

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Science Advisory Board (SAB) Drinking Water Committee (DWC)
Public Meeting of September 21-22, 2009**

Committee Members: See Roster (Attachment A)

Date and Time: Monday, September 21, 2009, 9:00 AM – 5:00 PM
Tuesday, September 22, 2009, 8:30 AM – 12:30 PM

Location: SAB Conference Center
1025 F Street, N.W., Suite 3705, Washington, D.C. 20004

Purpose: The purpose of the meeting was to provide advice on the Agency's draft *Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media* and to discuss the draft DWC advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule. The Federal Register announcement of the meeting is in Attachment B and the meeting agenda is in Attachment C.

Participants: Dr. Joan Rose, Chair
Dr. Mark Borchardt*
Dr. Penelope Fenner-Crisp
Dr. Jeffrey Griffiths*
Dr. Gary King
Dr. Joseph Landolph, Jr.
Dr. Desmond Lawler
Dr. Christine Owen
Dr. Richard Sakaji
Dr. Gary Saylor
Dr. David Sedlak
Dr. Gina Solomon
Dr. Laura Steinberg
Ms. Susan Teefy

*Participated via teleconference

Mr. Aaron Yeow, Designated Federal Officer (DFO)
Dr. Suhair Shallal, Designated Federal Officer (DFO)
Dr. Vanessa Vu, EPA SAB Staff Office
Dr. Edward Ohanian, Dr. Stephen Schaub, EPA Office of Water
Additional Attendees (See Attachment D)

September 21, 2009 Morning Session 1

Mr. Aaron Yeow, the DFO for the SAB Drinking Water Committee (DWC), opened the meeting. He noted that as required under the Federal Advisory Committee Act (FACA), the Committee's deliberations are held in public with advanced notice given in the Federal Register, and the meeting minutes will be made publicly available after the meeting. He noted that the DWC received no written comments and one registered public speaker, Mr. Steve Via from the American Water Works Association. He also noted that the Committee Members are all subject to federal ethics regulations and conflict-of-interest laws that pertain to them. He then turned over the meeting to Dr. Vanessa Vu, Director of the EPA SAB Staff Office and to Dr. Joan Rose, Chair of the Drinking Water Committee.

Dr. Vanessa Vu, Director of the EPA SAB Staff Office welcomed everyone to the public meeting of the Science Advisory Board Drinking Water Committee. She thanked the members of the DWC for their participation in this meeting and for their public service. She indicated that the purpose of the meeting was to provide advice on the Agency's draft *Protocol for Microbial Risk Assessment (MRA) to Support Human Health Protection for Water-Based Media* and to discuss the draft DWC advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule. She also stated that is looking forward to the discussions and deliberations over the next day and a half. She then turned the meeting over to Dr. Joan Rose.

Dr. Joan Rose, SAB DWC Chair, welcomed everyone and provided some introductory remarks on the importance of microbial risk assessment. She provided an overview of the charge questions for the MRA Protocol and indicated that the Committee will discuss its draft advisory report on the Agency's revised Total Coliform Rule at the end of the next day. She indicated that Dr. Jeffrey Griffiths was on the phone, Dr. Mark Borchardt would be joining by phone the next day, and two members would not be participating, Dr. Jack Colford and Dr. Stanley Grant. She then had the Committee members briefly introduce themselves.

Agency Presentation

Dr. Edward Ohanian, Health and Ecological Criteria Division Director, EPA Office of Water, indicated that his division conducts human and ecological risk assessments to support the requirements of the Safe Drinking Water Act and Clean Water Act. He stated that the MRA protocol will have many important applications and that the Office of Water is requesting assistance in ensuring that the Protocol contains all the necessary user-friendly tools for successfully conducting assessments and identifying any other microbial risk assessment methods, approaches, or technologies that should be added to the existing chapters.

Dr. Stephen Schaub, EPA Office of Water, provided a history of the Office of Water MRA development activities and an overview of the MRA Protocol (see his presentation in Attachment E). He discussed the differences between chemical risk assessments and microbial risk assessments, the general features of the Protocol, and specific features of the Protocol.

There was some discussion between the members of the Committee with regards to the target audience and whether this document was a framework, protocol, or guidance. The Office of

Water clarified that the primary audience of the document is EPA and its contractors performing MRAs and the secondary audience are external stakeholders. Several members noted that a protocol should be a “how-to” document with steps, decision trees, etc., but that this document did not have sufficient detail for that purpose. They felt that this document was not a protocol, but rather more of a framework and suggested that the title of the document be changed to reflect that. After a short break, the public comment period began.

