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Alan Roberson <aroberson@awwa.org>
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cc:
Subject: Comments on draft report

Enclosed are comments by the American Water Works Association on the 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations. If you have any questions about these comments, please feel free to call.

J. Alan Roberson, P.E.
Director of Regulatory Affairs
American Water Works Association
1401 New York Ave. NW, #640
Washington, DC 20005
Phone: (202) 628-8303
Fax: (202) 628-2846
Email: aroberso@awwa.org

- Comments on OMB Benefit Cost Report for 2004.doc

American Water Works Association

Government Affairs Office
1401 New York AVE, NW, Suite 640
Washington, DC 20005
(202) 628-8303 Fax: (202) 628-2846

May 20, 2004

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202
725 17th Street, N. W.
Washington, DC 20503

RE: Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations

Dear Ms. Hunt,

The American Water Works Association (AWWA) appreciates the opportunity to review and comment on the Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations as published on February 20, 2004 (69 Federal Register 7987).

The American Water Works Association (AWWA) is an international non-profit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Our over 57,000 members include more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water. We appreciate your review and consideration of the attached comments. We would also appreciate feedback from the agency on these comments.

If you have any questions regarding this letter or the attached comments, please contact me or Alan Roberson at (202) 628-8303.

Best regards,

Thomas W. Curtis
Deputy Executive Director

cc: Cynthia Dougherty—USEPA OGWDW
Ephraim King—USEPA OGWDW
Kim Nelson—USEPA OEI
Andy Battin—USEPA OEI
Al McGartland—USEPA OPEI

Headquarters Office:
6666 W. Quincy Avenue, Denver CO 80235
(303) 794-7711 Fax (303) 347-0804
http://www.awwa.org

COMMENTS BY THE AMERICAN WATER WORKS ASSOCIATION ON THE DRAFT 2004 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS, NOTICE AND REQUEST FOR COMMENTS

(February 20, 2004, 69 FR 7987)

INTRODUCTION

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, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water.

The comments provided herein reflect the consensus of the AWWA that, given the depth and breadth of its representation, also reflect the predominant view of the nation's drinking water professionals. It is therefore appropriate that these AWWA comments be heard on behalf of the drinking water community in general.

GENERAL COMMENTS

AWWA is pleased to submit this set of comments on the Office of Management and Budget's (OMB) *Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations,* as printed in the February 20th *Federal Register* (69 FR 7987). AWWA has commented on the previous OMB reports, and appreciates OMB's efforts to improve rulemakings by federal agencies through such actions as the Data Quality Guidelines and new updated guidance for Cost-Benefit Analyses (CBAs). Agencies are working to implement these in their traditional rulemaking processes and the success of this implementation varies substantially from agency to agency.

AWWA is dedicated to providing safe drinking water to the American public, and recognizes 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.

This Draft Report does not specifically address any drinking water regulations, as EPA did not finalize any drinking water regulations between October 1, 2002 and September 30, 2003. EPA's most recent final drinking water regulations were the radionuclides rule in December 2000, the arsenic rule in January 2001, and the Long-Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) in January 2002. EPA proposed the Stage 2 Disinfection By-Products Rule

(DBPR) and the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) in August 2003, and is planning to finalize these rules in mid-2005.

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.

We have also taken a look backwards at the CBAs in the final drinking water regulations. We were an active participant in the 2001 review of the arsenic regulation, and still have some unresolved concerns with the differences in the cost curves between different versions of EPA documentation on this rulemaking. As part of developing comments on EPA's proposed rules, the drinking water community as a whole has invested thousands of member manhours and spent millions of dollars with the hope of improving the regulatory development process. EPA has made some improvements in the quality of its CBAs for drinking water regulations. However, despite considerable efforts by Association staff, members, and experts on AWWA's behalf, and some improvement from EPA, significant concerns remain about many of the CBAs developed by EPA for drinking water regulations.

