American Water Works Association
Government Affairs Office

Dedicated to Safe Drinking Water

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May 28, 2002

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street NW
Washington, DC 20503

Re: Comments on the Draft Report to Congress on the Costs and Benefits of Federal Regulations

Dear Mr. Morrall:

Enclosed are the official comments by the American Water Works Association (AWWA) on the Draft Report to Congress on the Costs and Benefits of Federal Regulations as published in the March 28th *Federal Register* (67 FR 15014). AWWA appreciates the opportunity to comment on these important issues on Cost-Benefit Analyses (CBAs)

If you have any questions about these comments, please feel free to call me or Alan Roberson in our Washington Office.

Yours Sincerely,

Thomas W. Curtis

Thomas W. Curtis
Deputy Executive Director

Enclosures

cc: Ben Grumbles—USEPA OW
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COMMENTS BY THE AMERICAN WATER WORKS ASSOCIATION ON THE DRAFT REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS, NOTICE AND REQUEST FOR COMMENTS

(March 28, 2002, 67 FR 15014)

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 4,300 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 (OMB) draft *Report to Congress on the Costs and Benefits of Federal Regulations,* as printed in the *Federal Register* (67 FR 15014). 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.

For many years, AWWA has been carefully reviewing Cost-Benefit Analyses (CBAs) for federal rulemakings issued by EPA under the Safe Drinking Water Act (SDWA). We have extensively commented on many significant cost-benefit issues in our comments on the proposals for radon, radionuclides, groundwater, and arsenic. Appendix A of these comments details some of our concerns with these specific regulatory proposals. Appendix B is a detailed retrospective look at the uranium regulation. Appendix C is a recent report by the Awwa Research Foundation (AwwaRF), *Quantifying Public Health risk Reduction Benefits*. AWWA, AwwaRF, and the drinking water community as a whole have invested thousands of member manhours and spent millions of dollars with the hope of improving the regulatory development process. 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 on 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 becoming the benchmark for both OMB and EPA for the quality and dissemination of the data underlying the regulatory development process. 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. Appendix D is a copy of a technology and cost review from the recent arsenic Notice of Data Availability (NODA). This report details the differences in cost curves between different versions of EPA documentation on this rulemaking. This is typical for EPA's drinking water CBAs.

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 Government Accounting Office (GAO) faced similar difficulties in its recent review of the radon regulation (February, 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.

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)].

- Reliance on national *incremental* comparisons of benefits to costs. EPA is beginning to show national incremental CBAs in their 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 incremental CBAs by system size, especially as small systems are impacted by compounding regulations that particularly impact small systems such as the radon rule, the arsenic rule, and the groundwater rule. A comparison of total benefits and costs by system size indicates only whether or not a rule is a break-even proposition, and 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). 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 because 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.

- Unwillingness to account for latency periods and discounting estimating 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 their review of the benefits from the arsenic regulation (August, 2001). Nonetheless, EPA has been slow to alter its traditional approach of direct benefits transfer of VSL results without making these suitable adjustments for latency and discounting. In effect, for drinking water EPA assumes 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.

- 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 recent arsenic affordability study makes several recommendations that need to be implemented as soon as possible (March, 2002).

- 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 act upon these recommendations to improve their drinking water CBAs. The upcoming proposals for the Stage 2 Disinfection By-Products Rule (DBPR) and the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) could provide a forum to act upon many of these recommendations. The regulatory structure for these rules was approved through a lengthy Federal Advisory Committee (FACA) process. Therefore, the incorporation 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.

