented openly,

with bimonthly public hearings during the findings phase and with a set of hearings after the main report was issued. We prepared both a detailed scientific and policy report and a report for the general public, with important examples drawn from our public hearings [see www.riskworld.com/reports/1997].

3. Brief Comments on OMB/OIRA Criteria for Risk Assessments

Problem formulation/purpose of the risk assessment (RA):

Yes, of course, the purpose should be stated clearly and should be put in public health, ecological, or other appropriate context, as outlined above (Risk Commission). The RA is not just for the "agency decision-maker", but must be useful for many other stakeholders.

Completeness:

This criterion is obscure in scope and inadequate in terms of resources required and opportunity cost.

Effort and resources required:

These points are too soft and likely to lead to misunderstandings and disputes.

Peer review:

OIRA admirably revised the draft Peer Review Guidelines after inputs from the National Academies Workshop and the public; it would be appropriate here to summarize and cite assessments of the experience to date.

Missing criteria: Earlier Inter-Agency Cooperation

Improved risk communication with publics/stakeholders

4. Major Issues to be Addressed in the Revision of this Draft Bulletin

There is mission-creep in demanding, it seems, of hazard assessment/hazard identification (see Figure 1, above, from OSTP, 1980) the extensive analysis required for risk

assessment/risk characterization. These two steps should not be merged. The critical aspect of exposure assessment for risk assessment should be highlighted
(Lioy et al, 2005; Weis et al 2005).

The elaborate scheme of "risk assessments" and "influential risk assessments" is unhelpful, confusing, and likely to generate disputes about the classification in particular cases. In no way are these guidelines "minimal"!

The Bulletin should hew to the Red Book and many agency positions that risk assessment, while informing risk management, should be kept separate from risk management.

The Bulletin needs to reinforce the requirements to respect legal and budgetary context. A "value-of-information" concept would be helpful, as applied to carcinogenicity testing by Lave & Omenn (1986) and Lave et al (1988).

The Bulletin should clarify what are "central estimates" or "expected risks".

The Bulletin should enhance transparency—one of the primary attributes of quality espoused by OIRA—of intra-governmental processes, starting from agency discretion right through the roles of OIRA and OSTP.

5. Responses to Specific Questions: Recommendations

Breadth

The formulation is much too broad. On p.1, the Bulletin states that "Risk assessment is a useful tool for estimating the likelihood and severity…" However, it then states that "Risk Assessment refers to a document that assembles and synthesizes scientific information….whether a potential hazard exists". "Potential hazard" is NOT "risk" (see Major Issues, above). On p.8, there is mention of "an exposure or hazard assessment"; again, the term hazard is used loosely and with confusion.

Even if a more inclusive scheme is desired long-term, it would be wise to start with the most important and most relevant cases and gain experience.

We should remember and apply the wise counsel of U.S. First Circuit Chief Judge David Bazelon in his 1979 address at the University of Southern California entitled "The Perils of Wizardry". Starting from the premise that most regulatory issues tend to recur, Bazelon stated

that it is important to build a useful record. Technical experts (including risk assessors), both inside and outside the agency, should:

- Stay away from the ultimate policy decision (risk management), which it not their charge or their special expertise
- Delineate the specific elements of the risk characterization
- Focus on those specific elements—including those known, those feasible to know with present methods, and those beyond our present methods—to build the record; and
- Expect to be asked again!

And, he urged that policy makers respect the different roles of risk assessors and risk managers.

Different standards for different classes of risk assessment

I would prefer a single set of guidance, with narrower application and with the proposed flexibility. The nine special standards only embellish the basic set of six standards.

The classification introduces a fuzzy line that could lead to lots of unproductive disputes; for example, p.9 includes "hazard determinations" as "influential".

"Regulatory analysis" primarily introduces risk management, which should not be lumped together with risk assessment.

