American Water Works Association

The Authoritative Resource on Safe Water SM

Government Affairs Office
1401 New York Avenue
Suite 640
Washington, DC 20005
T 202.628.8303
F 202.628.2846
www.awwa.org

Headquarters Office
6666 W. Quincy Avenue
Denver CO 80235
T 303.794.7711
F 303.347.0804

June 13, 2006

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 57,000 plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, engineers, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,200 utilities that supply roughly 80 percent of the nation's drinking water.

AWWA appreciates the opportunity to comment on the proposed Risk Assessment Bulletin (71 FR 2600). AWWA and its members are dedicated to providing safe drinking water to the American public, and recognize the importance of setting health-based standards that are balanced against the need to keep drinking water affordable. This is a delicate balance for the Environmental Protection Agency's (EPA) Office of Groundwater and Drinking Water (OGWDW) that warrants careful oversight by OMB.

AWWA has commented on previous OMB reports on the costs and benefits of federal regulations, and on the recent Bulletin on Good Guidance Principles. AWWA appreciates OMB's ongoing efforts to improve rulemakings by federal agencies through such actions as the Data Quality Guidelines and the new updated guidance on Cost-Benefit Analysis (CBA). The various federal agencies are working to implement these in their traditional rulemaking processes and the success of this implementation varies substantially from agency to agency.

AWWA supports the Office of Management and Budget (OMB) in its quest for clear and consistent agency practices for developing risk assessments. AWWA commends OMB

for asking the National Academy of Sciences (NAS) for an expert review of this Bulletin. AWWA continues to be concerned with the potential for wide variability in risk assessments between different federal agencies, or even within different program offices within the same federal agency. Therefore, we support OMB in its efforts to develop a transparent risk assessment process for all federal agencies.

The risk assessment issues inherent in this Bulletin are critical for the development of appropriate national drinking water regulations as mandated by the Safe Drinking Water Act (SDWA). The "sound science" language in the SDWA is often referred to as the "gold standard" in several OMB Bulletins, including this Bulletin (page 13), and the risk assessment issues detailed in the Bulletin should assist EPA in meeting the "sound science" criterion as envisioned in the 1996 SDWA Amendments. Due to the criticality of the risk assessment issues, AWWA contracted with Dr. Douglas Crawford-Brown from the University of North Carolina to conduct a detailed review of this Bulletin. Some general comments follow, and his detailed comments are enclosed.

The exact intent of the Bulletin is not completely clear. The goal is clearly to "enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards" (page 3). However, the typical reader may have a difficult time understanding how specific aspects of the recommendations relate to specific stages of a risk assessment (hazard identification, exposure assessment, exposure-response and risk characterization). By contrast, the companion piece to this Bulletin (OMB's Information Quality Guidelines and Information Quality Bulletin) is significantly more explicit on the links between the recommendations and specific practices. The overall quality of reasoning in the present Bulletin, therefore, could be improved significantly by drawing the reader's attention to the key recommendations and their relationship to specific practices in risk assessment.

Overall, the recommendations in the Bulletin are timely, significant, and have implications that will, as the authors hope (again on page 3), ensure that risk estimates and health benefits calculations have "technical quality and transparency…" that "meet high quality standards". While the document refers at several points to improving benefit-cost analyses and cost-effectiveness analyses, the recommendations refer only to the risk calculations and not to the economic analyses. Economic analyses are often as contentious and obscure, particularly in quantifying health benefits, during the decision-making process, as the risk assessments. Presumably, OMB will insist on the same standards of quality for economic analyses as they have for risk assessments in some later document.

For many years, AWWA has been carefully reviewing Cost-Benefit Analyses (CBAs) for national primary drinking water regulations issued by EPA under the Safe Drinking Water Act (SDWA). We have extensively commented on many significant cost-benefit issues in our lengthy comments on EPA's proposals for radon, radionuclides, arsenic, the groundwater rule, and the multiple rules known as the Microbial/Disinfection By-Product (M/DBP) Cluster, which includes the Stage 1 and Stage 2 Disinfectants and Disinfection

Byproducts Rules, the Interim Enhanced Surface Water Treatment Rule, and the Long-Term 1 and Long-Term 2 Enhanced Surface Water Treatment Rules.

The Bulletin contains a number of important principles to improve the scientific basis and decision-analytic basis of risk assessments. These should be highlighted, either by the use of bold text or the use of text boxes, so that the typical reader clearly recognizes these important principles.

If you have any questions about these comments, please feel to call Alan Roberson or me in our Washington Office at 202-628-8303.