SPECIFIC COMMENTS

Page 15017, An Open Approach to Centralized Regulatory Oversight
AWWA supports OIRA's increased openness in their regulatory oversight. From a user's perspective, the increased information on the OIRA website is welcomed, and we commend OIRA for their efforts

Page 15019, SDWA as the Benchmark
AWWA supports OIRA in their efforts to make federal agencies responsible for health, safety, and environmental regulations using the basic information quality and dissemination standards in the 1996 Safe Drinking Water Act (SDWA) Amendments. AWWA and its member utilities strove to include this specific language in the 1996 SDWA Amendments to ensure that regulatory process was not hidden behind statistical "smoke and mirrors". EPA has made great progress in meeting these information quality and dissemination requirements in their implementation of the 1996 SDWA Amendments. However, frustration is starting to grow with the slow progress in meeting those requirements and the lack of an overall implementation to continually improve CBAs to move closer to the goals underlying those requirements. Overall, EPA's analyses for drinking water regulations have improved since the 1996 SDWA Amendments, however, there is still a lot of room to improve on these analyses.

Page 15019, Use of peer review, expert panels, and third party reviews
OMB makes reference to the importance of expert peer reviews, and points out the value added by the various expert panels that have reviewed the cost and benefit issues associated with the federal regulation for arsenic in drinking water (e.g., the work by the National Research Council on risks, the Science Advisory Board on benefits, and the National Drinking Water Advisory Council on costs). AWWA agrees that serious and objective reviews by third parties, expert panels, and other government entities (e.g., GAO) are extremely valuable ways to help ensure that benefit-cost analysis are transparent, objective, credible, and based on sound science and best practices.

AWWA would like to point out that the use of peer review and expert panel processes is only valuable to the extent that federal regulatory agencies (e.g., EPA) are willing to adhere to the points raised by these reviewers. In some cases, EPA does not agree with

the recommendations of these panels (for reasons that are not always clear) and does not implement those specific recommendations. It also is important that agencies not use peer reviews as a mechanism to delay making appropriate improvements to their analyses.

For example, the issue of accounting for latencies in cancer risks, and applying suitable discount rates to these future risk reductions, has been raised many times in public comments and by expert panels. Two separate SAB panels have provided written recommendations that EPA duly account for latencies (and cessation lags) and then discount these future benefits to their present value -- one being the Environmental Economic Advisory Committee (SAB, June 2000), and the other the Arsenic Rule Benefits Review Panel (SAB, August 2001). Even though the SAB recommendations were clearly stated as early as June 2000, subsequent EPA analyses of drinking water rules have yet to reflect these improvements.

Page 15019, Arsenic Example
AWWA notes with some amusement that EPA's decision to reaffirm the arsenic standard at 10 ppb is cited as an example of exemplary peer review. AWWA agrees that the health effects review conducted by the National Academy of Sciences (NAS) and the benefits review conducted by the Science Advisory Board were excellent examples of peer review.

However, the treatment cost review conducted by a workgroup under the National Drinking Water Advisory Council (NDWAC) was another story. The limited timing allowed for this review precluded any substantive technical analyses. Some of the workgroup members felt that EPA pressured the workgroup to reach pre-determined conclusions and to include specific language in the final report.

Page 15019, Use of SBREFA
The timing of SBREFA reviews in the regulatory development process really doesn't work that well. The SBREFA panels have not been that effective, as the regulatory information presented is typically vague based on where the Agency is in the regulatory development process. Regulatory options are not that well-defined in the early part of this process.

Page 15021, Promoting Data Quality and Transparency
A key component of enforcing the mandate that Agencies conduct credible and objective benefit-cost analysis is to provide effective administrative procedures that ensure that suitable data and methods are applied in these analyses. Toward that end, AWWA supports efforts by OMB to promote transparency and ensure data quality, and AWWA plans to review with interest EPA's draft *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA.*

AWWA notes with great concern that EPA's draft *Guidelines* state that data quality reviews related to rulemakings will NOT generally be allowed under the information review process. EPA's rationale is that the public comment periods provide suitable venue for previously airing these concerns. The problem is that EPA's analyses are often

too complex and lacking in transparency to fully address these issues within the limited public comment periods allotted. In addition, EPA has often chosen to substantively ignore data quality and transparency issues raised in submitted comments, and stakeholders have no recourse in such situations.

