

Comments on the OMB Proposed Risk Assessment Bulletin

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Disclaimer: I am submitting these comments as an individual, and not on behalf of NorthWorks, Inc., any of its clients, Stanford University, or any other organization or other individuals. I was a speaker at the Public Forum organized by the Society for Risk Analysis (SRA) on May 23rd, 2006. I spoke there as an individual, and not on behalf of SRA or any other organization or individuals.

I commend the Proposed Risk Assessment Bulletin issued for public comments January 9, 2006 as an admirable step in OMB's ongoing effort to "improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public." I believe it is an excellent idea for OMB, in consultation with OSTP and the federal agencies that produce risk assessments, to provide technical guidance on how federal agencies should prepare risk assessments. There are many good ideas contained in this proposed Bulletin. But I am concerned that some aspects need improvement, particularly, on the relationship of risk assessment to risk management decision making.

The goal of OMB's ongoing effort should be in improving the way that federal agencies, and those that use the information products of federal agencies, make decisions on the management of risks to human health, safety, or the environment. The Proposed Bulletin on page 1 states that the term, "risk assessment" refers to a "document." I prefer that this term be used to describe a **process, which may lead** to a "document," and may also generate a set of supporting informational materials. This process, and the documents that result from the process, should be appropriate for the needs of risk managers, by providing them information in a suitable form that will help them in making decisions. Neither the process nor the document should be forced into a "one-size-fits-all" mold. The National Research Council report, *Science and Judgment in Risk Assessment* (1994) (cited in the OMB Proposed Bulletin, Footnote 2, page 2) states on page 4:

Risk assessment is not a single, fixed method of analysis. Rather, it is a systematic approach to organizing and analyzing scientific knowledge and information for potentially hazardous activities or for substances that might pose risks under specified conditions.

The assessment process should involve not only the assembly of the available information, but also skill in understanding it and communicating it to stakeholders and those with risk management decision making responsibility. In my judgment, therefore, OMB should be focusing on how to encourage better practices in the risk assessment **process** by federal agencies, as well as on technical guidance for preparation of risk assessment documents.

There are a multitude of societal decisions on risk facing federal agencies and for which federal agency information products may inform risk management decision making. Many of these decisions are important, especially to those who are involved in making the decisions or may be impacted by the risk. OMB cannot oversee the quality of all that is done by federal agencies in putting out information products about risk except in the most general way – there are too many of them. The limited time and resources of OMB and the federal agencies should be managed so that the agencies are enabled to do the best possible job in supporting risk management. OMB should not place onerous broad quality requirements on risk assessment documents that may impede the timely flow of information from federal agencies to those with risk management responsibilities, both inside and outside of the federal government. Rather, OMB should help federal agencies to identify, understand, and remedy specific deficiencies in the risk assessment practices of these agencies.

I was a member of the National Research Council Committee that authored the so-called Red Book, *Risk Assessment in the Federal Government: Managing the Process* (1983), cited beginning at the bottom of page 1 and in Footnote 5, page 2. As I have described at length in a paper I wrote for the 20th anniversary of this National Academies' report ("Reflections on the Red/Mis-Read Book, 20 Years After," *Human and Ecological Risk Assessment*, Special Issue on the Red Book, Vol. 9, No. 5, August 2003, pages 1145-1154) this "seminal report" did *not* advocate *separating* risk assessment and risk management. It advocated *conceptual distinction*, not organizational separation, and it encouraged communication between risk assessors and risk managers. The Red Book most definitely did not advocate standardizing risk assessment into a single, fixed method. As one example, the report states:

... regardless of the sequence of steps and the number of steps used to determine whether regulatory action is warranted, risk assessment serves at least two major functions in regulatory decisions: first, it provides an initial assessment of risks, and, if the risk is judged to be important enough to warrant regulatory action, it is used to evaluate the effects of different regulatory options on exposure. In addition, it may be used to set priorities for regulatory consideration and for further toxicity testing.

These varied functions place different requirements on risk assessors, and a single risk assessment method may not be sufficient. A risk assessment to establish testing priorities may appropriately incorporate many worst-case assumptions if there are data gaps, because research should be directed at the most critical gaps; but such assumptions may be inappropriate for analyzing regulatory

controls, particularly if the regulator must ensure that such controls do not place undue strains on the economy. In establishing regulatory priorities, the same inference options should be chosen for all chemicals, because the main point of the analysis is to make useful risk comparisons so that agency resources will be used rationally. However, this approach, which may be reasonable for priority setting, may have to yield to more sophisticated and detailed scientific arguments when a substance's commercial life is at stake and the agency's decision may be challenged in court. Furthermore, the available resources and the resulting analytic care devoted to a risk assessment for deciding regulatory policy are likely to be much greater for analyzing control actions for a single substance than for setting priorities. (Page 39-40; emphasis added.)

The Red Book recommended that risk assessments be published as publicly available documents (Recommendation 2, page 153), and that these documents should be peer reviewed and the results of the peer review be published and made publicly available (Recommendation 3, page 156). Provision for exceptions to having a written, peer-reviewed risk document are set forth in the text. A written document is not needed for every substance, only to support "agency decisions concerning important human exposure to a hazard." (Page 155.) There is also an exemption for emergency situations posing a serious health risk, where agencies should be able to take immediate action to control the risk and prepare a risk assessment thereafter (page 159). It should be noted that these recommendations were made at a time when regulatory decisions on carcinogenic chemicals were a subject of great public controversy and extensive litigation. We on the committee believed that a formal risk assessment in the form of a publicly available document would greatly assist in clarifying the scientific information supporting such regulatory decisions, and would improve consistency among many decisions dealing with similar issues of complexity and uncertainty in the scientific information. We did *not* recommend that risk assessment documents be produced for all important risk management decisions facing EPA and other federal agencies.

