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April 3, 2003

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

Re: Comments on the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations

Dear Ms. Hunt:

Enclosed are the official comments by the American Water Works Association (AWWA) on the Office of Management and Budget's (OMB) Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations as detailed in the February 3rd *Federal Register*. AWWA appreciates the opportunity to comment on the important issues in this Draft Report.

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

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

Enclosure

cc: Jim Laity—OMB OIRA
Tracy Mehan-USEPA OW
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COMMENTS BY THE
AMERICAN WATER WORKS ASSOCIATION ON THE
DRAFT 2003 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS, NOTICE AND REQUEST FOR COMMENTS
(February 3, 2003, 68 FR 5492)

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 4,700 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* 2003 *Report to Congress on the Costs and Benefits of Federal Regulations,* as printed in the *Federal Register* (66 FR 5492). 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). 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, 2001 and September 30, 2002. 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 (LTlESWTR) in January 2002. However, 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. We also took a detailed retrospective look at the uranium regulation, and the report from that effort is attached as Appendix A, which we previously submitted in our comments on the *Draft 2002 Report.* AWWA 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. 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 strove 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.

However, 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 recent 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)].

Dr. Bob Raucher from Stratus Consulting, Inc., has assisted AWWA, and other drinking water associations, in preparing detailed comments on many components. Appendix B is a White Paper on the impacts of precautionary assumptions in setting drinking water standards. The recommendations in this White Paper are consistent with comments that AWWA and other drinking water associations have made 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 system size, as opposed to incremental benefits and costs by each size category, 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 act upon these recommendations to improve its 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

The Use of "Precaution" in Risk Assessment

We have previously addressed the issue of precautionary assumptions in risk assessment in these comments, and Appendix B is a White Paper that details the underlying issues from the drinking water perspective

The Balance of Precautionary Risk Assessment with Other Interests such as Economic Growth and Technological Innovation

EPA, and other groups, often assume that new regulations will force new technologies into the marketplace without any empirical evidence to back up this assumption. While we cannot offer any detailed empirical evidence, we can summarize the implementation of one new drinking water analytical method as an illustration on the probable lack of impact of new drinking water regulation on forcing new technologies into the market place.

Drinking water utilities have been hampered for years by the lack of a reliable and reproducible analytical method for *Cryptosporidium.* The lack of national *Cryptosporidium* occurrence data of sufficient quality necessary to develop a national occurrence distribution was problematic during the negotiated rulemaking in the early '90s for the Stage 1 Disinfectants/Disinfection By-products Rule (D/DBPR). The negotiators agreed to the Information Collection Rule (ICR) that required the large utilities to collect 18 monthly *Cryptosporidium* samples, even though all of the parties knew that the analytical method at that time was poor, with an average recovery of 11% (recoveries typically ranged from 0 to over 100%). EPA and other negotiators thought that due to this regulatory requirement, a market would be created for a new and improved *Cryptosporidium* analytical method that would be ready in time for the ICR monitoring.

This regulatory requirement did drive extensive research into new analytical methods, and a slightly improved method later emerged, but a new and improved method was NOT ready for widespread implementation for the ICR monitoring. AWWA commented extensively on the inadequacies of the ICR *Cryptosporidium* analytical method on the proposals for both the Information Collection Rule (ICR) and the Interim Enhanced Surface Water Treatment Rule (IESWTR). In fact, AWWA filed a lawsuit on the final ICR due to concerns with the *Cryptosporidium* analytical method, but later withdrew that lawsuit to allow the M/DBP Cluster rulemaking process to continue. So utilities ended up conducting the required *Cryptosporidiurn* monitoring, and EPA ended up with a dataset of questionable quality with more than 80% of the samples being non-detects. The scientific debate continues on how this dataset can be used in the regulatory development process.

The regulatory requirement did promote extensive research for an improved *Cryptosporidium* analytical method. However, the "silver bullet" never emerged fiom the research laboratories. As of this date, the current analytical method averages approximately 40% recovery, which is still well below what is considered acceptable for chemical analytical methods (generally 80%-120% recovery). Regulatory requirements, on their own, are not necessarily going to stimulate, or necessarily hinder, technological innovation.

The Analysis of Regulations Related to Homeland Security

The Department of Homeland Security (DHS) and the Environmental Protection Agency (EPA) have national leadership responsibility to develop cost/benefit (risk reduction) analysis for measures to prevent and respond to acts of terrorism and produce guidance for drinking water utilities. The measures that could be taken to reduce risk from terrorism in water utilities are many and the costs great. DHS needs to establish guidance that will lead to appropriate levels of cost/risk reduction for utilities.

DHS and EPA face formidable challenges in developing sensible regulations for the many potential issues that could improve security related to both forms of terrorism. The estimation of costs and benefits of those future regulations will not be simple. The uncertainties of when, how and where acts of terrorism will occur, complicate the ability to associate probabilities with such acts. Trying to quantify the risk reduction measures is equally perplexing when you have to consider the issues related to the human health, emotional anguish, and economics. Future federal regulations developed by DHS and/or other federal agencies such as EPA, should carefully consider the feasibility of regulating at all in the absence of reliable data to quantify benefits. Other mechanisms such as guidance should be an alternative to federal regulations in the absence of reliable data.

In considering the issue of terrorism on a water system and the applicable risk, acts of terrorism against the water industry will most likely take two forms, physical destruction and purposeful contamination. In review of the typical risk management model, environmental regulation could typically be considered as preventing potential medium

probability, medium consequence events. However, the issue of reducing the risk of terrorism may have very different beginning and endpoints.

Physical Destruction For example, weapons of mass destruction (WMD) are typically considered low probability, high consequence events. As a result the risk reduction systems employed by the nuclear power industry probably offers the most expertise in estimating the potential damages from such high consequence events, and the Nuclear Regulatory Commission (NRC) should be consulted for the consequence side of the equation. However, the nuclear power industry differs from the water utility industry in many respects, especially when it comes to estimating the probability of attack and the potential reduction of that probability as a result of future federal regulations. There are less than 100 nuclear power plants in the country, each contained with a defined and discrete perimeter boundary protected by a highly trained on-site security force. On the other hand, there are over 58,000 community water systems that have distributed facilities and minimal, if any, security forces.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188), required among other things, drinking water utilities serving greater than 3,300 people conduct a Vulnerability Assessment (VA) and update their Emergency Response Plan (ERP) within 6 months of submitting the VA. The law required that each water utility complete six tasks: characterize the system, determine critical assets and the adverse consequences to losing the critical asset, assess the likelihood of attack, evaluate the existing countermeasures, and analyze the risk and develop risk reduction measures. To assist in this effort, the AWWA Research Foundation (AwwaRF) contracted with Sandia National Laboratories to develop the Risk Assessment Methodology for Water (RAM-W). Version 1 was completed in 2001 as a guide to help the water industry accomplish the six tasks.

The RAM-W model offered some interesting insights into how water utilities are estimating the probability of attack, the reduction of that probability based on security efforts, and the potential damages. First the RAM-W assess risk to physical destruction of the facility or asset and assists in identifying how to detect the presence of an intruder to a site and possible means to delay the act of sabotage. It does NOT account for purposeful contamination. Second, the RAM-W model does not allow for estimating a probability of attack, because not enough information exists to even guess on that probability. Additionally, no matter what risk reduction measures are put in place, the potential probability is not estimated. Best professional judgment is used to estimate relative risks, and this judgment is further used to estimate the relative potential improvement in the effectiveness of the security measures. It should be emphasized that there is a limited body of knowledge of the effectiveness of water utility security measures. Limited, if any, quantifiable data exists on the effectiveness of video cameras, alarms, etc. at a typical water treatment plant.

Purposeful Contamination. Purposeful Contamination is likewise a low probability, high consequence risk management scenario. Prevention is a difficult, if not impossible, task in contamination events and casualties and significant infrastructure damage may occur

prior to detection. Protection of individuals in a terrorism contamination event in a public water supply is not practical. DHS must establish basic units of population to be protected and develop cost/benefit analysis to support guidance to effect such protection.

RAM-W does require the utilities to develop estimates of high measures of consequences such as economic loss to the utility and the community, and even illnesses or deaths (even though many utilities want to avoid such difficult issues). Similar work for contamination events has barely begun. But even this is only a measure of what the utility considers a high consequence for that specific utility, not what might be a likely or potential consequence as a result of a terrorist attack at other water utility. Basic information on the range of potential terrorist attacks and the resultant consequences for the water utility and its customers is still lacking. The consequences from a terrorist attack could vary substantially based on the target (source water, treatment plant or distribution system) and the tactics (physical destruction or contamination). Consequences resulting from contaminant could vary substantially based on the agent (chemical or biological).

The struggles that water utilities have faced in completing the initial round of VAs and on-going work to deal with contamination events are indicative of the potential struggles that DHS will face in estimating the probability of attack, the reduction of that probability based on security efforts, the potential damages and responses to minimize damages.

AWWA and its utility members stand ready to assist DHS and EPA in the establishment of guidance; however, DHS and EPA need to take the lead role in this endeavor. Alan Roberson from our Washington Office is one of the licensed trainers for RAM-W, and would be willing to discuss further the lessons learned by water utilities in completing the initial round of VAs and industry efforts to deal with contamination events.

APPENDIX A

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

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

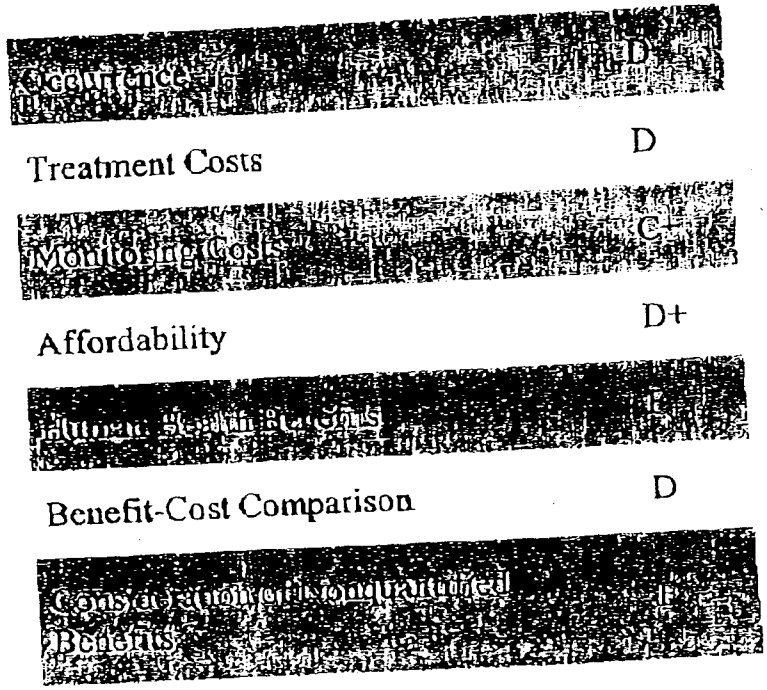


Exhibit S.1 (cont.)

[illegible] 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.

[illegible] 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).

[illegible] 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 (≤ 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.

[illegible] 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.

[illegible] Quantification of 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.

[illegible] 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.

[illegible] 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.

[illegible] 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 SafeWaterXI, 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.

CONTENTS

CHAPTER 1
INTRODUCTION

OBJECTIVE

This "report card" provides a brief review of the recent final EPA rulemaking for uranium, focusing on how well the Agency's supporting cost-benefit analyses (CBAs) — and EPA's policy interpretations of them — adhere to standard notions of best practices. The objective is to provide a basis for discussions on how EPA may need to modify how it develops and applies its CBAs in future rulemakings.

The regulation examined in this specific review is the recently promulgated radionuclides rule, and specifically the final uranium MCL, which was set at 30 µg/L. This rulemaking was finalized on December 7, 2000 (65 FR 76707).

BACKGROUND

In setting an MCL, important public health issues and sizable financial consequences often are at stake. Therefore, it is vital that EPA's drinking water regulations are based on sound science and adhere to the principles of good economic and public policy analysis.

Under statutory and executive mandates, EPA must develop cost-benefit analyses and other studies in conjunction with its rulemakings. These investigations by EPA address the science, engineering, and economic underpinnings of its rulemaking options. The intent is to have EPA develop human health risk assessments, technology and cost documents, and other studies to help ensure that its standards are based on sound science and provide a prudent balancing of benefits with costs. These EPA analyses are embedded in documents that are made publicly available when a rule is proposed or promulgated, or when a Notice of Data Availability (NODA) is issued. Such documents include Health Risk Reduction and Cost Analyses (HRRCAs), Economic Analyses (EAs, formerly known as Regulatory Impact Analyses, or RIAs), and Technology and Cost (T&C) Documents.

EPA must make these documents and other relevant materials (including full documentation) available for timely review by stakeholders and the interested public, as part of

the rulemaking docket. The public comments on these analyses often provide considerable insights and new information. For example, AWWA, among other organizations, typically submits detailed and relevant comments on many aspects of proposed rules, using the extensive expertise of its members, staff, and consultants. Public comments submitted on proposed rulemakings or NODAs must be addressed by the Agency as part of its development of a final rule.

Recent rulemaking activity in EPA's drinking water program has raised stakeholder concerns that standards are not always based on sound science, that the Agency's supporting analyses (RIAs, HRRCAs, etc.) are technically lacking or otherwise insufficient, and that they are lacking in appropriate transparency and documentation. There also is concern that recent EPA actions reveal that the Agency is not adhering to appropriate or best practices [including those articulated in Agency guidelines and Science Advisory Board (SAB) reports] for conducting or interpreting benefit-cost analyses in standard setting.

In addition, there is concern that EPA is not taking public comments into serious consideration when finalizing its rules. Some might argue that EPA's typical comment response document takes more of a "check-off" approach than a balanced consideration of the comments, merits, and implications. If this is the case, then the Agency may be overlooking key facts and valuable alternative perspectives when it revises its analyses and considers whether and how to alter the proposed standard into a final rule.

KEY QUESTIONS AND EVALUATION CRITERIA

In the sections that follow, key aspects of EPA's recent uranium MCL rulemaking are evaluated. The questions of principal interest include the following:

- How closely do the final rule and its Economic Analysis address or reflect AWWA's submitted comments on the NODA?
- How well do the final rule and Economic Analysis meet the intent of the CBA provisions of the Safe Drinking Water Act (SDWA), as amended in 1996?
- How closely do the final rule and Economic Analysis follow the Agency's new CBA guidelines, as provided in *Guidelines for Preparing Economic Analyses* (dated September 2000)?

- To what extent do the rulemaking and Economic Analysis conform with other regulatory guidance and directives, including Executive Orders (EOs) and Circulars from the Office of Management and Budget (OMB)?

In addressing these key questions, the following evaluation criteria are applied:

- Do the analyses adhere to best practices, guidelines, and directives?
- Are the analyses transparent, consistent, and replicable?
- Do the data, methods, and results of the analyses appear to be accurate and credible?
- Are the results of the analyses properly interpreted within the policy-making and statutory context?
- Do the analyses and rulemaking appear to be reasonably responsive to public comment, technical reviews, and other stakeholder input?

OUTLINE OF REPORT

The report addresses eight different topic areas. Each topic reflects a relevant component of the CBA that must be performed in accordance with the provisions of section 1412(b)(3)(C) of the SDWA Amendments of 1996. The issues addressed are:

- The occurrence analysis that underlies the cost and benefit analyses (Chapter 2)
- Treatment cost estimate development, especially for small systems (Chapter 3)
- Whether monitoring cost estimates are reasonable, and whether they are properly included in the CBA (Chapter 4)
- How the affordability analysis is performed with respect to cumulative regulatory impacts and the associated changes in baseline household water bills (Chapter 5)
- How latency and discounting issues are addressed in valuing the benefits of reduced cancer mortality risks (Chapter 6)
- How benefits are compared to costs, particularly in terms of whether incremental analyses are adequately developed and used (Chapter 7)

- How nonquantified benefits (potential kidney toxicity risks) are addressed and interpreted within the CBA (Chapter 8)
- The degree to which the CBA adheres to EPA's "Guidelines," other applicable federal directives and guidance, and general notions of best practices (Chapter 9).

CHAPTER 2
OCCURRENCE ANALYSIS

ISSUE

Occurrence analyses are the foundation for both benefit and cost analyses — estimating the number of community water systems that may exceed a given MCL option. This chapter examines the selection and interpretation of the two occurrence distributions EPA developed. Also examined is how the Agency interpolated between occurrence estimates for 20 µg/L and 40 µg/L to predict the number of systems above the final MCL of 30 µg/L.

EPA'S APPROACH AND FINDINGS (FINAL RULE)

In the final rule, EPA used two occurrence analyses for uranium based on the NRIS data for groundwater systems. One approach used a directly proportional method of extrapolating the data and the other used a lognormal interpretation of the NIRS data. In both cases, EPA split the NIRS data into two size categories: 25 to 500 people served and 501 to 1 million people served. For surface water systems, EPA assumed that that the occurrence values are one-third the values of those for the groundwater distributions. EPA analyzed systems serving over 1 million people individually.

EPA used these distributions to define low and high estimates for uranium occurrence, and states that the Agency's "best estimate" of occurrence is the average of the two distributions. Exhibit 2.1 summarizes these estimates.

EPA states that the number of affected systems at MCL options of 20 µg/L, 40 µg/L, and 80 µg/L is 900, 360, and 110, respectively. Exhibit 2.1 also includes the annual compliance costs for the direct proportional and log normal models, and its "best estimate" for these three MCL options. By inspection, one can easily see that the annual compliance costs are dramatically affected by the occurrence assumptions for these three MCL options.

Exhibit 2.1
EPA's estimates of systems exceeding uranium MCL options

MCL option	Direct proportional		Log normal		"Best estimate"	
	Systems	Annual cost ($M/yr)	Systems	Annual cost ($M/yr)	Systems	Annual cost ($M/yr)
MCL =20 µg/L	830	25.5	970	155.4	900	90.4
MCL = 30 µg/L[a]	400	6.3	600	93.1	500	49.7
MCL = 40 µg/L	300	2.2	430	64.3	360	33.3
MCL = 80 µg/L	40	0.2	170	25.5	110	12.9

a. Interpolated values.
Note: Number of systems based on Exhibit 7-2 of EPA's Economic Analysis and annual cost from Exhibit 6-7 of EPA's Economic Analysis.

Exhibit 2.1 also summarizes EPA's estimates for 30 µg/L, which was adopted as the MCL. However, rather than perform a new CBA for a 30 µg/L MCL, the Agency used interpolation to first compute the number of affected systems and then the associated costs, population affected, risk reduction, and benefits. The Agency fit the data with power functions to describe a relationship between MCL option and the parameter of interest (e.g., number of affected systems). EPA illustrated the relationship for number of systems in Exhibit 7-1 of the Economic Analysis.