Omissions

There are several significant matters which should be added:

a) Proactive engagement of stakeholders: the text is too much directed at serving "agency decision-makers". See Risk Commission, above.
b) Public health context: "comparative risk" guidance is too vague, and generally boomerangs when interpreted to include meteorite crashes or even cigarette smoking
c) Foolish or deceptive use of quantitation—one of the most frequent and most egregious misuses of numbers is the presentation of excessive significant figures, for example, using measurements or, worse, estimates in integers and then generating calculated estimates of risk to 4 or 6 decimal places! It is offensive to brush off this practice as just computers run amok; such precision is deceptive and distracting. Journals are just as guilty as agencies. Scientists who claim they are simply copying the original numbers

should be admonished to round off unjustifiably precise numbers. The rule is that the final figure cannot be more precise than the least precise number used in the calculation.

d) "Risk-related research": The Bulletin should provide an unambiguous exclusion for research agencies performing or funding what regulatory agencies may later, or concurrently, consider to be risk-related research. The present scheme is much too far-reaching.

e) Inter-agency and EOP review: The Bulletin should identify or propose an inter-agency mechanism, like a National Science & Technology Council-appointed steering committee, to work with OIRA and OSTP and the agencies. In the late 1970s there was a Regulatory Analysis Review Group, chaired by a member of the Council of Economic Advisers, which played a useful role. The EOP role, especially in a time of expanded Executive Office prerogatives, should not be a "black hole", especially in a Bulletin espousing transparency.

f) Symmetry: The Bulletin places considerable burdens on the agencies to justify their conclusions, while a symmetrical set of requirements of transparency, objectivity, and utility is explicitly excluded for manufacturers seeking licenses, approvals, and registration of agents subject to regulation. That is unwise and should be modified.

