

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.