EVOLUTION OF EPA'S APPROACH

Comparison to the NODA approach. The two occurrence distributions used in the final rule were unchanged from the two distributions developed for the NODA. The key difference is that for the final rule, EPA indicates that the two distributions bracket the actual occurrence, that the "best estimate" is the average of the two distributions, and that EPA has used interpolation methodology for the 30 µg/L MCL rather than redo the analysis for that case.

Key comments on the NODA approach. Comments submitted on the NODA (e.g., Comment No. 19.A.1) suggested that the NIRS occurrence data seem to resemble more of a Weibull distribution (i.e., exponential) rather than a log normal distribution and recommended that the Agency, at a minimum, should perform a statistical test of the log normal distribution. In addition, the Agency's extrapolation of the groundwater data to surface water occurrence, assumes that concentrations in surface water are one-third those observed in groundwater. A

further comment was that EPA should consider other factors, such as geological conditions, that could explain uranium occurrence, rather than relying solely on system size. The use of grouped data by geologic provinces was suggested to develop more robust occurrence estimates.

Degree to which the approach in the final rule reflects public comments. EPA indicates that the Agency had investigated the use of a Weibull and other distributions to analyze the NIRS data and found that the log normal model fit the data as well as any other. EPA refers the reader to the radon Regulatory Impact Analysis for details, but initial inspection of that document indicates that alternative statistical models for occurrence are not discussed. EPA indicated that it could not use the NIRS data for analysis by geological provinces because a much larger sample size would be required and indicates that was not the purpose of the NIRS study. However, EPA did not consider pooling its NIRS data across system sizes in order to enlarge the sample size, nor does it consider how uranium-specific interpretation of the NIRS data may differ from other contaminants in NIRS.

EVALUATION AND RELIABILITY OF THE EPA RESULTS

EPA has continued use of the direct proportional and log normal models, using an average of the two models as its "best estimates." The direct proportional method appears to be inappropriate for groundwater systems, because it indicates no occurrence for systems serving greater than 500 people for the 40 µg/L and 80 µg/L MCL options. However, there are data from larger water utilities in California and other states (e.g., in Nebraska) that indicate uranium levels above 40 µg/L in their groundwater. Occurrence issues are discussed further the Appendix A.

As a comparison to EPA's estimates of affected systems at the 30 µg/L MCL, Exhibit 2.2 was prepared to show how the interpolation could be done for groundwater systems by population served category. This analysis indicates slightly higher numbers than those predicted by EPA.

Exhibit 2.3 presents a similar analysis for surface water systems. Again, the analysis indicates a slightly higher number of systems than those predicted by EPA.

Exhibit 2.2
Occurrence distributions for groundwater systems

Population served category	Number of affected CWS							
	20 µg/L MCL		30 µg/L MCL[a]		40 µg/L MCL		80 µg/L MCL	
	DP	LN	DP	LN	DP	LN	DP	LN
25-100	369	324	256	217	144	146	21	60
101-500	391	342	272	230	152	155	22	64
501-1,000	20	83	10	54	0	35	0	13
1,001-3,300	24	101	12	65	0	42	0	16
3,301-10,000	11	44	0	29	0	19	0	7
10,001-50,000	5	23	0	15	0	10	0	4
50,001-100,000	1	2	0	1.4	0	1	0	<0.5
100,000-1,000,000	00.5	1	0	1	0	1	0	<0.5
Totals	821	921	550	625	296	408	42	165

DP = directly proportional
LN = log normal
a. Values for 30 µg/L are estimated for this analysis. For DP, based on arithmetic mean, and for LN, based on geometric mean, of results for 20 µg/L and 40 µg/L.

Exhibit 2.3
Occurrence distributions for surface water systems

Population served category	Number of affected CWS							
	20 µg/L MCL		30 µg/L MCL[a]		40 µg/L MCL		80 µg/L MCL	
	DP	LN	DP	LN	DP	LN	DP	LN
25-100	1	6	0	3	0	2	0	1
101-500	3	12	0	8	0	5		
501-1,000	0	5	0	3	0	2		
1,001-3,300	0	10	0	6	0	4	0	1
3,301-10,000	0	8	0	5	0	3	0	1
10,001-50,000	0	7	0	4	0	2	0	1
50,001-100,000	0	1	0	<1	0	<0.5	0	<0.5
100,000-1,000,000	0	1	0	<1	0	<0.5		0.5
Totals	4	50	0	30	10	19		

DP = directly proportional
LN = log normal
a. Values for 30 µg/L estimated for this analysis. For DP, based on arithmetic mean, and for LN, based on geometric mean, of results for 20 µg/L and 40 µg/L.

Adherence to best practices, guidance, and directives. EPA's occurrence efforts for uranium are very limited compared with efforts taken for other recent rules (e.g., the 1999 radon proposal and the 2001 arsenic rule). EPA did perform an analysis of uranium occurrence in NTNCS that examined the likelihood of higher uranium levels in various states, based on the same Oak Ridge study used to compare CWS groundwater and surface water ratios. In addition, the Agency obtained occurrence data from seven states, including California, but apparently did not use this information except to do a "what if" analysis of how subtracting California occurrence/noncomplying systems from the analysis, would affect compliance costs for the 40 µg/L option.

Transparency and replicability. EPA's analysis is generally transparent and can be replicated. However, an exponential equation better fits the direct proportional occurrence data for number of affected systems than the power equation EPA used (see Appendix A). The main effect of this difference is that the number of affected systems for the 30 µg/L MCL would be 500 rather than 400 for the direct proportional distribution, or 550 versus 500 affected systems for EPA's best estimate. This is also closer to the estimates shown in Exhibits 2.2 and 2.3. It is also closer to the 558 affected systems that EPA used in its Information Collection Request for Radionuclides analysis (see Chapter 4).

EPA'S INTERPRETATION OF RESULTS

EPA has acknowledged that its two occurrence models have limitations, but believes it has made the best use of the information it had available.

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. EPA has not made convincing arguments that actual occurrence of uranium in groundwater systems is bounded by its directly proportional and log normal distributions. This is especially true for groundwater systems serving populations above 500. The averaging method may be more appropriate for surface water systems, where occurrence is poorly understood. The Agency has not undertaken the effort to resolve these issues that it has with other recent rule makings.

CHAPTER 3
TREATMENT COST ESTIMATES
(FOR THE 25-500 PERSONS SERVED CATEGORIES)

ISSUE

Treatment costs are important in determining the financial impacts on water utilities of complying with a new MCL. Many of the impacted CWS are very small systems, with populations served between 25 and 500 people. EPA treatment cost estimates changed appreciably for the 25 to 100 and the 101 to 500 persons served size categories between the NODA analyses and the final rule. In this chapter, we examine the EPA documents to determine if the justification for the change is explained and supported.

EPA'S APPROACH AND FINDINGS (FINAL RULE)

Approach. In support of the final rule, EPA's Economic Analysis (U.S. EPA, 2000e) provided cost estimates for uranium MCL options of 20 µg/L, 40 µg/L, and 80 µg/L by population categories for affected groundwater and surface water sources. These estimates provided annualized capital costs, annual operations and maintenance (O&M) costs, and total annual costs (sum of the other two components). Separate cost estimates were developed for the direct proportional occurrence distribution and the log normal occurrence distribution by system size categories.

Findings. EPA estimated that most of the affected systems are in the two smallest population categories, serving 25 to 100 people and 101 to 500 people, and that these system would bear the major economic impact of setting a uranium MCL. Exhibit 3.1 compares the total annual costs for very small systems in these two categories estimated in the NODA and the final rule. The total annual costs decreased significantly between the NODA and the final rule. Specifically, the costs decreased by $900,000/year (11%) for the 20 µg/L option, about $1.8 million (37%) to $2.3 million (51%) for the 40 µg/L option, and about $2.3 million (66%) to $2.6 million (87%) for the 80 µg/L option.

Exhibit 3.1
EPA's total annual cost estimates for uranium MCL options
25-100 and 101-500 population served categories
(aggregate of groundwater and surface water systems)

MCL option	MCL =20 µg/L	MCL = 40 µg/L	MCL = 80 µg/L
Total annual costs (direct proportional occurrence): $/yr[a]			
NODA	8,400,000	4,500,000	2,800,000
Final rule	7,500,000	2,200,000	240,000
Total annual costs (log normal occurrence): $/yr[a]			
NODA	8,000,000	4,900,000	3,500,000
Final rule	7,100,000	3,100,000	1,200,000

a. Values rounded to two significant figures.

EVOLUTION OF EPA'S APPROACH

Comparison to the NODA approach. Exhibits 3.2 through 3.5 provide comparisons of EPA's cost estimates (both direct proportional and log normal cases) for the NODA and the final rule for the two smallest system size categories. Exhibits 3.2 and 3.3 are for groundwater systems and surface water systems in the 25 to 100 population served category, and Exhibits 3.4 and 3.5 are for groundwater systems and surface water systems in the 101 to 500 population served category.

These exhibits show that EPA has removed the monitoring costs from the compliance cost analysis and that minor changes have occurred in the annualized capital and annual O&M costs. Changes in the annual costs are discussed separately for each category.

Exhibit 3.2 summarizes these costs for groundwater CWS serving populations of 25 to 100. Note that there is a fairly significant increase in annualized capital and annual O&M costs from the NODA and the final rule, especially for the 20 µg/L MCL option, where annualized capital costs increase by over 80% and annual O&M costs increase by 50 to 60%. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.2

Compliance costs for groundwater CWS: 25-100 persons served category

	Direct proportional		Log normal	
Cost parameter	NODA	Final rule	NODA	Final rule
20 µg/L MCL				
Annual capital	511,761	914,095	457,562	860,920
Annual O&M	787,528	1,191,909	696,933	1,110,002
Annual monitoring	793,578	0	770,307	0
Total annual costs	2,092,867	2,106,004	1,924,802	1,970,922
40 µg/L MCL				
Annual capital	169,806	254,375	203,541	374,771
Annual O&M	284,584	350,877	312,671	485,856
Annual monitoring	678,582	0	679,981	0
Total annual costs	1,132,972	605,252	1,196,193	860,627
80 µg/L MCL				
Annual capital	21,458	26,658	82,691	149,222
Annual O&M	38,563	39,317	128,132	194,521
Annual monitoring	615,566	0	635,903	0
Total annual costs	675,587	65,975	846,726	343,743

Exhibit 3.3 provides a similar summary for surface water CWS serving populations of 25 to 100. In this case, note that including monitoring costs has a major impact on annual compliance costs. Again, there are increases in the annualized capital and annual O&M costs from the NODA and the final rule, but they are more modest. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.4 summarizes these costs for groundwater CWS serving populations of 101 to 500. Note that there is a fairly significant increase annualized capital and annual O&M costs from the NODA and the final rule, especially for the 20 µg/L MCL option, where annualized capital costs increase by 33 to 39% and annual O&M costs increase by 27 to 31%. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.3

Compliance costs for surface water CWS: 25 to 100 persons served category

Cost parameter	Direct proportional		Log normal	
	NODA	Final rule	NODA	Final rule
20 µg/L MCL				
Annual capital, $/yr	1,522	2,062	6,839	9,983
Annual O&M, $/yr	3,426	3,909	14,676	17,830
Annual monitoring, $/yr	587,313	0	621,781	0
Total annual costs, $/yr	592,261	5,971	643,296	27,813
40 µg/L MCL				
Annual capital, $/yr	0	0	2,638	3,772
Annual O&M, $/yr	0	0	5,772	6,838
Annual monitoring, $/yr	576,529	0	594,109	0
Total annual costs	576,529	0	602,479	10,610
80 µg/L MCL, $/yr				
Annual capital, $/yr	0	0	885	1,269
Annual O&M, $/yr	0	0	1,994	2,356
Annual monitoring, $/yr	576,289	0	582,564	0
Total annual costs	576,289	0	585,443	3,625

Exhibit 3.4

Compliance costs for groundwater CWS: 101 to 500 persons served category

Cost parameter	Direct proportional		Log normal	
	NODA	Final rule	NODA	Final rule
20 µg/L MCL				
Annual capital, $/yr	1,588,823	2,120,818	1,441,744	2,003,975
Annual O&M, $/yr	2,535,141	3,217,222	2,265,563	2,977,934
Annual monitoring, $/yr	906,457	0	879,877	0
Total annual costs, $/yr	5,030,421	5,338,041	4,587,184	4,981,909
40 µg/L MCL				
Annual capital, $/yr	472,833	587,789	634,899	871,900
Annual O&M, $/yr	859,822	993,251	1,009,588	1,309,207
Annual monitoring, $/yr	775,104	0	776,703	0
Total annual costs	2,107,759	1,581,020	2,421,190	2,181,108
80 µg/L MCL, $/yr				
Annual capital, $/yr	53,832	61,462	255,116	346,763
Annual O&M, $/yr	110,907	117,323	410,792	526,270
Annual monitoring, $/yr	703,125	0	726,355	0
Total annual costs	867,864	178,785	1,392,263	873,033

Exhibit 3.5 provides a similar summary for surface water CWS serving populations from 101 to 500. In this case, note that the inclusion of monitoring costs has a major impact on annual compliance costs. Here, there are decreases in the annualized capital and annual O&M costs from the NODA and the final rule, but they are modest. Again, the monitoring costs control the overall annual cost differences.

Exhibit 3.5
Compliance costs for surface water CWS: 101 to 500 persons served category

	Direct proportional		Log normal	
Cost parameter	NODA	Final rule	NODA	Final rule
20 µg/L MCL				
Annual capital, $/yr	9,025	8,158	42,040	40,993
Annual O&M, $/yr	18,524	17,884	81,976	82,275
Annual monitoring, $/yr	670,853	0	710,224	0
Total annual costs, $/yr	698,402	26,042	834,240	123,268
40 µg/L MCL				
Annual capital, $/yr	0	0	16,056	15,471
Annual O&M, $/yr	0	0	31,741	31,585
Annual monitoring, $/yr	658,535	0	678,616	0
Total annual costs	658,535	0	726,413	47,055
80 µg/L MCL, $/yr				
Annual capital, $/yr	0	0	5,517	5,344
Annual O&M, $/yr	0	0	11,224	11,076
Annual monitoring, $/yr	658,261	0	665,429	0
Total annual costs	658,261	0	682,270	16,420

Key comments on the NODA approach. EPA received comments on incomplete treatment cost backup (cost curves missing from T&C document) and lack of costs on residuals management. EPA also received comments on the decision tree, especially on use of high selection (34% of systems) for nontreatment options. In addition, the Agency received comments on the lack of transparency of its cost aggregation modeling (e.g., see Response to Comments Document, Section 20, U.S. EPA, 2000d).

Degree to which the approach in the final rule reflects public comments. EPA indicated that it had revised its treatment costs to reflect public comments; however, it did not adjust its decision tree for nontreatment options.

In general, EPA was basically defensive of its position or nonresponsive to comments. In one case (Comment No. 20.C.2, AWWA's detailed comments on EPA's cost assumptions), the EPA response refers the reader back to another comment (Comment No. 16.4), which concerns the MCL for beta/photon emitters.

EVALUATION AND RELIABILITY OF THE EPA RESULTS

The Agency's efforts on this rule are particularly disappointing when compared with other recent rulemaking efforts. The major transparency issue is that EPA's cost estimates cannot be replicated. Thus, it is not possible to evaluate why the treatment costs changed between the NODA and the final rule, and why these costs increased for the groundwater systems and go up and down for the surface water systems. The exclusion of monitoring costs is discussed in Chapter 4.

In addition, there are a number of issues regarding the Agency's cost assumptions that differ from other rules. One key issue is the high percentage of systems that EPA believes will implement nontreatment options. EPA believes 17% of affected systems will blend/regionalize and another 17% will drill new wells (alternative source). Blending seems unreasonable for very small systems unless another source is readily available, although it is more reasonable for large systems with many wells. The drilling of new wells in areas of high uranium has been discounted, even though, for naturally occurring arsenic, the Agency has assumed that option would not be productive. EPA bases its assumption on information from the California Department of Health Services that many systems originally drilled new wells when California implemented its uranium standard in 1989. However, EPA appears to be ignoring further comments from the California DHS on the NODA (Comment No. 20.B.7) that an unintended consequence of this action is that after some period of years, higher uranium levels are appearing in many wells and these systems are encountering significant logistical and economic problems and are now considering treatment for compliance. This is typical for naturally occurring contaminants. Thus, EPA appears to be recommending an option that may be doomed to failure. In addition, an analysis of uranium occurrence in California wells performed for this study indicates that most of the systems with uranium above 30 µg/L serve populations above 500 (see Appendix A).

Adherence to best practices and guidance. EPA has handled a number of cost issues differently in this rule than others, although it is not clear why. The biggest issues regard the decision tree and residuals management assumptions. Exhibit 3-6 provides a comparison of EPA's general cost assumptions for uranium with those in the final arsenic rule (U.S. EPA, 2001a).

Exhibit 3-6
Comparison of EPA's cost assumptions for uranium and arsenic CBAs

Cost assumption category	Uranium	Arsenic
Occurrence	Relied on NIRS data and questionable distributions	Supplemented NIRS with other occurrence data
Compliance responses	Included unusually high selection (34%) of non-treatment responses	Included no non-treatment responses, only treatment responses
Decision tree	Specific treatment technologies difficult to ascertain; specific waste disposal technologies not identified	Specific treatment and waste disposal technologies identified
Aggregation model	Aggregation methodology for cost aggregation not identified	Aggregation model identified

Transparency and replicability. EPA has not really made enough information available to replicate its cost estimates. Some of the missing information include the following:

- The aggregation model is not identified (e.g., was EPA's SafeWater Suite used?).
- Several of the treatment options are grouped into a category of softening/iron removal, which includes some technologies that are not appropriate for uranium removal. In addition, the specific technologies used in the Agency's cost estimates cannot be discerned.
- The residual management options selected for treatment technologies used in the cost estimate are not identified and thus it is impossible to determine what costs were used for residuals management.

The removal of the monitoring costs from the analysis is transparent to anyone that reviews the detailed cost tables.

EPA'S INTERPRETATION OF RESULTS

EPA concludes that it has used the best information available to it and has provided sufficient information for any interested party to replicate its cost analysis. The Agency has justified its removal of monitoring costs from the compliance cost estimates as not really being part of the analysis and, in any case, being a small portion of the costs (see Chapter 4 for additional discussion).

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. Just barely. EPA has done a poor job of developing and describing its cost analysis, especially when compared to other rulemaking efforts.

