EXPERT REPORT OF THERESA R. SLIFKO, Ph.D.
ON BEHALF OF PLAINTIFF-INTERVENORS THE
NATIONAL ASSOCIAION OF CLEAN WATER AGENCIES

NATIONAL RESOURCES DEFENSE COUNCIL
Plaintiff,

COUNTY OF LOS ANGELES, AND
LOS ANGELES COUNTY FLOOD CONTROL DISTRICT,
Plaintiffs-Intervenors,

NATIONAL ASSOCIATION FOR CLEAN WATER AGENCIES
Plaintiffs-Intervenors

v.

STEPHEN L. JOHNSON, et al., Administrator,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Defendants.

Civil Action No. CV 06-4834 PSG

GLOSSARY

ASIWPCA	Association of State and Interstate Water Pollution Control Administrators
AWQC	Ambient Water Quality Criteria
BEACH Act	Beaches Environmental Assessment and Coastal Health Act
CFU	Colony Forming Unit
CLAT	Coliphage Latex Agglutination and Typing
CSO	Combined Sewer Overflow
CWA	Clean Water Act
DNA	Deoxyribonucleic Acid
DWTP	Drinking Water Treatment Plant
EMPACT	Environmental Monitoring for Public Access and Community Tracking
EPA	Environmental Protection Agency
FC	Fecal Coliform
FIB	Fecal Indicator Bacteria
FS	Fecal Streptococcus
GAO	Government Accountability Office
GI	Gastrointestinal
HPC	Heterotrophic Plate Count
IFA	Immunofluorescent Assay
IMS	Immunomagnetic Separation
JOS	Joint Outfall System
LACSD	Los Angeles County Sanitation Districts
LT2	U.S. EPA Long Term 2 Enhanced Surface Water Treatment Rule
MGD	Million Gallons per Day
NACWA	National Association of Clean Water Agencies
NEEAR	National Epidemiological and Environmental Assessment of Recreational
NERL	EPA Microbiological and Chemical Exposure Assessment Research Division National Exposure Research Laboratory
NPDES	National Pollutant Discharge Elimination System
NRDC	National Resources Defense Council
POTW	Publicly Owned Treatment Works
QMRA	Quantitative Microbial Risk Assessment
qPCR	Quantitative Polymerase Chain Reaction
QPCRCE	Quantitative Polymerase Chain Reaction Cell Equivalent
RNA	Ribonucleic Acid
SCCWRP	Southern California Coastal Water Research Project
TC	Total Coliform
TMDL	Total Maximum Daily Load
UAA	Use Attainability Analysis
UV	Ultra Violet
USF	University of South Florida
USEPA	United States Environmental Protection Agency
WRP	Water Reclamation Plant
WWTP	Waste Water Treatment Plant

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1. Introduction

Summary of Litigation: Natural Resourced Defense Council (NRDC) v. U.S. EPA

The case involves a legal challenge regarding U.S. EPA's failure to establish new recreation water quality criteria as required by the Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act) (Civil Action No. CV 06-4834 PSG). NRDC filed a legal action in August 2006 against U.S. EPA for its failure to comply with its statutory obligations under the BEACH Act, Pub. L. 106-284, Oct. 10, 2000 (amending the Federal Water Pollution Control Act (Clean Water Act), to protect the public from the substantial adverse health effects caused by contact with contaminated beach water.

The BEACH Act called for U.S. EPA to perform studies to provide additional information for use in developing an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters by October 2003, and to then publish new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of those studies, by October 2005. However, U.S. EPA missed both of these deadlines and NRDC filed suit against the Agency. The County and Flood Control District of Los Angeles County were granted leave to intervene on February 7, 2007.

The National Association of Clean Water Agencies (NACWA) is a trade association representing the nation's publicly owned wastewater treatment utilities. NACWA intervened in the case in order to bring the clean water community's voice to the litigation and represent the interests of our nearly 300 public wastewater utility members. NACWA's public utility members play a critical role in protecting the health of our nation's waters, especially those waters that are used for recreational purposes. NACWA's membership will be among the most directly affected entities as a result of new recreational water quality criteria developed under the BEACH Act, and thus it is critically important that NACWA be involved in the present litigation to ensure that the court provides U.S. EPA with sufficient time to complete scientifically valid studies and develop new criteria that will be appropriate for protecting water quality in recreational waters.

NACWA was granted leave to intervene in the case as a plaintiff in March 2007, over the objections of NRDC. Also in March, the court granted NRDC's Motion for Summary Judgment on the Pleadings and ruled that U.S. EPA violated the BEACH Act by failing to publish the new criteria by October 2005.

This Report outlines NACWA's scientific position in the case including my opinion that EPA's proposed Critical Path Science Plan and Proposed Schedule is fundamentally flawed and requires modification. These flaws must be addressed if EPA is to continue to make progress on meeting Congress' requirements in the BEACH Act and promulgate new criteria for coastal and Great Lakes recreational waters. As such, the goal of completing the necessary studies concerning all types of illnesses, pathogens, coastal waters, and sources of beach water pollution by December 2010 and developing new or revised recreational criteria, including a revised list of testing methods for pathogens and pathogen indicators by December 2012 is ambitious. Without the required consultation and cooperation with appropriate Federal, State, tribal, and local officials (including local health officials), completing scientifically robust studies and revising criteria for

coastal recreation waters by a court ordered deadline date cannot be certain to have scientific credibility. This position is based on a review of existing U.S. EPA information produced during the discovery process and the published literature.

U.S. EPA has admitted the two main allegations outlined in the NRDC complaint from August 2006, which essentially state that:

1.) the Agency failed to complete the required epidemiological studies as outlined in the BEACH Act, and;

2.) the Agency failed to update the recreational water quality criteria as outlined in the BEACH Act.

Plaintiff NRDC makes the following request in its Complaint:

> *"WHEREFORE, the plaintiff respectfully requests that judgment be entered against EPA as follows:*
> *(1) Declaring that EPA has unlawfully failed to meet statutory deadlines to initiate and complete appropriate water quality studies and to publish revised water quality criteria;*
> *(2) Compelling EPA to initiate and complete appropriate studies that evaluate all types of illnesses, pathogens, coastal waters, and sources of beachwater pollution by a court-ordered deadline;*
> *(3) Compelling EPA to publish revised water quality criteria (including a revised list of testing methods) for pathogens and pathogen indicators for use in coastal recreational waters by a court-ordered deadline;*
> *(4) Awarding plaintiff its costs and attorneys' fees; and*
> *(5) Granting such other and further relief as the Court deems just and proper (Civil Action No. CV 06-4834 PSG."*

Plaintiff-Intervenor NACWA seeks the following relief in its Complaint in Intervention:

> *"WHEREFORE, the plaintiff respectfully requests that judgment be entered against EPA as follows:*
> *(1) Declaring that EPA has unlawfully failed to meet statutory deadlines to initiate and complete appropriate water quality studies and to publish revised water quality criteria;*
> *(2) Compelling EPA to initiate and complete, by a court-ordered deadline, appropriate studies to provide additional information for use in developing an assessment of potential human health risks resulting from exposure to pathogens in coastal recreational waters; appropriate and effective indicators for improving detection in a timely manner of the presence of pathogens that are harmful to human health; appropriate, accurate, expeditious and cost-effective methods for detection in a timely manner of the presence of pathogens that are harmful to human health; and guidance for state application of the criteria for pathogens and pathogen indicators to account for the diversity of geographic and aquatic conditions;*

(3) Compelling EPA to publish revised water quality criteria (including a revised list of testing methods, as appropriate) for pathogens and pathogen indicators for use in coastal recreational waters by a court-ordered deadline;
(4) Awarding plaintiff its costs and attorneys' fees; and
(5) Granting such other and further relief as the Court deems just and proper (Civil Action No. CV 06-4834 PSG".