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

cc: Ben Grumbles—OW
Brian Mannix—OPEI
Cynthia Dougherty—OGWDW
Pam Barr—OGWDW
Ed Ohanian—OST
Alan Roberson
Steve Via

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Review of the OMB Proposed Risk Assessment Bulletin

Prepared for the American Water Works Association by
Douglas Crawford-Brown
Carolina Environmental Program
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-1105

Specific Comments

1. A key recommendation is somewhat buried on page 3 near the bottom: that "the purpose of an assessment should be made clear before the analytical work begins". This recommendation bears some resemblance to one made by the National Research Council in their second book on risk assessment, Science and Judgment in Risk Assessment (1994), where the NRC claimed that risk assessments done for screening purposes often found their way into final, non-screening, risk calculations. The purpose of the OMB recommendation here is to ensure that the quality of a risk assessment, especially whether it is based on conservative default assumptions or on rigorous analysis of data on exposure and exposure-response, including probabilistic characterization of variability and uncertainty, will be tailored to the kind of decision being made. This mirrors the call by a number of staff within the EPA to include in all risk assessments a description of the decision criteria and decision framework before conducting the assessment. By properly stating the decision criteria first, readers of an assessment can understand the kinds of decisions legitimately supported by a given assessment, and the kinds of decisions that would require more detailed, data-driven, assessments. The OMB Bulletin does not do a very good job of stating HOW this recommendation should be implemented (and so there is danger that the recommendation will be overlooked), but it is an important recommendation nonetheless. They hint at it in the second paragraph on page 4, drawing attention to the fact that a screening assessment may lead to a "more comprehensive assessment", but they never state directly that the decision goal of a screening assessment is not the same as the decision goal of a "more complete assessment". They should be more explicit about this difference.

This raises another point concerning the overall Bulletin: there are a number of key recommendations in here, but the reader's eye is not drawn to them. Perhaps the authors could identify the recommendations they feel are most significant (I have tried to do that in this review), and then provide them in bold or in separate text boxes.

2. The discussion of Types of Risk Assessments beginning on page 5 is odd, and not in keeping with current scientific practice. It is clear that the authors want to draw attention to the fact that parameter values used in risk assessments can have varying degrees of support in existing data. The example they use is the classic distinction between probabilities of effect based on actuarial statistics and those based on extrapolations and models. But the basis for the estimate of the probability (actuarial or extrapolation/modeling) does not make these different "kinds" of risk assessments. It simply changes the epistemic quality (or the reliability) of the resulting predictions. And

then in the section on Failure Analysis of Physical Structures, they refer to "probabilistic risk assessments" as if these are unique to that field, but the meaning of "probabilistic" is different in that field than in human health risk assessment, and both fields have their versions of probabilistic risk assessments. My concern with this entire section is that it is too cursory, leaving the reader with the (perhaps mistaken) impression that the authors haven't done a very thorough review of the risk assessment literature before offering their recommendations. This is compounded by the fact that the authors also don't draw the reader's attention to the question of WHY they are discussing the distinctions between these four kinds of assessments.

This is a very odd classification system. They distinguish actuarial risk, dose-response extrapolation, infectious disease and epidemic modeling, and failure analysis of physical structures. I can find no reason to divide assessments up in this way. There may be a distinction between human health risk, ecological health risk, and technological risk (accident frequency), but dose-response analysis, actuarial assessments and infectious disease modeling are all TOOLS used in human health risk assessment. They are not different categories of risk assessments. The authors need to rethink the purpose of, and categorization scheme used within, this section of the Bulletin.

3. The section on Legal Authority beginning on page 7 is adequate, but oddly out of place. It should appear much earlier in the document, as it sets the stage for all of the other discussions.

4. On page 9, the authors refer to examples of risk assessments, in which they include margin of exposure estimates, etc. This listing suffers from the same problems as in Comment 2 above. Some items on the list (such as IRIS values) are not risk assessments, but rather parameter values that might be used in a risk assessment. The list is a kind of disjoint set, and bears no relationship to the categories of risk assessment described in the section described in Comment 2. The authors need to find a term other than "risk assessment" to cover many of these items that are relevant to risk assessments, and used in risk assessments, but are not strictly risk assessments themselves. The problem may lie in the mandate to OMB to examine "influential risk assessments", and they are trying to include as much material as possible under this mandate. But they could get around this by stating that they are interested in "influential risk assessments" and the supporting science and policy information used in those assessments, rather than re-labeling the supporting information as risk assessments. To do otherwise is to give the impression that the authors don't fully understand the field of risk assessment.