CHAPTER 4
MONITORING COSTS
(AND THEIR INCLUSION IN THE URANIUM CBA)

ISSUE

EPA's estimated monitoring costs went down appreciably between the NODA and the final rule. It also appears that EPA has not considered monitoring costs in evaluating the CBA tradeoffs of alternative uranium MCL options. This would be inappropriate, and also reflects a change in approach relative to the NODA. This chapter examines this issue and provides a critique.

EPA'S APPROACH AND FINDINGS (FINAL RULE)

In the final rule, EPA presented monitoring costs for the uranium MCL of 30 μg/L as part of the overall monitoring cost of the rule and did not consider monitoring costs in the cost-benefit analysis. EPA's Economic Analysis (see Exhibit 4-10 of EPA 2000e) indicates that the "average present value of annual monitoring costs over a 23-year period" for uranium would be $165,000 for the 30 μg/L MCL. Although not calculated or presented by EPA, the annual monitoring costs for the 30 μg/L uranium MCL, based on the NODA, would be about $5,100,000. This would add about 10 percent to EPA's cost estimate of $51,000,000 per year cited in the final rule for compliance with the uranium MCL of 30 μg/L (note that the estimate is $49,700,000 in the Economic Analysis).

EVOLUTION OF EPA'S APPROACH

Between the NODA and the final rule, EPA developed an Information Collection Request (U.S. EPA, 2000h), which EPA cites in the Economic Analysis (U.S. EPA, 2000e). The ICR provides the basis for the revised monitoring costs or the 30 μg/L MCL used in the final rule.

Comparison to the NODA approach. Exhibit 4.1 compares EPA's estimates of total annual costs for MCL options of 20 µg/L, 40 µg/L, and 80 µg/L from the Preliminary HRRCA (NODA) and the Economic Analysis (final rule) for the direct proportional and the log normal occurrence distributions. This exhibit shows that EPA did not include the monitoring costs in the final rule costs attributed to complying with any MCL option. The effect of removing the monitoring cost from the analysis becomes more important for the direct proportional occurrence cases and more important as the MCL increases. For example, for the 80 µg/L MCL option, the annual costs in the NODA are about $5 million and $30 million for the direct proportion and log normal occurrence cases, respectively, while the corresponding annual costs for the final rule are about $240,000 and $25.5 million. The differences of about $4.5 million correspond roughly to the monitoring costs included in the NODA analysis. As discussed in Chapter 3, there are some overall increases in annualized capital and annual O&M costs from the NODA to the final rule.

Exhibit 4.1
Comparison of monitoring cost included in the CBA from the NODA and the final rule

	Direct proportional		Log normal	
Cost parameter	NODA	Final rule	NODA	Final rule
20 µg/L MCL				
Annual capital, $/yr	11,056,377	11,062,035	58,753,136	63,802,746
Annual O&M, $/yr	15,327,095	14,393,211	92,795,827	91,583,169
Annual monitoring, $/yr	5,219,269	0	5,478,941	0
Total annual costs, $/yr	31,602,741	25,455,246	157,027,904	155,385,915
40 µg/L MCL				
Annual capital, $/yr	642,639	842,164	24,489,472	25,923,572
Annual O&M, $/yr	1,144,406	1,344,128	38,460,142	37,873,457
Annual monitoring, $/yr	4,891,622	0	5,051,315	0
Total annual costs, $/yr	6,678,667	2,186,292	68,000,929	63,797,029
80 µg/L MCL				
Annual capital, $/yr	75,290	88,120	9,720,428	10,530,897
Annual O&M, $/yr	149,470	156,640	15,348,851	15,009,606
Annual monitoring, $/yr	4,754,812	0	4,855,802	0
Total annual costs, $/yr	4,979,572	244,760	29,925,081	25,540,503

Key comments on the NODA approach. Comments on the NODA note that EPA should include labor costs for monitoring as well as analyses costs as was done for the Ground Water Rule proposal (Comment No. 17.1). These costs should be included in the CBA along with other administrative costs, as has been done in recent rule making.

In addition, other comments (e.g., from the California Department of Health Services; Comment No. 16.3) recommended that EPA use gross alpha screening to reduce the monitoring burden on water utilities with low uranium levels.

Degree to which the approach in the final rule reflects public comments. While EPA did not include the monitoring costs in the CBA, revised monitoring costs were included in the overall cost of the rule. In addition, the Agency indicates that it significantly reduced the monitoring burden for uranium monitoring by adopting changes in the gross alpha screening procedures and reduced the frequency for alpha monitoring for systems below the uranium MCL. The basis for the revised monitoring costs for the 30 µg/L MCL is included in the Information Collection Request (U.S. EPA, 2000h).

EVALUATION AND RELIABILITY OF THE EPA RESULTS

Adherence to best practices and guidance. EPA has treated monitoring costs differently in this final rule than it has in other recently proposed or final rules on drinking water regulations in that they are not included in the CBA. We note, for example, that the Final Arsenic Rule (U.S. EPA, 2001a) includes monitoring and administrative costs in the compliance costs for the CBA.

EPA has included monitoring costs for uranium with the cost for monitoring other radionuclides. These costs represent the "average present value of annual monitoring costs over a 23-year period." The ICR includes the methodology for calculating costs in this manner and the actual analysis for the 30 µg/L. EPA provides an estimate of $165,000/year for the 30 µg/L MCL, which it indicates would not substantially affect the CBA. While EPA's economic *Guidelines* allow use of the average present value method to estimate costs and benefits, the guidance indicate this should be done only when all costs and benefits are computed on the same basis. For this rule, only the monitoring and administrative costs are computed using this

approach. The corresponding undiscounted monitoring costs, on a 20 year basis, would be about $194,000 per year.

Transparency and replicability. An examination of EPA's analysis of uranium monitoring costs for the 30 µg/L MCL in the ICR indicates that it is transparent and replicable. EPA's effort in this respect is very good, especially when compared with the treatment cost estimates.

EPA'S INTERPRETATION OF RESULTS

Appendix B provides an analysis of the uranium monitor costs presented in the ICR. That analysis suggests that the EPA costs reflect the minimum monitoring costs associated with use of grandfathering some of the initial monitoring data (collected between years 2000 and 2003, but attributed to the old rule), maximum substitution of gross alpha data (when gross alpha ≤ 15 pCi/L) for uranium analyses, and compositing of samples after the initial monitoring period. Although the final rule includes these provisions, states strictly following EPA's "Implementation Guidance for Radionuclides" (U.S. EPA, 2000i) would likely require additional uranium monitoring (see Appendix B). Annual monitoring costs for the 30 µg/L MCL under that scenario could be as high as $1,800,000 per year (less than 4% of other annual compliance costs).

EPA has focused its uranium monitoring analysis on the 30 µg/L MCL and thus has excluded it from the CBA. For completeness, monitoring costs should be included in the CBA analysis, as has been done for other recent rules. EPA indicated that the monitoring costs were not significant compared with the treatment costs for the 30 µg/L MCL and it would not have a major impact on the CBA. This might not be true for the 40 µg/L and 80 µg/L potential MCLs, particularly when the direct proportional occurrence model is used. For example, the $194,000 per year monitoring cost at 30 µg/L is almost comparable to EPA's direct proportional annual treatment of $245,000 per year for the 80 µg/L MCL option.

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: C+. EPA appears to have reduced the monitoring burden for uranium from the NODA to the final rule, as recommended by some commentators. EPA is commended for this effort. However, comparison of the ICR analysis and EPA's Implementation Guidance for Radionuclides suggests that, based on state interpretation, monitoring costs may be higher.

In addition, EPA has excluded monitoring costs from the CBA. In addition, EPA has discounted these costs in concert with annualizing them. Discounting of monitoring and administrative costs in the ICR does not appear to be warranted for this rule, as this approach puts monitoring costs on a different basis than annualized treatment costs and benefits.

CHAPTER 5

AFFORDABILITY: CUMULATIVE IMPACTS AND THE WATER BILL BASELINE

ISSUE

An important issue is how EPA assesses the affordability of its drinking water regulations. A key concern is whether the Agency considers the cumulative impact of its rules, or examines the uranium standard as if it were the only new cost-imposing action on water utility customers. This chapter examines and evaluates how EPA handles this matter in the uranium rulemaking.

EPA'S APPROACH AND FINDINGS (FINAL RULE)

Approach. EPA agrees that it would be best to look at cumulative affordability, since it is a realistic indicator of affordability (U.S. EPA, 2000c). In practice, EPA includes a "water bill baseline" in its affordability assessments, which includes cumulative impacts from existing final regulations.

The affordability assessment supporting the uranium small systems compliance technology list is based on the current baseline, which is described in "Variance Technology Findings for Contaminants Regulated Before 1996" (U.S. EPA, 1998). Supposedly, as future rules that affect small water systems are promulgated (including this one), this baseline will be revised. When a rule is promulgated, the water bill baseline will be increased and the estimate of affordability decreases, the details of which depend on the percentages of systems impacted and the estimates of the annual per household costs associated with the regulation.

Baselines for the affordable technology analysis were determined using annual household consumption, current annual water bills, and median household income. Separate baselines for these parameters were established for each of the three system size categories. Annual household consumption was used to convert treatment cost increases into household impacts. Current annual water bills were subtracted from the affordability threshold to determine the available expenditure margin. The median household income was used to translate the threshold percentage into an actual dollar figure.

Results. The national-level affordability criteria are based on an affordability threshold of 2.5% of the median household income. Baselines values for current water bills range from 0.65% of median household income for large systems (serving 3,301 to 10,000 customers) to 0.69% for small systems (serving 25 to 500 customers) (U.S. EPA, 1998).

Applying these criteria, EPA uses a threshold of $500 in increased costs per household per year. In other words, technologies that increase costs by less than this amount are considered affordable. EPA's estimates of per household costs for the uranium rule are below a maximum of about $210 for the smallest systems, and thus compliance with the uranium requirements was determined to be affordable and variances would not be required (U.S. EPA, 2000e).

EVOLUTION OF EPA'S APPROACH

Comparison to the NODA approach. The same approach was applied in the NODA.

Key comments on the NODA approach. Baselines do not include the impacts of proposed rules. Many potentially expensive rules are proposed that will affect small groundwater-based community water systems in the near future (e.g., radon, arsenic, and groundwater disinfection). The cumulative impacts could be significant in any small community water system that is affected by more than just the uranium rule.

Within the radionuclides rulemaking, however, EPA did address the uranium rule in addition to "closure of the radium loophole." The Agency states that radium and uranium tend not to co-occur at elevated levels in the same system, and add that uranium can be removed by many of the technologies already included on EPA's list of compliance technologies.

Degree to which the approach in the final rule reflects public comments. EPA's response to comments on affordability indicates that it will update the baseline to reflect cumulative impacts, but only after a rule is promulgated. With several potentially costly rulemakings in progress at the same time, however, waiting until promulgation may not provide an adequate picture of the affordability problem, especially as faced by customers of small systems. In addition, the Agency should conduct sensitivity analyses over a range of affordability thresholds (e.g., the traditional 2% of income in addition to the recent move to 2.5% measure).

EVALUATION AND RELIABILITY OF EPA RESULTS

Adherence to best practices and guidance. With a modest effort, EPA could easily address cumulative impacts of a range of proposed rules that are simultaneously in progress. This could be a simple sensitivity analysis. Allowing more flexibility for baseline estimates would offer more accurate predictions of future household costs.

In addition, EPA's current analyses focus only on households of median income. This narrow perspective fails to reflect hardships that a rule may impose on households in poverty.

Third, the affordability threshold of 2.5% is an arbitrary measure of "affordability." There is no scientific or economic basis for its use other than as a consistent, subjective, and convenient benchmark. At a minimum, EPA should use thresholds over a range, and not solely the arbitrary 2.5% of median income.

Fourth, the affordability analysis must rely on EPA's estimates of the costs of compliance. If these estimates are unreliable or omit several important costs borne by households because of the rule (e.g., monitoring costs), then the affordability analyses will be misleading.

Transparency and replicability. The analyses are fairly transparent, if one accepts the basic cost estimates and other data used at face value.

EPA'S INTERPRETATION OF RESULTS

EPA's concludes the uranium rule is affordable to households with median incomes. This interpretation is dependent on whether EPA's costs estimates prove to be reasonably accurate and complete.

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D+. The rule may not be affordable for households below the poverty level. One study on the arsenic rule revealed affordability concerns for households that would see water costs increase by more than 0.5% of their income for households with incomes below the poverty level (Rubin, 2000). The use of a narrowly defined baseline water bill is also a problem that could easily be addressed with a small increase in effort. In addition, if costs are underestimated

and other proposed rules take effect that raise baseline costs, the rule may not be affordable to median incomes.

CHAPTER 6
HUMAN HEALTH BENEFITS:
USE OF LATENCY AND DISCOUNTING IN VALUING
PREMATURE CANCER FATALITIES AVOIDED

ISSUE

In the uranium rulemaking, EPA has valued future cancer cases avoided as if there were no latency period. This means that near-term compliance costs are inappropriately compared to health risk reduction benefits that actually will accrue many years (e.g., decades) into the future. This skews the cost-benefit comparison relative to alternative public health actions that would generate more near-term health benefits.

AWWA and other parties have provided extensive comment on this issue, and it also has been addressed by a recent Science Advisory Board (SAB) report, *An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Risk Reductions (U.S. EPA, 2000b).* The well-established "best practice" (as recommended by SAB) is to account for latency periods in relevant cancer risk settings, and discount these future benefits back to present value using the same rates that are applied to costs and other benefits. In this chapter we review the manner in which the final rule addresses this issue, and the justification EPA provides for its approach.

EPA'S APPROACH AND FINDINGS (FINAL RULE)

Consistent with the NODA and other prior rulemakings (e.g., for the proposed rules for radon and arsenic), EPA has not applied latency periods for the delayed onset of cancers associated with uranium. By implicitly assigning a zero latency period to the cancer risks, there is no discounting of the cancer benefits. This makes the cancer benefits appear to be greater than they really are, since risks borne 10, 20, or more years in the future have a lower (discounted) present value than risks reduced immediately.

It should be noted that in the "final" rule for arsenic, as published in the *Federal Register* on January 22, 2001 (66 FR 6978), EPA did take a step in the proper direction by providing some latency- and discount-adjusted fatality risk values as part of a sensitivity analysis.

EPA has established that a drinking water equivalent level (DWEL) concentration of 20 µg/L would be safe (i.e., pose zero risk of any cellular level changes within the kidney) to even highly sensitive and highly exposed individuals, with an adequate margin of safety. This "zero risk" level was derived by EPA based on its standard but highly conservative risk assessment techniques, including use of an uncertainty factor of 100 applied to the dose-response data and an exposure assumption of 2 L/day of water consumption (which approximately reflects a 90th percentile of per capita tap water consumption) over a 70 year lifetime. Using these precautionary principle assumptions is suitable for establishing a "zero risk" level for any plausible human exposure/sensitivity scenario, but overstates the anticipated benefits for the population (e.g., see GAO, 2000).

EPA recognizes that the compounded effect of the conservative assumptions underlying the DWEL implies that zero risk (or, at worst, de minimus risk) can be achieved with drinking water concentrations above 20 µg/L. The Agency explicitly uses this fact to establish an MCL above 20 µg/L. EPA states that there is "not a predictable difference in health effects due to exposures between the DWEL of 20 µg/L and a level of 30 µg/L" (U.S. EPA, 2000c, p. 76713). EPA goes on to add, "Given that the uncertainty factor of 100 provides a relatively wide margin of safety, the likelihood of any significant effect in the population at 30 µg/L is very small. EPA thus believes that the difference in kidney toxicity risk for exposures at 20 µg/L versus 30 µg/L is insignificant" (U.S. EPA, 2000c, p. 76714). This begs the question, If 30 µg/L is indistinguishable from 20 µg/L in terms of posing any risks to health, then is there any basis for believing that 40 µg/L poses any real risks of renal toxicity compared to the DWEL of 20 µg/L?

EVOLUTION OF EPA'S APPROACH

Comparison to the NODA approach. EPA's approach in the final rule is the same as provided in the NODA. In essence, the Agency relies on the fact that the kidney toxicity benefits cannot be directly monetized as a rationale for its not exploring very simple and informative CBA-related techniques, such as the "break-even" approach demonstrated in AWWA's submitted comments.

Key comments on the NODA approach. AWWA's comments on the NODA demonstrated how the nonmonetized kidney benefits could still be evaluated within the CBA

context, and revealed that the then-proposed MCL of 20 µg/L could not be justified on the basis these benefits. The approach demonstrated by AWWA (and updated here, in Appendix C) show the cost per person of getting all individuals exposed above the "zero risk" level at baseline down to below 20 µg/L. This cost per person exposed above the safe "oral reference dose" is approximately $200,000 for MCLs of 80 µg/L or 40 µg/L (which, as a point of reference, is approximately twice the cost to treat a cancer patient or to provide a kidney transplant with a year of follow-up medical care). This cost increases to approximately $2 million per person at MCL options of 30 µg/L or less.

The NODA comments thus indicated that EPA could easily use its data to estimate the cost of reducing a uranium exposure from above the "zero risk" level to below that level. These are costs to reduce exposures that may pose a risk of cellular level kidney changes in a small fraction of the exposed group, which in turn may or may not manifest in a kidney disease for some fraction of those people who have cellular changes. It is difficult to imagine that society is better off reducing exposure for one person who faces a very low (perhaps negligible) risk of suffering a kidney disease than it would be investing the same funds in treating two or more known patients with manifested cancers.

Degree to which the approach in the final rule reflects public comments. EPA's final rule does not appear to have taken the AWWA and related comments and supporting analyses into account. EPA's response claims that the "break-even" analysis used by AWWA to interpret the CBA data is "not relevant" (U.S. EPA, 2000d, p. 9-35), and the Agency makes no attempt to interpret the kidney toxicity information in a systematic or informative manner.

EVALUATION AND RELIABILITY OF THE EPA RESULTS

EPA's approach is to overlook the possibility of providing informative analysis. Simple and well-established techniques can be used (as demonstrated in AWWA's submitted comments to the NODA, and updated in Appendix C) to provide insights or whether an unquantifiable risk reduction may be attained at a reasonable cost. EPA has opted to ignore this possibility, and instead leaves the analysis vague and incomplete. Whether intentional or not, the EPA approach provides greater latitude for EPA decision-makers, but also appears to lead to an MCL that is most probably a relatively poor investment in public health. The Agency's approach also may

leave EPA open to legal challenge in terms of its inconsistent (and potentially arbitrary) approach related to using the CBA to set the MCL.

Adherence to best practices and guidance. Best practice suggests that some semi-quantitative effort be made to evaluate the data for nonmonetized benefits, because often some informative inferences can be made even when some key outcomes cannot be quantified. EPA has failed to consider this option, and considers it "irrelevant."

Transparency and replicability. Since EPA makes no effort to analyze its renal toxicity data in a CBA context, issues of transparency and replicability do not apply.

