REGIONAL/ORD WORKSHOP ON EMERGING ISSUES ASSOCIATED WITH AQUATIC ENVIRONMENTAL PATHOGENS

SUMMARY REPORT

September 5 - September 7, 2001
Fort Meade, MD

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FOREWORD

The *ORD/Regional Training Workshop on Emerging Issues Associated with Aquatic Environmental Pathogens* was the seventh in a series of Regional Science Topic Workshops sponsored by the Office of Science Policy (OSP) in the Office of Research and Development (ORD) at the U.S. Environmental Protection Agency (EPA). Other workshops in this series included:

- *Asthma: The Regional Science Issues*
- *Communicating Science: Waves of the Future Info Fair*
- *Fully Integrated Environmental Location Decision Support (FIELDS)*
- *Non-Indigenous Species*
- *Pesticides*
- *Endocrine Disruptors*

The objectives of the National Regional Science Topic Workshops are to: 1) establish a better cross-Agency understanding of the science applicable to specific region-selected human health and/or ecological topics, and 2) develop a network of EPA scientists who will continue to exchange information on these science topics as the Agency moves forward in planning education, research, and risk management programs.

Each year, EPA regions, through the Regional Science Council, identify priority science topics on which to conduct workshops. The workshops address the science issues of greatest interest to the regions on the selected topic area. Each workshop is planned and conducted by a team of regional, ORD, and interested program office scientists, and is led by a regional chairperson and facilitated by one or more Regional Science Liaisons to ORD. Participants maintain the cross-Agency science networks they establish at the workshops through planned post-workshop projects and activities, such as the identification of collaborative research opportunities, creation of information sharing mechanisms (e.g., interactive web sites), and development of technical fact sheets for regional use.

For additional information on a specific workshop or on the Regional Science Topic Workshop series, contact David Klauder in ORD's Office of Science Policy (202-564-6496).

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EXECUTIVE SUMMARY

The *ORD/Regional Training Workshop on Emerging Issues associated with Aquatic Environmental Pathogens* was held on September 5 - September 7, 2001, at Fort Meade, Maryland. The workshop was chaired by Ron Landy (Region 3 Liaison) and facilitated by Mick Kulik (Region 3).

The workshop was organized into six sessions:

I. Science Support to EPA Programs and Regions
II. Incidence and Risk Assessment of Emerging Pathogens
III. Assessing Exposures to Emerging Pathogens
IV. Emerging Pathogens Risk Management Challenges:
  A. Emerging Pathogens in Drinking Water
  B. Emerging Pathogens in Recreational Water
V. Pathogen TMDLs / CAFOs / Biosolids
VI. Over the Scientific Horizon – Meeting Regional Research Priorities

Regional, Office of Research and Development, and Office of Water scientists presented current work on methodologies being developed, and new data on a variety of pathogens of concern; EPA regulations or rules under development or in the process of revision, and new or improved approaches for risk assessment and risk management. The need for new and better methods as more pathogens are recognized was an often-repeated theme throughout the workshop; however, a number of the presenters described such new methods currently being developed, or, in the form of case studies, gave alternatives that have been used by regulators when a method was unavailable. The meeting was limited primarily to EPA staff, with representation from all ten regions, all 5 ORD National Labs and Centers, and all the relevant components of the Office of Water. When dealing with topics where external views were considered critical, outside speakers were invited.

Breakout sessions, and a panel discussion, were held with the express purpose of generating detailed lists of the type of data, procedures, and information needed to help with the regulation and control of different types of pathogens, in both drinking and recreational water.

Many participants expressed a wish to conduct workshops on this topic on a regular basis; reasons given were that there will always be new pathogens emerging, and new methods and data needed by regional scientists and regulators. The workshop provided an informal way of keeping in contact with individuals in similar fields and situations, as well as a way of keeping informed of new developments.

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RESEARCH NEEDS IDENTIFIED AT THE WORKSHOP

The list of research needs below was initiated by a panel discussion held on the first day of the workshop with the purpose of identifying high-priority regional needs. The list includes issues brought up during discussions, presentations, question and answer sessions, and break-out group sessions throughout the workshop.

METHODS – NEW/BETTER METHODS NEEDED

The most commonly and emphatically expressed need by the regions was the development of better methods: new methods for pathogens not currently being monitored, simpler methods that can be used reliably, and faster methods where time is an issue (e.g., beach closings). In particular, the need mentioned most frequently was the need to develop methods for directly measuring pathogens of concern so that we would no longer have to rely on using indicators. The problems with using indicators were discussed at length during the workshop.

A method is needed for the **detection of *E. coli* O157**, which is not detected by routine *E. coli* monitoring.

A better method for *E. coli*, specifically one that will not give as many false positive results due to the presence of a different organism (eg., Colilert™).

For coliform bacteria, a simpler method for determining assimilable organic carbon (AOC) is needed; AOC levels are correlated with coliform and *Mycobacterium avium* complex presence.

- Methods that give accurate results within the same day are especially valuable to regional offices performing assessment of beaches, as decisions on whether to close a beach have to be made quickly and often carry significant financial consequences.

- Methods specifically intended for **biosolids** and **groundwater** need to be developed, and existing methods standardized.

- Methods need to be developed or adapted to be able to detect organisms associated with **biofilms**.

- **Improvements to existing methods** for some pathogens were also suggested. Specifically, a better method for measuring *Aeromonas* that will be easier to use for routine, regulatory monitoring. In the case of *Cryptosporidium*, the existing method can be misinterpreted.

- Recovery methods for use in **soil** are needed for all pathogens.

TECHNICAL ASSISTANCE, AND RESEARCH NEEDS HIGHLIGHTED DURING WORKSHOP DISCUSSIONS:

- Criteria need to be developed for **selection of sampling sites**, especially for coliform bacteria testing, as false positive readings have been connected with sampling sites**.** Better information on the significance of **indicators** used in water quality monitoring would be helfpul. Indicators are sometimes the only available test, and as such will continue to be used, but a clear explanation of their shortcomings is necessary.

- Standard and detailed techniques for **risk management** are needed for pathogens in both drinking water and recreational water. More detailed information is needed to determine the efficacy of **disinfection** methods on the removal of various pathogens. Research is also needed on sample flushing procedures.

- New research is needed to develop a **database** on indicator organisms; the bulk of the existing data on indicators deals with the same few organisms.

- Consensus should be reached regarding the best indicator organisms for detecting pathogens in **biosolids.**

DATA NEEDED: PATHOGENS

All Pathogens:

- Better data on pathogen characterization is needed for all pathogens, particularly information on **virulence determinants** and **indicator regrowth**.

- Determination of **acceptable loads**: some studies exist, but information on acceptable loads should be available for all pathogens of major concern. **Dose-response** studies would be useful in determining acceptable loads by defining the dose that results in disease.

- **Antibiotic resistance** should be considered as a potential concern in all bacterial pathogens. Studies may need to be done to determine to what extent pathogens are exhibiting resistance, and if so, whether it is increasing.

- Development of **models** to predict die-off rates of pathogens in different environmental conditions.

Specific Pathogens:

- Studies are needed to show the impact of chloramines on ***Legionella***.

- More information is needed on pathogens associated with animal feeding operations, e.g., ***Campylobacter*** and ***Salmonella***.

- An assessment is needed on the potential public health impact of **prions**, which may be associated with stream effluent near meat packing plants.

EPIDEMIOLOGY

In general, a better understanding of the epidemiology of aquatic pathogens was considered necessary.

- **Endemic levels** of pathogens should be monitored, to help recognize instances when a pathogen reaches epidemic levels.

- The **characteristics of disease** caused by each pathogen should be studied; this information will be useful in tracing pathogens to the distribution system. Information on the disease progression and secondary infection is also needed.

- A system should be developed for better **tracking of outbreaks**, to help with regulatory management. This would require the identification of new ways to assess **disease occurrence**; hospital admissions, which is the indicator currently used, can give unreliable estimates of disease occurrence.

- Information is also needed on ways to deal with sensitive (young and elderly) and super-sensitive (immuno-compromised) populations, as opposed to the general population, when it comes to pathogens in drinking water.

DISTRIBUTION SYSTEMS

- The characteristics of the system that could allow for intrusion should be studied in all drinking water systems and all potential sources of pathogens external to the distribution system identified (e.g., distance between water and sewer/utility pipes, pressure drops that could allow pathogens to enter the system).

WATERSHED APPROACH

- More information, as well as performance standards, are needed on the subject of **watershed protection**.
- Techniques are not clearly understood when it comes to **bacterial source tracking** in watersheds. Some of the questions that still need to be answered are:

  - When is bacterial source tracking feasible?
  - What techniques work best for watersheds?
  - What is the size limit (when is a watershed too big for bacterial source tracking to be effective)?
  - How far can the source library extend when performing these tests?

COMMUNICATION (ORD/REGIONS/LOCAL AGENCIES)

- Communication **between ORD and the regions** would allow newly developed science to be a prominent part of the regulatory decision making.

- Communication **with local agencies** is also essential in reaching consensus regarding aquatic pathogens and when/if they should be considered a public health priority.

ORD'S RESPONSE TO REGIONAL RESEARCH NEEDS

On the last day of the workshop, a panel of ORD representatives addressed the research needs identified by the regions throughout the workshop. The **Office of Science Policy**, as well as four of the **ORD National Laboratories and Centers** were represented, and are listed below:

- Office of Science Policy (OSP) – Molly Whitworth
- National Risk Management Research Laboratory (NRMRL) – Gene Rice
- National Health & Environmental Effects Research Laboratory (NHEERL) – Rebecca Calderon
- National Exposure Research Laboratory (NERL) – Gerry Stelma
- National Center for Environmental Research (NCER) – Cynthia Nolt-Helms

OSP – Molly Whitworth – ***Introduction***: ***Organizational Structure within ORD***

The Office of Science Policy (OSP) coordinates the planning of ORD research. There are five Research Coordination Teams (RCTs) within OSP – Water, Air, Waste, Pesticides/Toxics, and Multi-Media – which are tasked with developing ORD research plans to support Agency science needs. Review of the current research programs takes place from January to May of each year, and recommendations are made on the priorities for future research funding.

Throughout the year, RCT members – Associate Lab and Center Directors, program office representatives and regional representatives – meet regularly to share and discuss information. Associate Lab Directors and Associate Center Directors are also available to give technical assistance. Alternatively, regional needs and requests for assistance can be communicated via the regional representative to each RCT.

Four of the ORD National Laboratories and Centers were represented in this discussion addressing the needs identified by the regions (listed in the preceding section of this report). Each representative directly addressed the research needs expressed by providing the answer to three questions:

1. Which research topics and needs are currently being addressed by the laboratory?
2. Where are the gaps in data (as perceived by the ORD laboratory)?
3. In what ways can the regions communicate their research needs to ORD?

NRMRL – Gene Rice

Question 1: Which research topics and needs are currently being addressed by NRMRL?

The National Risk Management Laboratory is primarily oriented toward the engineering aspects of water treatment. Ongoing research includes the following topics:

- Treatment strategies for the physical removal and chemical inactivation of pathogens in drinking water and wastewater
- Microbiological methods for indicators and some pathogens, for measuring occurrence
- Pathogen monitoring, tracing and watershed tracking
- Watershed management
- Models of:
  - Inactivation kinetics
  - Disinfection
  - Determining Ct (concentration over time) values
- Effects of biofilms on drinking water systems, such as:
  - Effect on total water quality
  - Presence of pathogens, especially opportunistic pathogens
- Regulation of pathogens from biosolids and Confined Animal Feeding Operations

Question 2: Where are the gaps in data (as perceived by NRMRL)?

- Data gaps exist in the removal efficiency for pathogens (efficiency is often limited by the methods used).

Question 3: In what ways can the regions communicate their research needs to ORD?

- Meetings/workshops are important for continued interaction between ORD and the regions.
- Often the research that addresses regional needs is not adequately communicated to the regions – meetings are an effective way of doing so.

NHEERL – Rebecca Calderon

Question 1: Which research topics and needs are currently being addressed by NHEERL?

Health Division of NHEERL:

- Maintaining a relationship with the Centers for Disease Control and Prevention, especially in collecting data on outbreaks
- Data collection on endemic levels of disease, which can help deal with outbreak situations as they arise
- Infectious dose studies are planned, especially for *Cryptosporidium*
- There is a new research initiative focusing on bathing beaches

Ecology Division of NHEERL:

- Programs involving landscape ecology, GIS and satellite imaging; NHEERL has worked extensively with the regions on some of these projects
- Source tracking of enteric microbial organisms
- Database on Enterococci
- Methods development (especially DNA micro-arrays) in conjunction with NERL
- Microbial community structure and identification of the ecological niches of pathogens
- "Coastal 2000" program: an extensive program dealing with marine environments

Question 2: Where are the gaps in data (as perceived by NHEERL)?

- Algal toxins – information was requested on whether this problem should be considered in epidemiological studies

Question 3: In what ways can the regions communicate their research needs to ORD?

- Scientists and program directors are interested in communicating with the regions, as regional problems can be incorporated into ORD studies
- Holding forums and meetings/workshops on a regular schedule

NERL – Gerry Stelma

Question 1: Which research topics and needs are currently being addressed by NERL?

- Occurrence data on hazardous organisms and chemicals
- Studies of human exposure to hazardous organisms and chemicals (a method is still needed to measure human exposure)
- Development of monitoring tools, including:
  - Real-time PCR
  - DNA micro-arrays (using real-time PCR)
  - Flow cytometry using labeled antibodies (a new, bench-top unit has been developed)
  - Biosensors to measure fecal indicators
  - Dose-response relationships, for both healthy and immuno-compromised individuals
  - Better understanding of where indicators come from; this would be especially useful for performing TMDLs and managing watersheds
  - Method for measuring Enterococci (which are more accurate indicators in marine water than *E. coli*)
  - Biosensors to measure algal toxins; some technologies already exist but cannot currently be used for water samples

Question 2: Where are the gaps in data (as perceived by NERL)?

- Better methods are needed for source tracking
- The best existing methods should be identified, and further research on those methods supported
- Data is needed on the transport of microorganisms in manure, soil, sludge

Question 3: In what ways can the regions communicate their research needs to ORD?

- Holding workshops on a regular basis would facilitate communication – especially after meeting in informal settings such as workshops
- Additional travel, both on the part of ORD and the regional labs would also maintain the lines of communication

NCER – Cynthia Nolt-Helms

Question 1: Which research topics and needs are currently being addressed by NCER?

Current programs funded by NCER:

- Too many areas to present them all in this forum, check out our website and use it's SEARCH feature to find specifics of interest to you: www.epa.gov/ncerqa/. Some examples include:

- Drinking water program – pathogens research including:
  - Dose-response relationships for *Cryptosporidium*
  - Infectivity and virulence of *Cryptosporidium* in healthy adults
  - Development of indicators, such as a portable system for on-site detection of *Legionella*
- Recreational water program (a small program which may not continue)
- Hazardous algal blooms
- Water and watersheds
- Global climate change

Question 2: Where are the gaps in data (as perceived by NCER)?

New programs initiated by NCER in response to data gaps include:

- Risk from pathogens in drinking water
- Risk from pharmaceuticals
- Risk from tropical waters (recreational water)
- Risk from "swash zone" – interface zone of a beach where the waves and sand meet (recreational water)

Question 3: In what ways can the regions communicate their research needs to ORD?