The Report of the *Presidential/Congressional Commission on Risk Assessment and Management* used the phrase "paralysis by analysis" as something risk assessment should avoid. My presentation before this Commission was summarized as follows: "Likewise, Warner North, [then] of Decision Focus, Inc. recommended incentives for both data collection and speedy risk management decisions." (Commission Report, Vol. 2, page 91; Commission Report is cited in Proposed Bulletin, Footnote 4, page 2.)

Research may be needed to improve the practice of risk assessment, particularly in the use of mathematical models and probabilistic methods. In comments I submitted (as an individual) for what became OMB Circular A-4, I stated,

"Section ... describes the appropriate concepts, but this key section is broadly written and does not provide illustrative examples or extensive references to the literature. ... An ongoing, extensive research program is needed to develop and refine the needed methodology ... I urge OIRA to encourage funding of such research and ... to monitor closely the progress of agencies in using formal

probabilistic methods ... Extensive peer review will be needed through ... the National Research Council ...

Web reference: <http://www.whitehouse.gov/OMB/inforeg/2003report/294.pdf>

I reiterate these comments here, recommending that OMB encourage agencies to invest in research and methods development to improve their practices on risk assessment, particularly in the use of advanced quantitative methods.

In my talk at the SRA Public Forum on May 23, I urged the audience to consider an analogy between societal decisions in managing risk and driving an automobile – a risky activity that most Americans carry out, with little or no formal risk assessment. My point is that one doesn't have time and resources to carry out detailed information collection and analysis in support of a multitude of management actions. Rather, we need to learn which decisions are most important and how we can reduce risk through experience and improved practices. We want to avoid “paralysis by analysis” and get where we are going, at deliberate speed and as safely as possible.

Sometimes very simple risk assessment procedures may suffice. The *White Paper* from the International Risk Governance Council (cited in the Proposed Bulletin in Footnote 15, page 5) describes on page 37 a “traffic light model” - a rating of risks as red: intolerable, green, acceptable, and yellow, tolerable but in need of reduction. As drivers we are used to making swift decisions based on traffic lights. Agencies facing large numbers of regulatory decisions may also be used to making many of them quickly and effectively, based on agency experience, with little formal analysis, documentation, and peer review. OMB should encourage federal agencies to select a manageable set of situations in which upcoming decisions are important and potentially controversial, as deserving risk assessment leading to formal federal agency documents to be published as scientific support for the decisions. The IRGC *White Paper* presents an “escalator” diagram on page 53 noting increasing levels of sophistication to deal as needed with complexity, uncertainty, and ambiguity. Risk tools should be selected and used appropriately to support the risk management decision process. A deliberative process involving managers and stakeholders, as well as risk assessors, may be needed. This theme is explored at length in the IRGC *White Paper*, in the *Presidential/Congressional Risk Commission Report*, and in the NAS Report, *Understanding Risk: Informing Decisions in a Democratic Society* (1996, Footnote 7 on Page 3 of the Proposed Bulletin).

The main flaw in the Proposed Bulletin is that it tries to provide technical guidance for risk assessment without considering in detail the risk management problems that form the context for the risk assessment. On page 3 the Proposed Bulletin includes two brief paragraphs, the first to the effect that “the scope of this document does not encompass how federal agencies should manage or communicate risk” and the second, that “the purpose of a [risk] assessment should be made clear before the analytical work begins.” In my judgment these aspects need much more detailed discussion than is provided in the two bottom paragraphs on page 3 and the text following on pages 4 and 5, to guide agencies away from current tendencies toward “one-size-fits-all” risk assessment

approaches and failures to achieve adequate (and iterative) communication between risk assessors and the users of risk assessment information products. There is far too much emphasis on analytical technique, and far too little emphasis on providing effective and timely support to risk management decision makers inside and outside the federal government.

I shall close with three admonitions to those in OMB who will revise this Proposed Bulletin.

First, recognize the limits of a prescriptive approach to collecting, organizing, and analyzing scientific information in support of a risk management decision involving uncertainty, complexity, and ambiguity. Such risk assessment does not follow a recipe or a formula: it is a creative process for which risk assessment following the four steps described in the Red Book provides a conceptual framework. Agency skills in risk assessment will be improved through experience, research, and training.

Second, the goal is not good risk assessment documents in some abstract sense, but improvement in societal decision making about risk. Risk management and risk communication are essential parts of the process and should be linked to risk assessment while maintaining the conceptual separation of risk assessment as a process of assembling and analyzing scientific information about the consequences of alternative choices. The risk assessment methods and level of detail need to be selected to fit the needs for decision making on the risk.

Third, there are not enough trained risk assessors, not enough time, and not enough resources to permit detailed risk assessments and formal risk assessment documents for all the important risk decisions of interest to government agencies. Formal risk assessment documents should be limited to the most important needs, and even then, OMB should try to keep these efforts from becoming overly complex and time-consuming. Simple methods should be used for easy choices, as illustrated by the traffic light model. More elaborate and sophisticated methods will be appropriate for more difficult problems. For these more difficult problems, research and innovation will be appropriate, as opposed to prescription of which methods to use where.

It is my impression that OMB has worked effectively with federal agencies such as EPA in pioneering advanced risk assessment methods. The analysis for health effects for the off-road diesel rule is one example with which I have some familiarity. I encourage OMB to undertake other such cooperative efforts to pioneer and evolve appropriate analytical methods in support of risk assessment, risk management and cost-benefit analysis, and improved risk communication with the public and the users of federal risk documents. Prescriptive guidance on how to prepare risk assessments will be of limited effectiveness unless placed in this broader setting of matching the analytical methods to the needs of the decision problems.

Respectfully submitted,

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