EPA'S INTERPRETATION OF RESULTS

EPA's statement that "the difference in kidney toxicity risks for exposures at 20 μg/L versus 30 μg/L is insignificant" is useful, valuable, and almost certainly correct. However, this opens the door to asking relevant and legitimate questions such as, At what level do the risks become distinguishably different from zero (or *de minimus*) levels? and To what degree are the risks and benefits at an MCL of 40 μg/L different or distinguishable from the benefits derived at an MCL of 30 μg/L?

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: F. The Agency makes no effort to examine the issue in an objective, informative, semi-quantitative manner (even though some standard techniques are available and were illustrated in public comments the Agency received). EPA hides behind the fact that key benefits are not readily quantified or monetized to justify the MCL it desires. Unquantifiable benefits should never be ignored; however, they likewise should never be used as a "carte blanche" to avoid any meaningful analysis and set a potentially arbitrary MCL.

CHAPTER 9

CONSISTENCY OF EPA'S ANALYSES WITH THE AGENCY'S NEW ECONOMIC GUIDELINES, OTHER DIRECTIVES, AND BEST PRACTICES ISSUE

EPA recently published *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000a), that are intended to guide how EPA conducts CBAs and interprets them. EPA also receives guidance and directives on CBA-related issues from OMB, SAB, and other parties (e.g., through Executive Orders). This chapter evaluates EPA's approach to the CBA issues addressed in previous chapters to determine if and how it is consistent with best practices and directives, including the Agency's own internal guidance for CBA.

OCCURRENCE

We are not aware of any EPA, OMB, or other official government guidelines or directives on how to perform occurrence analyses. However, there are accepted professional practices for how to perform any statistical analysis, and EPA's occurrence analyses fall short of the mark in several regards. For example:

- Significant explanatory variables (e.g., geologic province) are omitted, and the only explanatory variable EPA uses is system size (which may not be relevant).
- EPA relies on 2 approaches (direct proportional and lognormal), neither of which appear to fit the data. Nonetheless, EPA states that the two bound the truth (which does not appear supportable) and then interpolates what the Agency calls a "best estimate" by averaging them.

EPA's occurrence work can and should be much more robust and open-minded in the future (see, for example, Raucher et al., 1995).

TREATMENT COSTS

We are not aware of any EPA, OMB, or other official government guidelines or directives that focus specifically on how to estimate the costs of compliance. However, standard best practice procedures would be to make the analyses much more transparent and readily replicable. In addition, there is an Awwa Research Foundation *User's Guide* (Raucher et al., 1995) that EPA has followed to some extent in other rulemakings, and the same principles and practices should apply for uranium.

Finally, EPA's *Guidelines* (U.S. EPA, 2000a) and OMB's *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements* (OMB, 2000) provide general input on how cost estimates should be prepared. EPA's annualized costs for uranium MCL compliance deviates from those guidelines because different cost elements are annualized in an inconsistent manner [i.e., the monitoring costs are annualized on a present value basis whereas debt service on capital outlays and annual operation and maintenance (O&M) costs are not]. Further, monitoring costs have been deleted from the annual compliance costs (but were suitable included in the economic analyses accompanying the NODA).

MONITORING COSTS

We are not aware of any specific guidance from EPA, OMB, or elsewhere that supports deleting monitoring costs from the total costs of compliance. EPA does not include monitoring costs in its cost-benefit comparisons, which is contrary to best practices and inconsistent with how EPA has considered such costs in the NODA and in other rulemakings.

AFFORDABILITY

EPA's affordability analysis relies solely on (1) baseline household water costs considering promulgated rules only, (2) median household income only, and (3) a 2.5% affordability criterion only. Best practices, as reiterated in the EPA *Guidelines*, would be to conduct sensitivity analyses around these individual and combined assumptions, to determine how much impact the assumptions have on the final outcome.

For example, the 2.5% figure that EPA is now using was first announced in 1998, in its *Variance Technology Findings for Contaminants Regulated Before 1996*, (EPA 815-R-98-003, 1998). The background work for this, which supported a range of 1.5% to 3.0% of median household income, was completed earlier in 1998, in *National-Level Affordability Criteria under the 1996 Amendments to the Safe Drinking Water Act — Final Draft Report* (International Consultants Inc., with Jan Beecher, Aug. 19, 1998). Yet in the uranium analysis, EPA does not show results for any benchmark other than 2.5% of median income, even though EPA's prior work supports a range of 1.5% to 3.0%.

HUMAN HEALTH BENEFITS

EPA's approach to valuing cancer-related premature fatalities avoided is at odds with EPA and OMB *Guidelines*, and SAB recommendations (U.S. EPA, 2000b). Nonfatal cancers also need to be discounted back from age of onset to reflect the range of likely latency periods.

BENEFIT-COST COMPARISON

EPA's comparison of benefits to costs is suitable (and in conformance to statutory mandate) to the extent that it includes some comparison of incremental costs to incremental benefits. The CBA also conforms to some aspects of EPA and OMB *Guidelines* by providing ranges in addition to point estimates, and offering some indication of costs and benefits across systems of different size categories.

However, EPA should have included the full range of MCL options when conducting and portraying the incremental findings, and also offered a broader and more insightful handling of uncertainty (e.g., with broader sensitivity analyses). EPA also falls short of guidance and best practices in terms of its refusal to consider kidney toxicity effects within the CBA context. Even though the renal toxicity risks are not readily quantified, simple methods for taking them into consideration are available, and were in fact offered as illustrations to EPA in public comments.

CONSIDERATION OF NONQUANTIFIED BENEFITS

The Agency is not in conformance with the OMB *Guidelines* (OMB, 2000) or the spirit of EPA *Guidelines* (U.S. EPA, 2000b) in its handling of unquantified kidney toxicity risks. As OMB states, "if quantification is difficult, you should present any relevant quantitative information along with a description of the unquantifiable effects." (OMB, 2000, p 6). EPA does provide a reasonable discussion of the qualitative aspects, but deemed a simple semi-quantitative approach (as shown in Appendix C of this report) as "irrelevant."

OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. 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 approaches for annualizing different cost components, deleting monitoring costs, and omitting available approaches for placing important unquantified benefits within the cost-benefit framework.

CHAPTER 10
REFERENCES

OMB. 2000. *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements.* U.S. Office of Management and Budget, Memo M-00-08. March 22.

Raucher, R., E.T. Castillo, A. Dixon, W. Breffle, D. Waldman, and J.A. Drago. 1995. *Estimating the Cost of Compliance with Drinking Water Standards: A User's Guide.* Awwa Research Foundation, Denver, CO.

Rubin, S. 2000. *Estimating the Effect of Different Arsenic Maximum Contaminant Levels on the Affordability of Water Service.* Prepared under contract to the American Water Works Association. July.

U.S. EPA. 1998. Variance Technology Findings for Contaminants Regulated before 1996. 815-R-98-003. September.

U.S. EPA. 2000a. *Guidelines for Preparing Economic Analyses.* EPA 240-R-00-003. September.

U.S. EPA. 2000b. An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Cancer Risk Reductions. EPA-SAB-EEAC-00013. Science Advisory Board, Environmental Economics Advisory Committee, Washington, DC. June.

U.S. EPA. 2000c. Federal Register, 40 CFR Parts 9, 141, and 142. National Primary Drinking Water regulations; Radionuclides; Final Rule. 65 FR 76707. December 7.

U.S. EPA. 2000d. Comment-Response Document, National Primary Drinking Water Regulations, Radionuclides, Notice of Data Availability (April 2000). Washington, DC. November.

U.S. EPA. 2000e. *Economic Analysis of the Radionuclides National Primary Drinking Water Regulations*. Prepared for U.S. EPA by Industrial Economics. November.

U.S. EPA. 2000f. Federal Register, 40 CFR Parts 9, 141, and 142. National Primary Drinking Water regulations; Radionuclides; Notice of Data Availability; Proposed Rule. 65 FR 21576. April 21.

U.S. EPA. 2000g. Preliminary Health Risk Reduction and Cost Analysis. Revised National Primary Drinking Water Standards for Radionuclides. Review Draft. Prepared by Industrial Economics, Inc. January.

U.S. EPA. 2000h. Information Collection Request for National Drinking Water Regulations: Radionuclides. Final. September 22.

U.S. EPA. 2000i. Implementation Guidance for Radionuclides. EPA 816-D-00002. Draft. December.

U.S. EPA. 2001a. Federal Register, 40 CFR Parts 9, 141, and 142. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule. 66 FR 6976. January 22.

U.S. EPA. 2001b. Cost of Illness Handbook. Prepared for the Office of Pollution Prevention and Toxics by Abt Associates. Available at www/epa.gov/opptintr/coi (accessed May 2001).

U.S. Office of Management and Budget. 2000. *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements*. Memo M-00-08. March 22.

APPENDIX A
OCCURRENCE ISSUES

INTRODUCTION

This appendix addresses issues regarding EPA's uranium occurrence estimates in the Final Radionuclides Rule. The key issues evaluated are:

- Do the NIRS uranium data, stratified by system size, provide a good prediction of uranium occurrence?
- Do available state uranium data support EPA's occurrence assumptions?
- Can EPA's interpolation of affected systems vs. MCL option be confirmed?

NIRS URANIUM DATA

EPA relies entirely on uranium data from its National Inorganics and Radionuclides Survey (NIRS) to predict uranium occurrence in community water systems (CWS) in its Final Radionuclides Rule. The NIRS data are strictly for groundwater systems, so EPA assumed that uranium occurrence in surface water was one-third of the level reported in groundwater, based on a ratio from research conducted by Oak Ridge National Laboratory on uranium in U.S. groundwater and surface water (ORNL, 1981). EPA assumed that the uranium data were stratified by system size and not influenced by other parameters such regional or geological differences. EPA did use this later approach to estimate occurrence in non-transient, non-community water systems (NTNCWS) on a state-by-state basis, as described in Chapter 5 of the Economic Analysis (U.S. EPA, 2000e).

Comparison of NIRS Uranium and Arsenic Data

Arsenic, a predominantly naturally occurring contaminant like uranium, provides a useful example of how NIRS data compare with other occurrence studies. In its Final Arsenic Rule (U.S. EPA, 2001a), EPA compared the NIRS arsenic occurrence predictions with other

occurrence studies for arsenic. Exhibit A.1 summarizes this comparison. Note that EPA used log normal distributions for arsenic. This exhibit also suggests that NIRS under-predicts arsenic occurrence in groundwater system by a factor of 1.6 to 1.8. In addition, the exhibit suggests that the ratio of groundwater to surface water arsenic occurrence is near 3:1 for lower arsenic concentrations, but moves toward 7:1 as the concentrations (MCL option) increases. Uranium might follow a similar trend.

Exhibit A.1
Comparison of arsenic occurrence estimates

	% of systems with mean exceeding As concentration (µg/L)				
Occurrence study	2	3	5	10	20
Groundwater systems — % > MCL option[a]					
EPA — proposed rule (all CWS)	27.2	19.9	12.1	5.4	2.1
EPA — final rule (all CWS)	27.3	19.9	12.1	5.3	2.0
NIRS (all CWS)	17.4	11.9	6.9	2.9	1.1
USGS (all PWS)	25.0	NR	13.6	7.6	3.1
NOAS — small (PWS≤10,000)	23.5	NR	12.7	5.1	NR
NOAS — large (PWS>10,000)	28.8	NR	15.4	6.7	NR
Surface water systems — % > MCL option[a]					
EPA — proposed rule (all CWS)	9.9	6.0	2.9	0.8	0.3
EPA — final rule (all CWS)	9.8	5.6	3.0	0.8	0.3
NOAS — small (PWS≤10,000)	6.2	NR	1.8	0.0	NR
NAOS — large (PWS>10,000)	7.5	NR	1.3	0.6	NR
Estimate ratios					
EPA — final rule GW:SW	2.8	3.6	4.0	6.6	6.7
NIRS: final rule SW	1.8	2.1	2.3	3.6	3.7
EPA final rule GW: NIRS	1.6	1.7	1.8	1.8	1.8

a. Source: Final Arsenic Rule (U.S. EPA 2001a), Table III.C-8.
NR = Not reported.

Comparison with California Data

EPA has continued use of the direct proportional and log normal models, using an average of the two models as its "best estimates." The direct proportional method indicates no occurrence for systems serving greater than 500 people for the 40 µg/L and 80 µg/L MCL options.

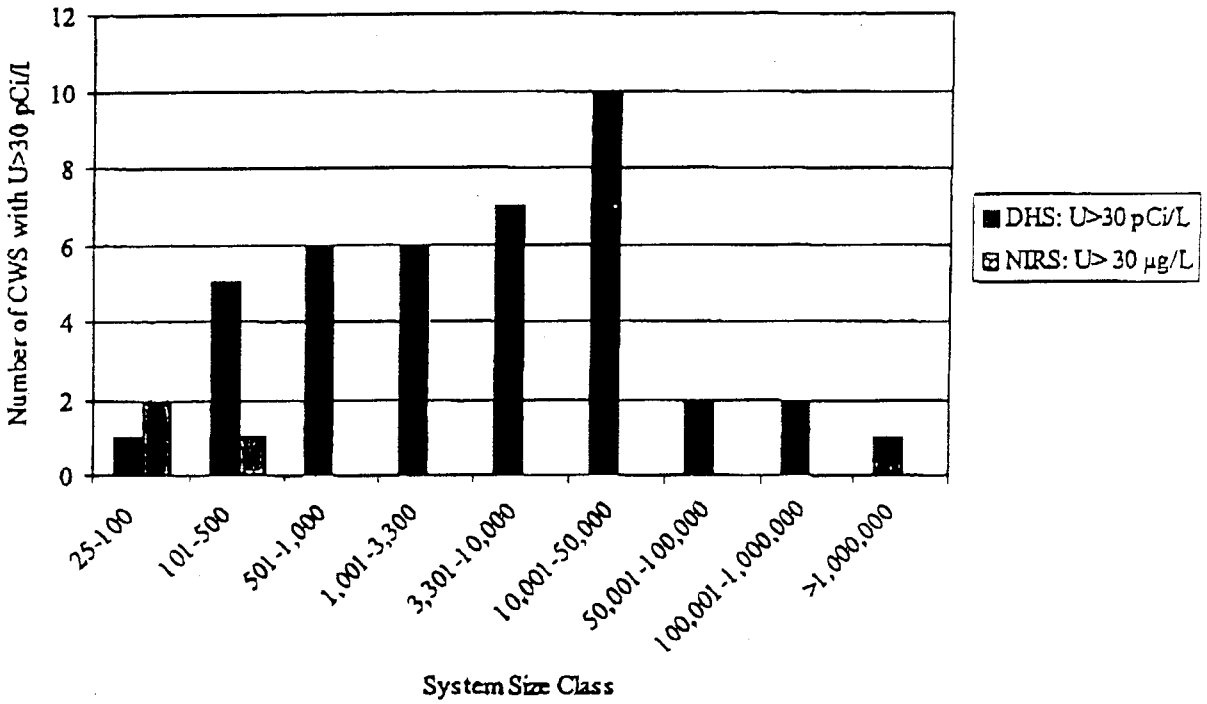
To test this assumption, uranium data from California, which has had a uranium MCL of 20 pCi/L (35 µg/L based on conversion factor of 0.67 pCi/µg and rounded down) since 1989, were examined. EPA has also examined uranium data from California and discussed these data

with California Department of Health Services representative (see Appendix C of the Economic Analysis). EPA cites David Spath, Chief, Division of California's DHS as indicating that approximately 125 systems have been out of compliance with the California MCL since it was promulgated and 25 are currently out of compliance. EPA indicated that it did not have information on the populations served by these systems, but that California DHS had described them as "primarily small" and interprets this to mean that these systems primarily serve between 25 and 500 people.

Examination of DHS uranium data for this study revealed that 40 CWS in California have at least one groundwater source with uranium concentrations above 30 pCi/L (using EPA's 1 pCi/μg assumption, this approximates CWS with sources exceeding 30 μg/L). The affected systems were compared with a database that provides population served data for these systems. Exhibit A.2 shows the distribution of these affected systems by population served. Note that only 6 of the 40 systems (12%) serve populations between 25 and 500 people and that only 25 systems (62.5%) serve populations ≤10,000. Fifteen systems (37.5%) serve over 10,000 people. Thus, the California data do not support the assumption that most of the affected systems will serve between 25 and 500 people and further indicates that the direct proportion estimate is inappropriate. The fact that many larger systems are impacted support the observation that many systems in California drill new wells or blend to met the MCL; the larger systems have multiple wells and large service areas where more than one source (including surface water and multiple aquifers) may be available. These non-treatment options may not be available to very small systems serving between 25 and 500 people.

NIRS uranium data for California were also evaluated. Longtin (1990) reported uranium data for 57 systems in 33 California counties. That study showed that 3 systems (one in Kern County and two in Riverside County) had uranium concentrations above 30 μg/L. As shown in Exhibit A.2, these systems served between 25 and 500 people. Thus, the NIRS data are not predictive of uranium occurrence in California when stratified by system size.

Exhibit A.2. Uranium distribution in California CWS

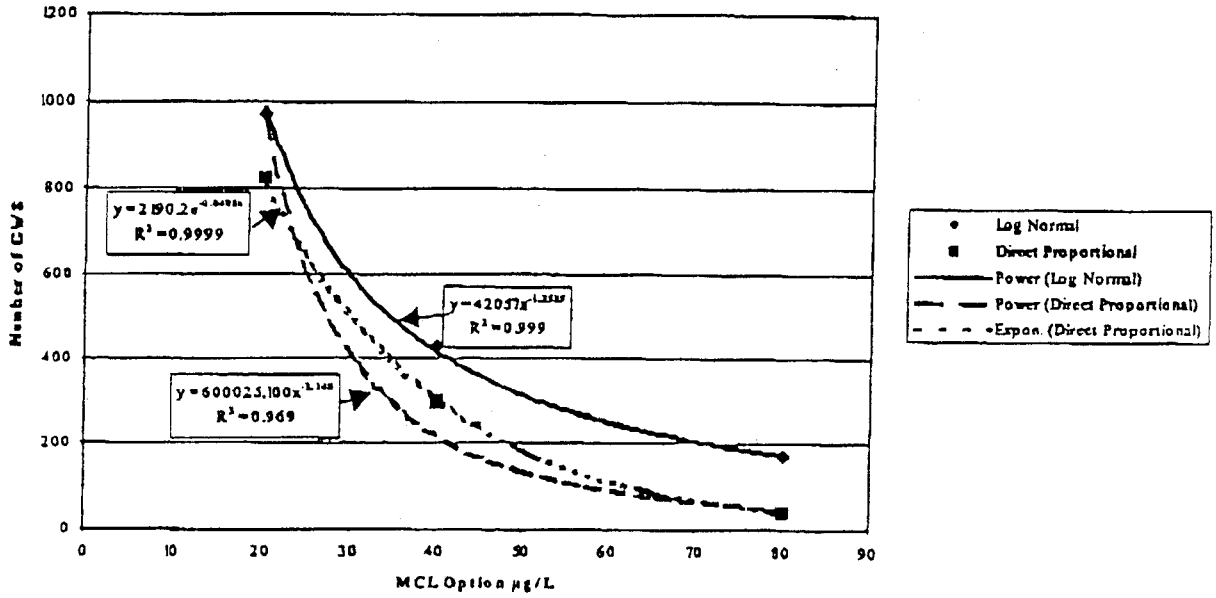


EPA'S INTERPOLATION METHODOLOGY FOR 30 µG/L MCL

Rather than perform a new CBA for a 30 µg/L MCL, the Agency used interpolation to first compute the number of affected systems and then the associated costs, population affected, risk reduction, and benefits. The Agency fit the data with power functions to describe a relationship between MCL option and the parameter of interest (e.g., number of affected systems). EPA illustrated the relationship for number of systems in Exhibit 7-1 of the Economic Analysis. However, inspection of Exhibit 7-1 of the Economic Analysis indicates that the power equation under-predicts the number of affected systems for the direct proportional occurrence distribution.