Therefore, AWWA is concerned that EPA's draft *Guidelines* do not offer any real opportunity for correction of Agency information. Our understanding of the OMB guidelines was to ensure data quality and transparency all the way through the regulatory development process to the final rule. EPA's draft process eliminates the opportunity to seek administrative remedy to Agency information for EPA's actions for which a public comment period was provided. This essentially eliminates the opportunity to seek correction of information of any final rule in which the proposal allowed for a public comment period, which is essentially any EPA rulemaking.

AWWA has been frustrated over the past several years with the lack of transparency in EPA's analyses and EPA's unwillingness to respond more constructively to data quality and transparency critiques offered in public comments submitted as part of rulemaking procedures. Accountability in the rulemaking process is an issue that the Agency needs to begin to take seriously. Hence, a critical element in the *Guidelines* will be an effective administrative procedure to fairly review data quality issues that are not suitably addressed by the Agency in its response to public comments.

The General Accounting Office (GAO) critique of the EPA's radon rule cost estimates is revealing in terms of the potential limits of relying only on the comment period to raise data quality issues. GAO had 6 months or longer to review and critique EPA's cost analysis. GAO also had ample access to EPA staff and materials with which to facilitate their review. Even so, GAO found EPA's analysis lacking in transparency and replicability (along with other shortcomings). For a stakeholder organization like AWWA that has to respond with critiques within 60 day public comment periods, the problem is magnified.

There is a clear need to have an open and constructive administrative review process on data quality and transparency issues, regardless of whether the issue could have been (or was) previously raised in rulemaking-related comment periods. In particular, there is a need for a process through which dismissive responses to such public comments can be reviewed and rectified.

Page 15021, Specific Analytic Issues
AWWA generally supports this listing of analytic issues, as AWWA has commented on multiple proposals that such issues should be appropriately addressed in regulatory analyses.

Discounting: A 7% real rate of discount is a reasonable value to apply as a baseline scenario. Additional sensitivity analyses can reveal how alternative justifiable rates would impact results. It also is important to distinguish discount rates as used to reflect

the opportunity cost of capital (as in annualizing capital investment costs) versus the social rate of time preference (as may be applicable in some present value applications).

Latency: As noted elsewhere in these comments, it is imperative that agencies consider the timing of risk reductions where latencies apply. Some care will be required to consider where latency applies and where cessation lags apply (the former being applicable to policies that affect individuals with little accumulated lifetime exposure, and the latter for polices that affect those with considerable accumulated lifetime exposures). Many rulemakings will require some blending of these concepts, based on the age distribution of the exposed population.

Methods to evaluate risks of premature fatality: AWWA suggests strong consideration of "Life Years Saved" (LYS) as a standard metric to be adopted in all analyses (along with more traditional estimates such as the number of premature fatalities avoided). The LYS approach is a useful metric to provide to stakeholders and decision-makers, especially in a cost-effectiveness context (incremental cost per LYS). The LYS may also be applied with (or without) accompanying valuation (i.e., there is debate over the value of a LYS). The LYS approach also leads to the possible application of quality-adjusted life years (QALY), although additional work is required to make the QALY scores less subjective.

Central tendency risks: AWWA applauds OMB for its interest in promoting (and hopefully enforcing) the presentation of central tendency estimates for risk assessments as applied in benefit-cost analyses. The use of precautionary assumptions in most risk assessments otherwise leads to highly distorted and over-stated baseline risk estimates and thus also overstates the estimates of risk reduction benefits.

Page 15021, Expanded and Diversified Professional Staff
AWWA supports OIRA in their efforts to expand their professional staff. Additional staff is needed to appropriately review the increasing number of regulations.

Page 15022, Formation of a Scientific Advisory Panel to OIRA
AWWA supports the formation of a Scientific Advisory Panel to provide specialized advice to OIRA in their ongoing efforts.