The relief sought in NACWA's Complaint adheres more closely to the explicit requirements of the BEACH Act, while NRDC's Complaint is a more broadly-worded paraphrase of the Act.

This report presents the opinions that I, Theresa R. Slifko, Ph.D., currently anticipate providing at the trial in the case, if requested to do so. The opinions are based on the following documents as well as the documents cited in the Bibliography:

- Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) Water Quality Standards Taskforce. Pathogen Criteria White Paper. November 2005.
- Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act): Public Law 106-284 – October 10, 2000. An Amendment to the Clean Water Act.
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- Colford, J.M., Jr., et al. 2007. Water Quality Indicators and the Risk of Illness at Beaches with Nonpoint Sources of Fecal Contamination, Epidemiology 18(1): 27-35.
- Documents provided by U.S. Environmental Protection Agency in response to NRDC's Second Set of Document Requests.
- Deposition of U.S. Environmental Protection Agency witness Ephraim King dated July 2, 2007 for Case No. CV 06-04843.
- Dorfman, M. and N. Stoner. 2007. Testing the Waters: A guide to Water Quality at Vacation Beaches, National Resources Defense Council, 17^{th} Ed.
- Dziuban, E.J., et al. 2006. Surveillance for Waterborne Disease and Outbreaks Associated with Recreational Water – United States, 2003-2004, Morbidity and Mortality Weekly Report 55(No. SS-12): 1-30.
- Official documents pertaining to Natural Resources Defense Council v. Johnson et al., Case No. CV 06-04843.
- SCCWRP's Evaluation of Rapid Microbiological Methods for Measuring Recreational Water Quality Technical Report 485 (May 2006)
- U.S. Government Accountability Office. Report to Congressional Requesters: Great Lakes – EPA and States Have Made Progress in Implementing the BEACH Act, but Additional Actions Could Improve Public Health Protection, GAO-07-591, May 2007.
- U.S. Government Accountability Office. 2007. Testimony Before the Subcommittee on Transportation Safety, Infrastructure Security, and Water Quality, Committee on the Environment and Public Works, U.S. Senate: Implementation of the Beach Act of 2000 - EPA and States Have Made Progress in Implementing the BEACH Act, but Additional Actions Could Improve Public Health Protection, GAO-07-591T, June 27, 2007.
- U.S. Environmental Protection Agency. Ambient Water Quality Criteria for Bacteria, EPA-440/5-84-002, January 1986.

- U.S. Environmental Protection Agency. Health Effects Criteria for Marine Recreational Waters, EPA-600/1-80-031, August 1983.
- U.S. Environmental Protection Agency. Health Effects Criteria for Fresh Recreational Waters, EPA-660/1-84-004, August 1984.
- U.S. Environmental Protection Agency. Review of Potential Modeling Tools and Approaches to Support the BEACH Program. EPA-823-R-99-002, March 1999.
- U.S. Environmental Protection Agency. The EMPACT Beaches Project: Results from a Study on Microbiological Monitoring in Recreational Waters. EPA-600-R-04-023, August 2005.
- U.S. Environmental Protection Agency. Implementing the BEACH Act of 2000 Report to Congress. EPA-823-R-06-001, October 2006.
- U.S. Environmental Protection Agency. Report of the Experts Scientific Workgroup on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria. EPA-823-R-07-006, June 2007.
- U.S. Environmental Protection Agency. Critical Path Science Plan for the Development of New or Revised Recreational Water Quality Criteria. August 2007.
- U.S. Environmental Protection Agency. Criteria Development Plan & Schedule: Recreational Water Quality Criteria. August 2007.
- Wade, T.J., et al. 2006. Rapidly Measured Indicators of Recreational Water Quality are Predictive of Swimming-Associated Gastrointestinal Illness. Environmental Health Perspectives, 114(1): 24-28.

2. Qualifications, Compensation, & Previous Testimony

I am an Associate Environmental Scientist at the County Sanitation Districts of Los Angeles County (Districts), a publicly owned treatment works (POTW) with headquarters located at the Joint Administration Office at 1955 Workman Mill Road, Whittier, CA, 90601. The Districts provide environmentally sound, cost-effective wastewater and solid waste management and, in the process, convert waste into resources such as reclaimed water, energy, and recycled materials. The Districts are a partnership of 24 independent special districts with a service area that covers approximately 800 square miles and encompasses 78 cities and unincorporated territory within Los Angeles County, CA. The Districts serve the water pollution control and solid waste management needs of over 5.2 million people in the county. Fifteen of the districts have collectively constructed an extensive regional sewerage system known as the Joint Outfall System (JOS), which conveys and treats approximately 450 million gallons per day (MGD) of wastewater from 72 cities and unincorporated county areas. The JOS consists of seven treatment/water reclamation plants (WRPs) and 1,200 miles of large diameter trunk sewers that form a network connecting the treatment plants and ocean outfalls off Whites Point on the Palos Verdes Peninsula. The Districts also operate four WRPs in northern Los Angeles County serving the communities in and around the cities of Santa Clarita, Lancaster, and Palmdale. On an annual basis, over 50 MGD of reclaimed water is reused for applications including groundwater recharge, landscape irrigation and industrial uses. The remainder is discharged to inland surface waters. The designated beneficial uses of the receiving waters to which the Districts' WRPs discharge are diverse and vary depending on location. These existing and potential use designations include groundwater recharge, water recreation, warm fresh water

habitat, wildlife habitat, commercial and sport fishing, and rare, threatened or endangered species spawning, reproduction, and early development.