Public Comments

Mr. Steve Via from the American Water Works Association (AWWA) made an oral presentation. Copies of his oral statement were distributed to Committee Members and meeting attendees. His oral statement is also in Attachment F.

September 21, 2009 Morning Session 2

Dr. Rose asked the lead discussants to present their comments regarding the first charge question (see Attachment G for assigned lead discussants and Attachment H for EPA’s charge questions). The first charge question posed to the Committee was to comment on the utility of the Planning/Scoping and Problem Formulation chapter and to provide any recommendations for enhancing the utility of the chapter. Several members felt that the chapter was generally useful, but that it was still missing sufficient detail, such as flow charts, figures, logic trees, etc. that would tie all the pieces together to get to the end product of planning/scoping and problem formulation. The committee members had further discussion on the target audience of the document and stressed for the need for this to be stated upfront in the document. Several members felt that the document was clear up until section 2.2.9, then starting with section 2.3 it became too technical and detailed, losing the focus of the chapter.

September 21, 2009 Afternoon Session

The Committee reconvened after breaking for lunch. Dr. Rose asked the lead discussants to start the discussion regarding the second charge question, which relates to the exposure chapter. The Committee was asked to comment on any additional exposure tools, methods, or approaches that should be included in the chapter. Several committee members felt that this chapter was a good introduction, but lacked sufficient detail to be a protocol. Some members noted a lack of discussion about the complexities of water treatment and distribution systems. Several members also felt that the discussion of “exposure profiles” could be strengthened. Some members also felt the chapter could be strengthened by adding a discussion about the use of indicators vs. pathogens as well as a discussion about episodic vs. chronic exposure and endemic vs. epidemic events.

Next, the lead discussants summarized their responses for charge question 3, which relates to human health effects. The lead discussants noted that this chapter did not have a discussion of human health effects. The chapter is mainly devoted to dose-response modeling. Several members suggested shortening the dose-response section of the chapter and having a greater discussion of human health effects from microbial pathogens, such as the types of illnesses, the severity of illness, the specificity of syndromes, etc. Some members did not feel that the quality

of life discussion belonged in the document. They felt that this discussion is not part of the risk assessment process, but rather, part of the cost-benefit analysis.

The lead discussants for charge question 4 generally felt that the historical context presented in chapter 5, risk characterization, was not needed. They did not identify anything that was missing from the chapter, but felt that it could be strengthened by removing the historical context discussion, adding a section for risk estimation, and removing the discussion about parsimony.

The Committee was adjourned for the day.

September 22, 2009 Morning Session

Mr. Yeow reconvened the meeting and provided the Committee members with a timeline for member comments, report writing, and a future teleconference in mid-November.

Dr. Rose provided some guidance on how the report should be structured – an overall impression of the Protocol, key recommendations, options, then specifics on the chapters (strengths, weaknesses). She would like to have very specific recommendations and action items.

The lead discussants began the discussion for charge question 5, which has to do with overall considerations regarding the document and the utility of the Protocol for outside stakeholders. There was agreement to move charge question 5 to be the first charge question in the Committee's report. Several members felt that the document overall was a good introductory document for MRA, that it was comprehensive, and that it was a good compendium of MRA information. They felt that a key decision needs to be made by EPA as to whether this document is an introductory document, a framework, a protocol, or guidance. The committee had some discussion as to whether this document should remain as a large document with improvements or to be broken up into an introductory document followed up by more detailed white papers. There was general agreement to leave it as a large document to be improved upon, but that it needed to state upfront that it was not a protocol and that as it stands now, it does not meet EPA's intended purpose. The Committee took a short break and then reconvened in the lead discussant groups to coordinate writing assignments for the report.

September 22, 2009 Morning Session 2

Approval of the draft report developed by the DWC's after reviewing the Agency's supporting analysis of the revised Total Coliform Rule

Dr. Suhair Shallal, DFO for the DWC's review of the Agency's Revised Total Coliform Rule, opened the second session describing the Committee's previous deliberations on the Agency's Revised Total Coliform Review. She indicated that there were no issues with Agency ethics requirements or conflicts of interest for any of the Committee members.