Judicious use of Cost-Benefit Analysis (CBA) is an important tool for evaluating rulemakings, but especially so for regulations issued under the Safe Drinking Water Act (SDWA). The 1996 SDWA Amendments have elevated the importance of CBA by providing explicitly for the consideration of costs and benefits in the development of drinking water standards. The 1996 SDWA Amendments are the benchmark for both OMB and EPA for the quality and dissemination of the data underlying the regulatory development process. AWWA commends OMB for its incorporation of the CBA language in the 1996 SDWA Amendments as the benchmark for information quality and dissemination standards for federal agencies to use in CBAs for their respective rulemakings. AWWA and its member utilities worked hard to include this specific language in the 1996 SDWA Amendments to ensure that the regulatory process was not hidden behind statistical "smoke and mirrors". EPA has made progress in meeting these information quality and dissemination requirements in its recent rulemakings, but more work is still needed.

Frustration is starting to grow within the drinking water community with the slow progress in meeting those requirements. Frustration is continuing to grow with the lack of a comprehensive implementation plan to continually improve CBAs to move close to the goals underlying those requirements. Some of our CBA comments have been incorporated in recent EPA rulemakings, but many comments have not been addressed and/or the response has been superficial in some cases. Overall, while EPA's CBAs have improved in recent rulemakings, there is still a lot of room to improve.

Hence, the concerns raised here are not only about how benefits and costs are estimated, but also about how they are compared to one another and interpreted in the standard setting context. Further, because the consumers who receive the benefits of drinking water standards are also the

same group that will bear the costs, it is especially important that the CBAs clearly and accurately reflect the risk/cost tradeoffs that regulations will impose on them.

AWWA understands the difficulties and frustrations of trying to evaluate federal agency CBAs for national regulations. AWWA commends OMB for its efforts in assembling and reviewing the complex issues associated with reviewing the entire federal regulatory program. However, most of EPA's drinking water CBAs have been difficult to review or replicate, and/or appear to be in error in several respects. Additionally, in certain respects, a number of EPA's CBAs also have not conformed to the explicit requirements of the SDWA (notably, CBA-related provisions under various portions of Section 1412). These include:

- Lack of transparency, replicability, and consistency. In several instances, it is difficult or impossible to follow the Agency's analyses. Key citations are not always made available (or refer back to other documents until the trail ends short of the key facts). Results from intermediate steps are not always provided, so it is impossible to "put the pieces together" to determine the source of numerical discrepancies. The General Accounting Office (GAO) faced similar difficulties in its 2002 review of the radon regulation (GAO, 2002). This means that in certain instances the public must accept the EPA estimates on faith. This is at odds with sound practice, and also does not conform to the SDWA requirement for public information [Section 1412(b)(3)(B)].

  There also has sometimes been a lack of consistency among studies in terms of data, methods, or assumptions applied. Inconsistency would not be a problem if the changes over time reflected a steady evolution toward improved methods and data. Regrettably, this is not the case for the CBAs coming out of EPA's Office of Groundwater and Drinking Water (OGWDW).

- Reliance on overly conservative assumptions and default values when estimating benefits. In the face of uncertainty, risk assessors traditionally apply the "precautionary principle" in determining what exposure levels are "safe." This is done through use of uncertainty factors, reliance on upper confidence limits and a linear dose-response model for carcinogens, and the application of other practices that are intentionally designed to avoid understating risk. The use of the precautionary principle is perhaps suitable in defining a risk-free goal such as an MCLG. For other purposes, however, it is inappropriate for risk assessment to include such conservative policy judgements.

  For its CBAs, EPA should provide unbiased estimates of risk that are in turn suitable for risk *management* applications such as the use of CBA in standard setting. Otherwise, the risk assessments will lead to a considerable overstatement of benefits. The degree to which benefits are overestimated (if at all) will vary considerably from the contaminant to contaminant, depending on many factors. The General Accounting Office (GAO) nicely summarized these issues surrounding regulatory and other policy decisions that are not always based on the best (most accurate) science information available (i.e., the most likely or central tendency estimates of risks and benefits) (GAO, 2000).

  Additionally, benefits analyses need to reflect "best estimates" (or suitable probability

distributions) for key exposure, dose-response, latency period, and benefits valuation issues. This is not only sound economics and policy analysis, but it also is required under the SDWA [Section 1412 (b) (3) (B)]. AWWA and other drinking water associations have made such recommendations in comments on EPA's recent drinking water proposals. Unfortunately, EPA appears to be hesitant to incorporate these recommendations in its final CBAs for final drinking water regulations.