I received my Master's and Ph.D. degrees from the University of South Florida (USF) at the College of Marine Science with a focus on water pollution microbiology. My research involved the development, optimization, and application of a tissue culture method to detect the waterborne protozoan pathogen *Cryptosporidium*. During my tenure at USF, I participated in numerous occurrence, survival, and disinfection studies, participated in various pilot studies, modeled dose response data, developed risk evaluations, compared *Cryptosporidium* infectivity in mice and tissue culture, and was involved with detecting, enumerating, and comparing occurrence of indicators and pathogens in a variety of water matrices. Notable accomplishments include being the first to develop and publish a quantitative in-vitro infectivity assay for detecting *Cryptosporidium*; first author to publish *Cryptosporidium* inactivation after pulsed UV irradiation; and the first author to report *Cryptosporidium* inactivation after electron beam disinfection.

After graduating in 2001, I was employed as a Staff Scientist at Orange County Utilities, Water Quality Section in Orlando, Florida where I was responsible for establishing and operating a fully functional Research Section of the Utilities Laboratory, including the design and management of projects to further the understanding of the quality and safety of water in the county. I was responsible for supervising the Microbiology and Water Quality Research groups for special projects as well as routine analysis of drinking, waste, and reclaimed water and biosolids samples for meeting local and state regulatory compliance guidelines. I also managed Section requirements for maintaining NELAC certification for total coliform, fecal coliform, *E. coli*, *Salmonella*, enterococci, HPC, and *Cryptosporidium* and *Giardia*, enteric viruses, bacteriophage, and helminth methods for potable, non-potable, and solids matrices. Part of this work included establishing and operating a fully functional molecular biology research area in the laboratory. My research included a focus in the water reuse arena and the pursuit of alternative water supplies to augment potable water for non-potable applications.

Through the past 12 years of working with microbial and chemical pilot challenge studies, occurrence and detection of the emerging microconstituents, pathogens, indicator organisms and surrogates, I've had the opportunity to design and implement major monitoring projects as well as evaluate a variety of disinfection and removal technologies for inactivating and removing microorganisms. In addition, for the past three years I held an adjunct Assistant Professor position at the University of Central Florida, College of Biomolecular Sciences in Orlando, Florida where I taught Environmental Microbiology.

Currently, I provide technical guidance and review for water quality and reuse issues at the Districts. I am responsible for overseeing and participating in projects relating to: recreational water quality; environmental and public health impacts of water recycling; evaluating potential microconstituent impacts on aquatic life; assessing and evaluating disinfection strategies; and tracking, participating and cooperating with local and national epidemiological studies. My responsibilities relevant to this report include project management, tracking, and support for bacteria standards development, regulation issues pertaining to beach water quality, bacteria total maximum daily loads (TMDLs), and sewage spill contingency and resolution. In particular, I am

the Project Manager for a Special Environmental Project designed to evaluate the source and mitigate bacterial exceedences at the Redondo Beach Pier study site.

Throughout my career, water quality assessment, regulation, and risk evaluation in the area of water pollution microbiology, with a particular emphasis on method development for detecting pathogens and indicator organisms in environmental water matrices, has been my main focal point. I've specialized in the detection, disinfection, removal, and risk of pathogens from water intended for consumption, reuse, or discharge. The summary of my education, professional appointments, professional affiliations, projects, presentations, and publications are provided in my curriculum vitae in Appendix A.

Time and resources to prepare the expert opinions provided in this report, deposition, testimony, trial, and necessary travel expenses are provided by the Districts as part of my employment responsibilities. I am not being compensated as a consultant for the study and testimony.

As of the date of this report, I have been with the Districts for three months. Since the Districts are members of NACWA, I am automatically considered a NACWA member. Prior to my employment at the Districts, I have not been involved with NACWA and had no prior interactions with NACWA activities. I have worked with the Districts on two research projects in the previous five years. I do not have prior affiliation with NRDC and have not received funding from any of the parties related to this litigation.

Dr. Fred Hauchman, the Director of the U.S. EPA Microbiological and Chemical Exposure Assessment Research Division National Exposure Research Laboratory (NERL), and I are both members of the WateReuse Association Research Advisory Committee. We often work together on various topics within the committee to develop research ideas and steer project advisory committees on behalf of the WateReuse Foundation.

As Principal Analyst at the Orange County Utilities in Orlando, FL for laboratory and analyst approval, I worked with U.S. EPA to report data for the U.S. EPA Long Term 2 Enhanced Surface Water Treatment Rule (LT2). Under my supervision, the laboratory was audited and gained approval to report data. I have worked with various U.S. EPA employees in the LT2 program.

I have not testified as an expert at trial or deposition within the preceding four years.

3. **Background**

3.1 BEACH Act of 2000: Summary, Accomplishments, and Deficiencies

Fecal contamination of water used for recreation can originate from many sources including swimmers, coastal and shoreline development, stormwater runoff, municipal wastewater treatment plant discharges, leaking septic systems, illegal sewage releases from marine vessels, animal feeding operations, bird excrement, feral and domestic animal excrement, and naturally occurring bacterial communities populating sand and soils. Public health protection and

waterborne illness protection from recreational waters has been a long term goal of early federal entities and the United States Environmental Protection Agency (U.S. EPA) since the 1930s (USEPA 2005). Through a series of efforts to recognize swimming-associated waterborne illness, defining useful measures to evaluate water quality, and implementing water quality monitoring programs, the U.S. EPA established numerical guidelines outlined in the Bacteriological Ambient Water Quality Criteria in 1986 that were based on 1976 Quality Criteria for Water. These criteria were called the "Red Book" and established numerical guidelines for fecal coliforms based on limited epidemiological studies and a perceived "acceptable" illness rate (USEPA 1986). These criteria were the first guidelines supported by scientific data but a mechanism to enforce them and require monitoring was not in place.

The Beaches Environmental Assessment and Coastal Health Act (BEACH Act) was developed and signed into law on October 10, 2000 to amend the Clean Water Act (CWA) (BEACH Act 2000). The BEACH Act directed U.S. EPA to establish uniform criteria for testing, monitoring, and notifying public users of possible coastal recreation water problems. The Act also provided funds to help state and local governments improve their monitoring and public notification actions. As summarized in the US EPA October 2006 Report to Congress written as a requirement of the BEACH Act, three significant provisions with designated deadlines were included in the act:

1. States and tribes with coastal recreation waters were required to adopt new or revised water quality standards by April 10, 2004 for pathogens and pathogen indicators. Provisions include the requirement of U.S. EPA to promulgate standards for states that failed to establish similar or more protective standards;

2. U.S. EPA was required to initiate and complete pathogen indicator and human health studies in coastal recreational waters to provide additional information for use in developing: (1) an assessment of potential human health risks for exposure to waterborne pathogens, (2) appropriate and effective indicators for improving detection and indication of human pathogen presence, (3) appropriate, accurate, expeditious, and cost effective methods for indicating human pathogen presence, including predictive models, and (4) guidance for State application of the criteria to account for geographic and aquatic diversity. This provision also required U.S. EPA to publish new or revised water quality criteria for pathogens and pathogen indicators, including appropriate methods, that were based on the results of the studies;

3. U.S. EPA was authorized to award grants to states or local governments to develop and implement beach monitoring and assessment programs (USEPA 2006).