5. On page 9, the authors state that a screening assessment would not have to meet the standard of "neither minimizing nor exaggerating the nature and magnitude of risk". This certainly is true given the decision goal of a screening assessment. But the authors need to make it clear that the upper and/or lower bounds on risk generated by a screening assessment need to have some relationship to PLAUSIBLE upper and lower bounds. Where there is inter-subject variability, these bounds must bear some relationship to points in the tails of underlying variability distributions. The standards for "minimizing" or "exaggerating" risk may not be the same for a screening assessment as they are for a

final assessment, but excessively minimizing or exaggerating risk can make the screening tool unreliable (either everything fails the screen or everything passes the screen, which makes the screen useless).

6. Perhaps the key recommendation from this Bulletin is buried on page 9, in the statement that "…it is expected that every risk assessment shall describe the data, methods, and assumptions with a high degree of transparency; shall identify key scientific limitations and uncertainties; and shall place the risk in perspective/context with other risks familiar to the target audience". Given the centrality of this recommendation, it should be emphasized, again either by placing it in bold or giving it a separate text box. The one problem that arises here is how the assessor is to determine the "perspective/context" given the multi-dimensional nature of risk. A simple comparison of mean risk values in a population, of expectation values of risk, of lifetime excess probability, etc, does not place the risk into proper context. There are a host of other characteristics of risk (the age at which effects occur, the severity of the effects, whether the effects are in special subpopulations of interest, the degree of uncertainty, etc) that are part of the "context" and yet are not captured by any single risk metric. Perhaps it is too much detail to include in this Bulletin, but the authors could offer more insight into appropriate ways to make a comparison between different sources of risk when there are many different characteristics to consider.

But the answer to this problem might be related to the earlier call for the assessor to state clearly the decision criteria that will be applied to the results of an assessment. If the decision criteria specified by an assessor state that the decision will be based on some specific characteristic of risk (e.g. the expectation value of the fraction of people who have an excess probability of cancer above 1E-4), then this is precisely the characteristic used in framing the context of the assessment and making comparisons with other sources of risk.

7. The statement on page 10 that the Bulletin does not apply to product labeling may be strictly correct legally, but it will strike the reader as odd and perhaps politically motivated (due to the connection to commerce) without further explanation. Presumably, such assessments SHOULD satisfy the same criteria applied to other risk assessments, especially when decisions on these commercial applications have some basis in risk assessment. These assessments and decisions might lie outside the mandate of the OMB, which would be a legitimate reason to exclude them, but this isn't clear from the document.

8. The five categories of goals in Section III (problem formulation, completeness, effort expended, resources expended and peer review and public participation) are good ones to highlight, but the reader is left wondering whether something more is going to be said about them later. The section comes across as cursory. Perhaps there is nothing more the OMB wishes to say on these issues, leaving it to the individual assessor or agency to interpret how these goals will apply in specific cases, but this should be stated directly. Otherwise, the reader is left with the impression that the goals have been left rather vague because they will give the OMB the most discretion possible in interpreting whether the

goals have been met by specific assessments they will be asked to review at some point. The laudable injunction to be transparent in assessments should also apply to the specification of goals and criteria in the OMB document.

9. Section IV does a better job of making specific recommendations than does Section III. The OMB might consider some guidance in IV.2 (Standards Relating to Scope) on the issue of risk-risk tradeoffs. Presumably, the scope of a risk assessment would constrain or enhance the ability to consider the trade-off of risks that inevitably accompany regulatory and other management decisions. But this issue is not current raised in this section. At least some mention of the issue of trade-offs, and how this relates to scope, is warranted.

Later in this subsection (on page 13), the authors mention "the causative role of other factors in producing the disease of interest". This discussion needs to be enhanced. There are confounding factors that must be dealt with using specific methodologies. There are other routes of exposure that must be considered through a second set of methodologies (e.g. aggregate exposure assessment). There are factors that affect sensitivity that require yet a third set of methodologies (e.g. those of attributable risk). The discussion in this paragraph is important and so deserves more careful thought and detail.

10. On page 13, in Section IV.3, the authors raise the important issue that quantitative characterizations of risk should contain a "range of plausible risk estimates". The focus in the discussion seems to be on the need to produce a range rather than point estimates, and that is a good recommendation in and of itself, but it is equally important to focus on the term "plausible". The authors might consider a few additional comments on what is meant by plausibility, referring to both the inter-subject variability and uncertainty aspects of risk characterization.