Page 15034, Review of Problematic Agency Guidance
EPA's guidance on implementing the arsenic regulation is problematic. The regulatory language in the January 22, 2001 final regulation (66 FR 6978) lists the Maximum Contaminant Level (MCL) as 0.01 mg/l. The lack of a zero after the one (i.e., 0.010 mg/l) creates a problem with significant digits. Monitoring data could be rounded such that 0.014 mg/l (or 14 ppb) could be rounded down to 0.01 mg/l. Several states have constitutional amendments that preclude any states standards from being more restrictive than the federal standard, and are stuck in this quandry of whether the standard is really 14 ppb or 10 ppb according to their interpretation of this constitutional provision. EPA has attempted to solve this dilemma through guidance. However, this quandry could be neatly solved with a technical amendment to the regulatory language to establish the MCL at 0.010 mg/l.

APPENDIX A

Examples of Differences Between EPA and Other CBA Estimates

Research and analyses sponsored by AWWA, the Awwa Research Foundation (AwwaRF), and/or other stakeholders have often found significant differences between their data and results and those provided by EPA. Some regulation-specific examples, and the magnitude (and source) of the differences are described briefly below. A more detailed analysis is provided in the attached detailed retrospective on the uranium rule (Attachment B)

1. Radon MCL Proposal

The EPA analysis of the benefits and costs of the proposed MCL for radon (November 2, 1999) included several CBA results and interpretations that we found troubling. The following are several examples of issues needing attention in the EPA CBA:

- EPA did not account for latencies or discounting when evaluating the lung cancer risks. These risks arise decades after exposure, and result in late-in-life premature fatalities with a relatively modest number of life years saved.

- EPA did not account for the considerable scientific evidence that indicates a strong synergistic relationship between tobacco smoking and radon in terms of lung cancer risks. An AWWA analysis revealed how EPA could easily use the NAS risk assessments to net out the tobacco smoking portion of the risk, and thereby develop radon-specific risk and benefits estimates.

- The impact of the above two factors alone was significant in terms of the final CBA results. EPA's estimates showed national level benefits roughly equivalent to costs. In contrast, the costs outweigh the benefits by a factor of roughly 10-to-1 when the simple corrections are made to net out smoking impacts and apply appropriate latency and discounting scenarios.

- EPA's analysis was based solely on the total benefits and costs, not the incremental tradeoffs in moving from one regulatory option to the next MCL option. An incremental analysis is important because it is the only way to ascertain if net social benefits are being maximized.

- EPA evaluated the radon rule at a national aggregate level, whereas the analysis should have been focused on the Community Water System (CWS) level to better reflect the inequities the rule would impose on residents served by smaller systems. This is especially important in a social justice context because the same people who realize the benefits of the radon rule are also the households that will bear the compliance costs.

  EPA estimated that 75% of the systems directly incurring compliance costs at an MCL of 300 pCi/L are in the less than 500 persons served category (and about half of these are in the 100 persons served or less category). These very small CWS will incur over 40% of the national compliance costs, but realize only 5% of the national benefits. It is inequitable and inefficient to have residents in small communities pay

so much for health protection (the equivalent of roughly $500 million per premature fatality avoided).

- AWWA and other parties that have examined compliance issues believe that EPA's estimated costs understate the likely actual cost of compliance by a considerable degree (perhaps by up to a factor of 10). More realistic cost estimates would make all the cost-benefit comparisons discussed above even less favorable. The broader issue, however, is that EPA needs to provide more realistic and more transparent and replicable cost analyses. This is not simply a matter of sound practice and good public policy, but also a requirement of the SDWA (section 1412 (b)(3)(C)).

2. Arsenic MCL Proposal and Retracted Final Rule

Many of the same issues raised above for radon also apply to the Agency's CBA for the arsenic MCL rulemakings. Some additional problems and concerns include:

- Use of overly conservative, precautionary principles when interpreting the risk assessment within the CBA context. For example, many in the scientific community believe (based on the mode of action) that arsenic has a sublinear dose-response curve. In a CBA context, the sublinear dose-response function should be used as the most likely scenario in estimating benefits. EPA's CBA relied on the linearized version of the dose-response function alone.