The BEACH Act enabled U.S. EPA to accomplish significant improvements in national monitoring efforts since the enactment in 2000. While the number of monitored beaches increased from 2,354 in 2000 to 3,771 in 2006 (total increase of 60%), the percent of beaches affected by advisories or closings only increased from 27% to 32%, leading to a total increase in postings or closures of 68% (USEPA 2007a). This increase in monitoring capabilities represents a significant improvement in our capacity to protect our nation's coastal recreational waters.

U.S. EPA also provided approximately $10 million dollars per year to assist state and local agencies for implementing monitoring programs.

U.S. EPA successfully accomplished much of their goals for implementing the BEACH Act, but fell short in two critical areas. The U.S. EPA did not complete the studies needed to support the adoption of new criteria and/or methods. Currently, states use interim standards based on the U.S. EPA 1986 criteria for evaluating recreational water quality shown in Figure 1. The U.S. EPA 1986 Criteria are different for fresh and marine waters and specify the use of either enterococci or *E. coli* in fresh water or enterococci in marine water. The criteria serve as a template for the states since they have the primacy to adopt and submit new or revised recreational water quality standards for coastal recreation waters of the state to which the new or revised water quality criteria are applicable. State criteria are required to be as protective of human health as the criteria for pathogens and pathogen indicators for coastal recreation waters published by the Administrator (BEACH Act, 2000). This is significant since revisions to the national criteria are likely to be adopted by the states for other waters and applications.

Information Box 1. U.S. EPA 1986 Criteria for Full Body Contact Recreational Waters (BEACH Act 2000).

EPA Criteria for Bathing (Full Body Contact) Recreational Waters

Freshwater

Based on a statistically sufficient number of samples (generally not less than 5 samples equally spaced over a 30-day period), the geometric mean of the indicated bacterial densities should not exceed one or the other of the following:[(1)]

E. coli 126 per 100 ml; or enterococci 33 per 100 ml;

no sample should exceed a one sided confidence limit (C.L.) calculated using the following as guidance:

designated bathing beach	*75% C.L.*
moderate use for bathing	*82% C.L*
light use for bathing	*90% C.L.*
infrequent use for bathing	*95% C.L.*

based on a site-specific log standard deviation, or if site data are insufficient to establish a log standard deviation, then using 0.4 as the log standard deviation for both indicators.

Marine Water

Based on a statistically sufficient number of samples (generally not less than 5 samples equally spaced over a 30-day period), the geometric mean of the enterococci densities should not exceed 35 per 100 ml;

no sample should exceed a one sided confidence limit using the following as guidance:

designated bathing beach	*75% C.L.*
moderate use for bathing	*82% C.L.*
light use for bathing	*90% C. L.*
infrequent use for bathing	*95% C. L.*

based on a site-specific log standard deviation, or if site data are insufficient to establish a log standard deviation, then using 0.7 as the log standard deviation.

Note (1) - Only one indicator should be used. The Regulatory agency should select the appropriate indicator for its conditions.

3.2 U.S. EPA 823-R-07-006 “Report of the Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria” Released June 15, 2007 – Summary (EPA 2007b)

The U.S. EPA conducted an expert workshop to discuss the state of the science on recreational water quality research and implementation from March 26 –30, 2007. Forty-three national and international technical, scientific, and implementation experts from academia, numerous states, public interest groups, U.S. EPA, and other federal agencies participated. The purpose of the workshop was to obtain input on the “critical path” research and science needs for developing scientifically defensible new or revised CWA 304(a) recreational ambient water quality criteria (AWQC) in the near term with the goal of releasing the new or revised criteria by 2012 (5 years from now). Their goal was to recommend approaches to develop criteria that are scientifically sound, protective of the designated use, implementable for broad CWA purposes, and when implemented, provide for improved public health protection. This report summarized the Expert Workshop members’ recommended approach by which the decisions to accomplish their goals could be made.

Seven main breakout groups consisting of five to seven people per group contributed to each chapter of the report. The chapters were summaries of breakout group findings and included elements to consider such as their individual knowledge and insight to help U.S. EPA define the critical path research and science needs for the near term goal of revising criteria within five years. It also recognized the “state of the science”, the reality that research that cannot be completed within 2-3 years will not be helpful, and identified “next generation” criteria that might be useful for the next CWA criteria revision in 10 or 15 years.

The following is a list of each chapter with a short summary of the charge for the group and the key findings that were listed in the report:

1. **Approaches to Criteria Development** – Discussion focused on potential approaches for new or revised recreational water quality criteria development. Significant attention was directed to a “toolbox approach” because of the potential for greater flexibility in selecting situationally-appropriate indicators/methods, and increased options for implementation. The working definition of the Toolbox approach is quoted from the Experts Report in Information Box 2.

Information Box 2. Toolbox Approach for Recreational Water Quality Criteria.

> *”The toolbox approach is a set of potential microbiological (i.e. a microbe plus a specified enumeration method) and/or physico-chemical assays that could be employed alone, or in certain combinations, to protect and restore the recreational use of waters. The contents of the toolbox (the “tools”) would be used by State public health and water quality agencies for beach advisory/closing program purposes and for all other Water Quality Standard related regulatory purposes under the CWA. The level of risk (or public health protection) would be the same regardless of which tool is used.)” – (USEPA 2007b).*

Predictive models were identified as potential integral parts of the toolbox. Findings included recommendations to use modifications of the three most relevant water quality criteria setting

approaches: World Health Organization – use of sanitary inspection and microbial water quality assessments; European Union – use of microbial water quality assessments and probability of exposure to human pathogens; and the U.S. EPA 1986 criteria – use of microbial water quality assessments and adherence to geographic means and allowable exceedences of single sample maximums. These approaches included identification of critical research science needs.

2. **Pathogens, Pathogen Indicators, and Indicators of Fecal Contamination** – Strengths and limitations of indicators of fecal contamination, pathogen index microorganisms, and specific pathogens for development of new or revised recreational ambient water quality criteria were discussed (AWQC). Findings included detailed summaries of indicator and index microorganisms that are or could be used for monitoring. High research priorities included investigating and validating usefulness of quantitative polymerase chain reaction (qPCR) assays for various microorganisms, conducting health and epidemiological studies with a wide range of indicators/microbial source tracking organisms as possible to determine risk correlations with occurrences, and identifying and evaluating reproducible, accurate, and cost effective methods to use for monitoring. The tiered toolbox monitoring approach was described as a flexible site specific approach for water quality and source tracking. Tools would include suites of different methods to assess water quality using increasingly more technical and specific methods, depending upon circumstances. Fecal indicator bacteria combined with sanitary investigations, chemical and physical water quality parameters, and human or animal specific pathogen detection would make up the "tools" for the toolbox.

