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Office of Water Efforts to Advance MRA Capabilities to Assess Risk of Exposure to Waterborne Pathogens

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Typical OW Requirements and Activities that Utilize MRA Applications

- Manage human health risks from microbial contaminant exposures in water media.
- MRA used for health protection for following exposures:
 - Drinking Water - specifically treatment & distribution
 - Swimming/Recreational
 - Biosolids – treatment performance or stds. for release
 - Shellfish growing/harvest
- Overarching Agency regulatory goals: water safe to drink; shellfish safe to eat; and water safe for swimming
- Desire harmonization within Agency & other Agencies having similar MRA needs & applications for maximum cross fertilization & conservation of resources & funds

OW's MRA Procedures Need to Consider Unique Microbial Concerns

- Multiple factors make using NAS "Red Book" protocol Difficult:
 - ✓ microbial growth and death in environment
 - ✓ single, low dose has a probability of causing infection or disease
 - ✓ variable host immunity (including genetic predisposition)
 - ✓ potential for secondary disease transmission
 - ✓ heterogeneous spatial & temporal distribution in water
 - ✓ broad dose response range for effects: infection, disease, and mortality
 - ✓ wide range of pathogen "type" responses to treatment & disinfection interventions
 - ✓ genetic diversity and mutations
 - ✓ cross species jumping

History of Office of Water (OW) MRA Development Activities

- In mid 1990s determined that National Academy of Science "Red Book" for chemicals was awkward to use for microbes in water media.
- Commissioned collaborative effort with the International Life Sciences Institute (ILSI) to Develop MRA framework (2000)
 - Expert workgroup process
 - EPA's Science Advisory Board & journal peer review for final framework.
- Subsequently sponsored numerous workshops and meetings to populate framework with MRA tools, methods, procedures. Input from FDA, WHO, USDA & academia.

History of OW's MRA Development Activities (cont)

- Drafted full MRA protocol in 2006 – oversight by EPA microbial risk assessor group.
 - Subsequently drafted ambient water MRA's for *Cryptosporidium* & *Giardia* as case studies to test the protocol's efficacy.
- Prepared a companion Thesaurus of MRA Terms & Definitions.
 - Identifies/organizes common uses of MRA terms & definitions used by US & international governmental organizations, focused on existing guidelines, protocols & frameworks for water, food, and environment.

Specific OW Requirements/Uses for MRA in Water Media

- Safe Drinking Water Act (SDWA) regulations require formal risk assessments during development (e.g., LT2ESWTR, Total coliform, & Groundwater Rules).
- Ambient Water quality criteria (AWQC) development under Clean Water Act (CWA) apply MRA:
 - establish Criteria - e.g., beaches, shellfish, biosolids
 - provide States with uniform way to prepare alternative or site specific standards
- Emergency response to pollution events & mitigation.
- Determine research needs & prioritization.
- Support epidemiological investigations.
- Comparative risk determinations or risk-risk tradeoffs.

MRA Considerations in Support of SDWA Rules

- Drinking water rules are intended to protect health by achieving very low probability of exposure to infectious pathogens.
- MCLGs are established and used in economic analyses that apply MRA risk results for development of a rule.
- Performance-based water treatment provides safe water by attaining MCLG level for particular pathogen or fecal contamination indicator.
- SWTR's focus on specific pathogen levels (MCLGs) (e.g., *Cryptosporidium*, *Giardia*, enteric viruses) from surface waters. MRA applies a target MCLG against established treatment capabilities to meet health protection goals.
- Total Coliform Rule (TCR) risk analysis focuses on fecal indicators as estimators of enteric disease risk for exposures from public water supply distribution systems.

MRA Considerations in support of Ambient Water Quality Criteria (AWQC) under CWA

- AWQC are EPA's health protection recommendations to States for setting water quality standards - based on fecal indicator or pathogen correlations to acceptable illness levels.
- Typically, establishment of swimming, shellfish, or biosolids numerical criteria will utilize MRA for assessing acceptable risks from exposure and correlations with fecal indicator (or possibly pathogen) indices.
- Other AWQC components such as NPDES permits & TMDLs will also apply MRA results.
- In future, OW may consider AWQC for irrigation and reuse waters using MRA to determine acceptable risk and to set indicator levels to protect health.

Current Efforts to enhance MRA for Water Media in OW

- Revising draft MRA Protocol
 - Enhance dynamic population susceptibility modeling applications
 - Include new section to inform community-based risk assessment procedures (NAS recommendations)
 - Provide microbial-focused Risk Characterization Chapter (based on EPA Risk Characterization Handbook)
 - External peer review late 2008, also SAB consultation
 - Maintain protocol's consistency with OW's MRA Thesaurus of Terms and Definitions
- Thesaurus submitted to WHO for international MRA "Lexicon" applications

Current Efforts to Enhance MRA Procedures for Water Media in OW (cont)

- Development of Quantitative Microbial Risk Assessment (QMRA) protocols - provide tailored risk assessment tools for specific applications of MRA
- QMRA typically has narrowly defined requirements to support particular RA needs:
 - some aspects of a complete MRA protocol may not be needed, or may apply pre-set assumptions or defaults
- QMRA **does** require a minimum level of critical hazard ID, characterization, human exposure, health, dose response data in order to run analyses.
- QMRA Applications:
 - support TCR development & use within rule
 - alternative recreational water AWQC development tool and use by States

Other Current Efforts - OW Collaboration & Harmonization with other Offices & Agencies

- Goal - work toward mature, robust approaches to MRA
 - ◆ Participate in EPA Risk Assessment Forum's MRA working group to develop tools, methods & procedures.
 - ◆ Co-lead for Inter-Agency MRA Guidance writing group - prepare universal, adaptable MRA guidelines - (EPA including Homeland Security R&D, USDA, DoD, NASA, State Dept.)
 - ◆ Participate in Interagency Risk Assessment Consortium - interagency expert working group that prepares priority MRA procedural enhancements.
 - ◆ Participate in harmonization activities with WHO for MRA in environmental media: goal - internationally accepted protocols.

Some OW Needs For Improved MRA Capability to Address Current/Future Issues

- MRA for OW, the Agency & Interagency activities could benefit from enhanced capabilities:
 - Development/validation of animal & in-vitro models for dose-response & health effects
 - Application of genomics/proteomics to characterize hazards (e.g., VFARs)
 - Procedures for improved assessments of antibiotic resistance & emerging pathogens
 - Characterize impacts of immunotoxicant & life stage factors in dose response/health effects
 - Application of biomarkers to assess infection endpoints
 - Risk-Risk assessment capability
 - Case studies to validate MRA components/protocols

For additional information

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