- EPA's interpretation of the exposure levels in the Taiwanese study population does not account for the notable contributions to daily arsenic intake due to that population's reliance on foodstuffs that absorb arsenic during the cooking process (e.g., rice). In its NODA (November 2000), EPA added a sensitivity analysis that revealed the cancer risks are reduced by roughly 40% when cooking water is taken into account. However, this is improperly portrayed as a "lower bound" risk estimate. Again, agencies should use best estimates (plus suitable bounding assumptions or probability distributions) when estimating risk reductions and benefits.

- EPA's cost estimates appear to be considerable underestimates, and differ significantly from independent estimates (most notably, those developed by the Arsenic Research Partnership, which includes EPA and is administered by AwwaRF). The magnitude of the cost discrepancy is so great, and the underlying reasons so obscure, that EPA has had to convene a National Drinking Water Advisory Council (NDWAC) working group to review the two sets of cost estimates in the hopes of determining an appropriate estimate. Many of the differences between these two estimates were never resolved. One potential source of some of the discrepancy is the need for EPA to better account for arsenic-related residuals management (e.g., hazardous waste handling and disposal arising from treatment-related waste streams).

- When some of the relevant corrections and enhancements are made to the EPA analyses (as discussed above, and provided in further detail in attached reports), the benefit-cost tradeoffs of potential MCLs change significantly from what is derived by

EPA. For example, a "best estimate" of the cost per premature cancer fatality avoided in going from a 20 μg/L to a 10 μg/L MCL option is over $75 million (whereas EPA benefit and costs data infer the cost per fatality avoided is only about $6 million).

- As in the radon CBA, EPA's arsenic analyses do not provide sufficient use of incremental (versus total) benefits and costs, and do not reveal the benefit-cost tradeoffs in smaller systems (relying on and reporting only national aggregate estimates).

3. Uranium MCL Proposal and Final Rule

The final uranium standard (65 FR 76714, December 7, 2000) establishes important precedent in that it represents the first time EPA has explicitly used its discretionary authority to use a cost-benefit analysis to establish an MCL. Because this rulemaking is precedent-setting, it is important that the CBA be performed in accordance with best practices and consistently applied according to the intent of the governing statute. Unfortunately, the CBA — and its interpretation by the Agency — has several limitations. A more detailed analysis is provided in the attached detailed retrospective on the uranium rule (Attachment B)

- The core problem with the analysis is how unquantified health risks (potential kidney toxicity) are used as the basis for the MCL. These unquantified benefits may be very important, but they need to be addressed in a more systematic manner in the CBA. The Agency uses its discretionary CBA authority in setting the standard, but at the same time, in its response to comments, the Agency claims it is irrelevant to apply useful CBA techniques for assessing the nonmonetary kidney toxicity benefits. This reveals a fundamental flaw in EPA's logic in this rulemaking — it uses its CBA authority to set the MCL, claiming that it "believes that 30 μg/L maximizes net benefits" (EPA response to comments 9.A.12). Yet at the same time, the Agency offers no CBA assessment of the MCL that considers the nonquantified benefits.

- The health concern that serves as the principal basis for the rule is a reduced risk of potential kidney toxicity. This potential health benefit cannot be quantified in terms of estimated numbers of cases avoided because it is not known whether the potential for cellular-level changes within the kidney may be associated with an increased risk of an adverse health effect. Since the level of risk (if any) is unquantifiable, it is not possible to put a dollar value on the risk reduction benefits. However, there are meaningful semi-quantitative ways to assess these types of benefits within a CBA, as demonstrated in the "break even" analysis submitted with AWWA's comments on the NODA. The cost-effectiveness approach reveals that at the final MCL, the rule is estimated to cost almost $2 million per person exposed above the "no risk" oral reference dose. This seems to be an unacceptably high cost per person when the adverse outcome (potential for cellular level changes in the kidney) may not even be associated with an adverse health effect.

- The cost estimates appear understated and are not supported by transparent explanations or readily available back-up documentation. It is difficult to determine the basis for the cost estimates or reproduce them. For example:

    - EPA's decision tree relies to an unreasonable extent on nontreatment options (34% of affected systems), which departs from other cost analyses. In addition, the treatment categories are too broad to determine what technology(ies) EPA used in its cost analysis.

