Comments to
Science Advisory Board Drinking Water Committee
on
Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media
prepared by the
American Water Works Association

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 57,000-plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water.

AWWA's members are actively engaged in protecting the public's health both through providing appropriate drinking water treatment, but also as advocates for adequate protection of drinking water supplies. AWWA was an active participant in the federal advisory committees that led to treatment standards under the Safe Drinking Water Act (SDWA) to protect against *Cryptosporidium* in drinking water, as well as the on-going Total Coliform Rule revisions. AWWA has also evaluated risk assessments prepared by EPA to support many other rules including the Ground Water Rule (GWR). AWWA has asked EPA to develop Clean Water Act (CWA) criteria that protect drinking water supplies including development of a water quality criterion for *Cryptosporidium*. AWWA is an interested and involved party in national microbial risk assessment and we believe that a protocol for microbial risk assessment is appropriate and necessary in order to both facilitate microbial risk assessment and to improve the quality of future microbial risk assessments. With these goals in mind, AWWA would appreciate your consideration of the following recommendations.

<u>Effective Guidance</u> – The draft attempts to achieve two goals and in doing so, it becomes quite difficult to extract useful information from the current format of the document. The first goal is

to educate new microbial risk assessors, EPA contractors, and others unfamiliar with microbial risk assessment. In this regard, the history and status of microbial risk assessment are interwoven throughout the document. Much of the current document could be condensed and compiled into an appendix or separate document to provide the necessary primer for the novice user.

The second goal is to provide direction to microbial risk assessors (e.g., EPA staff, contractors, etc.) as to how to undertake a microbial risk assessment, i.e., a benchmark against which future risk assessments can be measured. Here, the current document falls short, as it does not describe a clear path for microbial risk assessors to follow, nor provide a clear prioritization of options within particular aspects of the assessment process. Likewise, the draft does not describe clear boundaries for when particular approaches are not sound. Consequently, the current draft does not represent a clear "protocol." While many of the risk assessors referencing this document have relevant expertise, access to a document that provides a sound "framework" with boundaries on what is acceptable quality and reasonable performance benchmarks would greatly improve public perception of the quality of microbial risk assessments. The treatment of Bayesian statistical analysis illustrates one such area. Bayesian analysis is greatly dependant on the priors introduced to the analysis. Moreover, when Bayesian techniques are applied in the presence of sparse data, the choice of priors can have a major effect on the risk assessment. Given the regulatory consequences of many risk assessments, this raises potential legal as well as technical, issues:

1. How should priors be selected and by whom?
2. Should selection of priors occur at the problem formulation stage, or at the very least before significant analysis is conducted?
3. How can choice of priors be appropriately rebutted or discussed, ideally before the analysis?
4. Are there circumstances where Bayesian analysis is inappropriate, such as when the priors are "uninformative" and a frequentist approach would make more sense based on the principles of transparency?

<u>Clarity and Transparency</u> – The draft emphasizes early engagement of stakeholders and risk managers as well as clarity and transparency within the risk assessment process, particularly at the stage of problem formulation. This is consistent with recent National Academy of Science

recommendations to EPA, and AWWA strongly supports this concept.[1] Unfortunately, the current document was developed without stakeholder engagement and the team developing the document did not include important perspectives like that of the public health community and risk managers (e.g., community health agencies, drinking water utilities, etc.).

Consistency – There are many different EPA guidance documents on risk assessment; these documents should be consistent with each other. EPA's Risk Assessment Forum is currently developing agency guidance on probabilistic risk assessment to aid decision makers engaged in risk analysis.[2] The microbial risk assessment protocol and the probabilistic risk assessment white papers appear to be in development along parallel tracks. While these documents are at different stages of development, it isn't too late to cross check the documents to ensure consistency. AWWA has also provided comments to EPA on the probabilistic risk assessment white papers.[3]

Microbial versus Chemical Risk Assessment – The draft relies heavily on the chemical risk assessment model. Unfortunately, the chemical risk assessment model as practiced is inadequate for microbial risk assessment. While there are numerous sources of uncertainty and variability within both microbial and chemical risk assessments, the inter-relationships and dependencies among living systems in a microbial risk assessment are substantially greater than those addressed in the chemical risk assessment model (this is one area where MRA would benefit from a probabilistic method). Also, with few exceptions, microbial risk assessment involves an acute endpoint that occurs within a short time after exposure, while the chemical risk assessment framework stems primarily from a life-time exposure scenario. These differences can only be addressed by (1) enumerating and thoughtfully prioritizing and addressing the impact of inter-relationships on the quality of the risk assessment, (2) evaluating the attributable disease implied by the risk assessment to recognized disease in the real world (e.g., illness statistics, serology, etc.), and (3) considering alternative approaches outside the 1 in 1,000,000 (lifetime) or 1 in

[1] Science and Decisions: Advancing Risk Assessment; National Research Council of the National Academies of Science; National Academy Press: Washington, DC, 2009.
[2] Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision-Making With Case Study Examples, EPA, EPA-HQ-ORD-2009-0645, 2009
[3] Comments on Probabilistic Risk Assessment (PRA) White Papers, Docket: EPA-HQ-ORD-2009-0645, American Water Works Association September 16, 2009

10,000 (annual) framework such as "margin of safety" approaches where the emphasis is on differences above background exposure or morbidity.