The data were examined to set if another equation would provide a better fit. The results of that evaluation indicated that an exponential equation fits the direct proportional data better than a power equation, while the power equation used by EPA provides the best fit of the log normal data. Exhibit A.3 shows the three curves in question, with equations and r^2 values.

Exhibit A.3. Number of affected CWS vs MCL option



Similar analyses, not shown here, indicate that power equations provide the best fit for interpolating annualized capital and annual operation and maintenance costs for treatment compliance costs.

CONCLUSIONS

This analysis suggests that the NIRS data likely under-predicts uranium occurrence in groundwater systems, especially those serving populations above 500 people. Thus, the direct proportional model, which shows little occurrence in these larger systems for uranium concentrations above 20 µg/L, appears to be inappropriate, and the log normal model provides better occurrence predictions. Comparison with arsenic occurrence studies suggests that the 3:1 ratio of groundwater to surface water occurrence likely increases by a factor of at least two as uranium concentrations increase.

REFERENCES

Longtin, J. 1990. Occurrence of Radionuclides in Drinking Water, A National Study. In Radon, Radium and Uranium in Drinking Water. Cothern and Rebers, Editors. Lewis Publishing: Chelsea, Michigan.

Oak Ridge National Laboratory. 1981. Uranium in U.S. Surface, Ground, and Domestic Waters. EPA-570/9-81-001.

U.S. EPA. 2001a. Federal Register, 40 CFR Parts 9, 141, and 142. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule. 66 FR 6976. January 22.

U.S. EPA. 2000c. Federal Register, 40 CFR Parts 9, 141, and 142. National Primary Drinking Water regulations; Radionuclides; Final Rule. 65 FR 76707. December 7.

U.S. EPA. 2000d. Comment-Response Document, National Primary Drinking Water Regulations, Radionuclides, Notice of Data Availability (April 2000). Washington, DC. November.

U.S. EPA. 2000e. *Economic Analysis of the Radionuclides National Primary Drinking Water Regulations*. Prepared for U.S. EPA by Industrial Economics. November.

APPENDIX B

ANALYSIS OF URANIUM MONITORING COSTS

In the NODA, EPA included annual monitoring costs for potential uranium MCLs of 20, 40, and 80 pCi/L for occurrence estimates by the direct proportional method and by the log normal method. In the final rule and Economic Cost Analysis, EPA did not include monitoring costs in the cost-benefit analysis, but did provide monitoring costs for separate uranium monitoring cost for the 30 μg/L MCL. Exhibit B.1 below summarizes these cost estimates. The exhibit also includes interpolated values of monitoring costs for a 30 pCi/L MCL by direct proportional method (linear interpolation) and log normal (log interpolation).

Exhibit B.1
Annual uranium monitoring costs

EPA analysis source		MCL (1 pCi/L = 1 μg/L)	Annual monitoring costs ($M/yr)
NODA	Direct proportional	20 pCi/L	5.22
	Log normal	20 pCi/L	5.48
	Direct proportional	30 pCi/L	5.06
	Log normal	30 pCi/L	5.16
	Direct proportional	40 pCi/L	4.89
	Log normal	40 pCi/L	5.05
	Direct proportional	80 pCi/L	4.75
	Log normal	80 pCi/L	4.86
Final rule	Average of DP + LN	30 μg/L	0.165

The final rule costs were presented in terms of present worth costs annualized over 23 years after rule promulgation. The 23 year period includes a 3 year state startup period plus 20 year compliance period. The basis of the NODA costs is unknown; however, they appear to be developed on the same basis of annual treatment costs, which were not discounted. The undiscounted total annual uranium monitoring costs would be about $194,000 per year, over a 20-year period. Using the NODA data and interpolating between 20 pCi/L and 40 pCi/L, the average annual uranium monitoring costs would be about $5,160,000 per year for the 30 μg/L MCL. In any case, there is a substantial difference between monitoring costs presented in the NODA and the final rule.

URANIUM MONITORING REQUIREMENT

Exhibit B.2 provides a summary of the uranium monitoring requirements under the final radionuclides rule. The distribution of CWS by gross alpha and uranium concentrations are those EPA includes in its radionuclides Information Collection Request (ICR). The final rule also includes the monitoring requirements for uranium, including the substitution of gross alpha measurements for uranium when gross alpha is ≤ 15 pCi/L. The EPA analysis assumes that one pCi/L of uranium equals one µg/L of uranium. In that analysis, EPA estimates that 558 systems would exceed the 30 µg/L uranium MCL, while the final rule indicates that 500 systems would be affected.

Exhibit B.2
Projected final rule uranium sampling requirements

CWS classification by gross alpha and uranium concentrations	Number of CWS	Minimum number of initial U samples	Uranium samples for 9 year cycle
Gross alpha ≤ 3 pCi/L	47,179	0[a]	1 sample in 9 years[b]
3 pCi/L < gross alpha ≤ 15 pCi/L	4,862	0[a]	1 sample in 6 years[b]
Gross alpha > 15 pCi/L; uranium ≤ 30 µg/L	557	4 samples in 1 year	1 sample in 3 years
Gross alpha > 15 pCi/L; uranium > 30 µg/L	558	4 samples in 1 year	4 samples per year
Totals	53,156		

a. Final rule allows gross alpha to be substituted for uranium if gross alpha ≤ 15 pCi/L.
b. Guidance and Implementation Manual unclear as to whether GA measurements can be substituted for these samples.

URANIUM MONITORING COST COMPARISON

The Radionuclides ICR was examined to determine the basis of the uranium monitoring costs and whether the analysis could be replicated. The ICR provides a detailed year analysis of uranium monitoring costs (referred to as Scenario 2A) for a 23 year period beginning November 2000. The monitoring costs are presented in terms of present value and annualized present value. Although not cited in the ICR, EPA appears to have followed the procedures in Section 6 of its Guidelines for Preparing Economic Analyses for discounting costs. Exhibit B.3 summarizes the EPA ICR analysis, which can be easily reproduced if one accepts EPA's occurrence assumptions.

Exhibit B.3
Monitoring cost comparison for 30 μg/L uranium MCL

Monitoring cost parameter	EPA ICR estimate	Guidance manual estimate	This study best estimate
Number of uranium samples over 23 years	27,345	255,370	81,503
Present value of analytical costs, i = 7% ($M/y)	1.72	14.1	4.86
Annualized present values (23 year period)			
Annualized analytical cost ($M/y)	0.150	1.25	0.430
Annualized labor cost ($M/y)	0.015	0.13	0.043
Total Annualized monitoring cost ($M/y)	0.165	1.38	0.473
Undiscounted annual monitoring costs (20 year period)			
Number of uranium samples per year	1,367	12,786	4,075
Annual analytical costs ($M/yr)	0.175	1.63	0.522
Annual labor costs ($M/yr)	0.019	0.166	0.053
Total annual monitoring costs ($M/yr)	0.194	1.80	0.575

The EPA ICR uranium monitoring costs appear to represent the minimum costs that utilities may encounter. EPA assumes that about half of the affected systems (U > 30 μg/L) will grandfather data, gross alpha data will be substituted for uranium analysis where gross alpha ≤ 15 pCi/L, and that after the first sample round of quarterly samples, affected systems will composite quarterly samples and analyze yearly.

The discounted costs in the ICR analysis cover both analytical and labor costs. Exhibit B.3 also includes the undiscounted annual costs (20 year actual sampling period basis). This analysis indicates the total average annual uranium monitoring costs for EPA's ICR would be about $194,000 per year.

Exhibit B.3 also provides two alternative analyses to compare with EPA's ICR analysis. These include one scenario based on EPA's Draft Implementation Guidance for Radionuclides (EPA 816-D-00-002) and our best estimate of these costs. The Guidance document delineates how states should implement their monitoring programs and specifies sampling frequencies. The Guidance Manual estimate assumes that no data are grandfathered and that after the initial monitoring period, no gross alpha data are substituted for uranium measurements and that systems do not composite samples. This scenario represents the maximum monitoring costs for the assumed CWS distribution. The last column includes a best estimate developed for this study. This estimate is similar to EPA's ICR estimate, in that gross alpha analyses are substituted for uranium analyses when gross alpha ≤ 15 pCi/L and some grandfathering is allowed; however, affected systems do not composite samples and analyses are spread over monitoring periods

uniformly, rather than assume to occur in specific years (e.g., a third of the samples requiring once in 3 years monitoring would be monitored each year rather than all samples monitored every three years).

This comparison indicates that monitoring costs could range from $194,000 per year (ICR estimate) to $1,800,000 per year (Guidance Manual estimate), with a best estimate of $575,000 per year. These monitoring costs represent about 0.4% to 3.5% of the $49,700,000 per year annualized compliance cost estimate for the 30 µg/L MCL in the CBA.

APPENDIX C

USING CBA TO GAIN INSIGHTS WHEN IMPORTANT BENEFITS ARE UNQUANTIFIED OR OMITTED

BACKGROUND

A challenge in developing and interpreting CBAs arises when an important benefit or cost cannot be readily quantified or expressed in monetary terms. For example, the principal health risk benefit underlying the recent (December 2000) uranium standard is kidney toxicity. The level of renal toxicity risk is highly uncertain and therefore cannot be quantified (i.e., there is no way to estimate a projected number of disease cases avoided). In such a circumstance, benefits cannot be directly compared to costs.

When potentially important benefits (or costs) cannot be directly included in a quantitative CBA, an unsatisfactory option is to ignore the omitted benefits or costs, and base the decision only on those benefits and costs that can be included. This is undesirable because if important benefits are left out, then an MCL will not be set as stringently as it should. Likewise, if important costs are omitted, then the CBA would suggest an MCL that is overly stringent. On the other end of the spectrum, an omitted benefit or cost should not be given undue weight in setting a standard, because the objective is to try to set an MCL at a level that maximizes net social benefits. Therefore, even though an unquantified benefit may be important and should not be overlooked, it should not be used "carte blanche" to set an overly stringent MCL (and vice versa, for an omitted cost).

Given that a potentially significant unquantified (or unmonetized) cost or benefit should neither be ignored or afforded undue weight and influence, the question arises as to how analysts should address the problem. To determine how much weight should be given to considering an unquantified benefit or cost, several informative options can be explored to try to include the omitted (nonmonetized) benefits or costs within the CBA framework in as useful and objective a manner as possible. In some cases, this will simply entail providing a good qualitative discussion of the unquantified outcome so that decision-makers can take it into account along with the numeric CBA findings. If benefits already exceed costs, then a qualitative discussion of

nonmonetized benefits only helps reinforce the obvious outcome (and the same is true if the omitted component is a cost and the monetized net benefits are already negative).

Where the omitted element might alter the net benefit result (e.g., an important benefit is omitted where the monetized CBA components yield a negative net benefit), a "break-even" form of implicit valuation analysis may be useful. This is a semi-quantitative approach in which the analyst back-calculates from the estimated net benefit to determine how large the value of the omitted benefit (or cost) would need to be for the total benefits and costs to be equal (net benefits are zero). For example, if monetized costs exceeded benefits by $100 million, then a nonmonetized benefit would need to be worth at least $100 million for the CBA to "break even." It may be quite obvious that the omitted benefit is (or is not) likely to be worth this amount of money. This approach is particularly relevant and applicable to the MCL for uranium (promulgated December 7, 2000, at 65 FR 76707).

URANIUM AND KIDNEY TOXICITY: INTERPRETING UNQUANTIFIED BENEFITS IN A CBA CONTEXT

In the uranium example, EPA's analysis reveals that modest benefits are expected from reduced risks of cancer, but the monetized value of these benefits are well below the anticipated compliance costs (Exhibits C.1 and C.2). However, the primary health risk of concern is kidney toxicity, because there is some evidence of cellular-level changes in the kidney at elevated levels of long-term uranium exposure. This potential health benefit cannot be quantified as estimated numbers of cases avoided because it is unknown whether the potential for cellular level changes within the kidney are associated with an increased risk of a manifested adverse health effects (i.e., the potential change in kidney cells has not been associated with any increased risk of kidney disease).

Since the level of risk (if any) is not quantifiable, one cannot estimate a number of adverse health effect cases (kidney illnesses) avoided by alternative MCLs. Thus, it also is not possible to directly assign monetary values to these risk reduction benefits. Given the net benefits are negative for the MCL options when considering only the cancer risk reductions, how much weight should be assigned to the potential risks of kidney toxicity? An informative

Exhibit C.1
Total net benefits: Total benefit minus total cost
(millions 1998 $ per year, cancer benefits only)

MCL option	Total benefits	Total costs	Net benefits
80	$0.8	$12.9	$(12.1)
40	$1.2	$33.3	$(32.1)
30	$1.4	$49.7	$(48.3)
20	$1.8	$90.5	$(88.7)

Costs from EPA Economic Analysis (Dec 2000), Ex 7-7 (U.S. EPA, 2000e).
Costs appear to omit monitoring costs ($0.2M to $1.8M/yr at 30 µg/L).

Exhibit C.2
Incremental cost-benefit analysis
(millions 1998 $ annually, cancer benefits only)

MCL option	Incremental benefits	Incremental costs	Incremental net benefits
base ⇒ 80	$0.8	$12.9	$(12.1)
80 ⇒ 40	$0.4	$20.4	$(20.0)
40 ⇒ 30	$0.2	$16.4	$(16.2)
30 ⇒ 20	$0.4	$40.8	$(40.4)

Costs from EPA Economic Analysis (Dec 2000), Ex 7-7 (U.S. EPA, 2000e).

approach can be investigated based on examining the "cost per person exposed." More specifically, since the renal toxicity risks are based on a threshold (i.e., there is a lifetime dose that is considered zero risk, with a margin of safety), the approach can focus specifically on the cost per person for those individuals who would be exposed above the 'safe' level of lifetime exposure without the MCL, but moved below the no risk level by the MCL.

Using standard risk assessment practices for systemic risks, EPA established a drinking water equivalent level (DWEL) concentration of 20 µg/L for uranium. This is the level that EPA states poses no risk of cellular level changes within the kidney to even highly sensitive and highly exposed individuals, with an adequate margin of safety. This "zero risk" level was derived by EPA using standard risk assessment techniques, embodying conservative (precautionary principle) adjustments and assumptions. For example, an uncertainty factor of 100 is applied to the dose-response data, and a exposure is based on 2 L/day of water consumption (which

approximately reflects a 90th percentile of per capita tap water consumption) over a 70 year lifetime.[1]

For any potential MCL option, one can estimate a distribution for the percent of the population expected to exceed the lifetime safe dose. Using census data on the distribution of residential durations, coupled with EPA data on occurrence (estimates of the percent of CWS above each MCL), one can estimate the percent of individuals expected to have exposure durations of varying levels (combining how often people move with the likelihood that they will move into, out of, or return to a CWS with contaminant levels elevated above the given MCL option). The probability distribution of exposure durations can then be coupled with the distribution of tap water consumption derived by EPA, using the reasonable assumption that an individual's daily tap water consumption levels (L/day) are independent of their lifetime exposure duration (years in CWS with water above the MCL).

Given that the DWEL (20 µg/L for Uranium) reflects a 70 year exposure duration for an individual consuming 2 L/day of their CWS tap water, there is virtually no individual who would be expected to consume a total lifetime dose above the zero risk level implied by the oral RfD. Only those individuals that resided for 70 years or more within CWS with elevated uranium and also consumed above the 90th percentile of tap water would exceed the safe lifetime dose, and the joint probability of this occurring in any given individual is virtually zero. At a concentration of 40 µg/L, or twice the uranium DWEL, those who consumed a more typical (near mean) level of 1 L/day of tap water and also resided in uranium-impacted CWS for 70 years or more would be above the lifetime safe dose. At twice the DWEL, those individuals who consume 2 L/day but lived in elevated Uranium CWS for 35 or more years (as well as any person with any combination of water consumption and residence duration scenarios in between) also are above the safe lifetime exposure implied by the oral RfD.

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1. EPA recognizes that the compounded effect of the conservative assumptions underlying the DWEL implies that zero risk (or, at worst, de minimus risk) can be achieved with drinking water concentrations above 20 µg/L DWEL, stating that there is "not a predictable difference in health effects due to exposures between the DWEL of 20 µg/L and a level of 30 µg/L" (U.S. EPA, 2000c, p. 76713). EPA adds, "Given that the uncertainty factor of 100 provides a relatively wide margin of safety, the likelihood of any significant effect in the population at 30 µg/L is very small. EPA thus believes that the difference in kidney toxicity risk for exposures at 20 µg/L versus 30 µg/L is insignificant" (U.S. EPA, 2000c, p. 76714). Nonetheless, the illustration developed here uses 20 µg/L as the zero risk level for persons consuming 2 L/day for 70 years, and assumes some positive risk exists for lifetime exposures above that level.

Statistical simulations indicate that for any given safe lifetime dose, the following percentages of impacted CWS populations would be above the zero risk lifetime level of exposure: with tap water concentrations at 150% of DWEL (30 µg/L for U): 0.24%; 200% of (i.e., twice) the DWEL: 0.52%; and 400% (four times) the DWEL: 1.98%. Using these results, one can determine how many people are moved from above the lifetime safe dose to below the zero risk level by a given MCL increment. For uranium, the estimates are 4271 people from baseline to an 80 µg/L MCL, 4844 for the increment from 80 µg/L to 40 µg/L, 611 for the 40 µg/L to 30 µg/L increment, and 1317 if the standard is pushed from 30 µg/L to 40 µg/L.