3. **Methods Development** – Discussion focused on methods for quantifying indicators and pathogens, such as culture-based methods, molecular-based methods (such as qPCR), and faster culture-based methods and their applicability for AWQC. Findings included classes of indicators, new methods for existing indicators, performance criteria, evaluation process for alternative indicators, proficiency and evaluation of source identification methods, secondary uses of indicators (such as for an early warning system to use for imminent human health risk), and research needs. Rapid methods that can determine fecal contamination source were favored. The Methods Workgroup determined that the eight methods listed in Table 1 were the most important and are ready for immediate use in studies.

Table 1. Most Important Methods Identified by the Expert's Workshop Methods Workgroup for Inclusion in Epidemiological Studies.

Target Organism	Technique/Target
Enterococci	PCR/*Esp* gene
E. coli	PCR/virulence genes
Human enteric viruses: adenoviruses and polyomavirus	PCR/DNA
Human enteric viruses: enterovirus and norovirus	PCR/RNA
Methanobrevibacter smithii	PCR/*nifH* gene
Clostridium perfringens	Culture
Coliphage	Culture or antibody assay
Bacteroides	PCR/human-specific markers

4. **Comparing Risks to Humans from Different Sources** – Relative risks of illness to humans in waters contaminated with human fecal material versus animal fecal material was the main focus of this group. Findings included use of epidemiological studies at beaches impacted by fecal contamination and use of quantitative microbial risk assessment using occurrence and exposure data from situational monitoring. Other findings included fate and transport, pathogen occurrence at point and non-point source impacted beaches, and bathing studies.

5. **Acceptable Risk** – Group discussed the level of risk to various populations that would be associated with numeric AWQC. U.S. EPA was interested in the science necessary to inform the policy decision regarding the target risk range and the process through which the policy decision could be reached. Findings included the usefulness of the term “acceptable risk” and group members felt it should be avoided. Other interesting findings included the suggestion to involve the public in the criteria setting process. Also, establishing the risk to children should be a high priority research area whereas risk to immunocompromised individuals should be managed through education and strategies to minimize exposure of these individuals.

6. **Modeling Applications to Criteria Development and Implementation** – Discussion included summary and status predictive modeling approaches and their potential applications in implementation of AWQC. Findings included the concurrence that models are the most useful, timely, and accurate method for predicting microbial water quality, and are particularly useful for public notification during and immediately following specific rainfall events. Sanitary investigations are crucial for triggering toolbox options and higher tiered water quality evaluations.

7. **Implementation Realities** – The group identified and considered factors that influence implementation of criteria for each of the CWA uses (beach monitoring and notification, development of National Pollutant Discharge Elimination System [NPDES] permits, assessments to determine use attainment, and development of TMDLs. Findings included a detailed discussion about the four principal program areas where recreational bacteria criteria are currently employed (notification and advisory programs, NPDES permitting, monitoring and assessment as part of the CWA, and development of TMDLs. The States will be charged with implementation and much work should be conducted simultaneously in order to make the transition possible. This will include training, laboratory certification for new tests, capital cost considerations, etc. Resource issues and implementation concerns should be considered.

Table 2 provides a brief summary of the key elements identified in the Expert’s Report that are relevant to this litigation. The Experts were charged with providing their opinions about what U.S. EPA should do to develop a critical path science plan to help guide the Agency research activities over the next two to three years in support of the development of new or revised recreational water criteria. The Experts also mentioned that not only would the subsequent criteria be used for evaluating water quality at coastal beaches, they are likely to be used for assessing the adequacy of disinfection of treated wastewater effluent for NPDES permits, and include water quality requirements for combined sewer overflows, blending practices, and municipal stormwater.

Table 2. Elements and Recommendations in the Expert's Workshop Report that are Significant to this Litigation.

U.S. EPA should fast-track studies to evaluate the performance criteria of source-specific microbial targets (e.g. human vs. non-human).
Risk evaluation for subpopulations of concern should be addressed.
Work to better understand the health basis for allowable exceedence frequencies of the criteria.
Work to understand the impact of regrowth of indicator bacteria and persistence in soil, sand, and sediments under different environmental conditions.
Work to understand the fate and transport characteristics of individual pathogens in the natural environment.
Work to develop approved test methods and implementation guidance for multiple matrices, such as recreational waters, wastewater effluent, biosolids, and soils.
Criteria development efforts should include consideration of the tiered toolbox approach. This would allow flexibility, particularly for selecting situationally appropriate indicators/methods and increased options for implementation. It would allow the use of varied techniques and approaches to achieve public health protection.
Once adopted, the new/revised criteria would be used for CWA purposes including 303(d) listings (identification of impaired waters that need TMDL'S); TMDL calculations; NPDES permits, and public notification at beaches.
Consider "the role research results play in the ability of State and federal regulators to explain and gain public acceptance of changes in the existing CWA programs".
The usefulness of TMDLs for bacteria was questioned because expressing pollutant loadings of bacteria or pathogens in terms of mass (the requisite basis for a Total Maximum Daily "Load" of a pollutant) is nonsensical.

3.3 U.S. EPA Critical Path Science Plan (USEPA 2007c) and Criteria Development Plan & Schedule (USEPA 2007e).

Summary of Goals of U.S. EPA scientific research:

U.S. EPA presented its research and development plans to develop new recreational water quality criteria in late August 2007. According to U.S. EPA, the studies it plans to conduct are intended to provide additional information for developing 1) an assessment of potential health risks, 2) appropriate and effective indicators for the presence of pathogens, 3) appropriate, accurate, expeditious, and cost-effective methods for detecting pathogen presence, and 4) guidance for the states in various geographic aquatic conditions.

Summary of Planned Research Activities:

U.S. EPA has proposed an ambitious five-year Critical Path Science Plan with 32 projects including indicators/methods development and validation studies, epidemiological studies/QMRA, modeling, determination of the appropriate levels of public health protection, and literature reviews. U.S. EPA proposed to focus on the most promising for short term completion and usefulness for rapid water quality monitoring and included modeling studies. These studies are planned to begin in 2007 and go through 2009.

Most of the methods studies appear to be focused on rapid tests to detect fecal indicator bacteria and coliphages and do not include pathogens. Attempts to pursue bacterial source tracking are proposed. U.S. EPA proposed a limited evaluation of combinations of indicators for different CWA programs (Project #18).

Projects designed to evaluate appropriate level of health protection include data analysis with new statistical programs on raw data from the 1986 studies upon which the current criteria are based. This is important since it can validate or refute existing "acceptable risk" levels. Also included are two other studies to evaluate applicability of existing data to other waters. The study description is vague and offers only inland fresh-water comparisons. Marine waters applicability is not included.