- Reliance on national *incremental* comparisons of benefits to costs. EPA is beginning to show national incremental CBAs in its final drinking water regulations, along with the traditional comparison of total benefits to total costs in evaluating MCL options. This is a significant step forward in meeting the requirements of SDWA Section 1412 by comparing incremental benefits to incremental costs and maximizing net social benefits. Additionally, EPA needs to develop multiple incremental CBAs, using its system size categories. Small systems in particular feel the increasing impacts of compounding regulations such as the radon rule, the arsenic rule, and the groundwater rule. A comparison of total benefits and costs by each individual system size, as opposed to incremental benefits and costs by each of the major size categories (large, medium, and small), indicates only whether or not a rule is a break-even proposition. This is an insufficient basis for choosing whether or not to regulate, or how stringently to set the standard.

- Reluctance to use "state of the art" measures of risk reduction benefits, such as "Life Years Saved" (LYS) or other alternative measures. Reduced risks of premature fatalities need to be viewed in the context of the amount of increased longevity (years of life extension) provided by a regulation. This provides a more meaningful way to interpret regulations, some of which may reduce premature fatalities early in life, and others that are aimed more at risks faced late in life. EPA's Office of Groundwater and Drinking Water (OGWDW) has steadfastly adhered to the more generic, less informative "lives saved" approach, even though other EPA offices (in its own Clean Air Act analysis) and other federal agencies (e.g., FDA) have published more informative CBAs using the LYS approach.

  EPA has not used LYS in drinking water regulations for many reasons, including that the Science Advisory Board (SAB) raised some concerns with valuing LYS on the basis of adjusting estimates of the Value of a Statistical Life (VSL). Nonetheless, even if there are concerns about developing a monetary estimate of the value of a statistical life year (VSLY), this is no basis for refusing to at least quantify the degree of life extension provided by regulatory options developed under the SDWA regulatory program.

- Incorporation of latency periods and discounting estimated benefits. There is clear economic rationale for applying suitable latency scenarios to evaluate health effects that tend to manifest many years after exposure (as is typical of many cancers), and then discounting back to present value. EPA and OMB *Guidelines* point this out, and indeed an EPA Science Advisory Board (SAB) published a report (June 2000) reiterating the legitimacy of this practice. The EPA SAB again recommended using a cessation-lag concept in its review of the benefits from the arsenic regulation (August 2001). Admittedly, EPA is starting to alter its traditional approach of direct benefits transfer of VSL results without making these suitable adjustments for latency and discounting. In the past, EPA assumed that all benefits

accrue immediately with implementation of its rules, whereas this is clearly not the case for most carcinogens or other compounds that pose chronic risks. EPA is starting to account for latency in its latest drinking water regulations, and this practice needs to become consistent for future rulemakings.

- Lack of more systematic approaches for considering unquantified benefits and costs within CBA and standard setting. In some instances, important benefits or costs may not be readily quantified or portrayed in dollar value terms. In these instances, the unquantified or omitted benefits and costs need to be suitably considered in the regulatory decision-making process -- they should neither be ignored nor given undue weight. Again, EPA's SAB recommended that EPA take a harder look at unquantified benefits in its review of the benefits of the arsenic rule (August 2001). EPA's CBAs for drinking water standards have sometimes failed to use available information on unquantified outcomes in an informative manner, despite examples being provided to the Agency.

- Unwillingness to more adequately consider the affordability of rulemakings. EPA focuses only on median household incomes, and does not adequately consider the cumulative impact of multiple pending regulations on household water bills. This is a particular concern when considering low income households and residents of smaller communities. EPA's arsenic affordability study makes several recommendations that need to be implemented as soon as possible into future rulemakings (March 2002). EPA has established an Affordability Workgroup under the National Drinking Water Advisory Council to provide more detailed affordability recommendations. How EPA will incorporate these recommendations into future rulemakings is not yet clear.