Dr. Rose made some brief overview comments on the DWC draft advisory report. She felt that the revised TCR was very important, particularly for small communities, where there would be more corrective action measures undertaken when violations occurred. She noted the

deficiencies in the use of total coliform as a single measure and that there is a large research need, particularly for large distribution systems, and that the modeling did not go far enough (in terms of looking at outcomes with corrective action). The Committee felt that the draft advisory report did a good job in capturing the issues raised during the previous deliberations. Several members suggested being more positive regarding the Agency's efforts in developing the revised TCR in the letter to the Administrator. There was some discussion regarding the estimation that 10 percent of water systems would take corrective action as a result of the revised rule. Some panel members believed that EPA should raise the estimate to greater than 10% and be more public health protective. With those minor changes, panel members approved the draft report and believed that it was ready for review and approval by the Chartered SAB.

Dr. Rose indicated that this was the end of her term as chair and that several other members' terms also were expiring. She would like to draft a letter to the Administrator emphasizing the importance of drinking water, discussing what the DWC did and did not do, as well as the future of the DWC. This draft letter will be discussed during the November teleconference discussing the MRA Protocol.

The meeting was then adjourned by Mr. Yeow.

Respectfully Submitted:

/Signed/

Aaron Yeow
Designated Federal Officer

Certified as True:

/Signed/

Dr. Joan Rose, Chair
SAB Drinking Water Committee

ATTACHMENT A - ROSTER

U.S. Environmental Protection Agency Science Advisory Board Drinking Water Committee

CHAIR

Dr. Joan B. Rose, Professor and Homer Nowlin Chair for Water Research, Department of Fisheries and Wildlife, Michigan State University, East Lansing, MI

MEMBERS

Dr. Mark Borchardt*, Director, Public Health Microbiology Laboratory, National Farm Medicine Center, Marshfield Clinic Research Foundation, Marshfield, WI

Dr. Penelope Fenner-Crisp, Independent Consultant, North Garden, VA

Dr. Stanley B. Grant**, Professor, Department of Chemical Engineering, School of Engineering, University of California, Irvine, Irvine, CA

Dr. Jeffrey Griffiths*, Associate Professor, Department of Public Health and Family Medicine, School of Medicine, Tufts University, Boston, MA

Dr. Gary King, Professor of Microbial Biology, Department of Biological Sciences, Louisiana State University, Baton Rouge, LA

Dr. Joseph R. Landolph, Jr., Associate Professor, Molecular Microbiology and Immunology and Pathology, Keck School of Medicine and Associate Professor of Molecular Pharmacology and Pharmaceutical Science, School of Pharmacy, University of Southern California, Los Angeles, CA

Dr. Desmond F. Lawler, Bob R. Dorsey Professor of Engineering, Department of Civil, Architectural and Environmental Engineering, University of Texas, Austin, TX

Dr. Christine Owen, Water Quality Assurance Officer, Tampa Bay Water, Clearwater, FL

Dr. Richard Sakaji, Manager, Planning and Analysis for Water Quality, East Bay Municipal Utility District, Oakland, CA

Dr. Gary Saylor, Beaman Distinguished Professor, Joint Institute for Biological Sciences, Oak Ridge National Laboratory, University of Tennessee, Knoxville, TN

Dr. David Sedlak, Professor, Department of Civil and Environmental Engineering, University of California-Berkeley, Berkeley, CA

Dr. Gina Solomon, Senior Scientist, Health and Environment Program, Natural Resources Defense Council, San Francisco, CA

Dr. Laura Steinberg, Dean and Professor, College of Engineering and Computer Science, Syracuse University, Syracuse, NY

Ms. Susan Teefy, Principal Engineer, Water Quality and Treatment Solutions, Inc., Canoga Park, CA

* Will be participating by teleconference.

** Will be providing written comments only.

SCIENCE ADVISORY BOARD STAFF

Mr. Aaron Yeow, Designated Federal Officer, 1200 Pennsylvania Avenue, Washington, DC, Phone: 202-343-9878, Fax: 202-233-0643, (yeow.aaron@epa.gov)

ATTACHMENT B – FEDERAL REGISTER NOTICE

Science Advisory Board Staff Office; Notification of a Meeting of the Science Advisory Board Drinking Water Committee

[PDF Version](#) (2 pp, 63K, [About PDF](#))

[Federal Register: August 18, 2009 (Volume 74, Number 158)]
[Notices]
[Page 41697-41698]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr18au09-42]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-8946-6]

Science Advisory Board Staff Office; Notification of a Meeting of
the Science Advisory Board Drinking Water Committee

AGENCY: Environmental Protection Agency.
ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public face-to-face meeting of the SAB Drinking Water Committee (DWC) to provide advice on the Agency's draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media and to discuss its draft advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule.