- Information on research funded is available on the NCER webpage:
  - www.epa.gov/ncerqa
  - Abstracts, annual progress reports, and final reports for all funded studies are posted on the website
- Input (from both ORD and regions) can be communicated to NCER through participation in relevancy reviews of grant proposals or by contacting any NCER staff

- Outreach to regions to determine the best way of making research results known:
  - Progress Reviews where principal investigators provide presentations on their research (annually/semi-annually, and at the end of the study)
  - Posting of publications on the website
  - Regional informational meetings being held at most regional offices by NCER staff in FY01

WORKSHOP AGENDA

ORD/Regional Workshop on Emerging Issues Associated with Aquatic Environmental Pathogens

September 5-7, 2001
Ft. Meade, Maryland

Wednesday, SEPTEMBER 5

Introduction

8:00 Registration

8:30 Welcome – *Deborah Dietrich (ORD) and Rich Pepino (Region 3)*
Workshop Goals/Logistics –*Ron Landy (Region 3), Meeting Coordinator*
Workshop Structure – *Mick Kulik (Region 3), Meeting Facilitator*

Science Support to EPA Programs and Regions

1. Where/how do emerging pathogens fit within the Agency mandates? What are the scientific needs to support these mandates?
Chair: *Jake Joyce (Region 7)*

8:45 Overview of Emerging Pathogens – *Jake Joyce (Region 7)* **[PAGE 23]**
9:10 The Clean Water Act's Requirements for Pathogens – *Jim Pendergast (OW)* **[PAGE 25]**
9:30 Safe Drinking Water Act/Contaminants Pathogens Candidate List – *Paul Berger (OW)* **[PAGE 26]**
9:50 Workgroup updates (15 minutes each)
Unregulated Contaminant Monitoring of Pathogens – *Jim Sinclair (OW)* **[PAGE 27]**
Update on EPA's Implementation Guidance of AWQC for Bacteria – *Jennifer Wigal (OW)* **[PAGE 28]**
Developing a Strategy for Waterborne Microbial Disease Control – *Steve Schaub (OW)* **[PAGE 29]**
10:35 ***Break***
10:50 EPA Implementation of Beaches Environmental Assessment & Coastal Health (BEACH) Act – *Charles Kovatch (OW)* **[PAGE 30]**
11:30 Q & A

2. Is our science on pathogens appropriate to support regulatory management?

11:40 Summary of Major Regional Scientific/Technical Priorities – *Vicki Binetti (Region 3)* **[PAGE 32]**
11:50 Regional panel discussion – facilitated Q & A – *Moderator: Vicki Binetti*
Panel: Lisa Byron (Region 2), Joel Hansel (Region 4), Bob Benson (Region 8), Howard Neukrug (Philadelphia Water Department) **[PAGE 33]**
12:30 ***Lunch***

Incidence and Risk Assessment of Emerging Pathogens

1. What do we know about the nature and magnitude of waterborne disease in the United States?
Co-chairs: Kim Ngo (Region 6) and Rebecca Calderon (ORD/NHEERL)

1:30 Waterborne Disease Outbreaks in the U.S. – Regional Issues – *Kim Ngo (Region 6)* **[PAGE 37]**
1:45 Waterborne Disease: EPA's Intramural Epidemiology Program – *Rebecca Calderon (ORD/NHEERL)* **[PAGE 38]**
2:40 An Estimate of National Waterborne Disease Occurrence – *Susan Shaw (OW)* **[PAGE 39]**
3:00 Q & A
3:30 ***Break***

2. Are our microbial risk assessment tools (epidemiological and "toxicological") adequate to evaluate emerging pathogens?
Chair: Bruce Macler (Region 9)

3:45 Microbial Risk Assessment: State of the Art and Science – *Bruce Macler (Region 9)* **[PAGE 40]**

Microbial Risk Assessment in other Agencies
4:00 A Dose-Response Envelope for *E. coli* O157:H7 – *Mark Powell (USDA)* **[PAGE 41]**
4:15 *Vibrio parahaemolyticus* Risk Assessment – *Marianne Miliotis (FDA)* **[PAGE 42]**

Microbial Risk Assessment at EPA
4:45 Pathogen Risk Assessment Protocol for Environmental Water Media – *Steve Schaub (OW)* **[PAGE 44]**
5:00 Risk Assessment in Regulatory Development – *Stig Regli (OW)* **[PAGE 45]**
5:15 Microbial Risk Assessment Activities in Cincinnati Division of EPA's National Center for Environmental Assessment – *John Lipscomb (ORD/NCEA)* **[PAGE 46]**

Thursday, SEPTEMBER 6

Incidence and Risk Assessment of Emerging Pathogens (continued)

8:30 (Two concurrent breakout group discussions) **[PAGE 48]**

1. What endpoints and factors should be considered in microbial risk assessments? *Moderator: Bruce Macler (Region 9)*

2. Recognizing the uncertainties inherent in microbial risk assessment; what data would provide the most value added? *Moderator: Mike Messner (OW)*

9:20 Breakout group reports – 10 minutes each
9:40 Q & A session with leads for breakout groups
10:00 ***Break***

Assessing Exposures to Emerging Pathogens

1. How do we look for these organisms? What is the current status of methods to monitor exposure?
Co-chairs: Bobbye Smith (Region 9), Gerry Stelma (ORD/NERL), and Fred Genthner (ORD/NHEERL)

10:15 Assessing Exposures to Emerging Pathogens – What do the Regions Need? *Terry Fleming (Region 9)* **[PAGE 49]**
10:35 Assessing Exposure to Bacterial Pathogens –*Gerry Stelma (ORD/NERL)* **[PAGE 50]**
10:55 Development of Molecular Methods to Detect Emerging Viruses – *Ann Grimm (ORD/NERL)* **[PAGE 51]**
11:15 Detection of Protozoan Pathogens in Water – *Frank Schaefer (ORD/NERL)* **[PAGE 52]**
11:25 Current Approaches to Identifying Sources of Fecal Contamination – *Gerry Stelma (ORD/NERL)* **[PAGE 53]**
11:45 Antimicrobial Resistance Among Enteric Bacteria Isolated from Human and Animal Wastes and Impacted Surface Waters – *Mark Sobsey (University of North Carolina)* **[PAGE 54]**
12:05 Q & A
12:20 ***Lunch***

First of two concurrent sessions:

Emerging Pathogens in Drinking Water – Risk Management Challenges

Co-chairs: Kim Harris (Region 5) and Gene Rice (ORD/NRMRL)

1:20 User Friendly Models for Evaluating Hydrogeologic Barriers to Viruses – *Bart Faulkner (ORD/NRMRL)* **[PAGE 55]**

1:40 Water Supply and Water Resources Division Response to Waterborne Disease Outbreaks – *Kim Fox (ORD/NRMRL)* **[PAGE 56]**

1. What are the microorganisms of concern and how do they get into the distribution system?

2:00 Disinfection of Emerging Pathogens – *Gene Rice (ORD/NRMRL)* **[PAGE 57]**

2:20 Biofilms in Drinking Water Distribution Systems – *Mark Meckes (ORD/NRMRL)* **[PAGE 58]**

2. What is the drinking water distribution rule?

2:40 Update on Six-Year Review of TCR and Potential Distribution System Rule – *Ken Rotert (OW)* **[PAGE 59]**

3. How do we handle cross-contamination and biofilm problems in the field? What are the inherent risks to distribution systems? Can we minimize the risk? Case study example/panel discussion.

3:00 Case Study: Biofilm Problem at Greenville, South Carolina – *David Parker (Region 4)* **[PAGE 60]**

3:20 The View from the Field – Water Distributor's Perspectives – *Mark LeChevallier (American Water Works Service Company, Inc.)* **[PAGE 61]**

3:40 ***Break***

4:00 Panel Discussion – *Moderator: Dave Parker (Region 4)*
Panel: Kim Ngo (Region 6), Kim Harris (Region 5), Mark LeChevallier (American Water Works Service Company), and Mark Meckes (ORD/NRMRL)

(All participants reconvene)

4:45 ORD's Drinking Water Research Program Tracking System – *Al Dufour (ORD/NERL) and Cheryl Itkin (ORD/NCEA)* **[PAGE 69]**

5:00 Adjourn

Second of two concurrent sessions:

Emerging Pathogens in Recreational Water – Risk Management Challenges

Co-chairs: Nancy Grundahl (Region 3) and Al Dufour (ORD/NERL)

1:00 EPA's National BEACH Survey – *Rick Hoffman (OW)* **[PAGE 63]**

1:40 Development of Improved Monitoring Approaches for Recreational Water – *Steve Schaub (OW)* **[PAGE 64]**

2:00 Use of Molecular Biology Techniques to Provide the Public with More Information on Recreational Water Closures in Norfolk – *Alpha Diallo (Norfolk Public Health Lab)* **[PAGE 65]**

2:20 Acceptable Goals and Thresholds for Pathogens from Recreational Water Exposures - *Al Dufour (ORD/NERL)* **[PAGE 66]**

2:40 Determining Sources of Microbial Contamination – Regional Applied Research Effort – *Joel Hansel (Region 4)* **[PAGE 67]**

3:00 ***Break***

3:20 Rapid Methods for Measuring Recreational Water Quality: A Look to the Future – *Al Dufour (ORD/NERL)* **[PAGE 68]**

3:40 Facilitated Q & A with panel of previous speakers

(All participants reconvene)

4:45 ORD's Drinking Water Research Program Tracking System – *Al Dufour (ORD/NERL) and Cheryl Itkin (ORD/NCEA)* **[PAGE 69]**

5:00 Adjourn

5:00 - 7:00 ***Buffet Dinner and Poster Session****

Friday, SEPTEMBER 7

Pathogen TMDLs/CAFOs/Biosolids

Co-chairs: Stephanie Harris (Region 10) and J. E. Smith, Jr. (ORD/NRMRL)

8:30 A Regional Perspective on CAFO/Biosolid Regulations: How ORD Can Help Us! – *Stephanie Harris (Region 10)* **[PAGE 71]**

8:50 Overview of Watershed Features and Dynamics Associated with Drinking and Recreational Water Protection – *J. E. Smith, Jr. (ORD/NRMRL)* **[PAGE 72]**

9:00 Potential Watershed Movement of Pathogens of Animal Origin – *John Cicmanec (ORD/NRMRL)* **[PAGE 73]**

9:25 Emerging Infectious Disease Agents and Issues Associated with the Management of Treated Sludges (Biosolids) – *J. E. Smith, Jr. (ORD/NRMRL)* **[PAGE 74]**

9:50 Risks from Pathogens in Biosolid Fertilizers/Land Application of Sludge – NRC Report – *Tom Burke (Johns Hopkins University)* **[PAGE 75]**
10:10 Q & A
10:30 ***Break***

Over the Scientific Horizon – Meeting Regional Research Priorities

Moderator: Paula Estornell

Presentations by ORD panelists based on previous days' discussions and questions, especially those raised during first day session on "Is our science appropriate..."

10:45 *Molly Whitworth – Office of Science Policy (OSP)* **[PAGE 9]**
10:55 *Gene Rice – National Risk Management Research Laboratory (NRMRL)* **[PAGE 10]**
11:05 *Rebecca Calderon – National Health and Environmental Effects Research Laboratory (NHEERL)* **[PAGE 11]**
11:15 *Gerry Stelma/Al Dufour – National Exposure Research Laboratory (NERL)* **[PAGE 12]**
11:25 *Cynthia Nolt-Helms – National Center for Environmental Research (NCER)* **[PAGE 13]**
11:35 Q & A and Discussion with Panel

12:00 ***Closing Session*** *– Rich Pepino (Region 3)*

What have we learned from this workshop? Do we need new research initiatives?
Are there specific emerging pathogens or situations that merit regulation?
What science do we need to support this?
Were the goals of the workshop achieved? Where do we go next and how?
Discussion

12:30 Adjourn

*POSTERS
5:00 - 7:00 p.m. September 6
Ft Meade Golf Course Club House

- "Identification of Sources of Fecal *E.coli* in Minnesota Watersheds Using rep-PCR DNA Fingerprinting" - *Priscilla Dombeck (University of Minnesota)*

- "Alpine *E. coli* O157 Outbreak" - *Sandy Spence (Region 8)*

- "Calicivirus Outbreak at Big Horn Mountain Lodge" - *Barbara Barron (Region 8)*

- "Enterococci in the Water Column and Shoreline Interstitial Waters at Beaches on the Gulf of Mexico and Santa Rosa Sound, Pensacola Florida" - *Fred Genthner (ORD/NHEERL)*

- "NARMS (National Antimicrobial Resistance Monitoring System) Relevance to Environmental Pathogens" - *Linda Silvers (FDA Center for Veterinary Medicine)*

- "Identifying Sources of Fecal Coliform Bacteria in Selected Streams on Virginia's TMDL Priority List" - *Ken Hyer (VA USGS District)*

- "Survey of U.S. Public Health Laboratories: Detection of Microbial Pathogens of the Contaminant Candidate List"- *Elizabeth Hilborn (ORD/NHEERL)*

- "Waterborne Pathogen Best Management Practices in Agricultural Watersheds" - *Barry Rosen (USDA/National Resources Conservation Service)*

- "Antimicrobial Resistance Among Bacteria Isolated from Human and Animal Wastes and Impacted Waters: Comparison with NARMS Findings" - *D. Cole, D. Robinette, J. Bumgarner and M. Sobsey*

- ""Biological Assessment of Beach, Leachate, and Effluent Sites at Lake Texoma"- *Mary E. Gonsoulin (ORD/NRMRL)*

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Welcome: Deborah Dietrich (ORD) and Rich Pepino (Region 3)

Workshop Goals/Logistics: Ron Landy (Region 3), Meeting Coordinator

Workshop Structure: Mick Kulik (Region 3), Meeting Facilitator

Science Support to EPA Programs and Regions

Where/How do emerging pathogens fit within the Agency mandates? What are the scientific needs to support these Mandates?

Chair: Jake Joyce (Region 7)

Overview of Emerging Pathogens – Jerome (Jake) Joyce (Region 7)

Emerging pathogens are microbes that have relatively recently come into the view of the health sciences as a cause of disease. These pathogens can be a relatively newly-discovered agent of infection such as *Legionella* bacteria causing Legionnaire's disease. An emerging pathogen may also be a relatively well-known agent that changes in virulence such as the *E. coli* O157:H7 strain acquiring the Shiga toxin. Emerging pathogens can also result from the importation of a new infectious agent such as West Nile Virus, which is well-known in the old world, but recently introduced into the new world. Emerging pathogens can be re-emerging disease agents such as yellow fever or malaria which have been eradicated in the continental U.S. but can make a comeback due to global weather changes.

Emerging pathogens can be engendered by a complex mixture of factors, such as:

- Social factors: e.g., changing moral values, migration of human populations;
- Political factors: e.g., warfare or oppressive governments, resulting refugee populations;
- Economic factors: e.g., prioritization of health funds, access to primary health care and modern sanitation;
- Ecological factors: e.g., urbanization, land use changes, climate changes; and
- Technological factors: e.g., rapid transportation, bio-engineered pathogens.

The factors above are not freestanding, but are all intertwined with each other.

Finally, emerging pathogens can arise among an immuno-compromised population. An opportunistic infectious agent is one that is not able to harm a healthy individual, but can produce disease in a person with compromised immune status.

The Clean Water Act's Requirements for Pathogens – James Pendergast (OW)

The Federal Water Pollution Control Act amendments of 1972 (commonly known as the Clean Water Act) provide a comprehensive approach for protecting water quality of the nation's waters from chemical, physical, and biological stresses, including pathogens. This presentation described how the Act has been used to assess and control pathogens, and has served as the basis for addressing emerging environmental issues, both in the area of human health and aquatic life.

The Clean Water Act (CWA) utilizes a series of steps in controlling pathogens. The Act states that water quality criteria must be established by the EPA for pathogens and indicators in recreational and coastal waters. The states then develop standards for water considering both public health and recreation. The states also identify those waters which do not meet their standards, in compliance with Section 303d of the CWA. A listing is assembled of these waters, known as the "303d" list, and Total Maximum Daily Loads (TMDLs) must be determined for the pathogens or pollutants which are determined to be causing the impairment. Once established, the TMDLs are used to determine what actions are needed to return the body of water to the purposes designated by the state.