Exhibit C.3 summarizes the findings, showing the annual and lifetime (70 year) incremental net costs where the quantified benefits include only cancer risk reductions. When these net costs are divided by the number of lifetimes where the risk status has been changed by the MCL options, the incremental cost per person exposed above the lifetime safe dose is derived. As shown in the last column of Exhibit C.3, the implicit valuation outcome for the unquantified benefit was that the "cost per person exposed" (but not necessarily having any adverse health effect) would have to be worth at least $198,000 for the incremental benefits to be at least as great as the incremental costs of moving from baseline to the 80 µg/L MCL option, and jumps to approximately $2 million per person at the more stringent incremental options headed toward 30 µg/L or 20 µg/L.

Exhibit C.3
Incremental cost per person exposed to kidney toxicity risk
(monetary results in millions of 1998 $s per year, population in 000s)

	Incremental population exposed		Incremental net	Cost per person
MCL option	Total	Above RfD	benefit	exposed above RfD
base => 80	111.25	4.27	$(12.1)	$0.20
80 => 40	331.75	4.84	$(20.0)	$0.29
40 => 30	218.14	0.61	$(16.2)	$1.86
30 => 20	548.93	1.32	$(40.4)	$2.15

Source: Raucher et al, forthcoming, for Awwa Research Foundation

This type of analysis still leaves room for judgement and interpretation, but at least casts the issue into a framework that is informative. For example, based on the results shown in Exhibit C.3, the unquantifiable benefit now can be considered in the context of, "Is $200,000 per person (or $2 million per person) a reasonable investment in public health in this instance?" One

might argue that it seems unlikely that such an expense is warranted. For example, EPA's *Cost of Illness Handbook* (U.S. EPA, 2001b) and the uranium rule's Economic Analysis (U.S. EPA, 2000e) indicate that $100,000 is roughly the estimated cost to treat someone with an actual case of cancer, and treating 2 (or 20) known cancer patients seems to be a better public health investment than reducing exposures for 1 person who may not exhibit any discernable kidney function changes or disease. Alternately, the cost of a kidney transplant, including one year of medical care following surgery, now costs less than $90,000 (University of Maryland Medicine web page www.umm.edu/news/releases/kidcost/html). Should society pay twice this amount to reduce a risk of kidney cellular change in one person?

The analysis in Exhibit C.3 also shows how much the cost per person at risk increases with the more stringent MCL options (because fewer people are at risk, and concurrently the incremental net costs increase). By using this approach, the problem has been placed into a framework that can guide policy deliberations and reveal the consequences of MCL-setting decisions.

APPENDIX B

White Paper

Blending Science with Policy: Precautionary Assumptions and Their Impact on Benefit-Cost Analyses and Drinking Water Standards

Executive Summary

Under the 1996 Safe Drinking Water Act Amendments (SDWAA), benefit-cost analysis (BCA) is now an integral part of the regulatory development process in the United States. This paper reveals why and by how much benefits may be overstated when traditional precautionary science policy assumptions are embedded in the risk assessments that form the foundation for a benefits analysis.

Before the 1996 SDWAA, risk assessment was used in drinking water standards development only to identify the level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" — in other words, to establish what the statute defines as a Maximum Contaminant Level Goal (MCLG). In this limited role of determining a "no risk level" for a contaminant concentration, risk assessors have been guided by precautionary science policy choices that err on the side of safety when facing the considerable uncertainties and variabilities that enter the risk assessment process. Using these conservative assumptions and other precautionary rules of thumb is consistent with the objective of identifying a concentration that poses no risk for even the most highly exposed and most sensitive individuals, including a margin of error.

However, when risk assessments are applied in a risk management context, the conservative assumptions embodied in the precautionary approach are likely to lead to misleading results. In a benefit-cost application, risk assessments need to be well grounded upon what is likely to occur; the risk assessment must revert back to the underlying science rather than the policy judgments inherent in the conservative science policy choices. Because BCA contributes to risk management deliberations on how stringently to set MCLs, it is contrary to good science and statutory directives to carry forward risk estimates that are significantly impacted by myriad precautionary science policy assumptions. The treatment of these

uncertainties tends to inflate the level of risk posed by contaminants, and therefore leads to an overstatement of the benefits of regulations.

The degree to which risk reduction benefits are overstated (if at all) will vary considerably from contaminant to contaminant, depending on many factors. However, the illustrative examples shown in this paper indicate that it is not unreasonable to suspect that benefits derived using precautionary assumptions may be 10, 20, 100, or even many more times higher than one would expect at the mean or median of the benefits distribution.

In view of the potentially significant impact precautionary assumptions can have on estimated risks and associated BCAs, the following recommends are offered:

1. EPA and other entities that develop risk and benefit estimates should practice full disclosure and provide complete transparency by listing all the precautionary assumptions embedded in a risk reduction benefits assessment.

2. To the extent possible, EPA and other entities should remove precautionary science policy assumptions and provide central tendency estimates for their risk reduction and associated benefits estimates (as well as probability distribution information or, at a minimum, reasonable lower and upper bounds).

3. Comprehensive sensitivity analyses should be applied as an essential tool to help reveal the individual and collective impact of precautionary assumptions on the risk and benefits findings presented to decision-makers, regulatory reviewers, and other stakeholders.

Blending Science with Policy: Precautionary Assumptions and Their Impact on Benefit-Cost Analyses and Drinking Water Standards

Introduction

This white paper examines the use of "precautionary assumptions" and their implications for setting drinking water standards. The paper explores how "science" and "policy" must blend when mandates to protect public health come face-to-face with uncertainty about the risks posed by a contaminant. The focus here is on issues that arise in the context of how *risk assessments* derived using conservative assumptions are applied within the *risk management* context of benefit-cost analysis and standard setting.

When drinking water standards are being developed, regulators need to carefully weigh potentially sizable human health risk reduction benefits against the anticipated costs of a Maximum Contaminant Level (MCL). The estimated health benefits are typically based on science-based risk assessments that contain several critical uncertainties. Collectively, the manner in which these uncertainties are addressed within the risk analysis can have an overwhelming impact on the estimated level of risk reduction that a given MCL option is expected to generate.

In some instances, the scientific risk assessments are so affected by uncertainties that it is difficult to determine whether the most likely health benefits are trivially small, or whether they are large enough to constitute a wise investment in public health protection. These issues take on added significance when the regulations affect rural households served by small community water systems, because the cost of compliance per impacted household tends to be relatively high for these beneficiaries.

In such a policy-making context, the stakes are quite high. If we under-regulate, then we are exposing people to undue health risks. However, if we over-regulate, then we are imposing

high costs that are disproportionate to the health benefit people are receiving (and we are misdirecting resources that otherwise might be applied to reducing risks in other areas of life).

Making prudent public health regulatory decisions in this high stakes context is especially challenging when the "science" underlying the risk estimates is embedded with many conservative assumptions that are established as a matter of "policy." The use of conservative "science policy" assumptions is guided by what is often referred to as the "precautionary principle." The precautionary principle is sometimes defined differently by different entities and individuals (see below), but for the purposes of this white paper the term is used broadly to reflect an approach or philosophy that, in essence, calls for "erring on the side of safety" by using risk assessment protocols that are more likely to overstate a risk (rather than to under estimate it) when uncertainties and/or variabilities are present.

Policy-imposed conventions on how risk assessments are conducted with conservatism have merit in some risk policy applications (as described below). However, the cumulative impact of conservative science policy assumptions lead to health risk estimates that potentially are significantly overstated for drinking water contaminants in the relevant concentration range. This in turn leads to potentially significant over-estimates of the public health benefits of a potential MCL. This will create misleading benefit-cost comparisons and, in turn, may lead to regulatory decisions that are not well informed.

Accordingly, this paper examines how, and by how much, the use of conservative science policy assumptions can impact a risk estimate and the benefit-cost analysis that applies the risk results (and which, ultimately, is likely to affect the MCL selection). The objective is to reveal the potential impact of current practices and explore how science policy may need to be altered or re-interpreted when the resulting risk assessments are applied within the risk management contexts of benefit-cost analysis and standard setting.

A Basis for Erring on the Side of Safety: Where "Science" Ends and "Policy" Begins

When policies are made in the interests of protecting public health, officials typically need to make critically important decisions by relying on technical information that is incomplete and often highly uncertain. In such instances, "science" cannot provide clear-cut answers and policy-making requires taking account of many other considerations.

Where public health is at risk, there are prevailing moral codes and cultural values that suggest that society "err on the side of safety" to protect the innocent in the face of uncertainty. This core philosophy is deeply rooted in many of our nation's social and legal institutions, and in the regulatory context it is embodied in what is sometimes referred to as the precautionary principle. In short, it is part of the prevailing cultural belief system that is the fabric of our society.

When discussions are held on broad, philosophical terms, there is little debate about the importance of protecting public health and erring on the side of safety. However, the issues become far more complex and controversial when specific policy applications are being considered. When the stakes involved in making a poor regulatory decision are high if we err toward either too little or too much health protection (e.g., when compliance costs may be very high, and/or where the risk outcomes are irreversible), then several pragmatic concerns logically arise. Key issues include:

1. Are the individual and cumulative impacts of conservative science policy assumptions on the estimated risk and benefit outcomes transparent to analysts, decision makers, and stakeholders?

2. How much erring on the side of caution is embodied in the analyses? How far are the resulting risk and benefits estimates skewed upward to very low probability outcomes by

the cumulative use of precautionary assumptions? How do the final risk and benefit estimates compare to more likely (higher probability) scientifically based estimates?

3. How much will it cost to provide a broad margin of safety? What is the benefit-cost comparison when considering the most likely range of anticipated health risk reductions, and how different is this from the benefit-cost findings derived when highly conservative risk estimates are used as the basis for the analysis?

Defining the "Precautionary Principle"

In this paper, we apply the term "precautionary principle" in the broad context in which uncertain science-based findings are (1) directly affected by policy decisions about how conservative assumptions are applied in risk assessments, and/or (2) interpreted within a risk management context in which policy-making consciously errs on the side of safety. In other words, for the purposes of this paper, the term precautionary principle is interpreted broadly to include conservative science policy assumptions that are embodied within risk assessments, and also the manner in which those risk assessments are interpreted within the decision-making framework of risk management.

Readers should note that in some writings, a distinction is made between the two facets noted above. For example, the Commission of the European Communities (CEC) refers to the precautionary principle only in the context of how decision-makers manage risks. The CEC notes that the precautionary principle "should not be confused with the element of caution that scientists apply in their assessment of scientific data" (CEC, 2000). In the European Union, the precautionary principle is seen as a risk management tool, not a risk assessment tool. There, the best science is used for the risk assessment, the uncertainty is assessed, and this information is given to the risk manager. It is only after this point that the precautionary principle is applied, as the decision-maker decides what to do in the face of this uncertainty. In the United States, the process is somewhat reversed, with precautionary assumptions influencing the risk assessment

results upon which risk managers rely when making policy decisions. These issues are discussed below.

The Risk Assessment Context

The CEC (and others) make a key distinction between risk *assessment* and risk *management* when applying terms such as the precautionary principle. In reference to the former, some prefer to use terms such as "prudential approach," "precautionary assumptions," or "science policy" to reflect conservative assumptions that are embodied in risk assessments as a matter of policy:

> The prudential approach is part of risk assessment policy which is determined before any risk assessment takes place and ... is therefore an integral part of the scientific opinion delivered by the risk evaluators. (CEC, 2000, p 12).

This notion of "prudential approach" is more generically referred to (at least in the U.S.) as part of "science policy" and, in specific, refers to the set of conservative practices that are applied within risk assessments as a matter of established policy. Regardless of the term applied, the core concept is that scientists use predetermined (i.e., established) policy decisions to guide their scientific investigations.[1] The policy-influenced science estimates derived from these risk assessments are then reported back to policy-makers, who take the results into account (along with other factors) in determining how to shape policies or establish regulations.

For example, when estimating dose-response functions, estimates of cancer risk posed at high doses often need to be extrapolated to the low doses relevant for regulatory scenarios. As a

1. Perhaps a more accurate statement is that the policy decisions often guide the summarization of the scientific investigations, not necessarily the investigations themselves. For example, the risk assessor usually considers multiple models and their relative merit, but then provides only the high-end predictions from the upper confidence interval of the more conservative model when presenting a summary of the estimated risks to those making the risk management decisions.

matter of policy, the U.S. Environmental Protection Agency (EPA) applies a linear dose-response model to make these extrapolations, even though the linear model is not necessarily supported by emerging scientific evidence for many carcinogens and it is likely to overstate risks at low doses. The linear model is — as a matter of policy — EPA's default assumption, and it is used unless there is a considerable body of compelling scientific evidence supporting a more likely model for a given contaminant.

Why is the linear model used as a matter of policy? The linear model generally is not always justified on scientific merit.[2] It often is not the most accurate portrayal of the dose-response function; indeed, nonlinear functions are now believed to be more reflective of dose-response relationships for many carcinogens acting by nongenotoxic mechanisms. Rather, the linear model is applied because it is unlikely to underestimate risks at low dose. That is, the presumption of a linear model is a conservative assumption and has been adopted — as a matter of policy — to minimize the possibility that estimated risks will be understated at the dose of concern. This aspect of the "scientific" process of risk assessment is driven by a policy decision — and the policy decision that underlies the "scientific outcome" is that it is important to err on the side of safety when estimating the risk posed by carcinogens at environmentally relevant exposure levels.

Is it appropriate to err on the side of safety when conducting risk assessments? The answer depends on how the risk assessments are to be used. The use of conservative science policy assumptions arose from how risk assessments were initially conceived — as a process to provide estimates of "safe doses" at which there were no anticipated risks to even the most highly exposed and highly sensitive individuals, with an adequate margin of safety. In other

2. Many in the scientific community may say that the linear model is justified in the case of purely probabilistic events such as DNA damage, and becomes a better approximation as the variability in sensitivity and susceptibility increases. What is clear is that it is not justified to simply state that a dose-response curve should be linear *a priori*.

words, the risk assessors' original mission was to develop estimates of exposure levels that were risk free.[3]

In this context, the use of safety factors and conservative assumptions are a logical practice and are consistent with the narrowly defined mission. For example, this is a suitable approach for the intended use of risk assessments in the context of setting an MCLG, which is a "risk free" *goal*. However, this conservative approach is not appropriate in a risk *management* context such as where to set an enforceable MCL (or in estimating the benefits of a potential MCL). Risk assessments, when applied and interpreted within the context of risk management, need to be stripped of precautionary biases.

The Risk Management Context

Risk management refers to taking the risk characterization output from the risk assessment process (as well as many other factors such as economics, social justice), and deciding what actions, if any, are prudent for reducing the risk (e.g., by deciding whether or not — or at what level — to set an MCL). The risk characterization may include an estimate of the risk borne by an exposed individual (e.g., a $1.0 * 10^{-4}$ lifetime risk of developing cancer), and/or an estimate of the number of adverse health effect cases anticipated (e.g., 1.3 excess cancer cases per year nationwide). These outcomes of the risk assessment are policy-influenced scientific estimates (because precautionary assumptions are routinely used to develop them). These policy-

3. Another reason for these assumptions appearing in risk assessments was that the risk mitigation process in the U.S. tended to focus on one chemical and route of exposure at a time. As a result, it did not account for exposure of populations to multiple pollutants. So, the process of considering one chemical at a time tended to underestimate risk. The use of the default assumptions is in part a response to this, with the hope that it would compensate for this error introduced by the focus on a single chemical and route of exposure when comparing against risk goals. Hence, the default assumptions were not always introduced solely to provide a margin of safety, and not solely to err on the side of safety, in the face of uncertainty in risk estimation.

influenced estimates are then fed back to policy-makers for their consideration when developing a course of action.

Because regulatory policy decisions are made based in large part on estimates of risks and benefits developed from the risk assessment process, the use of precautionary assumptions may have a large (and nontransparent) impact on risk management decisions. Accordingly, the need to separate the precautionary principle out of risk assessments when they are applied in a BCA framework recently has gained increased recognition.

For example, the U.S. General Accounting Office (GAO) recently published an excellent report on this topic, *Use of Precautionary Assumptions in Health Risk Assessments and Benefits Estimates* (GAO, 2000). The GAO report was prepared in response to a request from Congress, and addresses Congressional concerns that EPA's use of precautionary assumptions in estimating health risks "could produce overly optimistic estimates of the benefits of regulatory actions" (p. 3).

The heart of the matter is that precautionary assumptions are built into risk assessments and thus become ingrained in the information (such as benefit-cost analyses) that regulatory decision-makers use to make their policy choices. Because these precautionary aspects tend to overstate risks and benefits (sometimes to a considerable degree), regulatory and other policy decisions 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). This potential for using skewed risk and benefits estimates in the risk management context is at odds with the principle of using "good science" in policy-making, and it also is contrary to applicable federal guidelines and statutory provisions, as shown below.

Federal Mandates and Policies on Precautionary Approaches for Drinking Water

As noted above, the application of precautionary assumptions to risk assessments can be a legitimate exercise — it all depends on the intended use of the risk assessment. For example, the Safe Drinking Water Act Amendments of 1996 (SDWAA) mandate that an MCLG must be established as a risk free goal. Accordingly, when risk assessments are used in the MCLG-setting process, they should contain suitable precautionary assumptions. For MCLGs, risk assessments are being used to define a "safe" level, with a margin of safety, for the most sensitive and exposed individuals. Yet even in this context, the risk assessment application has ramifications for risk management, because under the SDWAA the enforceable MCLs must be set "as close to the MCLG as feasible" (unless the Administrator determines that the benefits do not justify the costs).

In contrast, the use of precautionary assumptions is not appropriate in the risk management context of setting MCLs. As provided in the SDWAA of 1996, enforceable standards need to reflect a reasonable balancing of benefits and costs, and the risk reduction benefits should be estimated without the (generally) upward biases embodied in the typical precautionary assumptions of risk assessment. For analysts and decision-makers, the challenge becomes one of trying to isolate and remove the precautionary upward biases when using risk assessments in a benefit-cost or other risk management context (or at least to understand the magnitude of the conservatism, e.g., the percentile of the cumulative density function, so they can understand how much additional confidence in protection is being bought for the policy expenditure).

The SDWAA offer the following directions on the use of science in decision-making for drinking water standards [section 1412(b)(3)] (emphasis added):

> "...use the best available peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" [1412(b)(3)(A)].

- "...specify, to the extent practicable ...(ii) the expected risk or central estimate of risk" ... as well as "(iii) appropriate upper-bound and lower-bound estimates of risk"...and have "(iv) each significant uncertainty identified in the process of the assessment of public health effects..." [1412(b)(3)(B)].