DATES: The SAB will hold the public face-to-face meeting on September 21, 2009 from 9 a.m. to 5 p.m. (Eastern Time) and will continue on September 22, 2009 from 8:30 a.m. to 1 p.m. (Eastern Time).

ADDRESSES: The September 21-22, 2009 face-to-face meeting will be held at the SAB Conference Center, 1025 F Street, NW., Room 3705, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this public meeting should contact Mr. Aaron Yeow, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail: (202) 343-9878; fax: (202) 233-0643; or e-mail at yeow.aaron@epa.gov. General information concerning the EPA Science

Advisory Board can be found on the SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, 5 U.S.C., App. 2 (FACA), notice is hereby given that the SAB Drinking Water Committee (DWC) will hold a public meeting to provide advice on the Agency's draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media and to discuss its draft advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule. The SAB was established pursuant to 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under FACA. The SAB will comply with the provisions of FACA and all appropriate EPA and SAB Staff Office procedural policies.

Background: EPA's Office of Water (OW) is responsible for protecting human health and the environment from contaminants in water. To achieve this goal, OW conducts risk assessments that apply scientific principles and methods to determine the nature and magnitude of health risks from contaminant exposures. OW performs microbial risk assessments (MRA) to support new regulations for microbial

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pathogens in drinking water under the Safe Drinking Water Act (SDWA). MRAs also support the development of health-based ambient water quality criteria and biosolids criteria under the Clean Water Act (CWA). These criteria protect against adverse human exposures to infectious disease microorganisms in recreational waters, shellfish growing waters, and wastewater biosolids.

Because of the importance of MRAs, OW developed a Microbial Risk Assessment Framework and is developing a draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media to provide Agency guidance for performing microbial risk assessments. Current Agency risk assessment guidance is geared towards chemical risk assessment. MRAs do not fit easily within that framework because of microbial and host factors that do not affect chemical risk assessments. A separate protocol is needed to help risk assessors address these factors in a consistent way.

The draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media will be used as guidance for preparing qualitative or quantitative MRAs for recreational water exposures, evaluation of biosolids application to land, and drinking water regulation development applications. OW may also make the Protocol available to States, non-governmental organizations, and international agencies to use in conducting risk assessments related to water media. In addition to supporting new regulations under the SDWA and supporting the development of criteria under the CWA, the MRA Protocol may also be used for a number of different applications such as assessing the potential human health risks associated with a known pathogen, determining critical control points for risk mitigation/control measures, identifying and prioritizing research and development, assisting in epidemiological investigations, and determining consequences of management options to reduce risk.

The Office of Water is requesting that the SAB provide advice on the draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media and to provide recommendations

on: how to improve the overall approach, the applicability of the Protocol, the reasonableness of the protocol, the clarity of the Protocol, the completeness and robustness of the protocol, and the ease of use of the Protocol for conducting water-based microbial risk assessments.

The SAB DWC will also discuss its draft advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule during this meeting. The Committee met previously on May 20, 2009 and on June 9-June 10, 2009 to deliberate on the Agency's charge questions regarding the supporting analysis. A Federal Register Notice dated May 1, 2009 ([74 FR 20297-20298](#)) announced these meetings and provided background information on this advisory activity.

Availability of Meeting Materials: The meeting agenda and other materials, including a link to access the EPA review document(s) related to the draft Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media and draft advisory report on the Agency's supporting analysis for the proposed revised Total Coliform Rule, will be posted on the SAB Web site (<http://www.epa.gov/sab>) in advance of the meeting. For questions and information concerning the Agency's documents relating to the Protocol, please contact Dr. Stephen Schaub at (202) 566-1126 or schaub.stephen@epa.gov. For questions and information concerning the SAB's draft advisory report on EPA's proposed Total Coliform Rule revisions, please contact Dr. Suhair Shallal at (202) 343-9977 or shallal.suhair@epa.gov.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB to consider on the topics included in this advisory activity and/or group conducting the activity. **Oral Statements:** In general, individuals or groups requesting an oral presentation at a public SAB face-to-face meeting will be limited to five minutes, with no more than a total of one hour for all speakers. To be placed on the public speaker list for the Microbial Risk Assessment Protocol, interested parties should contact Mr. Aaron Yeow, DFO, in writing (preferably via e-mail), by September 14, 2009 at the contact information noted above. To be placed on the public speaker list for the draft SAB advisory report on the Total Coliform Rule revisions, interested parties should contact Dr. Suhair Shallal, DFO, in writing (preferably via e-mail), by September 14, 2009 at the contact information noted above.