Epidemiological studies identified in the Critical Path Science Plan and other relevant studies are listed in Table 3. An additional two Great Lakes beach studies were conducted but the results have not been published and study details locations are not known and were not mentioned in the Plan. Of nine studies identified in the Plan, four were not committed for use in criteria development (U.S. EPA did not specifically say they would use the data). All four of these studies were in the marine matrix. One of these non-committed studies was conducted in Mississippi in 2005, but was interrupted by Hurricane Katrina. The other three studies are in southern California. U.S. EPA supports one, but commitment to use the data is not included in the Plan. The three California studies do include a robust list of pathogens, pathogen indicators, rapid methods, and other water quality parameters not included in any of the U.S. EPA supported epidemiological studies.

Table 3. Proposed Critical Path Science Plan and other Epidemiological Studies that Should be Considered for Criteria Development.

Location	Standard Methods	Novel Methods	Notes
1) Fairhope AL (2007)* 2) Goddard, RI (2007)*	Enterococci (EPA 1600) (Does not include other standard methods for fecal indicator bacteria)	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR All Bacteroides qPCR F+ specific coliphage by antibody assay	Marine water impacted by POTW effluent. Will include pharmaceutical and industrial chemical analysis.
3) Indiana Dunes, IN (2003)* 4) Cleveland, OH (2003)*	None reported	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR All *Bacteroides* qPCR F+ specific coliphage by antibody assay	Fresh water impacted by POTW effluent. (Wade et al., 2006a)
5) TBD (2008 – 2010)*	Enterococci (EPA 1600)	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR All *Bacteroides* qPCR F+ specific coliphage by antibody assay	Marine water impacted by POTW effluent at beach near previous study location.

Continued on next page.

Table 3 (continued). Proposed Critical Path Science Plan and other Epidemiological Studies that Should be Considered in Criteria Development.

Location	Standard Methods	Novel Methods	Notes
6) Edgewater Beach, MS (2005)**	None reported	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR All *Bacteroides* qPCR F+ specific coliphage by antibody assay	Marine water impacted by POTW effluent. Survey interrupted by Hurricane Katrina. 1,500 interviews completed. (Wade et al., 2006b)
7) Avalon, CA (2007)**	Enterococci Total coliforms Fecal coliforms (all by both MF and Idexx)	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR *Bacteroides thetaiotamicron* qPCR Coliphage by antibody assay (total analyses includes 35 indicators including human viruses)	Marine water impacted by a combination of sources including bird and wildlife feces, urban runoff, and leaking sanitary sewers.
8) Doheney, CA (2008)**	Enterococci Total coliforms Fecal coliforms (all by both MF and Idexx)	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR *Bacteroides thetaiotamicron* qPCR Coliphage by antibody assay (total analyses includes 35 indicators including human viruses)	Marine water impacted by animal fecal sources (mostly birds).
9) Malibu, CA (2008)**	Enterococci Total coliforms Fecal coliforms (all by both MF and Idexx)	*Enterococcus* by qPCR *E. coli* by qPCR Human *Bacteroides* qPCR *Bacteroides thetaiotamicron* qPCR Coliphage by antibody assay (total analyses includes 35 indicators including human viruses)	Marine water impacted by a combination of sources including birds and humans.

* Identified for use in criteria development in U.S. EPA Science Plan.
**Data not identified for use in criteria development in U.S. EPA Science Plan or Criteria Development Plan & Schedule.

No studies were planned for tropical environments such as Hawaii or Florida. Instead, the U.S. EPA proposes to conduct a comprehensive literature review to determine the extent to which indicators may perform differently in a topical environment compared to temperate or subtropical environments. The rationale for not conducting epidemiological studies in tropical climates is because "*…research to date has yielded ambiguous results as to what may be influencing the presence and growth of indicators and pathogens*" (USEPA 2007c). In summary, only three studies in the marine matrix were identified that could be used for criteria development and these were all located in temperate climates or the northeast US.

3.4 The Indicator Microorganisms

Routine examination of environmental water samples for human or animal intestinal pathogens can be time consuming, expensive, labor intensive, and pose a risk to the analyst. Thus, the indicator organism concept was developed as a faster way to predict the presence of the pathogens using inexpensive and safer procedures that can be used on a routine basis by trained

analysts. The concept was created early in the 1900s for assessing fecal contamination of our nation's waters and depends on the fact that feces contain billions of non-pathogenic microorganisms that can be easily detected. These non-pathogenic microorganisms are called "indicator microorganisms" and are currently used to determine if feces are present in water and other matrices. However, all of the indicator microorganisms described below can survive outside a host and multiply in the environment. Their natural habitats include sand, soils, water, vegetation (including flowers, algae, and seaweed), insects, and environments other than the intestinal tract of humans and animals (Mundt 1962, Geldreich et al, 1963). It is important to remember that the presence of these organisms does not confirm fecal contamination and so their presence provides suggestive, but not definitive evidence of sewage contamination or a public health risk. Methods for detecting the indicator organisms and terms describing them are provided below.

Detection Methods

Table 4 summarizes the U.S. EPA approved methods currently used to detect pathogen and pathogen indicator organisms in water. States typically only use the methods for total and fecal coliforms, *E. coli,* and enterococci, even though other methods are available. Some pathogen methods are expensive, time consuming, and require special equipment, laboratory facilities, and advanced expertise which makes them impractical for use in a routine monitoring program. Traditional methods for detecting culturable bacteria include either a qualitative (presence or absence) or quantitative approach (membrane filtration or most probable number calculation). Either approach is based on the premise that if the organism is in a water sample, it can be detected by culturing the sample under favorable conditions using specific biochemical reactions to select and confirm different microorganisms.

Waterborne pathogenic protozoa *Cryptosporidium* and *Giardia* are detected using filtration, immunomagnetic separation (IMS), and immunofluorescent assay (IFA). The method detects the oocysts and cysts, respectively, and does not determine viability or infectivity. Coliphage and enteric viruses require a host to multiply and are detected using cultures of host cells by enrichment, plaque, or cytopathic effect assays.

Table 4. Summary of Approved and Accepted Microbiological Methods for U.S. EPA Water Monitoring Regulations (USEPA 2007f).