- Masking significant regional economic impacts under a national context. Several SDWA regulations have regionalized impacts due to contaminant occurrence being concentrated in a few geographic areas (e.g., uranium, radium). The regional impact of these rules can be significant, but this important perspective is masked when the Agency uses only a national aggregate analysis which makes the issue seem modest Again, EPA's recent arsenic affordability recommends investigating the feasibility of regional analyses, and this needs to be implemented as soon as possible (March 2002)

All of above recommendations (and more) are part of the recommendations in one of the following four recent reports on drinking water regulatory actions:

- *Report to Congress: Small Systems Arsenic Implementation Issues* (March 2002)
- *Drinking Water: Revisions to EPA's Cost Analysis for the Radon Rule Would Improve Its Credibility and Usefulness* (GAO, February 2002)
- *Report of the Arsenic Cost Workgroup to the National Drinking Water Advisory Council* (August 2001)
- *Arsenic Rule Benefits Analysis: An SAB Review* (August 2001)

While the recommendations from these reports (and other reports dating back several years) have been known and well articulated for several years, EPA needs to fully incorporate these recommendations in its drinking water CBAs. EPA took some small steps in addressing these recommendations in the proposed Stage 2 Disinfection By-Products Rule (DBPR) and the Long-

Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). The regulatory structure for these rules was approved through a lengthy Federal Advisory Committee (FACA) process. Therefore, the incorporation of all of these recommendations will not have any impact on options for these specific standards, but rather, will ensure that the CBAs are of the highest quality possible.

However, EPA still fell short in incorporating these recommendations in the proposed Stage 2 DBPR and LT2ESWTR. The EPA Economic Analysis (EA) supporting the Stage 2 DBPR entailed an analytical process with 13 distinct steps. In reviewing this analysis, AWWA found significant issues affecting the reasonableness and credibility of the final conclusion in nearly every step. Some of the most serious problems were as follows:

1. The SWAT model was likely to mis-estimate changes in number, duration, and levels of TTHM and HAA5, and in particular the occurrence of "peaks" above 80 µg/ L TTHM and 60 µg/L LRAAs, especially relative to Stage 2B DBPR compliance monitoring sites.
2. EPA may have substantially overestimated mean water consumption by 30% to 50% or more if one accounted for averting behavior and used CWS-based USDA distribution of tap water ingestion.
3. Even if EPA's "illustrative" reproductive / developmental benefit analysis were appropriate, the agency's interpretation of the ICR data overstated the risk estimate.
4. EPA's use of linear dose-response function for DBPs was inconsistent with agency's cessation-lag premise on promoting agents (i.e., nonlinear dose-response).
5. Toxicological evidence suggested far fewer cases avoided (e.g., <10%) than the agency's epidemiological premise for bladder cancer risk, which lacks causal association.
6. Fetal loss evidence was not suitable for quantification, and empirical illustration was based on erroneous interpretation of ICR data.
7. EPA's estimate of willingness to pay to reduce risk of nonfatal bladder cancer, based on percent of value of a statistical life, required greater scrutiny, and key documentation for underlying study by Magat *et al.* was unavailable for review.
8. Cessation lag based on tobacco smoking and lung cancer probably was inappropriate and too short for DBPs and bladder cancer.

The Economic Analysis for the proposed LT2ESWTR had similar shortfalls. The Economic Analysis (EA) and associated support documentation offered extensive detail and information. However, EPA needed to find a better balance in the support documentation so that it provided not only complete, but also the most critical information to interested and involved parties. To find this balance, EPA should use more fundamental, informative, and simple analyses of core components rather than using more sophisticated approaches for some less important aspects of the EA.

In some critical elements of the EA, the agency made powerful assumptions that could have significant impacts on the final results of the EA. The agency did not always clearly articulate what assumptions are being made and often presented a one-sided view of relevant uncertainties and data limitations to derive its interpretation. In some instances where the agency made key assumptions, the supporting analysis lacked sensitivity analyses based on equally or more plausible alternative assumptions.