Written Statements: Written statements should be received in the SAB Staff Office by September 14, 2009, so that the information may be made available to the SAB for their consideration prior to the face-to-face meeting. Written statements on the Microbial Risk Assessment Protocol should be supplied to the DFO via e-mail to yeow.aaron@epa.gov and written statements on the draft SAB advisory report on the Total Coliform Rule Revisions should be supplied to the DFO via e-mail to shallal.suhair@epa.gov (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format). Submitters are requested to provide two versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Aaron Yeow at (202) 343-9878 or yeow.aaron@epa.gov. To request accommodation of a disability, please contact Mr. Yeow preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: August 6, 2009.

Anthony F. Maciorowski,
Deputy Director, EPA Science Advisory Board Staff Office.
[FR Doc. E9-19752 Filed 8-17-09; 8:45 am]
BILLING CODE 6560-50-P

ATTACHMENT C – AGENDA

U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
Drinking Water Committee
Public Meeting
September 21 and 22, 2009
SAB Conference Center
1025 F Street, N.W., Suite 3705, Washington, D.C. 20004

AGENDA

September 21, 2009

9:00 - 9:10 AM	Opening Remarks	Mr. Aaron Yeow <i>Designated Federal Officer</i> <i>SAB Staff Office</i>
9:10 - 9:15	Welcoming Remarks	Dr. Vanessa Vu <i>Director</i> <i>SAB Staff Office</i>
9:15 - 9:30	Review of Agenda and Purpose of Meeting	Dr. Joan Rose <i>Chair</i>
9:30 – 10:15	Introductory Remarks and Highlights of Draft <i>Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media</i>	Dr. Edward Ohanian and Dr. Stephen Schaub <i>EPA Office of Water</i>
10:15 – 10:30	BREAK	
10:30 – 10:45	Public Comments on Draft <i>Protocol For Microbial Risk Assessment to Support Human Health Protection for Water-Based Media</i>	Registered Commenters
10:45 – 12:00	Charge Question #1 <i>Planning/Scoping and Problem Formulation</i>	Lead Discussants: Dr. Gary King Dr. Christine Owen Ms. Susan Teefy
12:00 – 1:00 PM	LUNCH	

September 21, 2009 (continued)

1:00 – 2:15	Charge Question #2 <i>Exposure</i>	Lead Discussants: Dr. Desmond Lawler Dr. Richard Sakaji Dr. David Sedlak
2:15 – 3:30	Charge Question #3 <i>Human Health Effects</i>	Lead Discussants: Dr. Jeffrey Griffiths Dr. Gary Saylor
3:30 – 3:45	BREAK	
3:45 – 5:00	Charge Question #4 <i>Risk Characterization</i>	Lead Discussants: Dr. Penelope Fenner-Crisp Dr. Gina Solomon
5:00 PM	Adjourn	Mr. Aaron Yeow

September 22, 2009

8:30 – 8:40 AM	Reconvening of Meeting	Mr. Aaron Yeow
8:40 – 10:00	Charge Question #5 <i>Overarching Considerations</i>	Lead Discussants: Dr. Mark Borchardt Dr. Joseph Landolph Dr. Laura Steinberg
10:00– 10:15	BREAK	
10:15 – 11:00	Summary of Major Advice and Action Items	Dr. Joan Rose
11:00 – 12:00	Committee Discussion on Draft Advisory Report on EPA’s Total Coliform Rule Revisions	Dr. Joan Rose and Committee
12:00 – 12:15 PM	Public Comments	Registered Commenters
12:15 – 1:00	Summary of Major Changes to Committee’s Draft Report	Dr. Joan Rose
1:00 PM	Adjourn	Mr. Aaron Yeow

ATTACHMENT D – LIST OF ATTENDEES

List of Attendees
SAB DWC Meeting on
EPA's Microbial Risk Assessment Protocol
September 21, 2009