Technique	Media	Method Designation[1]	Method Name (publication date)
		Total Coliforms	
Fermentation broth method	LTB -- BGLB Broth	SM 9221 B,C	Standard Total Coliform Fermentation Technique and Estimation of Bacterial Density (Standard Methods 18-20 Eds)
	P-A Broth -- BGLB Broth	SM 9221 D	Presence-Absence (P-A) Colifom Test (Standard Methods 18-20 Eds)
Enzyme substrate method	Colilert®, Colilert - 18®	SM 9223	Colilert Test (June 1992)
	Colisure Test[2]	SM 9223	Colisure Test (February 1994)
	Readycult® [3]	See footnote 3	Readycult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichla coli* in Finished Waters (November 2000, V.1.0)
	E*Colite® Test[4]	See footnote 4	Presence/Absence for Coliforms and *E. Coli* in Water (December 1997)
	Colitag® [5]	See footnote 5	Colitag® Product as a Test for Detection and Identification of Coliforms and *E. Coli* Bacteria in Drinking Water and Source Water as Required in National Primary Drinking Water Regulations (August 2001)
Membrane filter method	mEndo or LES-Endo -- LTB, BGLB	SM 9222 B,C	Standard Total Coliform Membrane Filter Procedure (Standard Methods 18-20 Eds)
	MI Medium	EPA 1604	Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002)
	m-ColiBlue24® Test[6]	see footnote 6	m-ColiBlue24® Test (August 1999)
	Chromocult agar® [7]	see footnote 7	Chromocult® Coliform Agar Presence/Absence Membrane Filter Test Method for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Finished Waters (November 2000 V. 1.0)
	Coliscan [8]	see footnote 8	Coliscan Test (August 2000)

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Table 4 (Continued). Summary of Approved and Accepted Microbiological Methods for U.S. EPA Water Monitoring Regulations (USEPA 2007f).

Technique	Media	Method Designation[1]	Method Name (publication date)
		Escherichia coli	
Enzyme substrate method	Colilert®, Colilert - 18®	SM 9223	Colilert Test (June 1992)
	Colisure Test[2]	SM 9223	Colisure Test (February 1994)
	Colitag® [5]	see footnote 5	Colitag® Product as a Test for Detection and Identification of Coliforms and *E. coli* Bacteria in Drinking Water and Source Water as Required in National Primary Drinking Water Regulations (August 2001)
	E*Colite® Test[4]	See footnote 4	Presence/Absence for Coliforms and *E. coli* in Water (December 1997)
	Readycult® [3]	See footnote 3	Readycult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichla coli* in Finished Waters (November 2000, Verson 1.0)
	LTB, P/A broth, M-Endo -- EC-MUG	SM 9221 B,D; SM 9222 B SM 9221 F	Standard Total Coliform Fermentation Technique and Estimation of Bacterial Density P-A test and *E. coli* confirmation (Standard Methods 18-20 Eds)
Membrane Filtration	mEndo or LES-Endo -- NA-MUG	SM 9222B	Standard Total Coliform Membrane Filter Procedure (Standard Methods 18-20 Eds)
	MI Medium	EPA 1604	Method 1604: Total Coliforms and Escherichia coli in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002)
	m-ColiBlue24® Test[6]	see footnote 6	m-ColiBlue24® Test (August 1999)
	Chromocult® Coliform Agar[7]	see footnote 7	Chromocult® Coliform Agar Presence/Absence Membrane Filter Test Method for Detection and Identificaiton of Coliform Bacteria and *Escherichla coli* in Finished Waters (November 2000. V. 1.0)
	Coliscan[8]	see footnote 8	Coliscan Test (August 2000)
	MTEC – urea agar	Method 1103.1	*Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using membrane-Thermotolerant *Escherichia coli* Agar (mTEC) (September 2002)
	Modified mTEC agar	EPA 1603	*Escherichia coli* (*E.coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC) (September 2002)

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Table 4 (Continued). Summary of Approved and Accepted Microbiological Methods for U.S. EPA Water Monitoring Regulations (USEPA 2007f).

Technique	Media	Method Designation[1]	Method Name (publication date)
		Fecal Coliforms	
Fermentation broth method	LTB -- EC broth	SM 9221 E	Fecal Coliform Procedure (Standard Methods 18-20 Eds)
	P/A Broth -- EC broth	SM 9221 D SM 9221 E	Presence-Absence (P-A) Coliform Test for Fecal Coliforms (Standard Methods 18-20 Eds)
	A-1 broth	SM 9221E	Fecal Coliform Procedure (Standard Methods 18-20 Eds)
Membrane Filtration	M-Endo medium -- EC broth	SM 9222 B SM 9221 E	Standard Total Coliform Membrane Filter Procedure for Fecal Coliforms (Standard Methods 18-20 Eds)
	MFC	SM 9222 D	Fecal Coliform Membrane Filter Procedure (Standard Methods 18-20 Eds)
		Enterococci	
Membrane Filtration	mEI agar	Method 1600	Enterococci in Water by Membrane Filtration Using membrane-*Enterococcus* Indoxyl-ß-D-Glucoside Agar (mEI) (September 2002)
	mE-EIA agar	Method 1106.1	Enterococci in Water by Membrane Filtration Using membrane-*Enterococcus*-Esculin Iron Agar (mE-EIA) (September 2002)
		Protozoa	
Filtration/IMS/IFA[9]	Does not assess viable organisms	Method 1623	*Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA (December 2005 update)
	Does not assess viable organisms	Method 1622	*Cryptosporidium* in Water by Filtration/IMS/FA (December 2005 update)
		Coliphage	
Enrichment Assay	Infects *E. coli* host	Method 1601	Male-specific (F+) and Somatic Coliphage in Water by Two-step Enrichment Procedure (April 2001)
Plaque Assay	Infects *E. coli* host	Method 1602	Male-specific (F+) and Somatic Coliphage in Water by Single Agar Layer (SAL) Procedure (April 2001)
		Enteric viruses of human origin	
Plaque Assay or Cytopathic Effect	Infects human tissue culture cells	EPA/600/4-84/013	USEPA Manual of Methods for Virology - EPA publication (1984)

[1] *Standard Methods for the Examination of Water and Wastewater*, 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005. The cited methods published in any of these three editions may be used.

[2] A description of the Colisure Test, Feb 28, 1994, may be obtained from **IDEXX Laboratories, Inc.**, One IDEXX Drive, Westbrook, ME 04092. The Colisure Test may be read after an incubation time of 24 hours.

[3] The Readycult® Coliforms 100 Presence/Absence Test is described in the document, "Readycult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichla coli* in Finished

Waters," November 2000, Verson 1.0, available from **EM Science** (an affiliate of Merck KGgA, Darmstadt Germany), 480 S. Democrat Road, Gibbstown, NJ 08027-1297, telephone 800-222-0342.

4 A description of the E*Colite® Test, "Presence/Absence for Coliforms and *E. Coli* in Water," Dec 21, 1997, is available from **Charm Sciences, Inc.**, 36 Franklin Street, Malden, MA 02148-4210.

5 Colitag® product for the determination of the presence/absence of total coliforms and *E. coli* is described in "Colitag® Product as a Test for Detection and Identification of Coliforms and *E. coli* Bacteria in Drinking Water and Source Water as Required in National Primary Drinking Water Regulations," August 2001, available from CPI International, Inc., 5580 Skylane Blvd., Santa Rosa, CA 95403, telephone 800-878-7654, Fax 707-545-7901, Internet address http://www.cpiinternational.com.

6 A description of the m-ColiBlue24® Test, Aug 17, 1999, is available from the **Hach Co.**, 100 Dayton Avenue, Ames, IA 50010.