The CWA National Pollutant Discharge Elimination System (NPDES) permit program exists to improve water quality by regulating point-sources of pollution. Compliance with the Act is monitored and enforced by EPA. Additionally, the states operate programs to abate nonpoint sources of pollution using funds supplemented by EPA under Section 319 of the CWA.

Safe Drinking Water Act and Contaminants Pathogens Candidate List – Paul S. Berger (OW)

The 1996 amendments to the Safe Drinking Water Act (SDWA) require EPA to regulate any contaminant that: 1) causes an adverse health effect; 2) occurs (or probably occurs) in drinking water at a frequency or concentration that warrants public health concern; and, 3) provides a meaningful opportunity to improve public health protection. The SDWA also requires EPA to publish a list every 5 years of non-regulated contaminants that occur, or probably occur, in drinking water and may need to be regulated. This list, known as the Contaminant Candidate List (CCL), becomes the focus for increased research and regulatory attention. According to the SDWA, within 5 years of publication of each CCL, EPA must decide whether or not to regulate at least 5 of these contaminants. In response to this Congressional mandate, EPA published a list of contaminants (CCL) in the Federal Register on March 2, 1998 (63 FR 1027410287). The pathogens on the CCL include:

Protozoa:	*Acanthamoeba*, Microsporidia *(Enterocytozoon*, *Encephalitozoon*)
Viruses:	Caliciviruses, adenoviruses, coxsackieviruses, echoviruses
Bacteria:	Helicobacter pylori, Mycobacterium avium complex, *Aeromonas hydrophila*
Algae:	Algae and their toxins

Many, perhaps nearly all, of the contaminants on the CCL cannot be regulated in a cost-effective manner without research into their health effects, occurrence in water, susceptibility to water treatment processes, effect on sensitive subpopulations, risk assessment, and/or the utility of inexpensive surrogates for their presence. Therefore, to allow the Agency to make a scientifically defensible decision on whether to regulate, the contaminants on the CCL are being given high priority with regard to drinking water research. (This situation, however, will not foreclose on research or regulations for contaminants not on the CCL.)

Unregulated Contaminant Monitoring of Pathogens – James L. Sinclair (OW)

The 1996 amendments to the Safe Drinking Water Act authorize monitoring of unregulated contaminants in drinking water. This provision is being implemented as the Unregulated Contaminant Monitoring Rule (UCMR). Monitoring will be done for contaminants that lack sufficient occurrence information. The occurrence data from unregulated contaminant monitoring will be used with other information to make regulatory determinations for contaminants in drinking water. Contaminants to be monitored will be selected from the occurrence priorities list of the Contaminant Candidate List (CCL). Of the 10 CCL pathogens, eight (8) are listed as occurrence priorities:

- Algae and toxins
- Microsporidia
- *Aeromonas hydrophila*
- *Helicobacter pylori*
- Echoviruses
- Coxsackieviruses
- Adenoviruses
- Caliciviruses

There are **three types of unregulated contaminant monitoring** based on analytical methods' availability for contaminants. The first monitoring option is **assessment monitoring** and will include all water systems serving more than 10,000 people plus a representative sample of 800 small systems (serving fewer than 10,000 people). Assessment monitoring will be done for contaminants with methods that were well-developed and validated when the UCMR was promulgated in September 1999. Sampling will be four times a year for surface water systems and two times a year for ground water systems. The next monitoring option is the **screening survey**. It includes a representative sample of 120 large systems and 180 small systems for a total of 300 systems. Screening surveys will be done for contaminants that will have methods ready by the time of screening survey monitoring. Sampling times and frequency are flexible. The third monitoring option is the **prescreen survey**. It includes up to 200 systems which are vulnerable to contaminant occurrence. Samples will be taken at vulnerable times, if possible. The prescreen survey is for contaminants that don't have well developed methods, or have methods that are expensive.

No CCL microbial contaminant has methods that could be used for assessment monitoring. *Aeromonas* has a method that can be used with a screening survey. The 7 remaining CCL microorganisms will be monitored with prescreen surveys when methods that can be used with these surveys are available. A lack of contaminant occurrence information may hinder designing a prescreen survey for vulnerable times and locations. Future work needed for UCMR monitoring of CCL pathogens is method development and preliminary surveys of source water and treated water. Preliminary surveys of pathogens will assist in the design of UCMR surveys.

Update on EPA's *Implementation Guidance for Ambient Water Quality Criteria for Bacteria* – Jennifer Wigal (OW)

The presentation provided an update on EPA's progress toward finalizing the Implementation Guidance for Ambient Water Quality Criteria for Bacteria – a document developed in response to commitments made in the Beach Action Plan (1999). The draft of the Implementation Guidance was distributed for public comment on February 14th, 2000. Key topics included the transition from fecal coliform bacteria as indicators to *E. coli* in freshwater and Enterococci in marine water, as well as a new recommendation to apply the criteria to waterbodies, rather than sources of contaminants. Additionally, the application of the criteria to tropical waters was recommended by EPA unless an alternate indicator is developed. A policy recommendation for secondary contact waters (used for activities such as boating) was also included in the document.

Approximately fifty comment letters were received from states, industry, and environmental groups, addressing all areas of the guidance, but focused especially in the following areas:

- Science underlying the criteria;
- Application of criteria to non-human sources;
- Application of criteria during high flows;
- Monitoring; and
- Extent of state flexibility in implementation.

The EPA workgroup is still in the process of revising the guidance – which is scheduled to be completed in the Fall of 2001 – based on discussions of the comments received. Additional revisions will include the relationship of the criteria implementation in WQS and BEACH programs, and considering the relative risk from non-human sources (i.e., how much is coming from each source?).

Finally, EPA's recommended Water Quality Criteria for Bacteria were presented for fresh and marine water, for designated beach areas, as well as moderately to infrequently used full-body contact recreation areas.

Developing a Strategy for Waterborne Microbial Disease Control – Stephen Schaub (OW)

In 1998, pathogens were the second most frequent cause of impairments to waters under Section 303(d) of the Clean Water Act. These impairments are primarily due to the increasing populations of humans and livestock, and their wastes. EPA has a number of existing mandates, regulations and initiatives such as the Interim Enhanced Surface Water Treatment Rule and EPA's Beach Action Plan which are important in reducing health risks from pathogens. EPA is adopting a strategy for future actions to integrate the protection of public health under both the Safe Drinking Water Act and the Clean Water Act. The strategy will guide decisions on the most effective use of available resources, support communication and partnerships with stakeholders, and enhance public communication.

The specific goals of the strategy include identification of priority activities for:

1) The recognition of significant known pathogens and emerging pathogens,
2) Identification and control of pollutant sources so that waters will meet protective use criteria,
3) Coordination of regulatory and research activities, regulatory approaches and R&D program support, and
4) Participation of public agencies and stakeholders.

The approaches to be used in meeting these goals were outlined as well:

- Develop Ambient Water Quality Criteria, as well as monitoring protocols, and indicators for pathogens.
- Establish risk assessment guidelines for the Agency.
- Establish treatment requirements or discharge criteria, as well as monitoring requirements for reused water and unregulated industrial water.
- Determine effectiveness and establish model management practices for contamination sources.

Further areas of concern not immediately addressed by the strategy included pathogens found in sediments, ecosystem microbiology, risks associated with animal-borne pathogens, and algal toxins in both marine and fresh water.

EPA Implementation of the Beaches Environmental Assessment and Coastal Health (BEACH) Act – Charles Kovatch (OW)

Swimmers need to know about microbial contamination at beaches to minimize their exposure and reduce swimming-related illness. Recreational water quality monitoring and public notification programs vary from state to state with respect to indicator organisms, sampling location and frequency, and beach postings and advisories. In an effort to protect public health and improve beach monitoring and public notification, Congress passed the Beaches Environmental Assessment and Coastal Health (BEACH) Act in October 2000 to amend the Clean Water Act; the BEACH Act assigned specific duties to EPA and the states, which were outlined in this presentation. The provisions of the BEACH Act apply to coastal recreation waters located in coastal and Great Lakes states.

As required by the BEACH Act, states must adopt EPA's current recreational water quality criteria by April 2004. Also, EPA (specifically ORD) is conducting research on health risks associated with exposure to pathogens in recreational waters, and improved and rapid detection methods for pathogen indicators. This research is scheduled to be completed by October 2003, and EPA will promptly publish revised water quality criteria based on the research by October 2005. Once EPA publishes the new recreational water quality criteria, states will have three years to adopt the criteria.

In order to address the inconsistency in beach monitoring and notification approaches among and within states, the EPA must publish performance criteria by April 2002 for:

- Monitoring and assessment procedures for pathogens and pathogen indicators, and
- Notification of exceeding or likelihood of exceeding recreation water quality standards.

To be eligible for BEACH Act grants states must be consistent with the criteria when developing and implementing their beach monitoring and notification programs. Currently, 34 out of 35 eligible states have applied and been awarded FY01 Development grants.

As part of its role in the implementation of the BEACH Act, EPA is also required to "establish, maintain, and make available to the public a national coastal recreational water pollution occurrence database" by October 2003. The database will list the coastal recreation waters subject to monitoring and notification under the BEACH Act, and their status.

Additional provisions of the BEACH Act include:

- State development and implementation of a program by 2003 for jurisdiction over coastal recreational waters;
- EPA provides technical assistance for assessment and monitoring of floatable material; and
- EPA implementation of monitoring and notification program when a state program is inconsistent with performance criteria.

Is our science on pathogens appropriate and adequate to support regulatory management?

Summary of Major Regional Scientific/Technical Priorities – Vicki Binetti (Region 3)

EPA regional offices, in conjunction with state regulators and state health departments, are responsible for implementing legal mandates to keep pathogens out of the drinking water system. At the regional level, the goal of regulation is to protect public health – guidelines are always being developed to be used for that purpose.

Regional needs that always exist include:

- Identification of sources of contamination, and guidelines on how to measure and monitor their impact;
- Information and guidance on enforcement and correcting of violations; and
- Guidelines on dealing with potential outbreaks / contamination / boil-water alerts.

At the end of this presentation, the panel of speakers participating in the discussion to follow was introduced. The panel members were Joel Hansel (Region 4), Lisa Byron (Region 2), Bob Benson, (Region 8) and Howard Neukrug (Philadelphia Water Commission). Each panel member briefly addressed the question: *"Is our science on pathogens appropriate and adequate to support regulatory management?"*

A summary of the scientific needs expressed during the panel presentations, and the ensuing discussion, can be found in Appendix D.

Regional Panel Discussion and Facilitated Q & A

Joel Hansel – Region 4

A clear distinction between recreation and consumption or ingestion (drinking water) would facilitate regulatory management of aquatic pathogens. Disease endpoints other than the gastrointestinal symptoms traditionally considered should be taken into account; *Pfiesteria* is an example of a pathogen (in recreational water) whose health effects include skin rashes, as well as neurological symptoms.

In the case of Total Maximum Daily Loads, the cause of the impairment has to be determined; **bacterial source tracking** can sometimes be used to make that determination. A case study was presented documenting the contamination with fecal coliform bacteria of a small watershed in a rural area. The surrounding land was used primarily for small-scale agriculture and keeping livestock. Leaking septic tanks were initially assumed to be the source of the contamination. Bacterial source tracing was conducted after a library of potential sources was prepared. It was determined, as a result, that the source of the contamination was the presence of livestock. Particularly, in light of the fact that the livestock were not contained and had free access to water bodies.

Fecal coliform levels decreased soon after the livestock were fenced and prevented from accessing the watershed. A new problem was encountered, however, when the increased presence of wildlife caused fecal coliform levels to increase again. As wildlife was not perceived to be a health concern – coliform levels were still lower than they had been – no steps were taken to keep wildlife away from the watershed.

Research needs mentioned, particularly with respect to bacterial source tracing, included:

- When is a watershed too big for bacterial source tracing to be effective?
- How far can a source library extend, and how many isolates are needed for each source?
- What technique works best, and can it be done faster?
- What is the risk associated with wildlife?

Lisa Gray Byron – Region 2

The New York City watershed was presented as an example of the special concerns associated with an unfiltered water supply, particularly the need to protect the entire watershed. *Cryptosporidium* and *Giardia* are two pathogens that the New York City watershed team is seeking to control, although at present there is a lack of science that can be used to evaluate the watershed for the presence of these two pathogens. New York City is currently concentrating efforts in performing a risk assessment on its watershed, and risk can be better assessed if the bacterial load can be characterized.

Science support needed for these purposes includes:

- Studies on the die-off rates of pathogens, and on the distance they are able to travel; to be used possibly in constructing models;
- Acceptable load information for the entire watershed (i.e., from all sources combined);
- Recovery methods to detect pathogens in soil;
- Evaluation of best management practices (BMPs), e.g., buffer strips; and
- Better detection methods. An example that illustrates this need is the existing method for total coliform bacteria which can give false positive results in the presence of *Aeromonas*.

Bob Benson – Region 8

Inadequate science is a problem often encountered in regulatory management, and is compounded by the fact that waiting for a method to be validated by science is not always feasible for the regions. Examples used to illustrate this point included:

- A case where data were misinterpreted because of a problem with the methodology for *Cryptosporidium* monitoring;
- A biofilm problem traceable to problems with methods used in routine monitoring;
- An *E. coli O157* outbreak which occurred eleven years ago, likely because *E. coli O157* is not detected by routine *E. coli* monitoring;
- An outbreak of calicivirus at a snowmobile park was traced to drinking water contamination using a research method (not a *validated* method); and
- In the case of *Aeromonas*, it is not always clear whether it is due to drinking water contamination or an isolated case. There is a method for measuring *Aeromonas*, but it will not be a part of routine, regulated monitoring until 2003.

Regardless of whether the science behind the methods has been validated, the regions frequently have to make regulatory decisions (e.g., issuing boil orders, or performing disinfection) without the benefit of the most advanced scientific knowledge.

Information that is helpful in making those decisions includes:

- Characteristics of the disease, especially for tracing a potential outbreak to the distribution system;
- Information on any highly susceptible population (e.g., immuno-compromised individuals); and
- Information on disinfection, especially for systems that do not disinfect on a regular basis.

Howard Neukrug – Philadelphia Water Commission

Along with the common goals of EPA and state regulators – safe drinking and recreational water – consideration must also be given to the public perception of the quality of drinking water. It is not realistic that good methods will always be available (once a method is perfected, another pathogen may then emerge as a disease-causing organism). Watersheds can be protected to an extent, but the sources of pathogens cannot be completely eliminated. It is important to know the endemic, as opposed to the epidemic (outbreak), levels of pathogens to be able to inform the public about potential problems. Additional ways of disease transmission, other than waterborne, should also be considered.
A multi-sided approach to the problem of pathogens in drinking water is essential, paying particular attention to source water protection.

Specific science needs include:

- Monitoring and tracking the incidence of pathogens at endemic levels;
- More research on the effects of disinfection; and
- Operator training, especially in dealing with outbreak levels.

Incidence and Risk Assessment of Emerging Pathogens

What do we know about the nature and magnitude of waterborne disease in the United States?

Co-Chairs: Kim Ngo (Region 6) and Rebecca Calderon (ORD/NHEERL)

Waterborne Disease Outbreaks in the U.S. – Regional Issues – Kim Ngo (Region 6)

Statistics kept by the Centers for Disease Control and Prevention (CDC) over the past twenty five years show that most waterborne disease outbreaks (86% of 371 outbreaks) can be associated with source water contamination. The source water was usually ground water. Some outbreaks (12%) can be traced to the distribution system. All of the water systems involved were in compliance with the Safe Drinking Water Act, and half of them (50%) were practicing disinfection. Protozoa, particularly *Giardia* and *Cryptosporidium*, bacteria (such as *E. coli*), and viruses were the most common pathogens.