Name	Affiliation
Steve Via	American Water Works Association
Edward Ohanian	USEPA
Stephen Schaub	USEPA
Patsy Root	IDEXX Labs
Cynthia McOliver	USEPA
Erica Martinson	Inside Washington Publishers
Sharon Nappier	USEPA
Darrell Osterhoudt	Association of State Drinking Water Administrators
Alan Roberson	American Water Works Association
Mike Broder	USEPA

List of Attendees
SAB DWC Meeting on
EPA's Microbial Risk Assessment Protocol
September 22, 2009

Name	Affiliation
Stephen Schaub	USEPA
Mike Broder	USEPA
Erica Martinson	Inside Washington Publishers
Michael Messner	USEPA
Marc Rigas	NIH
Sean Conley	USEPA
Jimmy Chen	USEPA
Jeanne Briskin	USEPA
Jeremy Bauer	USEPA
Hannah Helsinger	USEPA
Julie Javier	USEPA

ATTACHMENT E – PRESENTATION BY DR. STEPHEN SCHAU



Microbiological Risk Assessment (MRA) Protocol for Water

Stephen Schaub, Ph.D.
Office of Water
Office of Science & Technology

SAB Drinking Water Committee
September 21-22, 2009





History of Office of Water (OW) MRA Development Activities

- Historically, used National Academy of Science “Red Book” chemical risk assessment procedures for MRA
- Collaborated with International Life Sciences Institute to Develop MRA framework
 - framework document in 2000
 - peer reviewed in open literature in 2002
 - consulted with EPA’s Science Advisory Board in 2004
- 2 workshops in early-mid 2000’s to populate framework with tools, methods, & procedures - input from FDA, USDA, WHO





History of OW's MRA Development Activities (cont)

- MRA protocol (2006) – guidance from EPA microbial risk assessor workgroup
- Companion Thesaurus of MRA Terms & Definitions (2006) – see OST Website
- Interagency Risk Assessment Consortium
- review/revisions - 2007
- External Expert Peer review/revisions – 2009
- Next Steps:
 - SAB Expert Panel review/revisions – 2009
 - Peer review journal publication/revisions - 2009/2010





Office of Water Uses for MRA

- Manage human health risks from microbial contaminant exposures in water media.
- Support overall Agency regulatory goals: water safe to drink; fish & shellfish safe to eat; and water safe to swim.
- Focus on regulatory exposure scenarios:
 - Drinking Water regulations
 - Swimming/Recreational water criteria
 - Biosolids – treatment performance requirements or stds. for environmental releases
 - Shellfish growing/harvest water
 - Future – water reuse and irrigation





MRA and Chemical RA Protocols

- Difference - MRA Protocol focuses on unique microbe exposure & human health factors:
 - Microbial growth and death
 - Detection methodologies – variability at low microbial levels plus viability & speciation issues
 - Heterogeneous spatial and temporal distribution in environment
 - Genetic diversity of pathogens: infectivity, host range & diseases
 - Range of host genetics, immunity components & susceptibility factors
 - Dose-response ranges & outcomes
 - Secondary transmission