- consider within the mandated benefit-cost comparison "...health risk reduction benefits for which there is a factual basis ...that such benefits are likely to occur as the result of treatment to comply..."[1412(b)(3)(C)].

These statutory directives clearly indicate that EPA should develop and consider risk and benefit estimates that reflect the *most likely* outcomes from a potential MCL-setting regulation.[4] The statutory language acknowledges that uncertainties will exist and that upper and lower bounds need to be presented and taken into consideration. However, the statutory language also is explicit that Congress intended EPA to provide estimates of *expected* (central estimate) risks when comparing benefits to costs and making regulatory decisions. This means that risk assessments as traditionally developed need to be re-interpreted to reflect expected risks for a BCA (rather than using, for example, dose level estimates derived to be safe with a margin of error — such that the estimated risks levels are likely to be over-stated).

EPA conveys a similar philosophy in its *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000a). Economic Analyses (EAs) are developed by EPA for all "significant" rulemakings (not just drinking water), and are submitted for review to the Office of Management

4. The language "likely to occur" then raises the probabilistic aspect of the risk estimates, which in turn leaves the Agency open to considering some percentile of the cumulative density function other than expected value, most likely value (mode), etc. Some may argue that the interpretation of this phrase has led to the incorporation of conservatism into estimates of risk, and is central to understanding the rationality of conservatism. Conversely, arguing against conservatism in this context requires development of an alternative, philosophically and legally sound, interpretation. Nonetheless, it is clear that a focus on central estimates — or at a minimum, a clear presentation of the central tendency risks and benefits (along with high end results) — is essential in the risk management context.

and Budget (OMB) in accordance with Executive Order 12866 (Federal Register, October 4, 1993). EAs contain assessments of the benefits and costs of the options under consideration in a given rulemaking. EPA's *Guidelines* explicitly state that benefit-cost outcomes should be presented "based on expected or most plausible values" and accompanied by sensitivity analyses to reflect the impact of key assumptions and uncertainties embedded in the analysis (p. 27). "...Uncertainties should be explored through the use of expected values supplemented by upper and lower bounds" (p. 176).

OMB has also issued similar directives in its recommended approaches for developing benefit-cost analyses to support regulatory decision-making. The Office's *Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements* (OMB, March 2000) directs federal agencies to "...calculate the benefits (including benefits of risk reductions) that reflect the full probability distribution of potential consequences ...and include upper and lower bound estimates as complements to central tendency ...estimates" (p. 9). The OMB guidelines further state that "some estimate of central tendency — such as the mean or median — should be used" for developing benefit-cost comparisons and decision-making (p. 15).

Therefore, it is clear from the governing federal statute — as well as in the relevant federal agency guidelines — that standard setting and other risk management activities should be based on central, most likely estimates of risks.[5] Plausible upper and lower bounds of risk also should be used to reflect uncertainties (and, if available, probability distributions are preferred to bounds). However, the application of risk assessments that embody the typical array of precautionary assumptions will not furnish the necessary "most likely" estimates of risks that are necessary and appropriate for BCA and standard setting

5. Court rulings can also affect how this problem is approached. Benzene and vinyl chloride-related decisions by courts in the early 1980s apparently have caused EPA to examine its risk management policies, and these court rulings do not necessarily support the idea that risk management activities should be based on central tendency or most likely estimates.

Where and How Precautionary Assumptions Affect BCAs for MCLs

Precautionary assumptions can enter into each component of a risk reduction benefits assessment, and then become compounded when the components are linked together. In this section, we describe each component of a typical analysis, starting with exposure assessment and proceeding to dose-response estimates and valuation. For each component, we outline major uncertainties and variabilities and whether and how they are addressed using standard precautionary assumption practices. Where we can provide empirical evidence, we also show the degree to which the use of the assumptions or uncertainty factors might overstate the estimates of exposure, risk, or value.

Readers should take note that the empirical illustrations of the impact of precautionary assumptions reveal quantitative effects that are case-specific. The results reveal the type and potential magnitude of the impacts of precautionary assumptions, but the results cannot typically be generalized as "assumption X always has a quantitative impact of Y% on the benefit or risk estimate." The numeric examples provide a sense of how much impact these assumptions have in the specific circumstances applied here, but the magnitude of the impact could be much different in other applications (e.g., when the same assumption is applied to other contaminants, or applied to other sets of circumstances that entail different combinations of assumptions and protocols).

Exposure Assessment

Most drinking water-related risk assessments rely on a standard set of exposure assumptions. These include the assumption that a person consumes 2 liters of contaminant-impacted tap water each day over a 70 year lifetime. These assumptions are used to develop "safe" or "risk free" concentrations. For example, for compounds that pose systemic (noncancer) risks from chronic exposure, EPA uses a zero risk "oral reference dose" (the dose at which no risks are anticipated in humans, including an ample safety margin) and converts it to a Drinking Water Equivalent Level (DWEL) based on these two exposure assumptions. The DWEL is then

used to develop the MCLG (typically, the MCLG is set equal to the DWEL, apart from rounding off the values).

In reality, most people consume considerably less than 2 L/day of tap water. The mean daily tap water consumption is slightly greater than 1 L/day (the mean is approximately 1.1 L/day, and 2 L/day is closer to the 90th percentile). In addition, people typically have activity patterns that take them out of the home (e.g., to schools or places of business) where they spend a significant portion of the waking hours and consume a significant portion of their daily water (often from a different water system than the one that serves their residence). People also undertake exposure averting behaviors, such as using bottled water or home treatment devices. Therefore, a typical or expected in-home tap water consumption level is probably well under 1 L/day. If the 2 L/day ingestion rate is applied in a BCA, exposure reductions (and hence risk reduction benefits) would in most cases be more than double the expected real outcome. Fortunately, in recent rulemakings EPA has applied an estimated distribution of daily water consumption in its benefits assessments, so that this potential bias is reduced in recent BCAs.

Duration of exposure is another key variable (especially for contaminants posing chronic rather than acute risks), and 70+ years is the standard assumption applied in risk assessments (73 years was used in the recent National Science Academy evaluation of arsenic risks [NRC, 2001]). However, in reality few people remain in the same community and receive exposures for a duration that is near that long. Median residential duration is 5.2 years in the U.S., meaning that members of half the U.S. households will occupy 14 or more different homes in a typical lifetime.

If a contaminant is present in only 5% of U.S. systems, then the expected additional exposure after a move is 3.4 years or less (.05 probability times 13 or fewer remaining moves, times 5.2 years at each location). Thus, even if a typical person is born in a water system where a contaminant is present at levels of concern, more often than not their total lifetime exposure

duration is expected to be 8.4 years or less (5.2 years at the outset, plus an expected 3.4 years (or less) from water served to their future home sites). In this example (in which we are assuming a 5% occurrence of the contaminant in water systems), the use of a lifetime duration of exposure would overstate the more typical or central tendency estimate by a factor of over 8 to 1 (73 years divided by 8.4 years = 8.7). EPA continues to estimate benefits based on lifetime exposure durations rather than more realistic scenarios.

How much might exposure assumptions alter a BCA? If a linear no-threshold dose-response function is applicable, the estimated lifetime cancer risk levels derived from the standard risk assessment (i.e., embodying exposure — related precautionary assumptions of 2L/day over 73 years) would yield a lifetime cancer risk estimate that is nearly 16 times greater than the expected (typical) risk reduction (2 L/day over 73 years implies a lifetime exposure that is 15.8 times larger than a more central estimate of 1.1 L/day over 8.4 years). If the contaminant occurred at elevated levels in 10% of the nation's community water systems (CWS) — rather than 5% as assumed above — then the precautionary assumptions overstate central tendency lifetime exposures by a factor of over 11 to 1 (but if occurrence was 1%, then the expected lifetime exposure is overstated by a factor of 22.6 when using the standard assumptions).[6] Table 1 summarizes this information.

In a nonlinear dose-response context, the impact of the assumptions can be greater or less than described above, depending on how anticipated exposures compare to the threshold dose (or, compared to the localized slope for nonlinear models that do not have thresholds). For example, the no-risk MCLG for uranium was recently set at 20 μg/L, using the usual precautionary assumptions of 2 L/day for 70 years (an uncertainty factor of 100 was also applied,

6. Note that with a linear no-threshold dose-response model, the exposure scenarios described here affect the typical (e.g., median) lifetime individual risk level but may not affect the national risk reduction estimates (e.g., number of cases avoided). With a nonlinear model, however, individual risk levels and national estimates of cases avoided will both be impacted by using empirically based exposure distributions rather than precautionary exposure assumptions.

as part of the dose-response interpretation, as discussed below). EPA's occurrence estimates indicated 550,000 people were served by systems with waters at a uranium concentration between 20 μg/L and 30 μg/L.

Under the standard precautionary assumptions, all of these 550,000 people would be identified as being exposed to uranium at levels that posed a nonzero risk (i.e., lifetime exposures of up to 150% of the no-risk level). However, given more realistic exposure variable distributions, only 1,300 people out of the 550,000 people in these systems with uranium concentrations over the MCLG were actually expected to have lifetime exposures above "zero risk" level (Raucher et al., 2001). Thus, the benefit of bringing these water systems down to 20 μg/L would be overstated by a factor of more than 415 (i.e., 550,000 people served divided by the 1,300 people who actually would be above the "no-risk" lifetime exposure level at 30 μg/L, but below it at 20 μg/L).

Dose-Response Assessment

Precautionary assumptions are generally most pervasive in the dose-response portion of the risk assessment. The many unknowns involved with dose-response components of human health risk assessments are systematically addressed through the use of uncertainty factors (and other assumptions) that can lead to expressions of risk that may be 100, 1000, or many more times greater than what might be called a "best" or "central estimate." The use of such uncertainty factors and other conservative assumptions (or default values) in risk assessments includes factors for extrapolations from high doses to low doses, across species (e.g., laboratory rodents versus humans), and other elements.

The type of precautionary assumptions applied and their impact on risk estimates depends on what type of risk the contaminant is expected to pose (i.e., the adverse health effect endpoint) and the type of data available. Consider, for example, ***noncancer risks*** posed by low-level chronic exposures, such as renal toxicity due to uranium exposure in drinking water (a systemic

or noncarcinogenic risk associated with long-term exposure). For uranium, the EPA risk assessment relied on data derived from laboratory animal experiments. A "no effects level" was observed in the laboratory studies of 60 μg/kg/day. To translate this rodent-based finding to humans, Agency risk assessors applied an uncertainty factor of 100 when converting the rodent results into the human-oriented safe dose (the "oral reference dose") of 0.6 μg/kg/day (i.e., 60 divided by the uncertainty factor of 100). This is how uncertainty is typically addressed for noncarcinogens posing risks from chronic exposure.

There are several similar, pre-established uncertainty factors that are routinely applied to risk assessments for systemics. These often are applied in compound manner, depending on the type and quality of the toxicological studies available and the data they generate. For example, an uncertainty factor of 10 may be applied for one reason (e.g., variations in population sensitivities), and other uncertainty factors of 10 each applied for two other causes (e.g., due to cross species extrapolations, the reliance on only short-term exposure studies, or application of a lab outcome using a "low observed adverse effects level" rather than a "no observed adverse effect level"). This would result in a combined uncertainty adjustment of 1,000 (10 times 10 times 10). The National Commission on Risk Assessment and Risk Management found that two or three safety factors are typically used in assessing noncancer risks, such that a 100- or 1000-fold combined impact is common (GAO, 2000).

How much do these uncertainty factors push the resulting risk or benefit estimates from the central, expected values? The uncertainty factors are applied to develop estimates of suspected thresholds, so the magnitude of the uncertainty factors is not necessarily the same as the magnitude of the potential overestimate of effects for exposures above the true threshold. Still, the impact can be sizable. Research suggests that a single 10-fold uncertainty factor typically is protective at the 95th percentile, whereas a single uncertainty factor of 3.2 is likely to generate an outcome protective of the median (50th percentile) and beyond (Swartout et al., 1998). The amount of protection depends on whether the factor is applied for inter-subject

variability or for one of the causes of uncertainty (interspecies extrapolation, weak data base, etc.). In general, though, the use of an uncertainty factor of 3.2 ensures protection of at least 68% of the population if only inter-subject variability is considered (the percentage protected is higher if the original human data were obtained on sensitive and/or susceptible individuals).

Typically, uncertainty factors are applied that are greater than 3.2 (as noted above, values of 100 or 1000 are common). If there are two uncertainty factors with a combined product of 50, this would yield a 95th percentile result, and if two uncertainty factors had a product of 100 (e.g., where both factors equal 10), the result is protective at the 99th percentile (Swartout et al., 1998, as discussed in the Awwa Research Foundation report by Raucher et al., 2001).

How much might these uncertainty factors impact an oral reference dose or DWEL for a noncarcinogen? An illustration developed in conjunction with an Awwa Research Foundation report suggests that for MTBE, standard EPA procedures would indicate a DWEL in the range of 8.8 mg/L, whereas an alternative approach using distributional data would suggest a standard 26 times higher (or more) (Crawford-Brown, 2000). This difference is based solely on the dose-response components (and does not account for possible changes to reflect central tendency exposure patterns). Although this illustration is MTBE-specific, the results probably are not atypical. Table 2 offers a generic illustration.

For ***carcinogens***, there are several precautionary assumptions that typically are applied in a compound manner, making it difficult to differentiate what the "best estimate" might look like given the multiple types of safety margins that enter the analysis. For example, the linear no-threshold model is used to extrapolate observations at high doses to the low doses relevant to most environmental exposures. In conjunction with this, a 95% upper confidence limit often is used to interpret this extrapolation (although some EPA decisions are now based on the maximum likelihood estimate). Cross-species extrapolation procedures may add additional safety margins. Numerous other factors and assumptions enter the analysis as well (e.g., the sensitivity

of the lab species tested, accounting for different types of tumors or tumor sites, adjusting for early mortality).

Some empirical estimates have been made to reveal the degree to which some factors or precautionary assumptions affect risk estimates in the dose-response estimation stage for carcinogens. For example, if the dose-response function for a carcinogen is truly linear, then the use of the 95th upper confidence limit in making the extrapolation from high to low dose leads to an estimated risk at low dose that generally is 2 to 3 times greater than the central or best estimate (D. Crawford-Brown, University of North Carolina, personal communication). If the dose-response relationship is nonlinear, the extent of risk exaggeration created by using the upper confidence limit is likely to be much greater.

There also is empirical evidence available on how the model selected to extrapolate from observed effects at high doses to environmentally relevant low doses can affect the results to a considerable degree. In one illustration, when a linear multi-stage model was applied to benzene data to extrapolate from a 10 ppm dose to a 0.1 ppm dose, the estimated risk at the lower dose level was $4*10^8$ times greater than that derived using a log-normal extrapolation model, even though both models yielded similar results at the higher dose range (Reichard et al., 1990). In other words, the choice of the extrapolation model led to a difference in the estimated risk that was 400 million times greater for the linear model than for an alternative dose-response function, when fitted to the same lab data.

The choice of extrapolation model may not always have such an exaggerated impact as shown above for the benzene example, but the model choice can have a significant impact on the estimated risk outcome in many cases. The degree to which the use of a linear model by default might mis-state the risk estimate compared to a nonlinear function (where the latter is more likely) will depend on several important factors. The factors include the degree of nonlinearity in the function (nonlinear functions can be nearly linear, especially over limited exposure or dose

ranges). Also, the greater the degree of extrapolation required from the high dose data observations to the low doses of regulatory relevance, the greater the potential for nonlinearity to make a notable difference in the low dose risk estimate (all else constant).

A recent illustration using MTBE found that the use of a linear model led to estimated results at the mean that were 13 times greater than when a more suitable, nonlinear model was applied (371 cases versus 29 cases) (Raucher et al., 2001).[7] Because the mean (average) results were influenced by outcomes at the extreme upper tail of the distribution, the results are even more striking when comparisons are made at other points from the distribution. For example, at the 50th and 95th percentile, the nonlinear model predicted 0 and 177 lifetime cancer cases in the modeled population, respectively. In contrast, the linear model predicted median and 95th percentile outcomes of 275 and 967 cases, respectively (Raucher et al., 2001). Thus, the absolute difference in the projected outcomes increases at the upper percentiles, but the percentage difference between the models' outcomes is higher as one compares results at lower percentiles of the distributions.

The recent inquiries over the risk posed by arsenic in drinking water provide some additional useful illustrations. The risk estimates are derived from epidemiological interpretations of data drawn principally from people exposed to relatively high levels of water-borne arsenic in a rural region of Taiwan. There are complex scientific debates over how these Taiwanese data should be interpreted, which in turn have significant implications for what risk levels are implied for U.S. populations at the lower concentrations relevant to the American regulatory alternatives. Taiwanese exposures in the data tend to range in the 100s of µg/L, and the relevant U.S. regulatory options are in the 3 µg/L to 20 µg/L range.

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7. The extent to which the nonlinear model differs in outcome from the linear model depends on the form of nonlinear model selected. In comparing the drinking water concentration of MTBE associated with a lifetime cancer risk of 10^{-4}, the non-threshold nonlinear model yields a concentration 4.2 times greater than

In the newly issued report by the National Research Council (NRC) panel assembled to review the evidence on arsenic risks, a linear model was used to interpret the epidemiological data, because this is the default precautionary assumption applied unless there is "definitive" scientific evidence to indicate an alternative model is proper (NRC, 2001). For arsenic, the scientific opinion is that arsenic's mode of action for cancer development points toward a sublinear dose-response relationship (but the scientific opinion also is that the dose-response data do not show a strong nonlinearity). For example, the NRC panel initially assembled to review the arsenic risk evidence in 1999 noted that the most plausible scientific evidence supports a sublinear dose-response relationship (NRC, 1999). However, because the available evidence was not sufficiently conclusive, it did not meet EPA's criteria (as stated in the Agency's 1996 proposed cancer risk assessment guidelines) for departure from the default assumption of linearity (NRC, 1999; GAO, 2000).

The NRC panel convened in 2001 to review the arsenic data also found that there was an "absence of definitive mode-of-action data" and that the existing "data on arsenic do not provide a biological basis for using either a linear or nonlinear extrapolation" (NRC, 2001, pp. 5 and 6). Absent "definitive" data, the risk assessment process reverted back to the conservative linear model, even though it probably is not the "most likely" model for this substance based on the scientific (albeit nondefinitive) understanding of arsenic's mode of action.