Following a storm event in July 1998, lighting struck a wastewater lift station causing 167,000 gallons of raw sewage to spill into Brushy Creek. Samples were taken from the distribution system and tested negative for total coliform bacteria. When ground water was tested, four out of five wells were found to be positive for *E. coli*. The Texas Department of Health was notified of a potential outbreak situation. Following further studies by the Health Department it was determined that 6,000 people were exposed, 25% of which became ill. Eighty five confirmed cases of cryptosporidiosis were reported during the outbreak, and another forty five from September to December of 1998.

The multiple barrier approach is a multi-faceted approach in protecting drinking water, which involves identifying all the "barriers" – components of the drinking water system where pathogens can enter – and taking steps to protect each one. Brushy Creek and other recent outbreak cases can be attributed to one component or "barrier" failing to prevent pathogens from entering.

Better reporting of outbreaks is one of the foremost regional needs mentioned – currently, reporting is mandated only by the states, and each state's list of reportable diseases is different. Keeping such data, especially on endemic levels of disease, will allow occurrence trends to be monitored, and potential outbreak situations to be recognized. One suggestion made to improve reporting was to possibly include an enforcement team within the EPA's investigative team.

Waterborne Disease: EPA's Intramural Epidemiology Program – Rebecca Calderon (ORD/NHEERL)

The current epidemiology program is focused primarily on evaluating endemic (a high background prevalence of disease) and epidemic (a temporal excess of illness over some background level) disease associated with drinking water microbes. Waterborne disease surveillance has been a joint activity between the EPA and the Centers for Disease Control. Information is collected on outbreaks or epidemics associated with drinking water, recreational water, and outbreaks aboard ocean-going vessels. However, using a self-reporting, or passive surveillance system, can result in under-reporting and inconsistency in reporting. New etiologic agents that have emerged in studies of outbreaks include *Giardia, Cryptosporidium, Legionella,* and *E. coli O157.*

In addition to the epidemic work, there are **two basic approaches** to evaluating endemic gastrointestinal illnesses associated with exposure to drinking water microbes. The **first approach** is an evaluation of "acute gastrointestinal illness", in which illness is measured by study participants' self-reported symptoms. In order to evaluate the risk attributable to water, community intervention studies have been conducted or are in progress in which illness rates are measured before and after a community upgrades community drinking water treatment to reduce exposure to microbes in drinking water. The **second approach** is to evaluate health effects for specific organisms such as *Cryptosporidium*. Serological surveys in paired cities involve systematic collection and antibody-testing of blood samples from representative populations in the exposed and unexposed cities. The *Cryptosporidium* serological work suggests that some exposure may be protective – 2 and 1/4 times higher portion of the population is antibody positive – and that efforts to reduce exposures through drinking water treatment may lead to more disease and outbreaks. Other organism-specific work is being conducted on some of the Candidate Contaminant List microorganisms, specifically by testing stool samples of volunteers before, during, and after illness.

Intervention studies are conducted on the same population (before and after intervention) and one such study has shown that up to 35% of microbial gastroenteritis can be linked to drinking water. After intervention at the community level, gastrointestinal disease rates decreased.

Future work planned includes continued monitoring of outbreaks, as well as serology (paired-city) and intervention studies. Microbe-specific studies will focus on the Contaminants Candidates List pathogens. Finally, epidemiology studies are planned in response to the October 2000 passage of the BEACH Act; and NHEERL has begun discussion on the formulation of a pathogen strategy.

An Estimate of National Waterborne Disease Occurrence– Susan Shaw (OW)

Section 1458(d)(1) of the Safe Drinking Water Act requires EPA and CDC to conduct epidemiology studies in five communities, and to prepare a report on the findings of the studies and on the national occurrence of waterborne disease. In response, EPA and CDC will conduct disease occurrence studies focusing on infectious disease, specifically gastrointestinal (GI) illness and specific pathogens. The National Estimate will focus on drinking water related gastrointestinal illness.

Several studies are ongoing or have recently been completed, including:

- Household Intervention Studies, including a "special population" intervention study;
- Community Intervention Studies;
- A national survey study (FoodNet); and
- A study on childhood cryptosporidiosis and drinking water.

In order to estimate national occurrence of waterborne disease, the gastrointestinal disease rate (from all causes) is needed, as well as an approximation of the fraction of disease that can be attributed to drinking water. Several studies (Payment '91, Colford '01, Calderon '01) estimate that 30% of all GI disease is drinking water attributable – that fraction being most accurate for highly challenged drinking water systems. A national telephone survey study (FoodNet) is being conducted to determine the total rate of GI disease. A recent estimate, based on findings of the studies mentioned above, predicts the national rate of waterborne GI disease to be 211 million cases per year, or 0.79 cases per person per year. Similar preliminary estimates have been developed using an attributable fraction of 15% and 5% to account for better drinking water systems.

As ongoing epidemiology studies are completed and more data is gathered through FoodNet, the National Estimate will become more representative of the entire population; an updated report on the National Estimate is scheduled for 2003. Analysis of the data will also be done by categories, such as the presence or absence of a Public Water System, the type of source water, and the region.

Are our microbial risk assessment tools (epidemiological and "toxicological") adequate to evaluate emerging pathogens?

Microbial Risk Assessment: State of the Art and Science – Bruce Macler (Region 9)

Microbial Risk Assessments are used to collect relevant information that may be used in management decisions involving the control of aquatic pathogens; information such as estimating disease incidence rates, predicting levels of specific diseases, and evaluating the effect of regulatory measures can be obtained using microbial risk assessments. Approaches used in risk assessment can be based on epidemiology, to provide direct, quantitative data; on system analysis, for qualitative assessments of vulnerability; or on dose-response or exposure modeling.

Experimental **epidemiology studies** can include clinical studies, such as determining the infective dose for a specific pathogen; or population intervention studies, to estimate the endemic waterborne disease risk from drinking water. Other epidemiology studies are observational, such as disease surveillance studies. Even though they provide quantitative data, epidemiology studies are limited by confounding factors (human variation, number of participants, other factors), and do not always show a clear connection between cause and effect.

System analysis methods, specifically Hazard Assessment Critical Control Point (HACCP) methods, use a non-quantitative approach to assess vulnerabilities in a system. Once hazards are analyzed, control points are established at key points in the system and monitored, taking corrective actions when necessary. This procedure is currently being used widely in the food industry to comply with the Food and Drug Administration's (FDA) regulations.

Dose-response modeling is based on the toxicological risk assessment approach for chemicals. Dose-response data for infectivity are typically derived from healthy, adult populations, and therefore would have to be corrected to include sensitive populations. Relevant disease endpoints could be used to that effect. Mixtures of organisms may also need to be considered in dose-response modeling.

Microbial **exposure assessments** take into account the routes of exposure, and the levels and distribution of the organisms of concern, as well as the relative risk posed by each pathogen. Estimates of occurrence are needed for these studies, as well as some information on pathogen viability.

All of the approaches mentioned above are used in making regulatory decisions; each can be used to clarify certain risk questions, but not others. Further research is needed to improve all approaches currently used in microbial risk assessment.

A Dose-Response Envelope for *E. coli* O157:H7 – Mark Powell (USDA)

The objective of the research conducted was to develop a dose-response model for illness by *E. coli* O157:H7 that bounds the uncertainty in the dose-response relationship for the organism. No human clinical trial data are available for *E. coli* O157:H7 dose-response; however, data exist for two surrogate pathogens: enteropathic *E. coli* (EPEC) and *Shigella dysenteriae.* Using that data, and *E. coli* O157 outbreak data, a most likely value of the dose-response for *E. coli* O157:H7 can be estimated – and was inferred to be somewhat higher than *S. dysenteriae* and somewhat lower than EPEC. The predicted exposure distribution of *E. coli* O157:H7 was determined (by another model) for the approximate number of ground beef servings consumed annually in the United States. Using both the predictive exposure distribution model, and the dose-response data, an estimated distribution can be derived for the annual number of cases of *E. coli* O157:H7 that can be attributed to ground beef.

Some recognized sources of under-reporting include ill persons not seeking medical care, physicians not obtaining cultures from all patients thought to be infected, and laboratories not culturing all stool samples for *E. coli* O157:H7. The uncertainty due to each of these sources of under-reporting was characterized (using a variety of epidemiological data) and the estimates were corrected accordingly to take under-reporting into account.

The dose-response envelope modeling concluded that at a dose level of 100 colony forming units (cfu), fewer than fifteen persons exposed would become ill. The median response rate was predicted at six percent, meaning that six percent of persons exposed are likely to become ill.

Vibrio parahaemolyticus Risk Assessment – Marianne Miliotis (FDA/OFSAN)

Vibrio parahaemolyticus (*Vp*) is an important agent of diarrhea associated with consumption of seafood. It has been isolated from clinical sources, as well as nonclinical sources including estuarine and marine environments in many regions of the world. Since it was first isolated in 1950, it has accounted for about 40-60% of all foodborne illnesses in Japan. Up until recently, the allowable numbers of *Vp* associated with oysters was 10^4 *Vp*/ml. Studies following recent outbreaks in 1997 and 1998 estimated infectious doses to be as low as 100 to 1000 organisms. The FDA conducted a risk assessment on the potential public health impact of *Vibrio parahaemolyticus* infections resulting from the consumption of raw molluscan shellfish, in response to these outbreaks. The objectives of the risk assessment were twofold: 1) to produce a mathematical model of the risk of illness incurred by consumers of raw oysters containing pathogenic *Vp*; and 2) to provide FDA with information that will assist the agency with the review of current programs relating to the regulation of *Vp* in raw molluscan shellfish to ensure that such programs protect the public health.

The risk assessment was conducted according to the conceptual framework recommended by CODEX, which involves four steps:

1) Hazard Identification: the identification of pathogenic *Vp* as the hazard;
2) Exposure assessment: the likelihood and levels of ingesting *Vp* by eating raw molluscan shellfish harboring this organism;
3) Hazard Characterization/Dose-Response: the relationship between the levels of *Vp* ingested, and the frequency and magnitude of illness; and
4) Risk Characterization: the integration of dose-response and exposure assessments to assess illness.

This risk assessment is a product pathway analysis and is divided into three modules: Harvest, Post Harvest, and Public Health. Because of significant differences in oyster harvesting methods, handling practices, and climates within the United States, five geographic regions (Northeast Atlantic, Mid-Atlantic, Pacific Northwest, Louisiana Gulf Coast, and the remaining Gulf Coast) for each of the four seasons were modeled separately for the three modules. Like all risk assessments, because of data gaps and uncertainty, assumptions had to be made in order to conduct the risk assessment.

The risk assessment provided estimates of risk for illness among consumers of raw oysters of 4,750 cases per year, ranging from 1,000 to 16,000 cases. Risks increase with increasing levels of total *Vp* and, therefore, increasing levels of pathogenic strains of *Vp*.

Water and air temperatures at the time of harvest were found to be the major factors influencing the initial levels of this pathogen in oysters. Air temperature was also found to influence the growth of *Vp* in oysters after harvest and, thus, the levels in oysters at the time of consumption. The single most important factor related to the risk of illness caused by this organism is the level

of *Vp* in oysters at the time of harvest. Intervention measures aimed at controlling or reducing the levels of *Vp* in oysters such as mild heat treatment (5 min at 50°C) of oysters, practically eliminates the likelihood of illness occurring. Quick-freezing and frozen storage of oysters, which causes a one to two log decrease in viable *Vp* oyster levels, also substantially reduces the probability of illness. Rapid refrigeration after harvest also significantly reduces risk of illness.

The risk assessment also suggested that approximately 15% of the illnesses were associated with the consumption of oysters containing greater than 10,000 *Vp*/g at the time of harvest.

The model was validated using "real-world" data not incorporated in the risk assessment, and comparing model predicted levels with actual survey levels recorded by a 1998-1999 FDA study. The model predictions were in good agreement with the data recorded in the study, confirming the validity of the model.

Pathogen Risk Assessment Protocol for Environmental Water Media – Stephen Schaub (OW)

EPA's Office of Science and Technology (OST) has been working through the process of developing a microbiological risk assessment protocol for water that accounts for all of the unique features of microbial pathogens and human infectious disease, while remaining consistent with common threads of risk assessment from the existing chemical and ecological risk assessment protocols. In microbial assessments for water, human infection attributes to be considered are specific to microorganisms (growth and die-off, strain variability in infectivity, occurrence and risk) and to human exposure (immunity, variable infection endpoints, secondary spread). The pathogen risk assessment protocol has adopted the approach of ecological risk assessment protocol, and is consistent with major food microbiology components of the *Codex Alimentarius*. Model development is the first step in the process and serves the purpose of formulating the problem. Risk characterization in this model would include characterization of exposure (pathogen) and characterization of human health effects (host).

The goal of the protocol, once completed, is to be used as a non-regulatory agency protocol for conducting risk assessments, as are the models currently used for providing ecological and chemical guidance.

In order for the protocol to be validated, additional research is needed to fine-tune the model, such as:

- Testing to validate protocol for different types of pathogens (e.g., Contaminants Candidate List pathogens) and in all media;
- Risk analysis tools such as models on human susceptibility, dose-response, animal and *in-vitro* models and mechanisms of infection;
- EPA's risk characterization procedures incorporated into the model;
- Risk assessment procedures that are in a form useful to risk managers and the public;
- Procedures to assess environmental factors' impact to infectivity; and
- Approach to deal with exposure doses and duration.

EPA is also involved in refining the existing system for implementing microbial risk assessment.

Risk Assessment in Regulatory Development – Stig Regli (OW)

The presentation was a comparison of risk assessment under various regulatory rules: the 1989 Surface Water Treatment Rule (SWTR), the 1996 Safe Drinking Water Act (SDWA), the final Interim Enhanced Surface Water Treatment Rule (IESWTR), and the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).

The Maximum Contaminant Level Goals (MCLGs) were promulgated by EPA to be zero for *Giardia, Legionella*, and viruses; for regulatory purposes, the 1989 SWTR set the limits as close to the MCLGs as feasibly possible. SWTR was then characterized as reducing risk to less than one infection per 10,000 people per year from giardiasis, assuming that in controlling *Giardia*, the rule would also protect the public from most other pathogens. In reality, infection was a conservative indicator of illness from *Giardia*. The risk model used suggested that most systems using the rule would be protected to an acceptable risk (less than one infection per 10,000 people per year). A provision made for systems with poor source water quality recommended removal or inactivation to a set level, greater than the SWTR. Source water quality was difficult to quantitatively evaluate, however, and the recommendation was one that could not be implemented.

In 1996, the Safe Drinking Water Act (SDWA) changed the existing rule by stating that the MCGLs should first be recommended at levels at which no health effects occur; actual levels of pathogens were promulgated to be as close to MCLGs as (economically) feasible; sensitive sub-populations were to be taken into consideration in the cost-benefit analysis.

The regulations were amended next in 1998 with the publication of the Interim Enhanced Surface Water Treatment Rule (IESWT). In this case, an MCLG of zero was established for *Cryptosporidium,* and recommendations were to control *Cryptosporidium* and other pathogens to the extent that was feasible both economically and technically. Risk assessment could be performed to support the cost benefit analysis, and for most models more costs were avoided than incurred. Risk assessment carried large uncertainties, however, due to the limited occurrence and dose-response data available.

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) reflects the evolving role of risk assessment in regulatory management. It is different from IESWT in that it is not based on a specific risk goal; rather, risk characterization is incorporated into the proposed rule. Taking into account the uncertainties inherent in characterizing occurrence, treatment, and dose-response data for different pathogens, the rule recommends performance of a risk analysis, taking into account the level of uncertainty, in order to evaluate the costs and benefits as required.