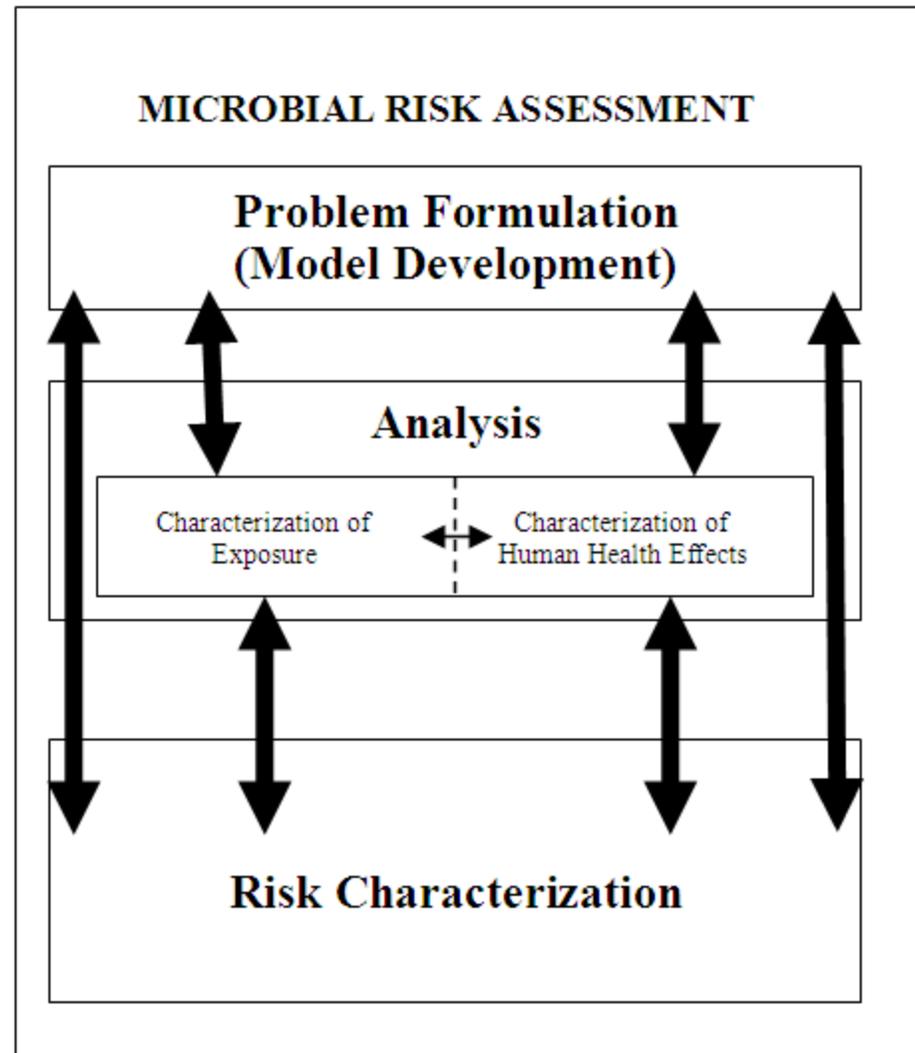
General Features of MRA Protocol

- Modular component concept & not prescriptive
- Unique Agency requirements can be inserted or replace default guidance
- Various types of RAs – regulatory, outbreak, ID/prioritize R&D requirements, risk-risk tradeoffs, emergency response and mitigation
- Consistent with its companion document: Thesaurus of Terms and Definitions in MRA – MRA terms and definitions from US and international agencies
- Appendices: details on dose response modeling applications, flow diagrams for various types of assessments, & general considerations for conducting MRAs





EPA MRA Protocol Framework





Specific Features of MRA Protocol

- Expanded Problem Formulation Chapter: planning & scoping, tiered conceptual modeling
- Exposure Chapter: pathogen occurrence and exposure analysis
- Health Effects Chapter: dose response and health effects, dose response modeling applications, and dynamic population susceptibility models
- Risk Characterization Chapter (applies EPA's Risk Characterization Handbook): uncertainty, variability, comparison to similar risks, alternative approaches/solutions, input to inform risk management decisions





Overview of Desired SAB Review Recommendations to Improve the Protocol

- To provide a more robust MRA Protocol containing all relevant tested & validated tools, methods, & procedures
- To make the Protocol easier to understand and use, and meet EPA's goals of Transparency, Clarity, Conciseness and Reasonableness
- To refine the protocol so that risk assessors and stakeholders can readily apply it, reproduce findings, and fully understand its approach, procedures, and products
- To enhance the overall Protocol's utility so it is a document that risk assessors & managers really want to use or recommend for risk assessments



ATTACHMENT F – PUBLIC ORAL STATEMENT

**Steve Via, American Water Works Association
September 21, 2009**

**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.

Effective Guidance – 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?

Clarity and Transparency – 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
<i>Cryptosporidium</i>	265	5	<i>C. parvum</i>	255	3
			<i>Cryptosporidium</i>	10	2
Norovirus	259	10	<i>Norovirus</i>	151	6
			<i>Norovirus G2</i>	50	1
			Norwalk-Like Virus	48	2
			<i>Norovirus G1</i>	10	1
<i>Shigella</i>	160	8	<i>Shigella sonnei</i>	150	7
			<i>Shigella flexneri</i>	10	1
<i>E. coli</i>	105	10	<i>E. coli O157:H7</i>	90	8
			<i>E. coli O121:H19</i>	11	1
			<i>E. coli O26:NM</i>	4	1
<i>Giardia</i>	11	2	<i>Giardia intestinalis</i>	11	2
<i>Pliesiomonas</i>	5	2	<i>Pliesiomonas shigelloides</i>	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.

