



Microbiological Risk Assessment (MRA) Protocol for Water

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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





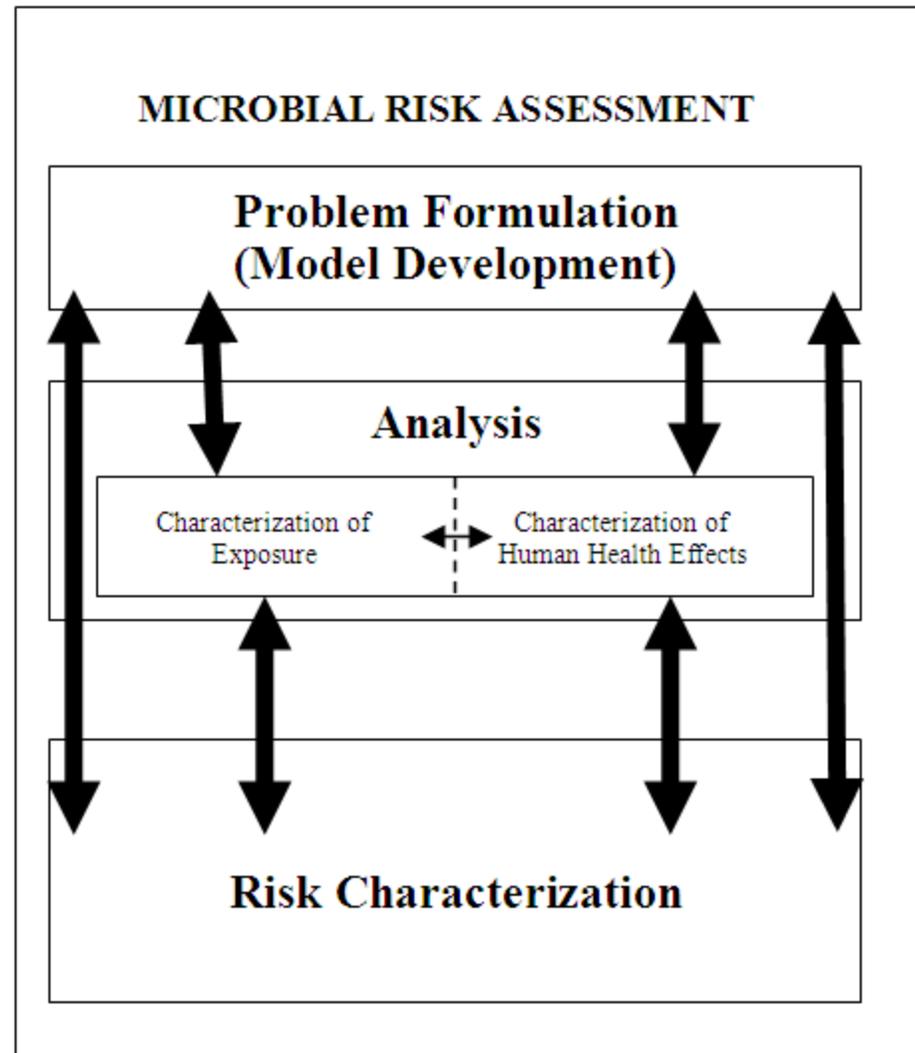
General Features of MRA Protocol

- 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