Reasonable Extrapolation – Risk assessment in any venue involves using limited data to estimate or project potential risk. Frequently, limited data lead to numerous "conservative" assumptions and extrapolations that ultimately combine to produce an unrealistic estimate of risk. This document would be particularly helpful if it established guidelines for arriving at reasonable estimates, appropriate checks on estimates, or clear boundaries on extrapolating from limited data. This need is apparent in exposure assessment. Recent estimates of *Cryptosporidium* occurrence projected by EPA are one example where modeling of exposure was dramatically different from reality.[4] The levels of *Cryptosporidium* occurrence reflected in EPA's support documents for the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) were substantially higher than observed concentrations gathered under both the Information Collection Rule and subsequently in LT2ESWTR source water monitoring to-date. Similarly, projecting infections and illnesses involves many assumptions, and recent analyses such as those underlying the GWR stretch the boundaries of sound science, when the economic analysis was based on a synthetic organism that does not actually occur.[5] Also, setting statistically valid performance metrics for analyses of marginal changes in endemic disease would be a tremendous benefit to the microbial risk assessment community.

Appropriate Target Organisms – The draft appears to focus on protozoa as the worst-case organism. This target can be misleading in many applications as we believe that the agents responsible for a substantial portion of unmanaged disease occurrence are viruses (see Attachment A). A related but different challenge is the control of indicators as surrogates for pathogens. This added link in the risk management chain further complicates the risk assessment and is distinct from assessing the risk associated with a true pathogen. Simple correlation of surrogates with pathogens is insufficient. Surrogates seldom occur at the same concentrations or behave exactly like the target pathogens; consequently, use of surrogates introduces additional uncertainty into the risk assessment analysis. This uncertainty must be addressed in order to

[4] Occurrence and Exposure Assessment for the Final Long Term 2 Enhanced Surface Water Treatment Rule, EPA, 2005, EPA 815-R-06-002.
[5] Economic Analysis for the Final Ground Water Rule, EPA, 2006, 815-R-06-014.

prepare a credible risk assessment. The current draft should have a more robust treatment of both viruses and indicators.

Conclusion – With respect to drinking water, microbial risk assessments must be sufficiently robust and clearly organized to allow risk managers to have confidence in the estimates, as pathogens in finished water seldom occur at concentrations of demonstrable concern and separating disease attributable to drinking water from other routes of exposure is very difficult. We applaud EPA for beginning the process of developing a microbial risk assessment framework and look forward to working with the agency as it revises the current draft into the benchmark guidance document that the agency needs.

Attachment A – Recognized Disease Agents in Natural Water Recreational Contact, 1997 – 2006

Rank Etiological Group and Agent by Number of Cases

Etiological Group	Cases	Outbreaks	Etiological Agent	Cases	Outbreaks
Cryptosporidium	265	5	*C. parvum*	255	3
			Cryptosporidium	10	2
Norovirus	259	10	*Norovirus*	151	6
			Norovirus G2	50	1
			Norwalk-Like Virus	48	2
			Norovirus G1	10	1
Shigella	160	8	*Shigella sonnei*	150	7
			Shigella flexneri	10	1
E. coli	105	10	*E. coli O157:H7*	90	8
			E. coli O121:H19	11	1
			E. coli O26:NM	4	1
Giardia	11	2	*Giardia intestinalis*	11	2
Pliesiomonas	5	2	*Pliesiomonas shigelloides*	5	2

Source: Personal communication, Anthony Bennett, September 10, 2009, An unpublished analysis based on MMWR reports titled "Surveillance for Waterborne Disease and Outbreaks Associated with Recreational Water". Only those outbreaks listed as "AGI" and for untreated recreational water were included. "Etiological groups" were added to aggregate etiological agents into genus groupings (Except all *E. coli* subtypes were grouped into *E. coli* at the species level).

Attachment B: Detailed Comments

Reviewers that contributed to AWWA's comments also identified the following specific detailed items, of which AWWA would like to make the SAB aware.

1. Page 60. The paragraph discussing models alternative to the exponential and beta-Poisson fails to consider the fact that the alternative models do not have theoretical justification, nor have they been validated against outbreak data (as the exponential and beta poisson have) at low dose. There is a much fairer discussion of this in Appendix G (section G5 specifically) and the spirit of that lengthy discussion needs to be more accurately captured in the discussion on page 60.

2. Page 61 (bottom). The Nauta paper does not really criticize the exponential or beta-Poisson models *per se* but rather the exposure assessment, and the need to correct the models for non-random distribution of doses amongst consumers. Also this paper is food related rather than water related, so some rewording of the paragraph is needed.

3. Page 152 (bottom). The bootstrap method is not an alternative (e.g., to Bayesian or likelihood) methods but rather provides a method to estimate parametric uncertainty. Some rewording here is needed to clarify.