Microbial Risk Assessment Activities in Cincinnati Division of EPA's National Center for Environmental Assessment – John Lipscomb (ORD/NCEA)

The microbial risk assessment group of NCEA-Cincinnati has several ongoing projects within a Pathogen Risk Assessment Program. These activities can be separated into four general areas:

(1) Methods assessment and development, including the use of alternative statistical methods in the presence of limited dose-response data;
(2) Modeling the impact of microbial contamination of waterways and systems on human exposure;
(3) Assessment of the risk contribution of variance in strain virulence; and
(4) Human population susceptibilities and contribution of differentially susceptible sub-populations to endemic and epidemic infectious waterborne disease.

The ultimate goal of the research efforts is to develop guidance on the conduct of quantitative assessments for waterborne pathogens. Within the **first area**, the evaluation and development of methods to quantify microbial risk is being addressed through the development of draft assessments for three of the pathogens on EPA's Contaminant Candidate List (*Coxsackievirus, Calicivirus*, and *Mycobacterium avium* complex). Limited by the availability of dose-response information, NCEA is investigating alternative approaches towards estimating the dose-response relationship for pathogens.

Within the **second area**, the development of a model to integrate the exposure to microbial contamination from watershed through treatment to drinking water delivery will provide additional information to more realistically weigh the risk of contamination, and evaluate the contribution of environmental factors ultimately contributing to pathogen survival and human exposure.

Within the **third area**, the estimation and comparison of the human disease burdens associated with specific pathogens and with exposure to specific water sources is being examined. This project is evaluating the usefulness of three different measures of health impact: Natural Units (cases, deaths, etc.), Disability Adjusted Life Years, and Cost of Illness. A joint EPA/FDA project has been established to quantify infective foodborne and waterborne doses of microbial strains with different virulence in animal models of susceptibility.

Within the **fourth area**, NCEA is addressing the importance of the secondary spread of disease and the contribution of differentially susceptible segments of the population. Cooperative Agreements are producing: 1) an infectious disease framework based on disease transmission theory; and 2) a deterministic differential equation incorporating three modes of transmission – endogenous pathogen-to-human, human-to-human, and human-to-water to human – and sensitivity analysis to determine the relative contributions of each. An Inter-Agency Agreement with FDA/NCTR has been established to evaluate the usefulness of animal models of susceptibility as surrogates for human susceptible segments of the population (infants, the elderly, diabetic, immuno-compromised, and malnourished individuals). The isolation of pathogenic organisms

shed in feces from these models will provide some information useful in estimating the contribution of these segments of the population to recirculation of pathogens, and the secondary spread of disease via waterborne and foodborne routes.

Breakout Group Discussions

See APPENDIX C: Breakout Group Summaries

Assessing Exposures to Emerging Pathogens

How do we look for these organisms? What is the current status of methods to monitor exposure?

Co-Chairs: Bobbye Smith (Region 9), Gerry Stelma (ORD/NERL) and Fred Genthner (ORD/NHEERL)

Assessing Exposures to Emerging Pathogens – What the Regions Need – Terry Fleming (Region 9)

In implementing the goals of the Clean Water Act, to protect the public against exposures to disease causing pathogens in drinking and recreational waters, regions and states must be able to monitor for these pathogens.

The Regions have identified five major research needs to improve monitoring for pathogens:

1) Rapid detection methods for indicator bacteria and pathogens in recreational waters; current methods for testing recreational water may take three days, when contamination may be present for one day.
2) Better indicators, including an approved source-tracking method. Indicators need to be appropriate for non-point source problems, and yield results quickly.
3) Dose-response relationships (relative risk) for these pathogens, alone and/or in combinations, so that standards can be set.
4) Predictive models or other tools for evaluating exposures due to storm events or sewage overflows; such models would allow the state to protect public health (e.g., close beaches after a storm).
5) Approved "alternative" methods for detection of pathogens in drinking and recreational waters. New, faster, less expensive methods are being developed, but need to be approved by the EPA quickly so they can be used.

Regions are often compromised due to the lack of adequate methods. When new methods are developed, the approval process is a crucial bottleneck.

Assessing Exposure to Bacterial Pathogens – Gerard Stelma (ORD/NERL)

Human exposure to bacterial pathogens can be measured by looking for specific biomarkers of exposure. Examples include antibodies, reactions to bacterial antigens to which prior exposures have occurred, or measurement of specific products of the infecting agent in bodily fluids. Exposure studies generate information on the sources and geographic distribution of exposures, and on the number of people exposed to various pathogens.
Three pathogens of importance were discussed in the presentation: *1) Helicobacter pylori; 2) Mycobacterium avium;* and *3) Legionella pneumophila*.

Serum antibodies are the biomarker currently used for the detection of *H. pylori* exposure; this method works well even for asymptomatic individuals. Another method considered is testing for salivary antibodies – a less invasive method, which, however, is not as effective at detecting exposure even in individuals with clinical symptoms. *H. pylori* is suspected of being potentially waterborne, although that is not its usual mode of transmission. If it is determined that the pathogen is waterborne, *H. pylori* exposure and its association with untreated drinking water could be studied.

Detection of exposure to *M. avium* has so far been done using a skin test method; non-specific reactions, however, led to false positive and/or negative results. Another disadvantage of the skin test is the requirement that patients return to have the test read. NERL microbiologists are currently examining the efficacy of interferon induction by *M. avium* antigens as a potential replacement of the skin test method for monitoring exposure. A pilot study is being conducted in collaboration with a Los Angeles hospital – where *M. avium* occurs commonly in the water. Specifically, interferon assays are being conducted to determine whether it is possible to obtain historical exposure data. A full scale study using interferon assays would provide nationwide exposure data, identifying areas of high and low exposures, and examine the relationship between *M. avium* occurrence and its presence in potable water.

Legionella pneumophila exposures are also being studied, using a urinary antigen for a biomarker; the antigen is present only in patients currently infected. The study is intended to generate accurate data on the incidence of legionellosis in the United States. Only a small number of cases are currently reported annually to the Centers for Disease Control (400-500), most likely because, while patients are often hospitalized, they are simply treated for pneumonia symptoms. In most cases, no cultures are taken to determine the organism responsible. A realistic nationwide estimate of the incidence of legionellosis is likely to be much higher than the current number of reported cases. The study will also attempt to relate data on incidence with the occurrence of *L. pneumophila* in potable water.

Development of Molecular Methods to Detect Emerging Viruses – Ann Grimm (ORD/NERL)

Enteric viruses are believed to cause a large number of gastroenteritis cases in the United States; **caliciviruses** specifically can be a major cause of waterborne, viral outbreaks. Methods are being developed by NERL for the detection of calicivirus: primers and probes have been designed to detect the virus in water samples. Polymerase chain reaction (PCR) techniques are used to amplify many of the caliciviruses, since cell culture methods are not generally available. Different primer sets and real time PCR (RT-PCR) conditions are being examined, and clinical samples are screened for new types of calicivirus to test primer conditions. A combination of different methods can also be used, and has the advantage of allowing testing for several viruses at once. Current methods were used to confirm that a calicivirus outbreak in Wyoming was waterborne, when nucleic acid in two viruses – from a water sample and fecal samples – was found to be identical.

The **Hepatitis E** virus (HEV) is another emerging virus of concern; although it has a fecal-oral transmission route, an outbreak in India in 1959 appears to have been waterborne. HEV causes infectious hepatitis in adults, and has a fatality rate of 15-25% in pregnant women. Sporadic cases have appeared in the United States, but a recent estimate using a new assay showed that up to 15% of the population could have antibodies to the virus – a fraction too high to be attributable solely to infections related to foreign travel. In addition, a recent United States-acquired infection was 97% similar to the (endemic) swine strain of the virus, raising the possibility that this might be a zoonotic virus.

Assays have been developed to detect the presence of Hepatitis E virus, including:

- A general assay, which detects all strains except the "Mexico" strain;
- An assay specific to the "Mexico" strain; and
- And a United States assay, to specifically match the swine strain.

In order to test the assays, the infectious dose (ID_{50}) was determined for several strains of the virus, and it was concluded that assays could detect a single infectious dose present in a sample. Further testing showed that all assays were able to detect HEV in spiked environmental water samples. The assays can now be used for exposure studies, and future research will involve the testing of natural waters for the Hepatitis E virus.

Detection of Protozoan Pathogens in Water – Frank Schaefer (ORD/NERL)

Parasites, by their nature, do not replicate like bacteria, outside a host. With rare exception, the waterborne parasites of significance to the Agency are enterics which are transmitted by food, person-to-person contact, fomites, or water. Unlike clinical fecal specimens in which parasites are numerous, water samples, due to the tremendous dilution of the contaminant fecal material, contain very few parasites. Consequently, large amounts of water must be concentrated in order to detect them. Once the particulates are concentrated, the transmission forms of the parasites must be processed to selectively remove them from other particulates. This processing step is critical for both microscopic and molecular methods, so the transmission forms are not masked by the particulates in the case of microscopy, or inhibited by the particulates and other residual chemicals in the case of molecular methods. It is only when these first 2 steps have been completed that an assay can be performed successfully.

The current approach to detecting protozoan parasites like *Giardia*, *Cryptosporidium*, Microsporidians, *Cyclospora*, and *Toxoplasma* in water involves concentrating 10 liters of water using either a flat plate membrane filter or a capsule filter with an absolute porosity smaller than the organism. The parasites are then separated from the concentrated particulates either by buoyant density centrifugation or by immunomagnetic separation. Assays to detect the parasites include fluorescence microscopy, fluorescent *in situ* hybridization molecular probes, and real-time PCR.

Once a complete method is developed and published, it still is considered a "research" method. For regulatory purposes the Agency needs validated methods which have appropriate positive and negative controls associated with them, as well as performance characteristics. Validation is a multi-laboratory exercise which determines the precision, accuracy, and robustness of the method. Presently, only Methods 1622 and 1623 for the detection of *Giardia* cysts and *Cryptosporidium* oocysts are validated.

Current Approaches to Identifying Sources of Fecal Contamination – Gerard Stelma (ORD/NERL)

A number of approaches are being tested for their ability to trace sources of fecal contamination:

- DNA-based approaches: ribotyping, PCR and RT-PCR, pulse field gel electrophoresis (PFGE), and toxin biomarkers;
- Antibiotic resistance patterns;
- Bacteriophage analyses;
- Chemical markers;
- Neural networking.

Ribotyping, **PCR** and **PFGE** methods assume that bacterial population structure is clonal, therefore *E. coli* from different animal species should be genetically divergent. If the assumption is correct, then isolates from a contaminated site can be divided into groups of clonal origin and matched to their sources; the proportion of isolate coming from each source could also be determined.

The same assumption applies to **toxin biomarker** methods, however these methods require a larger sample size. Toxin biomarkers have a high animal species specificity, although only three species-specific probes exist so far.

Antibiotic resistance methods assume that a different set of antibiotics would be used to treat humans than animals; furthermore, different domestic animal species would be treated with different combinations. This approach could distinguish between contamination from wild and domestic animals, as wild animals should receive little exposure to antibiotics. These methods are easy to perform, and their results are comparable to those of molecular methods; they do require numerous isolates, and the use of a wide battery of antibiotics in different concentrations.

Bacteriophages – male-specific coliphages – can be used if all that is required is to distinguish between human and animal contamination, with no need for animal species specificity. **Chemical markers** can also be used for this purpose.

Neural networking utilizes several different measures of fecal contamination, and is easy to perform and inexpensive. However, it currently detects total coliform bacteria - a disadvantage since many coliform bacteria are not necessarily of fecal origin. Additionally, some of the methods can be difficult to interpret. The use of fecal *Streptococcus* bacteria is being considered for this method, as they tend to persist longer than coliform bacteria.

The approaches outlined above and others show promise for use in the detection of fecal contamination and source tracking. The best methods will not be found, however, until a multi-lab comparative study is done using the same environmental samples.

Antimicrobial Resistance Among Enteric Bacteria Isolated from Human and Animal Wastes and Impacted Surface Waters – Mark Sobsey (University of North Carolina)

Human infection with antimicrobial resistant (AR) pathogens has been steadily increasing since the late 1960's. Prevalent AR pathogens include *Salmonella* spp., *Enterococcus* spp., and *Escherichia coli (E. coli)*. These bacteria have livestock as well as human reservoirs and some, notably *Salmonella* spp. and pathogenic *E. coli*, have been associated with waterborne disease. Furthermore, *E. coli* and Enterococci are microbial indicators of fecal contamination used by the EPA as quality criteria for recreational and/or drinking source water. AR microbes and transferable genetic elements containing resistance genes may be transmitted via fecal contamination, and human acquisition of Multiple Antimicrobial Resistant (MAR) pathogens or transferable genetic elements from fecally contaminated water can occur either through direct ingestion of drinking and recreational waters or through consumption of fecally contaminated foods (e.g., edible bivalve molluscan shellfish and uncooked, irrigated produce).

Recent studies have been determining the occurrence and properties of AR enteric bacteria in human and animal waste and impacted surface waters in North Carolina. Results reported are from ongoing studies of cattle and swine farms and wastewater treatment plants (WWTPs) that are supported in part by the EPA. Findings to date indicate that humans and animals shed multiple antibiotic resistant bacteria in high proportions and these bacteria enter surface waters. *Salmonella typhimurium* and other *Salmonella* in swine wastes and impacted waters show MAR *S. typhimurium* DT-104, which is a major human pathogen. Enterococci isolates downstream from a swine farm exhibited resistance to Vancomycin, which has not been previously reported in the literature. Vancomycin-Resistant Enterococci (VRE) are a major public health problem, especially among vulnerable populations in health care settings. Rural, background sites of surface water often exhibited high levels of AR bacteria (more than 40% in one case). This is likely due to human or animal fecal waste impacts because these sites are not true "background" stations. Higher prevalence of AR bacteria are found downstream than upstream from swine farms, and their AR profiles are similar. The results of these studies indicate high prevalence of MAR bacteria in surface waters impacted by animal agriculture and human waste sources. The high concentrations and prevalence of these MAR bacteria suggest that waterborne exposure may pose a risk to people and animals downstream.

Emerging Pathogens in Drinking Water – Risk Management Challenges

First of two concurrent sessions

Co-Chairs: Kim Harris (Region 5) and Gene Rice (ORD/NRMRL)

User-Friendly Models for Evaluating Hydrogeologic Barriers to Viruses – Bart Faulkner (ORD/NRMRL/Kerr Environmental Research Center)

The EPA Office of Water requested the Subsurface Protection and Remediation Division of NRMRL to develop a groundwater "vulnerability" model for predicting virus attenuation. The Office of Water's Draft Ground Water Rule states that aquifers – other than ones known to be highly vulnerable – are subject to hydrogeologic sensitivity assessment. In order to be considered a barrier to viruses, a layer between the virus and the water supply must provide 4-log (or 99.99%) attenuation of active viruses. The computer model constructed reports the probability of log-4 attenuation considering the parameters entered, such as type of soil and species of virus. The model was designed with the premise that limited information would be available to the users. A literature review was performed in order to be able to incorporate in the model default parameters for previously-studied viruses and the twelve United States Department of Agriculture (USDA) soil categories. In addition, the model is designed to be expandable, and to report uncertainty.

The user interface runs on a Java application, and fields are filled in for the users once they supply the information available. Should more parameters be known, users can change the information in the fields as necessary. The model then performs Monte Carlo Analyses and reports the results in graphical and text format, as well as the probability of failure.