    - EPA provides cost curves for residuals management, but does not indicate what residuals management technologies were used in its cost estimates.

    - EPA does not include monitoring costs in its CBA for the final rule, but did properly include them in the NODA CBA. Monitoring costs may be a significant portion of the total costs of the rulemaking.

The above are selected examples of issues and concerns AWWA has with how EPA has developed and interpreted CBAs for drinking water standards. AWWA recommends that OMB more strictly enforce Executive Order 12866 and the applicable requirements as specified in the SDWA so that EPA improves their CBAs for drinking water rules. AWWA also suggests OMB modify the CBAs when they appear to be flawed in key areas. If the SDWA-related CBAs were performed in full accord with the statutory mandate, and done well, then EPA management would likely have a better basis for considering its MCL decisions.

APPENDIX B

A Report Card of EPA's Cost-Benefit Analysis For the Uranium Rule, And Its Use in the Supporting the Final Rule

A REPORT CARD ON EPA'S COST-BENEFIT ANALYSIS FOR URANIUM, AND ITS USE IN SUPPORTING THE FINAL RULE

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June 4, 2001

CONTENTS

EXECUTIVE SUMMARY

The Maximum Contaminant Level (MCL) for uranium was finalized on December 7, 2000 (65 FR 76707). Key points regarding the uranium MCL and the cost-benefit analysis the Agency developed in support of the rulemaking are:

1. **The uranium MCL establishes precedent in the use of cost-benefit analysis in standard setting.**
   - The uranium standard setting establishes important precedent in that it represents the first time EPA has explicitly used its discretionary authority to use a cost-benefit analysis (CBA) to establish an MCL.[1]
   - Because this rulemaking is precedent-setting, it is important that the CBA be performed in accordance with best practices and consistently applied according to the intent of the governing statute. Unfortunately, the CBA — and its interpretation by the Agency — has several limitations.
   - The report card on the CBA (Exhibit S.1) indicates several areas in which the Agency receives poor grades.
2. **The unquantified health risks (potential kidney toxicity) are the basis for the MCL, but need to be addressed in a more systematic manner in the CBA.**
   - The health concern that serves as the principal basis for the rule is a reduced risk of potential kidney toxicity. This potential health benefit cannot be quantified in terms of estimated numbers of cases avoided because it is not known whether the potential for cellular-level changes within the kidney may be associated with an increased risk of an adverse health effect.
   - Since the level of risk (if any) is unquantifiable, it is not possible to put a dollar value on the risk reduction benefits. However, there are meaningful semi-quantitative ways to assess these types of benefits within a CBA, as demonstrated in the "break even" analysis submitted with AWWA's comments on the Notice of Data Availability (NODA), issued in May 2000, and as updated here in Appendix C.

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1. Under section 1412(b)(6) of the Safe Drinking Water Act Amendments of 1996, the Administrator can set an MCL at a level other than what is as close to the MCLG as technically feasible if the benefits at that level do not "justify" the costs.

Exhibit S.1.

AWWA Report Card on EPA's Uranium Rulemaking

AWWA Report Card on EPA's Uranium Rulemaking

Occurrence	D
Treatment Costs	D
Monitoring Costs	C+
Affordability	D+
Human Health Benefits	F
Benefit-Cost Comparison	D
Consideration of Nonquantified Benefits	F
Adherence to Guidelines and Directives	D

Exhibit S.1 (cont.)

D — Occurrence

The Agency relies on interpolation between two unsatisfactory sets of occurrence estimates, and fails to address key technical issues raised in prior rulemakings and reiterated in public comments. The occurrence results are at odds with limited available field data, and underestimate the number of systems impacted, especially in the larger size categories.

D — Treatment Costs

EPA's estimated treatment costs are not transparent or replicable, and are based on an unreasonable assumption that 34% of systems will comply by tapping alternative, low cost water sources. EPA does not specify waste management technologies used in the cost analysis. EPA also omits the costs of compliance monitoring (which typically are included in cost-benefit comparisons).