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Figure 1

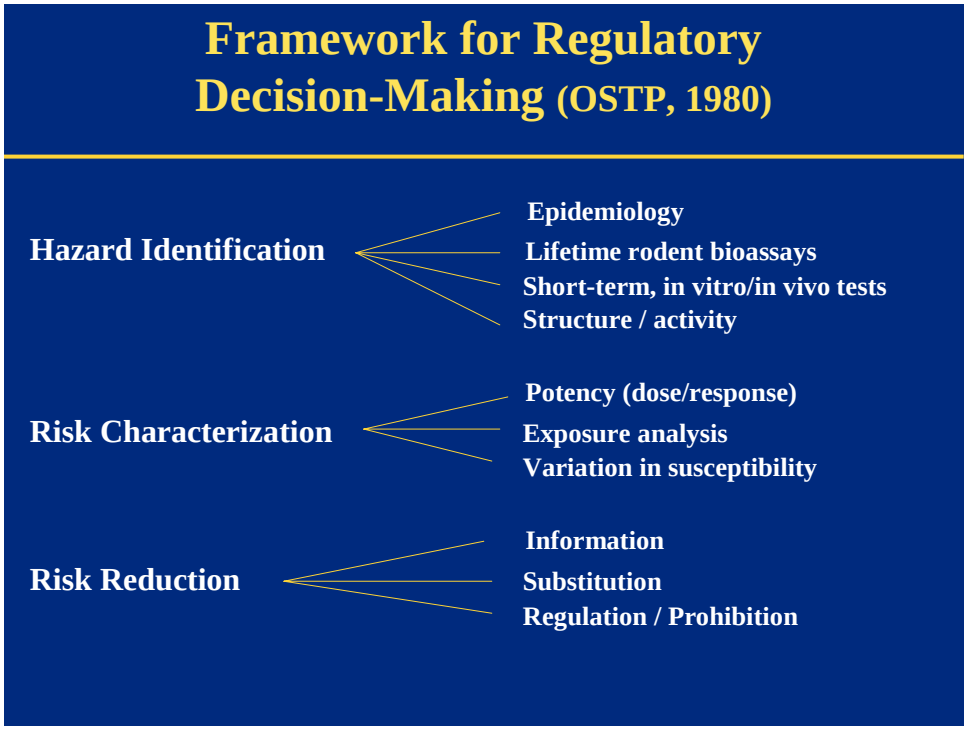


Figure 2

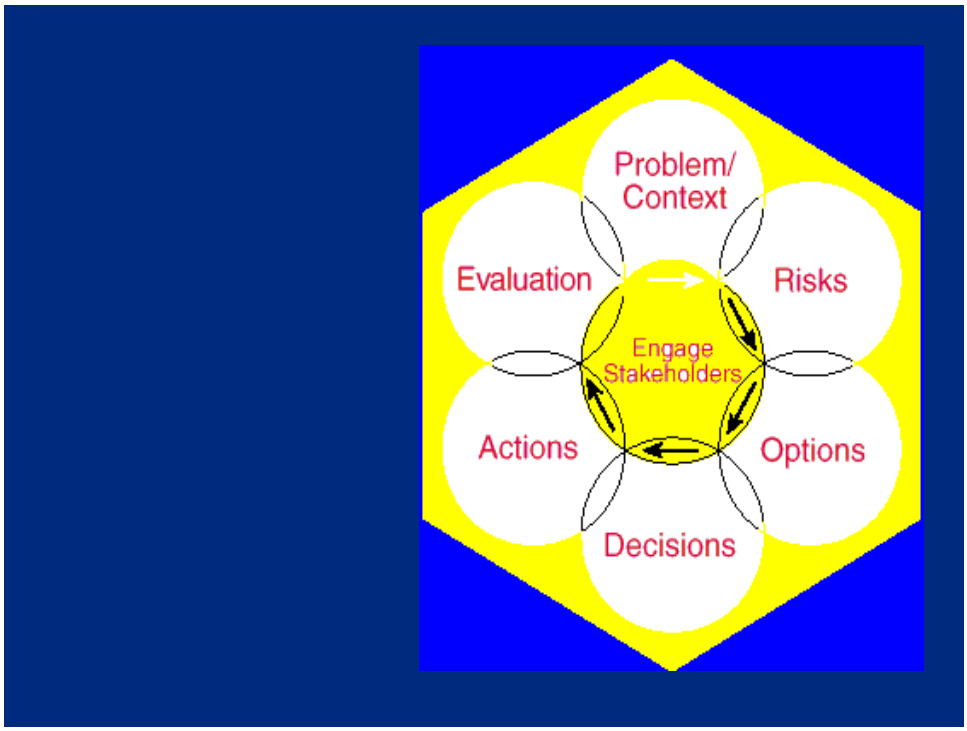
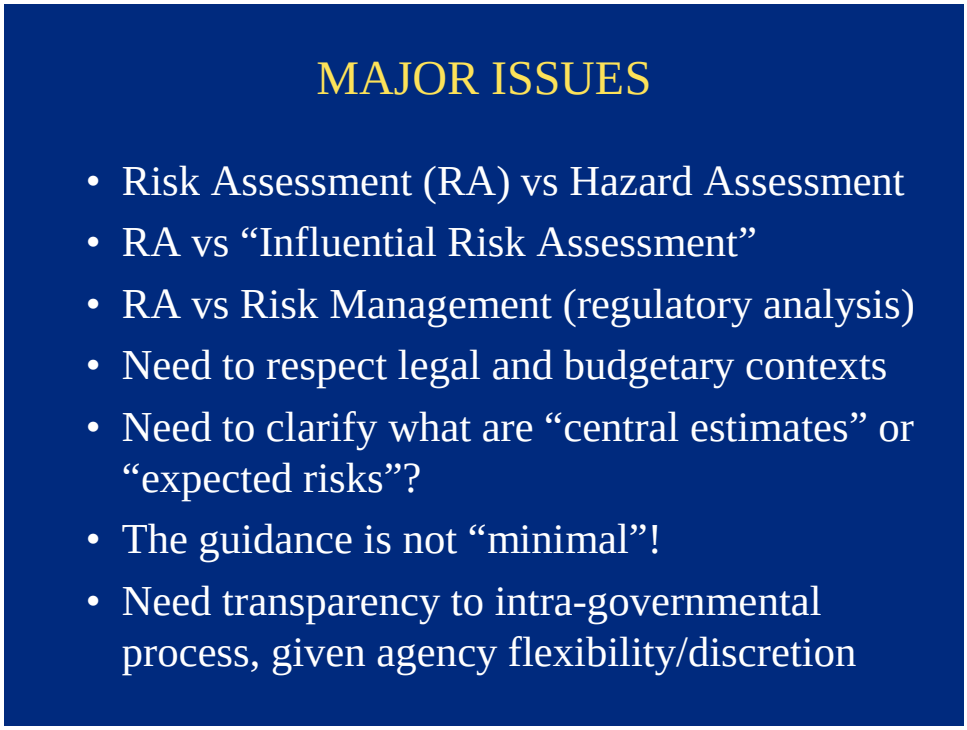


Figure 3


MAJOR ISSUES
• Risk Assessment (RA) vs Hazard Assessment
• RA vs "Influential Risk Assessment"
• RA vs Risk Management (regulatory analysis)
• Need to respect legal and budgetary contexts
• Need to clarify what are "central estimates" or "expected risks"?
• The guidance is not "minimal"!
• Need transparency to intra-governmental process, given agency flexibility/discretion