In comparing estimated risks posed by arsenic at MCL-relevant levels in the U.S., the model choice can make an appreciable difference. For example, at 5 μg/L, the lifetime risk estimate using a nonlinear repair-based model leads to a much lower risk estimate than that obtained from the recent NRC panel's application of the linear default (the repair model is perhaps a most scientifically plausible model for arsenic, reflecting evidence suggesting that

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the linear model, whereas the nonlinear model with a threshold yielded an estimated 10^{-4} risk concentration 282 times greater than the linear model (Crawford-Brown, 2000).

arsenic's likely role in cancer development is through interfering with the repair of DNA damage caused by other agents rather than through direct damage to DNA itself). Using the linear model yields estimates that imply a risk 3 to 5 times greater than that obtained from the data using the repair model, all else equal (Crawford-Brown, 2001).

Another issue in the arsenic risk assessment is whether the estimates should be applied to U.S. or Taiwanese background cancer rates in order to infer the risks posed in the U.S. The NRC panel held divided views on this point, and ended up publishing both results (NRC, 2001). The net result is that the implied risks in the U.S. are 2.5 times greater when the U.S. baseline is applied (it is these higher results that are shown in the summary tables of NRC, 2001).[8]

If one combines the two elements of arsenic risk assessment, NRC obtains lifetime cancer risk estimates — using the combined assumptions of linearity with U.S. baseline cases — that are 7.5 to 12.5 times greater than are obtained if a (perhaps more) plausible nonlinear repair model is used along with Taiwanese baseline cases (7.5 = 3 times 2.5, and 12.5 = 5 times 2.5). This is not to imply that the NRC's published estimates are necessarily overstated by this amount, but the discussion here does illustrate the degree to which risk results can shift with two scientifically plausible modifications, even for a contaminant such as arsenic that is relatively well understood and for which there is a considerable body of data from human exposures. Table 3 provides a more generic illustration.

Valuation

The assignment of monetary values to reductions in health risks is a controversial issue for many people, because it may appear as if analysts are placing a dollar value on an individual's life. Instead, the analyst is simply using observed data to infer how people value

8. While there was some disagreement about the use of Taiwan or U.S. background, the members of the panel with the most epidemiological experience elected the use of U.S. numbers.

changes in low level risks spread over a large population. There is an extensive empirically based literature available for this purpose (see NRWA White Paper, Raucher, 2001, for a more extensive discussion).

There has been some debate about how to interpret the body of literature for valuing reduced risks of premature fatalities or avoided illnesses. For example, if $6.1 million (1999 dollars) is viewed as a central estimate for the value of a risk reduction that statistically implies one fewer premature fatality (known as the value of a statistical life, VSL), the issue that arises is how to account for the delayed timing of the risk reduction (e.g., due to latencies and cessation lags in cancer risks). The net impact on the final benefit results typically is not very great (as compared to the exposure and dose-response factors). If no latency is applied, the VSL is $6.1 million, and if a 20 year latency is used and a 5% discount rate is applied, the adjusted VSL is $2.3 million. This implies a factor of 2.7 in terms of the difference in values ($6.1 divided by $2.3).

In reality, the difference factor is likely to be much smaller in the future, since past debates over whether (and how) latency and discounting should the applied seem to have been resolved by the EPA Science Advisory Board (SAB). SAB has consistently advocated the use of discounting and latencies (SAB, 2000; SAB, 2001). Therefore, the possible differences may dwell on the length and trend of cessation lags and the discount rate to apply, which might impact valuation outcomes by a factor of 2 (or less).

Interactions, Compounded Impacts, and Benefit-Cost Comparisons

As shown above, several stages in the risk assessment and valuation steps can lead to a large divergence in risk or benefit estimates when precautionary assumptions are applied. The degree to which a single precautionary factor can alter an outcome (relative to a more central or plausible estimate) can be relatively modest (e.g., a factor of 2 or less) or quite large (e.g., a factor of 10 or even several orders of magnitude greater). However, the most significant

implications are revealed when one examines how the outcomes become compounded when the series of precautionary assumptions are linked together in a specific benefit-cost analysis.

How much impact do the typical precautionary assumptions have on an estimated risk level posed by a contaminant at drinking water-relevant concentration levels? There is no single, clear-cut answer, since the degree of cumulative risk or benefit exaggeration depends on many factors. However, the potential magnification of the risk above "expected" levels can be staggering.

For example, if there are 10 sources of uncertainty in risk assessment calculation, and in each case the precautionary assumption introduces only a 2-fold factor of risk (i.e., each assumption alone simply leads to an estimated risk that is twice the expected value), then the cumulative impact would be an estimate more than 1000 times greater than the expected risk (2 raised to the 10th power equals 1,024). Because the individual factors are often greater than 2, the impacts may often be much greater — for example, if there are 10 sources of uncertainty that are addressed using default assumptions that each contribute a 3-fold factor of risk overstatement, then the overall outcome is nearly 60,000 times greater than expected risk (3 raised to the 10th power equals 59,049). If there are only 5 sources of uncertainty that each have a 3-fold impact in terms of overstating risk reduction benefits, then the cumulative effect would be 243 times greater than a central tendency outcome (3 raised to the 5th power). Table 4 provides a summary illustration.

An Illustration of Compounded Precautionary Impacts: Arsenic Risks

A relevant illustration can be developed using the arsenic risk issues. What is the risk reduction anticipated in a water system of 350 people served and a current arsenic concentration of 11 μg/L if the MCL is set at 10 μg/L? If one estimates these benefits using several of the standard precautionary assumptions such as embodied in NRC (2001), one would calculate risk reductions as follows:

- Exposures based on 73 years of exposure (NRC also assumed, plausibly, 1 L per day of ingestion). Each person would thus face a lifetime exposure of 293,095 μg of arsenic (73 years * 365 days per year * 1 L/day * 11 μg/L).

- Assuming post-compliance arsenic is at 80% of the MCL, the lifetime exposure reduction is a 3 μg/L drop in arsenic concentrations (11 minus 8, where 8 = 80% of 10), implying a lifetime exposure reduction due to regulating at 10 μg/L of 79,935 μg.

- The excess combined bladder and lung risk associated with lifetime exposure is $3.35 * 10^{-4}$ per μg/L, according to NRC's interpretation using the linear model and U.S. baselines cancer rates (NRC, 2001).

- For each person exposed, the baseline risk is $36.9 * 10^{-4}$, and compliance reduces the risk of cancer by $10.1 * 10^{-4}$ per lifetime. This translates into the equivalent of 0.35 cancer cases avoided over the 350 people over a 73 year time frame (0.00484 cases avoided per year).

- If annualized compliance costs were $17,500 per year, the cost per cancer avoided would be about $3.6 million ($17,500 divided by 0.00484 cases per year).[9]

If the same analysis is repeated, but *using central or best estimates of exposures and risks*, then the step-by-step and overall outcomes would be as follows:

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9. The $17,500 per year cost estimate is consistent with EPA's estimate, as applied in the EA that accompanied the arsenic rulemaking package of January 2001 (US EPA, 2000b). EPA data suggest an annual cost of $15,100 per year for a system of 350 people (based on our extrapolating from data for a system with an average population of 230 people). Actual field experience suggests a cost closer to closer to $19,000 per year (Ramesh Narasimhan, NCS Engineering, personal communication, November 2001). Note too that EPA is revising these cost estimates, and the Agency's costs for systems of this size are likely to increase. Also, note that a $17,500 per year systemwide cost implies an average household cost increase on the order of $150 per year (assuming 3 persons per household, and that households are the entire revenue base for a small system of this size).

- Exposure estimates are based on a 73 year life span, but also are derived by drawing on (1) a distribution reflecting duration of residence, (2) occurrence-based probabilities of living in an arsenic-impacted water system after any given move, and (3) a distribution of daily water consumption levels (with mean of approximately 1.1 L per day). The "mean" person would thus face a lifetime exposure of 81,875 µg of arsenic (note that this is 27.9% of the 293,095 µg lifetime exposure estimated using the precautionary assumptions above). [10]

- Assuming post-compliance arsenic is at 80% of the MCL, the lifetime exposure reduction is a 3 µg/L drop in arsenic concentrations (11 minus 80% of 10), implying a lifetime exposure reduction due to regulating at 10 µg/L of 22,330 µg/lifetime (or 27.3% of the precautionary estimate).

- The excess combined bladder and lung risk associated with lifetime exposure is $3.35 * 10^{-5}$ per µg/L, based on NRC's interpretation of the linear model coupled with their application of Taiwanese baseline data (a 2.5-fold decrease, as per NRC, 2001), and combined with a 4-fold reduction if a nonlinear repair-based dose-response function is applied instead of the linear model (based on empirical evidence from Crawford-Brown, 2001). Note that this yields a 10-fold decrease in the unit risk factor relative to the precautionary interpretation above.

- For the average person exposed, the baseline risk is $1.0 * 10^{-4}$, and compliance reduces the risk of cancer by $2.8 * 10^{-5}$ per lifetime. This yields an expected reduction in cancer cases equivalent to 0.010 cases over the 350 people served by the system, over a 73 year time frame (0.00013 cases avoided per year).

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10. Note that our simulations show that the mean is well above the median (50th percentile) value for the population. Well over two-thirds (>70%) of the impacted population have exposures below the mean.

- If annualized compliance costs were $17,500 per year, the cost per cancer avoided would be $130.4 million ($17,500 divided by 0.000134 cases per year).

In comparing the outcomes of the two risk assessment scenarios, the combined impact of the two exposure and two dose-response precautionary assumptions is a risk reduction estimate that is over 36 times greater than one might more reasonably expect to be an average or expected outcome (in a cost-effectiveness context, the results suggest the cost per case avoided is 36 times greater). In a risk management context, this significantly alters the manner in which a regulatory decision might be made. Based on the available empirical literature, spending $3.6 million per cancer avoided may not be an unreasonable investment in public health protection.[11] However, spending over $130 million per cancer avoided is clearly beyond the realm of a wise investment in public health.

Finally, readers should note that this arsenic illustration (with a 36-fold difference in estimated risk reductions) is atypical in some ways. For example, NRC estimated risk based on "maximum likelihood estimates" rather than the upper confidence limits as is typically done in making high to low dose extrapolations. This avoided one potential source of risk adjustments that might have contributed another factor of 2 to 3 (or more) to the estimated risks. In addition, the reliance on human epidemiological data enabled the risk assessors to avoid cross-species extrapolation issues that typically contribute additional uncertainty factors to the analysis.

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11. This may be considered a "reasonable" (if marginal) public health investment to consider because most of these arsenic-related cancers would be fatal, and a central estimate for a 20-year latency-adjusted VSL is $3.4 million (using a 3% discount rate, for example). Thus, the benefit value of the action would be close to the costs. Other options might have a better payoff, however, and a full incremental analysis of various MCL options, across system size categories, would be much more informative.

Uncertainties and Variabilities have Distinct Implications

To simplify the discussion provided in this paper, the rationale for using precautionary approaches has thus far been conveniently lumped under the rubric of addressing "uncertainty." In reality, precautionary assumptions are applied because of the presence of two quite distinct concepts — uncertainty and variability. Because important distinctions exist between uncertainty and variability, there are important implications of how uncertainties and variabilities should be addressed as distinct issues when conducting or interpreting risk assessments.

The terms "variability" and "uncertainty" have been broadly used to encompass a multiplicity of concepts, and the precise meaning of these terms varies across disciplines. Risk assessors view variability and uncertainty as very distinct concepts that distinguish between inherent physical (or natural) characteristics on the one hand (i.e., variability) and limitations of knowledge or understanding (as displayed by the risk assessor) on the other (i.e., uncertainty). For example, there is variability in terms of how much of a contaminant a person is exposed to at a given concentration in water — some people ingest more tap water per day than others. There also is variability in body weights, and across human sensitivities to a contaminant. Variabilities are facts of nature and reflect observable differences that exist across people and circumstances. Variabilities are especially prevalent in exposure assessments.

In contrast, uncertainty reflects a lack of understanding about complex phenomena. The dose-response aspect of risk assessment tends to be dominated by uncertainties, including issues such as not knowing the true shape of the dose-response function or how evidence observed in a laboratory species translates into dose-response relationships for humans.

Benefits analyses contain elements of both variability and uncertainty, and the key to developing or interpreting a BCA is to understand how these enter the analysis and influence its outcome. In general, variability cannot be reduced by further research and measurement, but uncertainty can. The distinction between variability and uncertainty can have significant

implications for decision-making. Variability is a fact of life, and must simply be recognized in an analysis and risk management context (e.g., some people will be more exposed and/or more sensitive than others). With variability, probability information can be used to form meaningful averages (expectations) and distributions (e.g., to understand impacts at the 99th percentile) using tools such as Monte Carlo analysis. Uncertainty potentially can be reduced through further scientific research, but in the meantime is best addressed in a BCA through the use of sensitivity analyses (or second order random variables) that reveal the impact of alternative plausible assumptions or models.

With respect to variability, mathematically we know a great deal more about the median or average person and less about people as they move farther from the central portion of the distribution. Uncertainties expand (perhaps without bounds) the further we move away from the median or mean of a variability distribution. In a policy context, this means that as risk managers try to protect more people by moving to higher percentiles of the variability distribution (e.g., a most exposed or most sensitive subpopulation), the uncertainties begin to expand radically (perhaps exponentially). Hence, the results of a risk assessment or BCA will be increasingly distorted as one moves away from the central part of the distribution. This is another reason for trying to ensure that risk managers are presented with (at least) risk and benefit estimates that are drawn from the central portion of the combined risk and benefits distribution.

Irreversibilities

Irreversibility is another important concept to consider in whether and how precautionary approaches are applied. A risk outcome that is likely to be irreversible is one that will have a relatively strong logical and philosophical basis for taking a precautionary approach. For example, species extinction or immediate human mortality are two types of irreversible high-cost outcomes that society will typically wish to avoid (subject to feasibility, cost, and other considerations). In general, the greater the consequences of making a "poor" risk management

decision because of uncertainty, the greater the rationale for taking a precautionary tact in managing the risk — and irreversibility is an important element in determining whether a risk is of high consequence.

In drinking water applications, irreversibility arises in the context of whether a given risk arises from acute (as opposed to chronic) exposure. For example, a microbial agent may pose an immediate risk. If a person is exposed to a sufficient number of pathogens within a short time span, then any associated adverse health effect typically will manifest quickly. Failure to adequately manage the microbial may thus pose an irreversible risk because there is no opportunity to adjust policy or exposure after the fact (the person has been exposed, the risk is thus already borne). If the health endpoint is critical (e.g., potential mortality) and the risk agent is fast acting, and/or not responsive to antibiotics or other medical treatment, then the consequences of exposure are irreversible.

In contrast, risks associated with chronic (long-term, accumulated) exposures are largely reversible. For example, if new evidence emerges about a potential carcinogen that associates a higher risk to drinking water exposures than current data imply, then the risk can still be managed by reducing the level of future exposures. Chronic risks can still be effectively managed except in cases where life-long exposures have already accumulated. Because chronic risks can be managed in this manner, they are "reversible" and current risk management activities should not be overly influenced by precautionary motives.

Conclusions and Recommendations

The blending of science and policy is a necessary byproduct of the facts that (1) uncertainties and variabilities exist in estimating risks and these uncertainties cannot be easily resolved or circumvented, and (2) high-stakes public health policy matters require decision-makers to proceed despite the existence of large and unresolved uncertainties. To address these uncertainties, many policy-based judgments are embedded in how risk assessments are

performed. These science policy assumptions tend to be very conservative, based on a precautionary approach that seeks to err on the side of safety when deriving estimates of what dose poses no risks to even the most exposed and sensitive individuals.

In estimating risk levels associated with a concentration of a contaminant in drinking water, the use of precautionary assumptions and adjustment factors is suitable when the calculations are being used strictly in a risk assessment context such as establishing a no risk goal such as an MCLG. However, for BCA and other risk management activities contributing to deliberations on how stringently to set MCLs, it is contrary to good science and statutory directives to carry forward risk estimates that are significantly impacted by myriad precautionary science policy assumptions. The treatment of these uncertainties tends to inflate the level of risk posed by contaminants, and therefore leads to an overstatement of the benefits of regulations.[12] The degree to which risk reduction benefits are overstated (if at all) will vary considerably from contaminant to contaminant, depending on many factors. However, the illustrative examples shown above indicate that it is not unreasonable to suspect that benefits derived using precautionary assumptions may be 10, 20, 100, or even many more times higher than one would expect at the mean or median of the benefits distribution.

In view of the potentially significant impact precautionary assumptions can have on estimated risks and associated BCAs, the following recommends are offered:

1. EPA and other entities that develop risk and benefit estimates should practice full disclosure and provide complete transparency by listing all the precautionary assumptions embedded in a risk reduction benefits assessment.

12. It is conceivable that in some cases further research might reveal that a "true" risk level might actually exceed the risk estimated with precautionary assumptions. However, this is very unlikely.

2. To the extent possible, EPA and other entities should remove precautionary science policy assumptions and provide central tendency estimates for their risk reduction and associated benefits estimates (as well as probability distribution information or, at a minimum, reasonable lower and upper bounds).

3. Comprehensive sensitivity analyses should be applied as an essential tool to help reveal the individual and collective impact of precautionary assumptions on the risk and benefits findings presented to decision-makers, regulatory reviewers, and other stakeholders.

Table 1. Impact of exposure-related assumptions.

Factor	Impact relative to central estimate
(a) Daily tap water consumption (2L/day)	1.8x
(b) Duration of exposure (70+ years)	
— Occurs in 1% of systems	≥ 12.4x
— Occurs in 5% of systems	≥ 8.7x
— Occurs in 10% of systems	≥ 6.1x
(c) Combined impact in lifetime exposure estimate	
— Occurs in 1% of systems	≥ 22.4x
— Occurs in 5% of systems	≥ 15.7x
— Occurs in 10% of systems	≥ 11.0x

Table 2. Impact of illustrative uncertainty factors in reference dose estimates.[a]

Issue	Typical factor	Safety margin[b]
(a) Inter-subject variability in sensitivity	10	3.1x
(b) Cross-species extrapolation	10	3.1x
(c) (a) + (b) combined	100	9.8x
(d) Reliance on short-term exposure data	10	3.1x
(e) (a) + (b) + (d) combined	1000	30.5x

a. Dose at which no adverse health effects anticipated, including margin of safety.
b. Relative to 68th percentile, assuming log normal distribution.

Table 3. Impact of cancer risk assessment assumptions.[a]

(a) Use of linear dose-response function (relative to suitable nonlinear alternative)	
— MTBE illustration (at mean)	12.8x
— arsenic illustration (repair model)	3x to 5x
(b) Use of 95th upper confidence limit (relative to maximum likelihood)	2x to 3x
(c) Combined illustrative impact (if both (a) and (b) are relevant)	6x to 38.4x
(d) Impact when combined with exposure illustration (Table 1)	66x to 860x

a. Note that results are case-specific, depending (for example) on degree and type of nonlinearity over relevant exposure range, and difference between high dose data points and low doses of regulatory relevance.