The user interface is available on the EPA intranet at the following address:

http://intranet.ada.epa.gov/research/virmod.html

Water Supply and Water Resources Division Response to Waterborne Disease Outbreaks – Kim Fox (ORD/NRMRL)

The Water Supply & Water Resources Division (WSWRD) in NRMRL/ORD has had a successful collaborative relationship with the Centers for Disease Control & Prevention (CDC) for over twenty years. When invited, EPA has supplied technical assistance and advice on tracking causative events, evaluation of drinking water problems, and on how to ensure drinking water was safe to consume. These requests for assistance have come from CDC, EPA regional offices, states, municipalities and foreign countries. The most publicized recent waterborne disease outbreak was the *Cryptosporidium* event in Milwaukee, Wisconsin. Another well publicized drinking water problem that WSWRD assisted with was the boil water order in Washington, DC. In both cases, an on-site investigation was conducted.

Some organisms that have caused recent problems or outbreak situations include *Giardia, Cryptosporidium, Vibrio, Shigella, E.coli* O157:H7*, Salmonella, Entamoeba histolytica,* and others. Due to the fact that there is a time lag effect – from ingestion to illness – each outbreak must be investigated based on what evidence is available at the time. The majority of outbreaks have occurred because of failure in one of the barriers keeping pathogens out of the drinking water supply, the likely sources of contamination being pathogens coming from the watershed, treatment plant, distribution system, or a system in the affected building. Some of the outbreaks investigated by WSWRD are outlined below:

- In Gideon, Missouri, a *Salmonella* outbreak involved birds contaminating an unprotected storage tank; when the storage tanks were flushed, *Salmonella* bacteria from the storage tanks flowed through the drinking water system, and illness followed the pattern of the water flow from the tanks flushing event.
- In Karl Meyer Hall, storage tanks on the roof of the building had a zone of stagnant water at the bottom; the system shut down overnight, and when it was turned back on, water from the stagnant zone entered the system.
- In the Milwaukee, Wisconsin *Cryptosporidium* outbreak, the onset of disease correlated with the onset of high turbidity in the water. In Washington, DC, no outbreak occurred but a boil-water order was issued after turbid water passed through the treatment plant.
- In Alpine, Wyoming, an *E. coli* O157:H7 outbreak was linked to fecal contamination in the watershed, when bacteria in fecal samples and in water samples were tested.

In order to more successfully prevent future waterborne disease outbreaks, the multiple-barrier system is the best approach. Raw source water cannot be presumed to be free of pathogens, therefore each barrier is equally important. Removal of particulate matter is especially important, given the link between turbidity fluctuations and the passage of particulate material through the treatment process. Treatment goals for water systems are also needed, as an additional barrier to pathogens.

What are the microorganisms of concern and how do they get into the distribution system?

Disinfection of Emerging Pathogens – Eugene Rice (ORD/NRMRL)

There is a growing awareness of the need to control waterborne microbial pathogens. The presentation concentrated on the role of chemical inactivation, using chlorine, chloramines and ozone as a means of controlling bacterial and protozoan species. Some of the pathogens discussed were organisms on the Contaminant Candidate List including *Aeromonas, Helicobacter pylori* and Microsporidia; as well as other pathogens of concern, e.g., *E. coli* O157:H7*, Giardia* and *Cryptosporidium.*

The effects of chlorine and chloramine were tested for a variety of exposure times on different *Aeromonas* species; chlorine was more effective and faster at disinfection at similar temperature and pH levels.

Helicobacter pylori were found to be more resistant than *Aeromonas* and slightly more resistant than *E. coli* O157:H7 to disinfection with chlorine, possibly due to aggregation with particulates. *Giardia* was one of the organisms tested that is known to be resistant to disinfection with chlorine; in this case, ultraviolet light was used and found to effectively inactivate *Giardia.*

Better characterization of the effects of agents used in disinfection was suggested as a topic for further research, particularly of the effects of disinfection techniques at low temperatures.

Biofilms in Drinking Water Distribution Systems – Mark Meckes (ORD/NRMRL)

Biofilm forms in drinking water distribution systems when bacteria and other organisms adhere to wetted surfaces and begin producing an extracellular polysaccharide envelope. That glue-like substance can anchor the bacteria to surfaces, where they can reproduce and grow. Increased temperature and rainfall (and the resulting increase in turbidity) are factors which contribute to the growth of biofilms, as are structural features of pipes and the velocity of the water running through them. Biofilm growing on surfaces which are normally in contact with water under low flow velocities can be released with a sudden increase in flow. Biofilm growth is also influenced by the availability of nutrients, the surface materials, and the concentration of residual disinfecting agents present in the water. Furthermore, the presence of biofilm as pioneer organisms provides an environment which could influence the colonization or entrapment of pathogenic or indicator organisms.

Studies currently being conducted to understand the problem include the development of rapid, cost-effective methods for detecting groups of bacteria specifically associated with biofilm, and for obtaining quantitative information regarding their occurrence. One group of bacteria, the non tuberculosis mycobacteria, are currently being studied to determine if baiting techniques can be used to concentrate them, so that they may be more easily detected.

Studies have been completed or are ongoing to determine the effects of the following factors on biofilms:

- pH;
- Disinfecting agents;
- Nutrients; and
- Cross-connection.

Another study, in the planning stage, will look at the survival and growth of *Aeromonas* spp. in biofilm. This work will be designed to determine if unique control strategies are needed for these organisms.

What is the Drinking Water Distribution Rule?

Update on 6-Year Review of TCR and Potential Distribution System Rule – Ken Rotert (OW)

The Total Coliform Rule (TCR) and other rules related to drinking water, must be reviewed, and appropriate revisions made at least every 6 years according to the 1996 Amendments to the Safe Drinking Water Act (SDWA). Since the TCR was promulgated in 1989, the TCR is currently under review. Part of this review includes the examination of unsolicited comments received since the Rule's promulgation, as well as comments from the EPA Regions, the States, ASDWA, AWWA, AMWA and ASM received as a result of a January, 2001 solicitation by EPA's Office of Ground Water and Drinking Water (OGWDW). Some of the comments received addressed the topics of waiving total coliform (TC) monitoring in undisinfected supplies, statistically determining the number of samples to collect each month, using the stakeholder process to review monitoring requirements, eliminating fecal coliforms as an indicator, using fewer than five routine samples, and allowing flexibility in the sample collection location. Additional comments addressed dropping the Maximum Contaminant Level (MCL) for TC, providing a clarification regarding whether two positive E. coli samples at different sites constitutes a violation and allowing the use of dedicated sampling taps.

EPA intends to couple the review and potential revisions of the TCR with a broader distribution system rulemaking effort intended to address the potential public health risks associated with finished water in the distribution system. This follows the recommendation of the M/DBP Federal Advisory Committee (FACA) Agreement in Principle. To initiate this process, an expert workshop was convened to discuss the health risks associated with distribution systems. Workshop attendees included representatives from EPA, American Water Works Service Company, academia, utility personnel, State regulators and private consultants. Nine white papers are under preparation as a result of this workshop. First drafts of all of the white papers are expected to be completed in December, 2001.

How do we handle cross-contamination and biofilm problems in the field? What are the inherent risks to distribution systems? Can we minimize the risk? Case study example/panel discussion.

Case Study: Biofilm Problem at Greenville, South Carolina – David Parker (Region 4)

The presentation focused on the problems encountered in a drinking water system in North Carolina. The system was not filtered, under the assumption that the source water was protected – high turbidity and raw coliforms were, however, present in the source. The filtration plant did not operate continuously ("start-stop" operation), and the finished water storage areas were not covered (until 1992 when a floating reservoir cover was installed). The disinfection agent – chloramine – was also thought to be inadequate.

Initially avoiding filtration on the grounds that the watershed (source) was tightly controlled to limit human access, Greenville was unable to meet the filtration avoidance criteria due to high turbidity, and entered into an agreement which mandated construction of a filter plant by 2000. Events that preceded that agreement included a series of Total Coliform Rule violations, and boil water notices when fecal coliform bacteria were found. An analysis made of the species of coliform bacteria present, coupled with the observation that their occurrence was correlated with higher temperatures (above 17°C) led to the realization that the water contamination was related to a biofilm problem. In this case, sediment in the water system was the source of the biofilm organisms, and the unfiltered lakes (source) provided nutrients for their growth.

Since biofilm organisms can be pathogenic, or mask the presence of other pathogenic forms, an action plan was developed to remedy the problem. Total coliform samples were to be taken twice as often as required per month, and species analysis conducted on any positive samples. An annual, system-wide flushing program was implemented, with additional instructions to switch the disinfecting agent from chloramine to free chlorine with each flushing; and the filtration plant was instructed to run continuously, rather than starting and stopping. Finally some public education measures were undertaken (for immuno-compromised individuals, in particular) and a public health surveillance program was initiated.

As a result of the action plan – initiated in 1995 – Greenville has had no Total Coliform Rule violations; the new filtration plant (mandated by the agreement mentioned above) began operations in the summer of 2000, and improvements were made to the existing filtration plant.

The View from the Field – Water Distributor's Perspectives – Mark LeChevallier (American Water Works Service Company)

Distribution system problems were outlined in this presentation, including control of pathogens through disinfection, pathogen monitoring, and problems associated with pressure changes in the system.

Studies on *Mycobacterium avium* complex (MAC) have shown that it can grow in biofilms, and has been found both in water and biofilm samples from distribution systems. MAC is a pathogen of concern in drinking water since it can affect immuno-compromised individuals. Disinfection studies have shown resistance to chlorine, but inactivation at high temperature (60^{o}C); in addition, low nutrients and turbidity levels in raw water reduce its occurrence. Assimilable Organic Carbon (AOC) and Biodegradable Organic Carbon (BDOC) levels were correlated with MAC occurrence in water; the development of simpler AOC and BDOC methods, and improved MAC detection were suggested areas where research was needed.

Literature on the disinfection of *Legionella* suggests that chloramines may be more effective for biofilms of *Legionella* than free chlorine. Conversion of a hospital water system from free chlorine to chloramines reduced *Legionella* levels 1,000-fold.

Monitoring of pressure in water systems was also mentioned as a way of preventing pathogens from entering the drinking water system. Specifically, a pressure wave passing through the system can result in negative pressure (briefly) in some areas; negative pressure would have the effect of drawing material – potentially including pathogens – through a pipe connection. Start and stop operations of plants are a major cause of pressure changes; however, they can not always be avoided (e.g., in one case, lightning caused a plant to shut down and resulted in negative pressure). Shutting down pumps during a pump test was shown to cause brief moments of low pressure. High-speed pressure monitoring is essential in identifying potential areas where the system might have been breached.

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Emerging Pathogens in Recreational Water – Risk Management Challenges

EPA's National BEACH Survey – Rick Hoffmann (OW)

Each year since 1997, EPA has conducted its *National Health Protection Survey of Beaches (Beach Survey)*. The annual Beach Survey is sent to more than 300 states and local governments. It is designed to gather information about beach water quality, standards, monitoring, and beach health advisories or closings issued during the previous year's bathing season. The survey's goal is to provide comprehensive, reliable beach information to the public via the Internet.

For each beach, information is collected in three areas: 1) programmatic information, including water quality standards, 2) monitoring procedures and costs, and 3) closing/advisory information; beach-specific information, such as physical characteristics, usage, possible pollution sources; and advisory/closing details, including the number of days, length of beach affected, reason and source(s) of contamination and indicator used.

All coastal states and the Great Lakes states are sent surveys. Most (86%) returned the surveys for the 2000 swimming season; however, incomplete information was often submitted. According to survey results for the 2000 season:

- The majority (96%) of beaches have a monitoring program, with more than half of those testing samples at least one per week.
- A quarter of the beaches (26%) had at least one advisory or closing in the past season. Past surveys indicate that the percentage of beaches with at least one closing has remained at or near 25% for the past four years.
- The sources identified as causing the pollution were unknown much of the time; of the known causes, storm water and other runoff, and wildlife, were the most frequently reported.
- The survey showed significant differences in the kinds of indicators used by different states – most using one or more of the following: total or fecal coliform bacteria, *E. coli* or Enterococci.

As mentioned above, the results of each national survey are posted on the Internet for purposes of informing the public and can be viewed at:

http://www.epa.gov/ost/beaches

Many of the states and territories also maintain their own web sites where the information on state beaches can be found.

Development of Improved Monitoring Approaches for Recreational Water –

Stephen Schaub (OW)

The EPA Office of Research and Development and Office of Water, under the Environmental Monitoring for Public Access and Community Tracking (EMPACT) program, jointly sponsored a study during the summer of 2000 to better define the temporal and spatial sampling requirements at recreational beaches, and more accurately determine potential public health risks for acute gastrointestinal disease when monitoring for bacterial indicators of fecal pollution. To establish the monitoring protocols for the study a data quality objectives process was conducted to insure that there was a statistically valid approach and protocol to sampling and data gathering to answer the questions regarding the minimum amounts of sampling data (frequency, location, sample number, etc.) to be gathered for a beach at any given time to accurately assess water quality. The study utilized five sites: a river, a lake, an estuary, and east and west coast ocean beaches. These beaches were monitored daily over a period of two consecutive summer months. Sampling grids were utilized to provide a common set of data points for characterization of indicator levels at the beaches and included three distances from shore, multiple sampling depths, and distances along the shoreline. Samples were taken daily: routine morning and afternoon samples, intensively, at hourly sample intervals over a day, or intensively during/after significant rainfall events. A statistical analysis of the study results revealed that in at least certain instances, wind, wave height, tides, sun intensity, the presence of bathers, and rainfall events, in addition to sampling time and sample location, could have an impact on levels of fecal bacteria indicators detected.

This fall, 2001, the EPA will sponsor an expert workshop to evaluate the EMPACT program beach monitoring data, and statistical representation of critical elements impacting on fecal indicator values at beaches. The workshop will determine the minimum sampling procedures required to gain various levels of confidence regarding indicator levels at a beach for beach managers, regulators or operators who are responsible for assessing recreational exposure risks and their acceptability. This monitoring guidance will be used in later updates of the EPA's recreational water criteria and guidelines.

Use of Molecular Techniques to Provide the Public with More Information on Recreational Water Closures in Norfolk – Alpha Diallo (Norfolk Department of Public Health)

The Norfolk Department of Public Health, in cooperation with the School of Public Health, University of Washington has established the relative significance of *E. coli* isolates from avian, domestic animal and urban wildlife origins over the past two years.

Testing is performed once a week at 34 sites for fecal *Streptococcus*, fecal coliform and *E. coli* during the recreational season. This is reduced to twice monthly during the winter months. Standards are a geometric mean standard of 35 *Enterococcus* bacteria per 100 ml. For fecal coliform a geometric mean of 200 fecal coliform/100 ml for two or more samples over a 30 day period or a fecal coliform bacteria level of 1,000/100 ml at any time. Secondary contact water fecal coliform shall not exceed a log mean of 1,000 per 100 ml during a 30 day period. Exceeding the above may trigger notification or advisories.

Of 714 isolates that were submitted for microbial source tracking by ribotyping 34% were from avian origin, 17.9% from domestic animals (cats and dogs), 14.8% from humans, and only 6.2% from urban wildlife. Although the weekly microbial counts were not high enough to warrant action in most cases, these results make a case for the screening and testing for specific pathogens in beaches and recreational waters.

Specific pathogen testing by PCR was initiated using primers supplied by Dr. Samadpour. Subsequently these have been purchased from Sigma Genosys. Validation of the protocol was performed using water samples known to be free of *E. coli* and testing for presence of the toxins stx1 and stx2. Validation for other pathogens is in progress and will be available if the need arises.

A web site has been developed, but needs to be set up on to the network of either the City of Norfolk or the Virginia Department of Health. This action is in progress. Data generated in the laboratory is maintained in an Access database file. Results are recorded and sent to the Environmental Health Manager and Health Director at the same time as posting occurs. If any results are found to be actionable, the Environmental Health (EH) Team is dispatched to resample and more rigorous testing is effected.

The EH Director plays a key role in this monitoring program. He is the principal link with other City Departments concerned with either regulating or alleviating risks to the community.