Our major observations and findings with respect to the EA included:

1. Overall, we believed EPA considerably overstated the occurrence and risks associated with endemic levels of cryptosporidium in finished waters, and thus the agency overstated the benefits of the proposed rule to a considerable degree. The costs of the rule may also be overstated to some degree.
2. The ICRSS data indicated a much smaller percentage of systems will end up in bins 3 and 4 under the proposed rule than do the analyses based on the ICR data, implying that the net benefits (benefits minus costs) of the proposed rule may be 20% of the high end estimates shown by EPA (all else equal). The ICRSS data would be better predictors than the ICR data of what the impact of the rule would be as proposed.[1]
3. EPA applied a Bayesian interpretation to the ICR and ICRSS data that was suspect and driven by unsubstantiated and perhaps extreme assumptions. For example, EPA imposed an assumption that only 1 out of every 1000 "zeroes" observed in the database is truly a zero. The agency estimated occurrence and risk based on a presumption that 999 out of every 1000 observed zeroes in the database were instead, one oocyst or more.
4. EPA's exposure assessment was based on considerably over-estimated levels of direct ingestion of CWS-provided waters. Relevant exposures (and, hence, risks) may be overstated by a factor of 2 or 3 when direct ingestion rates for CWS waters, and increased bottled water use, are properly considered.
5. The infectivity dose-response relationship applied by EPA was subject to considerable uncertainty and probably overstated the risk associated with exposures to an infectious oocyst by a significant degree.
    a. The underlying clinical studies used extremely high doses relative to oocyst levels in finished waters (levels of oocysts ingested of 23,000 to 2.3 billion times higher than now found in finished waters) and relied on extremely small number of subjects and strains (between 14 and 29 subjects, for each of only 3 strains).
    b. The results of the clinical studies were interpreted liberally, based on a "presumed infection" approach that assumed that any subject with symptoms had cryptosporidiosis, even when several of the symptomatic

[1] The ICRSS data are more indicative of what the rule's impacts will be because they (1) probably are more accurate than the ICR data (ICRSS results are based on Method 1622/1623 with higher recovery rates than the IFA method applied in the ICR data) and (2) reflect the method (1622/1623) that utilities will apply in their compliance monitoring.

subjects had no documented infection (e.g., via positive oocyst shedding). EPA's risk estimates were overstated to the extent that reported symptoms could be attributable to causes other than cryptosporidiosis.

c. The results of the clinical studies were interpreted via complex statistical models that were driven by -- and highly sensitive to -- unsubstantiated assumptions. While the modeling approaches used by EPA in the EA were suggested by the SAB, the obscurity of the presentation and the sensitivity of the results to the model assumptions (e.g., increasing a key estimated mean risk parameter by a factor of 4 or 5 over the level found in the peer reviewed published literature) revealed the need for more transparency, continued scientific discourse, and greater use of sensitivity analyses in portraying the possible risk levels.

6. The extent by which EPA's risk model overstated risks can be viewed, in part, by comparing the agency's estimated number of waterborne cases of cryptosporidiosis at the pre-LT2 baseline to its estimated reduction in cases due to the proposed LT2 rule:

   a. EPA estimated the pre-LT2 baseline (i.e., post IESWTR) is between 60,000 and 111,000 cases per year.

   b. The agency's risk model used for the LT2 rule benefit-cost analysis predicted 256,000 to over 1,000,000 cases per year will be avoided due to the rule as proposed.

   c. Therefore, EPA estimated a reduction in cases that is up to 9+ times higher than the number of cases it stated existed at the baseline.

7. EPA should explore the soundness and implications of its questionable assumption that the risk of illness (as well as severity and duration of illness) was independent of dose. The morbidity assessment -- used to project the number, severity, and duration of illnesses due to a possible infection – was based exclusively on results from the Milwaukee outbreak of 1993, where oocyst levels were much higher, exposure durations much longer, and opportunities for secondary spread and exposure more pervasive than anticipated under the endemic low dose exposure context addressed by the proposed rule.

8. EPA's use of an "enhanced" cost of illness (COI) approach to value avoided cases of nonfatal cryptosporidiosis was highly problematic. The approach was a significant departure from standard economics practice, did not appear to have been subjected to expert peer review, and yielded results that seem implausible and unrealistic compared to other well-established risk valuation benchmarks.

9. EPA's presentation of regulatory costs and benefits was overly aggregated, and failed to reveal how affordability and net benefits vary across system size categories or across other relevant program elements in the proposed rule (e.g., reservoir covering, filtered versus unfiltered systems).