C+ — Monitoring Costs

EPA significantly reduced its estimated monitoring costs between the NODA and final rule by changing the requirements — relying now on gross alpha measurements for systems with low gross alpha ($\leq$ 15 pCi/L). Monitoring costs are excluded from the CBA, however, and are annualized in a manner that makes them inconsistent with the other components of annualized compliance costs.

D+ — Affordability

The Agency relies only on the costs of promulgated rules in setting its baseline household water bill, and does not assess affordability in a simple sensitivity analysis that considers the impact of multiple proposed rules. EPA also relies solely on 2.5% of median household income as its measure of affordability, and should also show sensitivity to alternative threshold values (e.g., 2.0%), and also show water bills as a percent of income for households in poverty.

F — Human Health Benefits

EPA quantifies and assigns a monetary value to cancer risk reductions, but fails to apply standard latency and discounting principles in its assessment. Accounting for latencies and discounting (and income growth effects) are the proper ways to conduct these analyses, and were endorsed by the Science Advisory Board. EPA needs to follow accepted best practices for benefits valuation.

D — Benefit-Cost Comparison

EPA avoids a failing grade by providing estimates of incremental benefits and costs. However, the Agency fails to show incremental net benefits for each relevant regulatory option, and also fails to make any effort to account for unquantified kidney toxicity benefits. Given that the Agency claims to use the CBA results as the basis for selecting an MCL at a level other than what is technically feasible, the incomplete benefit-cost comparison is especially problematic.

F — Consideration of Nonquantified Benefits

EPA claims it relied on the CBA to select the MCL, and that the primary health benefit of the standard is for kidney toxicity. However, the Agency failed to undertake any efforts to examine how the CBA results relate to renal toxicity concerns, even though it received public comments illustrating a useful approach for doing so.

D — Adherence to Guidelines and Directives

In several regards the Agency adheres to internal and external guidelines and directives. However, important deficiencies remain, such as failing to discount future benefits, using inconsistent bases for annualizing different cost components, and omitting monitoring costs and important unquantified benefits from the cost-benefit comparisons.

- The Agency uses its discretionary CBA authority in setting the standard, but at the same time, in its response to comments, the Agency claims it is irrelevant to apply useful CBA techniques for assessing the nonmonetary kidney toxicity benefits. This reveals a fundamental flaw in EPA's logic in this rulemaking — it uses its CBA authority to set the MCL, claiming that it "believes that 30 μg/L maximizes net benefits" (EPA response to comments 9.A.12). Yet at the same time, the Agency offers no CBA assessment of the MCL that considers the nonquantified benefits [and EPA claims that the demonstrated "break-even analysis is not relevant" (EPA response to comment 9.B.19)].

3. **The cost estimates appear understated and are not supported by transparent explanations or readily available back-up documentation.**

   - EPA relies on questionable occurrence distributions, especially when determining its "Best Estimate" of affected systems.
   - It is difficult to determine the basis for the cost estimates or reproduce them.
     - EPA's decision tree relies to an unreasonable extent on nontreatment options (34% of affected systems), which departs from other cost analyses. In addition, the treatment category "softening/iron treatment" is too broad to determine what technology(ies) EPA used in its cost analysis.
     - EPA provides cost curves for residuals management, but does not indicate what residuals management technologies were used in its cost estimates.
     - EPA outlines its aggregation method in general terms, but does not identify the actual model (e.g., was SafeWater Suite or SafeWaterXL used?).
   - EPA does not include monitoring costs in its CBA for the final rule, but did properly include them in the NODA CBA. Monitoring costs may be a significant portion of the total costs of the rulemaking (e.g., in the NODA, monitoring costs ranged from 10% to over 50% of total costs, depending on the MCL option and occurrence estimation approach used). This share will be much less using compliance monitoring costs as revised under the final rule (i.e., less than 5% of total compliance costs for the selected MCL of 30 μg/L).
   - If the costs are understated, then the cost-benefit rationale for the final MCL (30 μg/L) becomes less defensible.