Acceptable Goals and Thresholds for Pathogens from Recreational Water Exposures – Al Dufour (ORD/NERL)

The debate about what is an acceptable risk regarding exposure to recreational waters has been ongoing for many years. Risk managers must make decisions based on the benefits of a popular leisure time activity and the potential health risks that may be suffered because of that activity. In addition to using risk-benefit data, risk managers are frequently required to examine the cost-benefit paradigm. Neither the risk-benefit nor the cost-benefit models have been followed in the past. This presentation reviewed the historical approaches used in the United States to set thresholds for water quality safety and discussed the current direction of U.S. EPA research with regard to how it may provide valuable information for making acceptable risk decisions.

The Office of Water has made great efforts in the past and present toward making the risk assessment data available to the public, however, some feedback is necessary in order to determine whether the meaning behind the data is understood.

A rationale for using coliform bacteria for testing was developed from some early studies (e.g., in 1951, shoreline in Connecticut was sampled for coliform bacteria and found 93% of samples tested negative). EPA recommended threshold values for coliform bacteria in 1976, and used a ratio to later convert those thresholds for fecal coliform bacteria densities. More recent studies indicated that extrapolation of the total coliform to fecal coliform values was not always accurate. New guidelines were developed for testing, taking into account that total or fecal coliform bacteria may not be the best indicators of fecal contamination.

New EPA-recommended guidelines specify the use of either *E. coli* or Enterococci for fresh water beaches, and the use of Enterococci for marine waters as indicators.

Determining Sources of Microbial Contamination – A Regional Applied Research Effort – Joel Hansel (Region 4)

The research proposal presented was based on the premise that Total Maximum Daily Loads that are submitted by the states must include load allocations to the sources of contamination. Bacterial source tracing methods are needed, therefore, for the states to be able to identify sources of pathogens.

The proposed research will consider the techniques of ribotyping, multiple antibiotic resistance, and pulsed field gel electrophoresis and determine ways in which they can be used for performing bacterial source tracing.

Fecal coliform bacteria, *E. coli*, and Enterococci from multiple sampling sites will be analyzed using antibiotic resistance and ribotyping. Information on these bacteria from existing databases will be incorporated into developing the new bacterial source tracing methods. Soils and sediments will also be examined as possible sources of contamination.

The proposal is currently undergoing peer review, and research will start as soon as that process has been completed. The project is expected to be completed by December 2003.

Rapid Methods for Measuring Recreational Water Quality: A Look to the Future – Al Dufour (ORD/NERL)

Traditional methods used to monitor the quality of recreational waters require 24 to 48 hours before results are available. This delay provides a situation where the potential health risk associated with positive findings of poor water quality are identified long after recreationists are exposed. Since adverse health effects have been associated with swimming in recreational waters of poor quality, it is in the public's interest to eliminate this shortcoming in current monitoring practices. A solution to this problem is to develop an inexpensive, fast, easy, specific, and accurate test, which will give near real-time results regarding the quality of bathing waters. There is a small number of biosensor technologies that may meet the characteristics listed above and that may be available in the near future. Biosensors are analytical devices that integrate microorganisms, enzymes, antibodies or nucleic acids into optical, electrochemical or other forms of electronic devices to yield a signal which is proportional to the concentration of the analyte. The technologies described fall into three categories: 1) those that make use of enzyme reactions, 2) those that use antibodies for immobilizing or labeling proteins, and 3) those that identify specific nucleic acids. One such method utilizes luciferin and luciferase to measure production of bioluminescent adenosine triphosphate (ATP) by the bacteria. The amount of ATP can then be measured by measuring the bioluminescence.
A second method uses a fluorophore labeled antibody which attaches to the bacterium; this process can be completed in 10 minutes using a portable instrument, and is currently being tested. Molecular methods are also being developed using non-viable cells, as is a method using a Charged-Coupled Device (CCD) camera – which, however, may not be feasible to use due to cost. New technologies were summarized at the end of the presentation with some of the advantages and disadvantages of each.

Advantages and Disadvantages of High-technology Methods for Rapid Measurement of Water Quality

Technology	Approach	Limit of Sensitivity	Viable Cells	Cost
Flow Cytometry	Antibodies	1	No	Medium
Bioluminometer	ATP	100 - 1000	Yes	Low
Fiber Optics	Antibodies	1000	No	Medium
Taqman	Molecular	1	No	Medium
CCD camera	ATP	1	Yes	High

ORD's Drinking Water Research Program Tracking System – Al Dufour (ORD/NERL) and Cheryl Itkin (ORD/NCEA)

In response to the need to organize, manage, and disseminate information about environmental research areas shared across EPA's Office of Research and Development (ORD), ORD Laboratories and Centers together piloted the "ORD Drinking Water Tracking System." This is a new approach that supports a single inventory of all the drinking water research projects across ORD Laboratories and Centers and utilizes the latest web technology. The Environmental Information Management System (EIMS), the EPA's repository of descriptive information (a.k.a., metadata) about projects, models, data, and documents, is being used as the foundation for the Drinking Water Tracking System. The EIMS stores the project descriptions in a Web-enabled Oracle database and generates the dynamic interface web pages including search forms, data entry forms and dynamic reports organized by drinking water category. Scientists can access the tracking system to create, view, maintain, and deliver information about drinking water projects in ORD. Currently, the tracking system is only available to EPA, but may be made publicly available in the future.

EPA access to the Drinking Water Research Tracking System
http://cfint.rtpnc.epa.gov/dwportal

For additional information on the ORD Drinking Water Tracking System contact:
Al Dufour 513-569-7330 or Clyde Dempsey 513-569-7842

For information about EIMS visit http://www.epa.gov/eims or contact:
Robert Shepanek 202-564-3348 or Cheryl Itkin 202-564-3357

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Pathogen TMDLs / CAFOs / Biosolids

Co-Chairs: Stephanie Harris (Region 10) and J.E. Smith, Jr. (ORD/NRMRL)

A Regional Perspective on CAFO/Biosolid Regulations: How ORD Can Help Us! – Stephanie Harris (Region 10)

The presentation offered a regional perspective on several topics of concern which would be best addressed by ORD; the topics presented have been raised by microbiologists and project officers, legal counsel, and field inspectors.

Region 10 contains a large number of cattle pastures – a likely source of human pathogens if the manure is directly deposited or washed into the water source. Human pathogens which have been identified in cattle manure include *Salmonella, Cryptosporidium, Giardia,* and *E. coli* O157:H7. Methods for measuring these pathogens exist, however, in the case of *Salmonella* and *E. coli* they have been designed for use in food and drinking water; their application on source water has not been evaluated. Another area where information is needed is the effectiveness of buffer zones in reducing pathogen runoff, particularly for *Cryptosporidium.* The holding time regulation for microbiological samples (6 hours) presents logistical problems and, if exceeded, puts the data into question. The problem would be eliminated by using a mobile lab or portable instrument, thereby performing the tests in the field; or, a way of preserving the sample could be tested.

Biosolids were also discussed, particularly the discrepancy between Class A and Class B biosolids; Class A biosolids meet exceptionally stringent regulations and can have more applications than Class B; more information is needed on whether these regulations are enforced and, if so, whether they are protective of public health. Methods for testing biosolids were also suggested as an area for more research, specifically coming up with simpler methods; some of the methods currently accepted – e.g., two methods for *Salmonella* and virus assays – are complicated methods that cannot be performed by all laboratories.

Overview of Watershed Features and Dynamics Associated with Drinking and Recreational Water Protection – J. E. Smith, Jr. (ORD/NRMRL)

In considering a surface body of water it is difficult not to think that the water may at some time be used either for recreational purposes or as a source of drinking water. In either case it is good practice to minimize the entrance of pathogenic organisms. Based on the characteristics of the watershed, and its use, the likely sources of pathogens can be identified and management plans put in place.

Drinking water is the main concern where pathogens are involved, and recent waterborne disease outbreaks have shown that compliance with the Surface Water Treatment Rule (SWTR) is not always easy. While drinking water treatment requirements have become more stringent, treatment can be even more efficient and effective when the sources of contamination in the watershed are controlled. Sources are varied, and include onsite wastewater treatment systems; wet weather flows, as from combined sewer and storm sewer overflows; and the application of treated wastewater, treated sludge and/or animal manure to farm land and other areas.

Land application of treated sludge (biosolids) is a beneficial use. However, various human pathogens have been identified in both raw sludges and animal manure, and some of these can persist in the soil for long periods of time. Buffer zones between farm (application) areas and the surface water may prevent transport of the pathogens – some data shows that organisms remain viable for significantly shorter periods when plants are present. Other ways of removing pathogens from sludge and/or manure include treatment by composting, aerobic digestion, alkaline stabilization, anaerobic digestion and long-term storage.

Treatment of sludge has had as a goal reducing the levels of pathogens to below the number required to cause human disease; better and cheaper methods are still needed to accomplish this task. This is especially true since the trend is to reduce the number of pathogens to below the detection level of current analytical methods. More sensitive analytical methods are under development.

A workshop on emerging infectious disease agents associated with biosolids was completed in June of 2000. State-of-the-science reports are being produced from information developed at the workshop and will assist the National Academy of Science review of the science behind the United States Sewage Sludge Regulations, as well as helping to define the need for controls on pathogens associated with CAFOs.

Potential Watershed Management of Pathogens of Animal Origin – John Cicmanec (ORD/NRMRL)

Microbial diseases/agents of concern typically include cryptosporidiosis, *Escherichia coli* O157:H7, giardiasis, salmonellosis, and the caliciviruses – i.e., Norwalk agent. Animal microbial diseases transmitted to humans account for up to 136 diseases**.** To give some feel for the magnitude of the animal wastes problem, it is estimated that 50 times as much animal manure is produced as are human wastes, and one calf sheds 10,000,000 *Cryptosporidium* oocysts per day. Several of the waterborne disease outbreaks in recent years have been connected to animal pathogens being transmitted through drinking water. *E. coli* O157:H7 is rare in most cattle, yet can be present in 25% of animals in some herds; it remains viable in the soil for four months. Sheep are the most common animal carriers of *E. coli* in Europe. *Cryptosporidium parvum* is most often ingested with recreational water, and has a human and bovine genotype. *Salmonella typhimurium* exhibits multiple antibiotic resistance, causes forty percent mortality in cattle and can be found in many other mammals and birds. Risk assessment studies have been performed for all three pathogens named above to estimate the number of infections per person, per year, from drinking water. Infectivity assays have helped determine the infective dose for each organism.

The primary factors that affect transport of the pathogens to the watershed include:

- Percolation Factor (pathogens leach through the soil);
- Annual Runoff Factor (pathogens in water are washed off into the watershed); and
- Soil Erosion Factor (pathogens are carried into the watershed while adsorbed to soil particles).

By studying each of these factors, the watersheds most at risk for pathogen contamination have been determined. These watersheds pose a higher risk of infection, either by accidental ingestion of recreational water, or by drinking water, if pathogens have passed through the barriers of the treatment plant. This information is important to risk managers, so that a potential outbreak situation can be controlled more effectively.

Emerging Infectious Disease Agents and Issues Associated with the Management of Treated Sludges (Biosolids) – J. E. Smith, Jr. (ORD/NRMRL)

Human pathogens sometimes found in sludge cause uncertainty about the practice of applying it to land. EPA regulations published in 1993 regulate the treatment and testing for biosolids, and define the areas where different classes can be applied. Class A biosolids are treated using processes like composting, heat drying, and/or alkaline treatment before land application to control pathogens. Sludge can also be considered class A based solely on testing for enteric viruses and helminth ova. This alternative is now coming into question, since such testing does not provide information about other pathogenic organisms that may be present. Class B biosolids meet less stringent requirements and rely more heavily on the natural attenuation of pathogens after treatment; most of the sludge applied to land is Class B.

Concerns of the public and some regulatory bodies relate to the fact that sludge (especially Class B) being applied to land may still contain some pathogens. Research is ongoing to develop improved analytical methods for measuring pathogens in biosolids, as well as for treating them to reduce pathogen levels. Modifications of existing processes (heat treatment, lime stabilization) are under consideration, and some new and innovative processes have been proposed (microwave processes, solar drying, "gold coast" stabilization). In addition, how best to restrict access to land treated with biosolids needs evaluation, since the possibility for pathogens to be transported by animals (wildlife) or wind still exists.

Major research needs include: the standardization and validation of methods for both monitoring and treatment of sludge; the development of a simple procedure for achieving a Class A sludge; and investigation of some of the concerns that have been raised regarding worker safety at sludge treatment and application sites.

Risks from Pathogens in Biosolid Fertilizers/Land Application of Sludge – National Research Council Report – Tom Burke (Johns Hopkins University)

The purpose of this research study was to review the risks and risk assessment methods used by EPA for establishing standards for chemical pollutants and pathogens in biosolids, and to consider whether chemical and pathogen risks should be integrated. In 1993, EPA published Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503). The rule set limits for chemical pollutants and operations standards for eliminating pathogens in sludge. The standards set for pathogens were based on the technology available for their detection and treatment.

The Clean Water Act requires EPA to periodically re-assess the scientific basis for the Part 503 rule. In addition, public concern about health risks and advances in risk assessment methods led to a review of the current rule. The previous review by the Water Science and Technology Board, in 1996, concluded that properly treated and managed sludge can be safely used in food crop production; however, the definitions of "treated and managed sludge" were vague, leading to inconsistencies. The 1996 report recommended the development of methods for monitoring specific pathogens in sludge, and a re-evaluation of the adequacy of a thirty-day waiting period following applications of Class B sludge to pastures used for grazing.

The Committee on Toxicants and Pathogens in Biosolids Applied to Land is conducting a study funded by the Office of Water, to be completed in the spring of 2002. The study plans to examine new information on risks, and evaluate current practices (the thirty-day limited access period, for example, does not seem to prevent wind-blown soil particles from transporting pathogens). Data on chemicals and pathogens will also be examined, including data on organisms recently identified as pathogens, and those that persist in soil. Infectious dose studies will be incorporated in the study, to determine if current approaches are adequate or need to be revised. Information and comments will finally be sought from a broad range of stakeholders.

Formulation of new approaches and identification of critical gaps are some of the major implications expected from the study. The report should also provide an incentive for harmonization in the way agencies approach the issue of risk management in biosolids.

