Overview of Microbial Risk Assessment Activities in EPA's Office of Research and Development

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ORD Organization

- National Health and Environmental Effects Research Laboratory
- National Exposure Research Laboratory
- National Risk Management Research Laboratory
- National Center for Environmental Assessment
- National Center for Environmental Research
- National Homeland Security Research Center
- National Center for Computational Toxicology

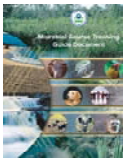
ORD Research on Microbial Risks

- Risk assessment/risk management paradigm
- Research encompasses continuum
  - –Source
  - –Risk management
  - –Exposure
  - –Health outcomes
  - –Regulatory issues
- Research Challenges
  - –Dose-response
  - –Relationships between indicators and pathogens
  - –Use of risk assessment for risk management

Examples of ORD Research Questions for Drinking Water

- Impacts of alternative disinfection (e.g. chloramination) on microbial ecology/pathogen distribution, microbial risk
- Impacts of water distribution system management practices—chlorination, flushing, etc.—on microbial risk?
- Risk assessment for sensitive populations
- Trends of alternative pipe materials-impacts on microbial risk

Research Progress Highlights



- Pathogens
  - –Proteomics-based approach for characterizing drinking water pathogens
  - –Improved method(s) for Mycobacterium paratuberculosis, rotavirus, hepatitis E virus, pathogenic fungal species
  - –Method for characterizing human exposure to mycobacteria
  - –Characterization of the virulence of bacteria in biofilms and/or cooling towers; Includes methods to distinguish virulent and avirulent isolates

Research Progress Highlights

- –Contribution of enterohemorrhagic Escherichia coli (EHEC) in watersheds from wastewater effluents
- –Evaluation of conferred antibiotic resistance in microbial communities resulting from pharmaceuticals and personal care products
- –Improved methods to measure concentrations of *Cryptosporidium spp.* and *Giardi spp.* in source waters

Research Progress Highlights

- Ultraviolet irradiation for pathogen inactivation
- Cost and performance evaluations for advanced oxidation processes (e.g., ozone/UV/hydrogen peroxide combinations) to control pathogens in small drinking water systems
- Evaluation of conferred antibiotic resistance in microbial communities resulting from pharmaceuticals and personal care products

STAR Grants

- Key areas:
  - Methods development
  - Epidemiology studies
- In 2005 STAR Grants Total Over $5.8M
- Examples:
  - Simultaneous Concentration and Real-time Detection of Multiple Classes of Microbial Pathogens from Drinking Water
  - On-chip PCR, Nanoparticles, and Virulence/Marker Genes for Simultaneous Detection of 20 Waterborne Pathogens

Examples – 2007 STAR Grants

- Fiber Optic Array System for Detection and Enumeration of Potentially Toxic Cyanobacteria
- Assessment of Microbial Pathogens using Molecular Methods with Solid Phase Cytometry
- Selective Field-Deployable Biosensor for Cyanotoxins and Cyanobacteria using Antibodies and DNA-Signatures
- Automated Quantification and Infectivity of Human Noroviruses in Water
- Rapid Concentration, Detection, and Quantification of Pathogens in Drinking Water

Dose Response Characterization in Susceptible Populations and Life Stages

EPA Risk Assessment Forum Workshop (Feb 2007)

- Colloquium on immunotoxicity & lifestage impacts on dose response to environmentally derived pathogens
- Multidisciplinary approach
- Data needs
- Address regulatory needs: immunotoxicology and microbial risk assessment guidance

EPA Risk Assessment Forum – Development of MRA Guidance

- Technical review of Office of Water's MRA protocol and thesaurus of terms/definitions
- Evaluation of existing MRA Frameworks
- Development of MRA risk communications procedures
- Major involvement in Interagency MRA guidelines development efforts

Anticipated Outcomes of EPA Activities

- Interagency guidance - Greater consistency in MRA
- Bridge key data gaps in characterizing microbes using advanced methods and innovative approaches
- Better understanding of susceptible populations and life stages
- Informed planning
- Prioritized research initiatives
- More transparent regulatory decisions