ATTACHMENT G – CHARGE TO THE COMMITTEE

SAB Review of MRA Protocol

BACKGROUND

Over the past decade, the Office of Science and Technology (OST) in the EPA's Office of Water has been involved in the development of a Microbiological Risk Assessment (MRA) Protocol to better inform persons conducting EPA sponsored MRAs about available approaches, methods, and tools, thus enhancing the capability of the assessors to prepare successful products. Initially, OST enlisted the International Life Sciences Institute through a cooperative agreement to help develop a MRA framework based upon the specific or unique risk assessment factors that risk assessors need to consider in conducting MRAs in water media. Subsequently, the OST sponsored a number of workshops to identify existing or generally accepted developmental approaches, tools, methods, and procedures for application in populating the framework to establish the protocol for conducting MRAs, especially for water-based media (drinking water, recreational water, biosolids, shellfish growing water, etc.).

At this time the OST has developed a draft MRA Protocol document that it believes captures the essential components for risk assessors to use to successfully conduct microbiological risk assessments in water media. The current Protocol focuses only on risk assessment components and does not broadly consider all aspects of risk management or risk communication although it is recognized that these features are essential components for conducting a successful risk analysis. After review by the EPA's Science Advisory Board the OST will make essential modifications to the protocol and will then list this document on its website so that it will be available to all EPA staff and contractors involved in risk assessment as well as the general microbiology community.

CHARGE QUESTIONS

The following non-prioritized list of questions to the Science Advisory Board reviewers has been prepared to help EPA's Office of Water, Office of Science and Technology, improve the MRA protocol's effectiveness for users. It is envisioned that the SAB Reviewers will provide new insights and technical additions or modifications to improve the ease of use, technical robustness, clarity, and efficacy of the MRA protocol as a resource for guidance or support in conducting risk assessments. The focus of the MRA Protocol is to support professional microbiologists and risk assessors conducting water-based microbial risk assessments on conventional waterborne microbial pathogens and the water route of exposure.

1. Planning/Scoping and Problem Formulation – Chapter 2:
Please comment on the utility of this Chapter to ensure that risk assessments are adequately conceptualized and planned appropriately to address risk management's issues. Please provide any recommendations for enhancing the utility of this Chapter.

Please comment on any enhancements or expanded guidance needed to allow users to prepare and conduct risk assessments to address a broad range of types of risk management questions. Examples of types of EPA uses of MRA may be:

- a) approaches to mitigation of environmentally-based microbial pathogen exposure risks;
- b) determination of acceptable health risks;
- c) identification of different exposure factors/routes;
- d) identification of microbial-based hazards in disease outbreaks;
- e) development and prioritization of research needs;
- f) competing risks ranking.

2. Exposure – Chapter 3:

Please comment on any additional exposure tools, methods, or approaches that should be included to ensure a robust approach to adequately determining the microbial occurrence and human exposure factors relevant to health risks from water. This includes support for the estimation of the magnitude, frequency, duration, and also additional types of exposure to microbial pathogens by the water route, as well as the range of characteristics of the exposed population and their exposure profiles.

3. Human Health Effects – Chapter 4:

Please comment on any additional scientifically accepted dose response models (including advanced and validated threshold, empirical, or mechanistic models) which should be included as tools for determining human dose responses from waterborne exposures via oral, inhalation, and dermal routes, especially for low dose extrapolation.

Please comment on whether any specific animal or *in vitro* dose response protocols, models, and methods should be included in this Chapter. If so, please describe their applications and limitations in establishing human dose response curves.

4. Risk Characterization – Chapter 5:

Please comment on any improvements needed to achieve the necessary outputs or linkages between the components of the problem formulation, exposure, and health chapters to make risk characterization easier to conduct.

Please comment on any additional approaches or methods to address uncertainty, variability, and sensitivity analysis of the various pathogen, health and exposure factors used in risk characterization.

5. Overarching Considerations:

OST would like this Protocol to provide a comprehensive and robust suite of approaches, tools, methods, and procedures to meet EPA's overall needs in preparing for, and conducting typical MRAs. OST would also like the Protocol to be informative, easy to use and understand, and useful to outside stakeholders (states, communities, utilities, industry, and impacted parties).

Please comment on the following:

- a) utility of the Protocol for meeting EPA's overall needs, particularly on the comprehensiveness and robustness of the Protocol;
- b) flow and continuity within and between chapters;
- c) ease of use and utility for outside stakeholders;
- d) any changes or enhancements to the Protocol to ensure it meets the needs of EPA and outside stakeholders.