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Over the Scientific Horizon – Meeting Regional Research Priorities

Moderator: Paula Estornell (Region 3)

See page 9: ORD's RESPONSE TO REGIONAL RESEARCH NEEDS

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Appendix A: List of Participants

Appendix B: Slides from Presentations

Appendix C: Breakout Group Summary

Appendix D: Flip Chart Notes

Appendix E: Workshop Participant Evaluation Summary

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Appendix B: Slides from Presentations

These slides can be found at
http://intranet.epa.gov/ospintra/regsci/pathogen.html

1.	*Overview of Emerging Pathogens*	**Jake Joyce**
2.	*The Clean Water Act's Requirements for Pathogens*	**James F. Pendergast**
3.	*Safe Drinking Water Act/Contaminants Pathogens Candidate List*	**Paul S. Berger**
4.	*Unregulated Contaminant Monitoring of Pathogens*	**James Sinclair**
5.	*Update on EPA's "Implementation Guidance for Ambient Water Quality Criteria for Bacteria"*	**Jennifer Wigal**
6.	*Developing a Strategy for Waterborne Microbial Disease Control*	**Stephen Schaub**
7.	*EPA Implementation of Beaches Environmental Assessment and Coastal Health (BEACH) Act*	**Charles Kovatch**
8.	*Summary of Major Regional Scientific/Technical Priorities*	**Vicky Binetti**
9.	*Waterborne Disease Outbreaks in the U.S. -- Regional Issues*	**Kim Ngo**
10.	*Waterborne Disease: EPA's Intramural Epidemiology Program*	**Rebecca L. Calderon**
11.	*An Estimate of National Waterborne Disease Occurrence*	**Susan Shaw**
12.	*Microbial Risk Assessment: State of the Art and Science*	**Bruce A. Macler**
13.	*A Dose-Response Envelope for E.coli O157:H7*	**Mark Powell**
14.	*Vibrio parahaemolyticus Risk Assessment*	**Marianne Miliotis**

15.	*Pathogen Risk Assessment Protocol for Environmental Water Media*	**Stephen Schaub**
16.	*Risk Assessment in Regulatory Development*	**Stig Regli**
17.	*Microbial Risk Assessment Activities in Cincinnati Division of EPA's National Center for Environmental Assessment*	**John C. Lipscomb/Brenda Boutin**
18.	*Assessing Exposures to Emerging Pathogens -- What the Regions Need*	**Terry Fleming**
19.	*Assessing Exposure to Bacterial Pathogens*	**Gerard N. Stelma**
20.	*Development of Molecular Methods to Detect Emerging Viruses*	**Ann C. Grimm/Christina Newport/G. Shay Fout**
21.	*Detection of Protozoan Pathogens in Water*	**Frank W. Schaefer**
22.	*Current Approaches to Identifying Sources of Fecal Contamination*	**Gerard N. Stelma**
23.	*Antimicrobial Resistance Among Enteric Bacteria Isolated from Human and Animal Wastes and Impacted Surface Waters*	**Mark Sobsey**
24.	*User-Friendly Models for Evaluating Hydrogeologic Barriers to Viruses*	**Bart Faulkner *et. al.***
25.	*Water Supply and Water Resources Division Response to Waterborne Disease Outbreaks*	**Kim R. Fox**
26.	*Disinfection of Emerging Pathogens*	**Eugene W. Rice**
27.	*Biofilms in Drinking Water Distribution Systems*	**Mark C. Meckes**
28.	*Update on 6-year Review of TCR and Potential Distribution System Rule*	**Ken Rotert**
29.	*Case Study: Biofilm Problem at Greenville South Carolina*	**David Parker**
30.	*EPA's National Beach Survey*	**Rick Hoffman**
31.	*Development of Improved Monitoring Approaches for Recreational Water*	**Stephen Schaub**

32. *Use of Molecular Techniques to Provide the Public with more Information on Recreational Water Closures in Norfolk*	**Alpha Diallo**
33. *Acceptable Goals and Thresholds for Pathogens from Recreational Water Exposures*	**Alfred P. Dufour**
34. *Determining Sources of Microbial Contamination*	**Joel Hansel**
35. *Rapid Methods for Measuring Recreational Water Quality: A Look to the Future*	**Alfred P. Dufour**
36. *ORD's Drinking Water Research Program Tracking System*	**Alfred P. Dufour/Cheryl Itkin**
37. *A Regional Perspective on CAFO/Biosolid Regulations: How ORD Can Help Us!*	**Stephanie Harris**
38. *Overview of Watershed Features and Dynamics Associated with Drinking and Recreational Water Protection*	**J. E. Smith**
39. *Potential Watershed Movement of Pathogens of Animal Origin*	**John Cicmanec**
40. *Emerging Infectious Disease Agents and Issues Associated with the Management of Treated Sludges (Biosolids)*	**J. E. Smith**
41. *Risks from Pathogens in Biosolid Fertilizers/Land Application of Sludge -- NRC Report*	**Tom Burke**

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Appendix C: Breakout Group Summary

DISCLAIMER: *The thoughts below were collected during a brief interactive session at the workshop. They do not represent Agency policy.*

GROUP 1: What endpoints and factors should be considered in microbial risk assessments?

Moderator – Bruce Macler (Region 9)

A. How do we account for mixtures of pathogens in sources in risk assessment?

Premise:

- It is typical to have more than one pathogen present in the source
- Only fecal pathogens are considered
- There is no indicator or single pathogen that can predict the kind or number of other pathogens that may be present

Suggestions:

- Consider the worst-case situation for the source
- Evaluate sources for general types of pathogens

B. How should we consider more sensitive people in risk assessment and management?

Premise:

- Approximately twenty percent (20%) of the general population can be classified as **sensitive**
- Approximately one percent (1%) of the general population is considered **super-sensitive**

Suggestions:

- Use a modifying factor in dose-response assessment to account for sensitivity (as is done for Reference Dose)
- Focus on illness endpoints rather than infection

- Focus risk management on sensitive and supersensitive populations:
  - Education/Outreach to limit exposures
  - Guidance Materials
  - Vaccination programs
  - Minimize pathogens in sources
  - Redirect sources
- Identify all sensitive and super-sensitive populations
- Determine if sensitivity varies with pathogen type
- Consider the acute, subacute, and chronic effects of pathogens
- The cumulative impact of multiple pathogens must also be considered

GROUP 2: Recognizing the uncertainties inherent in microbial risk assessment: what data would provide the most value added?

Moderator – Mike Messner (OW)

Participants in this second breakout group were asked to break into smaller groups in order to consider separately the data needed for each of **three groups of organisms**, both in drinking and recreational water, and the needs for **total microbial risk in drinking water** for all organisms:

1. Viruses in Drinking and Recreational Water (Subgroup 1)
2. Bacteria in Drinking and Recreational Water (Subgroup 2)
3. Protozoa in Drinking and Recreational Water (Subgroup 3)
4. Total Microbial Risk attributable to Microbes in Drinking Water (Subgroup 4)

The four sub-groups above each focused on **four major areas** where data is needed:

1) **Occurrence** – Where are they and in what quantities before they enter the treatment or distribution system?
- Organisms that originate in the source water and pass through the treatment barriers
- Organisms that enter through pipe connections (not originating in source water) and/or grow in the distribution system

2. **Treatment and Distribution (Drinking Water)** – What happens to the organisms in the treatment plant? In the distribution system?

3. **Control (Recreational Water)** – How effectively do watershed and other controls reduce risk?

4. **Infectivity/Illness** – How infectious is the organism? (How is the probability of infection related to dose? Given infection, what is the probability of illness / severity of illness? How protective is immunity?

At the end of the breakout sessions the four subgroups reported their findings to the attendees. Summaries of each subgroup's conclusions follow, below.

SUBGROUP 1: *Viruses in Drinking Water and Recreational Water*
Moderator – Ann Grimm (ORD/NERL)

Research priorities were decided to be the same for all viruses, with no distinction made between specific types of viruses. Additionally, needs were deemed to be similar in both drinking water and recreational water.

The **research needs** were ranked in order of importance, and the justification for these rankings was reported.

Priorities:

1. Development of **methods**
2. Data on **occurrence**
3. Research to identify an **indicator**

Justification:

1. Consideration of acute effects, especially on sensitive sub-populations
2. Consideration of potential long-term, insidious effects

SUBGROUP 2: Bacteria in Drinking Water and Recreational Water
Moderator – Gerard Stelma (ORD/NERL)

Bacteria were listed by genus in order of their importance to drinking water and recreational water. For each bacterium, the data needs were ranked: one (1) was assigned to the type of data most needed for estimating risk, and three (3) to the type of data least needed or already available.

In **drinking water** the most important bacteria were:
(1) *Legionella;*
(2) NT Mycobacteria; and
(3) *E. coli* O157:H7 **and** Cyanobacteria.

Data on **treatment** was the type most needed for both *Legionella* and NT Mycobacteria, while data on **occurrence** was ranked most important for Cyanobacteria and *E. coli* O157:H7.

In the case of **recreational water**, the most important bacteria were:
(1) *E. coli* O157:H7
(2) *Shigella* **and** *Campylobacter*

Several other bacteria were considered equally important to be included under #3

(See Recreational Water table below)

Data was needed most in the area of **control** for *E. coli* O157:H7. Data on **occurrence** was considered most important for *Shigella,* whereas data needs were not ranked in the case of *Campylobacter.*

The information on research needs for all the bacteria considered by Subgroup 2 is outlined in the two tables, below.

Bacteria in Drinking Water

Bacterium (Rank)	Occurrence (Rank)	Treatment (Rank)	Infectivity (Rank)
(1) *Legionella*	2	1	3
(2) NT Mycobacteria	2	1	2
(3) *E. coli* O157:H7	1	2	3
(3) Cyanobacteria	1	2	3 - toxicity
Helicobacter			
Aeromonas			
HPC			

Bacteria in Recreational Water

Bacterium (Rank)	Occurrence (Rank)	Control (Rank)	Infectivity (Rank)
(1) *E. coli* O157:H7	2	1	3
(2) *Shigella*	1	2	3
(2) *Campylobacter*			
(3) *Vibrio*	2	1	3
(3) *Aeromonas*			
(3) *Pseudomonas*			
(3) *Streptococcus*			
(3) *Enterococcus*			
(3) *Leptospira*			
(4) Cyanobacteria	2	1	3

SUBGROUP 3: Protozoa in Drinking Water and Recreational Water
Moderator – Mark LeChevallier (American Water Works Services Company)

Protozoa were first categorized by this subgroup according to the **risk level** each species presents in drinking water and recreational water. The same three protozoan species were listed as having a high risk level in **both recreational** and **drinking water**:

Cryptosporidium, Giardia, and *Acanthamoeba*.

Two additional protists, *Entamoeba* and *Naegleria* were identified as carrying a high-risk level in **recreational water only**.

With regard to **data needs**, the group focused on the data needed for **drinking water treatment**. These needs were considered to be the same for all protozoa, regardless of species, and were ranked in order of importance as follows:

(1) Exposure data
(2) Viability and infectivity data
(3) Data on strain variations

The full results reported by this subgroup are presented in the two tables on the following page.

Risk Level in Drinking Water and Recreational Water

PATHOGEN	RISK LEVEL	
	Drinking Water	**Recreational water**
Cryptosporidium	H	H
Giardia	H	H
Acanthamoeba	H	H
Microsporidia	M	?
Entamoeba	L	H
Naegleria	L	H
Cyclospora	L	L
Toxoplasma	L	L
Isospora	L	L

[H = High; M = Medium; L = Low]

Data Needs for Protozoa in Drinking Water

SOURCE WATER	GOAL: TREATMENT	1. EXPOSURE	2. VIABILITY INFECTIVITY	3. STRAIN VARIATION
Occurrence ↕ Outbreaks ↕ Reservoir and transport hosts	↓ Variation ↓ No surrogates ↓ Difference in design and operation ↑ NO MODEL	High volume methods Frequency monitoring Attributable risk from water Relate to antibody levels	Cell culture=? Animal infectivity = Human infectivity	Infectivity Variation Genotypes Pathogenicity Role of immunity
To improve treatment estimates it is necessary to improve exposure, viability and strain variation.				

SUBGROUP 4: Studies of Total Microbial Risk Attributable to Drinking Water
Moderator – Rebecca Calderon (ORD/NHEERL)

This last subgroup considered the data most needed to assess total microbial risk in **drinking water**.

The types of **data needs** they considered crucial are listed in order of importance below:

1. Intervention studies
2. Drinking water system classification strategy
3. Increased FoodNet coverage to correlate with the system
4. Serology data
5. GIS [Geographic information systems] data
6. Investigation of alternative disease surveillance
7. Probabilistic risk analysis
8. Medical outreach and education

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Appendix D: Flip Chart Notes

PART 1: WEDNESDAY, SEPTEMBER 5TH:

The notes included in this appendix represent the main points brought up during a Regional panel discussion and facilitated question and answer session intended to develop a list of some of the highest priority science issues to be addressed. These issues, and others brought up throughout the meeting, were addressed by ORD representatives at the end of the workshop.

The discussion centered around two posed questions:

Question 1: Is our science on pathogens appropriate and adequate to support regulatory management?

Question 2: What can be done today to address some of the microbial problems that are just now emerging?

QUESTION 1:
Is our science on pathogens appropriate and adequate to support regulatory management?

Discussion of this question focused on the areas where more and/or better science is needed to support regulatory management. The needs discussed can be divided into two general areas: **waterborne disease characterization** and **indicators.**

WATERBORNE DISEASE CHARACTERIZATION NEEDS/GAPS

- For recreational water, characterization of disease endpoints other than gastro-intestinal symptoms
- Analytic and disease incidence monitoring tools, such as:
  - Quick, unambiguous methods for pathogen screening
  - Non-traditional methods: expansion of FoodNet; monitoring of the sales of over the counter anti-diarrheal medications
- Definition of an outbreak and better ways to monitor and characterize outbreaks
- Linking of outbreak/disease to source (whether drinking or recreational water)
- Dose-response relationships
- A better understanding of disease progression and its secondary spread
- Understanding of the special susceptibilities of "at-risk" populations

- Improved characterization of the incidence of waterborne disease. Specifically:
  - Endemic vs. epidemic levels of disease incidence

  - Disease pathways, other than waterborne
- Bridge the gap between drinking water, environmental, and health agencies

INDICATORS

- Faster and better indicators are needed for the detection of pathogens, especially bacterial pathogens.
- A better understanding is needed of what indicators really mean, as well as what information they **cannot** give.

QUESTION 2:
What can be done today to address some of the microbial problems that are just now emerging?

Discussion of this question centered around risk assessment and risk management.

- Emphasize multi-barrier approach to risk management:
  - source protection
  - treatment
  - disinfection
- Information on how to approach risk management on a watershed basis, and for source water assessment and protection
- More information on the effectiveness of controls such as disinfection and best management practices (BMPs)
- Importance (to risk assessment) of factors such as die-off/survivability of pathogens in varying environmental conditions
- Better knowledge of the risks associated with recreational water use (ambient water quality)
- Data on bacteria source tracking (especially important for TMDLs)
  - Methods
  - Dimensions of investigation area
  - Size of library
  - Number of isolates
- Assessment of risks from various pathogen sources; some examples include:
  - Combined sewage overflows (CSOs)
  - Storm water
  - Biosolids
  - Publicly owned treatment works (POTWs)
  - Algal toxins

Appendix E: Emerging Aquatic Pathogens Workshop

Participant Evaluation Summary

Most participants found that the workshop gave them a better overall understanding of the issues associated with Emerging Aquatic Pathogens. Several participants were of the opinion that the workshop was useful, but covered too broad a topic, and could have been longer, or divided into separate, more specific workshops[1]. Attendees from the regional offices also liked the fact that the sessions began by addressing regional needs from the perspective of regional presenters. Some commended the inclusion of speakers from outside the EPA.

The responses regarding the most interesting and least interesting topic varied widely, with most attendees explaining they were most interested in topics related to their own field (e.g., drinking water vs. recreational water, microbiology vs. epidemiology.). The breakout sessions were thought to be a good opportunity to delve deeper into specific topics, and participants especially appreciated the reporting of each group's conclusions at the end of the sessions. Several attendees did caution that there was not enough time to come up with meaningful, well-thought-out results.

The majority of participants found the format of the workshop to be a good balance of presentations, discussions, and small group sessions; some, however, thought the time for questions should be more flexible, to accomodate presentations that elicit longer discussions.

Many participants appreciated the opportunity to establish contacts between ORD and the regional offices. Suggestions for continuing this interaction included the creation of an email listserv and an arbitrated intranet discussion forum divided by topic. In general, the feedback for this workshop was very favorable. The most common suggestion was that this workshop should be held regularly (e.g. on an annual basis) to continue the interaction between ORD and the regions.

1

Note from the Organizers: Topics for the workshop were solicited from all 10 regions, leading to a fairly extensive list including bioterrorism, airborne pathogens, resistant pathogens, and cyanobacteria. Because this broad list covered far too much material for one workshop, the organizing team for the workshop selected two major topics on which to focus: drinking water and recreational water. It was decided that the other topics would be covered in the future, using the Placeware™ remote conferencing system. At one point there was discussion on having parallel presentations for those interested in the two topics selected by the organizing team, however, it was decided that there was more benefit in having the two groups interact.