11. Another important recommendation, albeit a bit buried, in this subsection is the call to include …"peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk]…". There are two aspects to this recommendation. The first is the need to consider all studies and not just those showing effects. The call here presumably is to some form (quantitative or qualitative) of meta-analysis. This should be emphasized, as methods for such meta-analyses are now well established and can improve the current state of risk assessment, which too often culls information rather than reflecting the full body of data. Equally important, and perhaps leading to more contention, is the call for "peer-reviewed" studies. It is not completely clear why the authors have included this phrase. It must be based on the claim that peer review is central to the judgment of scientific validity, although they would be hard pressed to support that claim in the literature on the philosophy of science. The problem here is that many studies, while very useful in a risk assessment, may not warrant publication in the scientific literature, which already is struggling to accommodate all of the calls for publication. The important criterion here should be the quality and reliability of a study, rather than using peer review as a surrogate for these characteristics. Perhaps the authors are thinking that peer review is called for under the Daubert rules in law, which is a common interpretation, but there is nothing in those rules that makes such an explicit call. The call is instead to methods demonstrated to be reliable, and general

acceptance by the scientific community. In any event, this call for a focus on peer-reviewed studies deserves greater explanation in the Bulletin. The same issue arises in section IV.4.

12. Page 15, section IV.5, raises a potentially significant issue of the use of scientific judgment in a risk assessment. The call here is to include the full range of scientific opinion. This is a valid recommendation, but requires some nuance. There are opinions held by all scientists, by the majority of scientists, by a minority of scientists, and by a single scientist. This section appears to fail to distinguish these cases. The classic example is climate change, where there certainly is a range of opinions, but where the "climate skeptics" constitute a group that is tiny compared to the opposing view. I assume the OMB does not intend to have these two views weighted equally in the "range of scientific opinions". More detail is needed in this section so the reader can determine how the validity of specific scientific opinions, including the DEGREE of support for a given position in the scientific community, is to be reflected in an assessment.

13. On page 15, in section IV.7, the authors refer to the benefits and costs of a rule. Perhaps it is outside the scope of this Bulletin, but further guidance on what is to be meant by benefits and costs seems in order here. The natural questions this issue raises are: Benefits and costs to whom? Are the costs to be estimated under classical microeconomic approaches? Are they to reflect macroeconomic considerations? If the latter, what are to be the boundaries of the macroeconomic assessment?

14. In section IV.7.1, the authors might draw the reader's attention more clearly to the issue of comparative risk. This also is a good point at which to introduce the idea of the precautionary principle as it is viewed by the European Commission, which calls for an explicit comparison of the risk of a given compound or product against the risk that will occur if alternatives are applied. This would help move the U.S. regulatory community away from the current focus on building in margins of safety for a given source of risk and over to issues of risk tradeoffs that are at the heart of EC interpretations of the precautionary principle.

15. In section V.3, the authors give a rather cursory reference to the use of "qualified experts" to provide "central or expected estimates of risk in the face of model uncertainty". This is a very contentious issue in both risk assessment and the philosophy of science and deserves greater attention here. It is not clear what the authors intend by this statement. Is the suggestion that expert judgment can be used to assign measures of confidence to models? Can experts provide subjective judgments of probabilities of effect? More detail is needed here. Otherwise, the section seems to be a disguised call for greater use of expert elicitation as a substitute for careful, data-driven, scientific analysis.

16. In section V.4, on page 18, the authors also call for use of alternative plausible models. This is a good recommendation, but also requires consideration of the quality of models. Two models may be plausible, but not EQUALLY plausible. It is not clear in this section how the authors intend for this distinction to be reflected in an assessment. They presumably mean to have some sort of weighting process when they call (later on that

page) for a “central or expected estimate of risk (that) may be a weighted average of the results from alternative models”. Many risk assessments would have substantially altered (often lower) risk estimates if such model weighting were to take place, and so this issue deserves some more thought in the document.

17. On page 20, the authors mention that risk refers to the “possibility of an adverse consequence”. Perhaps it is outside the scope of this document, but this seems a good point at which to introduce the idea of harmonizing the cancer and non-cancer risk assessment methodologies. Only the former currently reflect fully the idea of possibility, and yet tools are now available to make non-cancer risks also probabilistic.

18. In that same section, in the third paragraph, the authors raise another important issue that deserves a slightly enhanced discussion: the distinction between effects and adverse effects. This distinction often accounts for the major differences of opinion between risk estimates, especially for non-cancer effects, and so the recommendation should be highlighted in the Bulletin and some guidance given as to what the OMB will expect as evidence for an effect being judged adverse.