7 Membrane Filter Technique using Chromocult® Coliform Agar is described in the document, "Chromocult® Coliform Agar Presence/Absence membrane Filter Test Method for Detection and Identificaiton of Coliform Bacteria and *Escherichla coli* in Finished Waters," November 2000. Version 1.0, available from **EM Science** (an affiliate of Merck KGgA, Darmstadt Germany), 480 S. Democrat Road, Gibbstown, NJ 08027-1297, telephone 800-222-0342.

8 A description of the Coliscan® test, August 10, 2000, can be obtained from **Micrology Laboratories**, LLC, P.O. Box 340, Goshen, IN 46527-0340.

9 Filtration/IMS/IFA is described in the document "Method 1623: *Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA - December 2005 Update (EPA 815-R-05-002).

Several other microbiological methods based on molecular or immunological approaches for detecting bacteria and viruses have been developed into standard operating procedures by U.S. EPA for use in water monitoring. The methods listed in Table 5 were provided by U.S. EPA though the discovery process and are close to being ready for validation and routine use.

Table 5. Summary of Microbiological Methods in Development for U.S. EPA Water Monitoring Regulations.

Technique	Media	Method Designation	Method Name
		Enterococci	
qPCR	Detects DNA	EPA 1606	Enterococci in Water and Wastewater by TaqMan® Quantitative Polymerase Chain Reaction (qPCR) Assay
	Detects DNA	EPA 1607	Enterococci in Water and Wastewater by Scorpion™ Quantitative Polymerase Chain Reaction (qPCR) Assay
		Coliphage	
Coliphage Latex Agglutination and Typing (CLAT)	Detects virus particles	Modified EPA 1601	Modified Method 1601: Male-Specific (F+) Coliphage in Water by Rapid Coliphage Enrichment Procedure and Latex Agglutination and Typing (CLAT) Assay (April 2007)
		Enterococci, Total *Bacteroides* and [TEXT REDACTED]	
qPCR	DNA	Rapid PCR Method	Rapid, PCR-Based Method for Measuring Total *Enterococci,* Total *Bacteroides* and [text redacted] in Water Samples

Fecal Indicator Bacteria

Fecal indicator bacteria are defined as the group of bacteria that are commonly used to detect the presence of human or animal feces. These include the enterococci, total coliforms, and fecal coliforms. The term used to describe the fecal indicator bacteria is used interchangeably with "indicators", "indicator organisms", "coliforms", and "coliform bacteria". The following is a summary of the most common terms related to the fecal indicator bacteria provided as background to clarify the terminology and to help develop the rationale for the opinions relayed in this report (Bitton 2005; Hurst et al., 2002).

Total Coliforms (TCs) – The TC group of indicator bacteria is composed of *Escherichia coli (E. coli)*, *Enterobacter, Klebsiella, and Citrobacter*; all of which are gram-negative[1] bacteria and are unrelated to the fecal streptococci and enterococci groups (see below). These bacteria are released in human and animal fecal material and are consequently found in high numbers in sewage. There are other sources of these bacteria as well (*i.e.*, environmental sources such as soil, vegetation, sediment, some surface waters, insects, etc.). As a result, their presence in certain environmental matrices does not guarantee that they are of a fecal origin. The TC group has been the most widely used indicator group for assessing wastewater treatment performance and for drinking water surveillance. They have also been used extensively for recreational water monitoring.

Fecal Coliforms (FCs) – The FC group is a subset of the TC group. It is composed of the thermotolerant or homeothermic *E. coli* and *Klebsiella*. The presence of FCs generally indicates pollution by fecal material from warm-blooded animals and is a more definitive indicator of homeothermic fecal contamination than the TCs. However, human and animal sources cannot be differentiated and there are instances in which *Klebsiella* from non-fecal sources may be found.

E. coli – *E. coli* is a member of both the FC and TC groups. It has been shown to be a more specific indicator for the presence of fecal contamination than the FC group. Its presence in surface waters or drinking water is accepted as a strong indication of recent fecal contamination, since they typically do not survive long in temperate environments. However, they have been known to survive and proliferate in tropical environments, which is a significant drawback for use as an indicator in those zones.

Fecal Streptococcus (FS) – The fecal streptococci are gram-positive[1] bacteria and are not related to the coliform bacteria. Members of the fecal streptococcus group inhabit the intestines of humans, warm blooded-animals, and birds. The group consists of at least 13 different species in the *Streptococcus* and *Enterococcus* genera. They have been used extensively as indicators of fecal pollution and have also been used in conjunction with FCs in the controversial and highly

[1] *"Definition of Gram Stain: The Danish bacteriologist J.M.C. Gram (1853- 1938) devised a method of staining bacteria using a dye called crystal (gentian) violet. Gram's method helps distinguish between different types of bacteria. The gram-staining characteristics of bacteria are denoted as positive or negative, depending upon whether the bacteria take up and retain the crystal violet stain or not. Gram-positive bacteria retain the color of the crystal violet stain and include many pathogens such as staphylococci ("staph"), streptococci ("strep"), pneumococci, and the bacterium responsible for diphtheria (Cornynebacterium diphtheriae) and anthrax (Bacillus anthracis). Gram-negative bacteria lose the crystal violet stain and include most of the bacteria normally found in the gastrointestinal tract that as well as gonococci (venereal disease) and meningococci (bacterial meningitis). The organisms responsible for cholera and bubonic plague are Gram-negative,"* (http://www.medterms.com).

debated FC/FS ratio. The organisms in the FS group show a strong relationship with health hazards (gastrointestinal symptoms) associated with bathing in marine and freshwater environments.

Enterococci – The enterococci are a subset of the Fecal Streptococcus group and are currently thought to be more closely related to the presence of human feces than are the other fecal streptococci. Some members of this group are salt tolerant and are used to determine the extent of fecal contamination of recreational surface waters including marine and freshwater recreational areas. However, recent evidence suggests that the enterococci are ubiquitous in the environment and are capable of surviving and multiplying in the water column and in sand and soils.

It is important to emphasize the fact that the vast majority of enteric bacteria do not cause disease and are known to provide many health benefits. In fact, probiotics are used in Good Start Natural Cultures infant formula produced by Nestle. The formula contains *Bifidobacterium lactis* and has been shown to produce a similar immune stimulation compared to babies that are breast-fed. Numerous studies show beneficial uses for consuming enteric bacteria (Harder 2002, Moal and Servin 2006, Gluk and Gebbers 2003; Consumer Reports 2005)

Use of fecal indicator bacteria for water quality monitoring became a popular concept in the 1950s and 1960s. Much of the early work to establish the utility for using a substitute to a pathogen for monitoring water quality was conducted following increased use of disinfection for potable water treatment. Pathogenic bacteria were difficult to culture from water and soil samples since their concentrations are so low (compared to clinical detection) and the growth media allowed other bacteria to multiply and interfere with results. Testing for the pathogens continues to be problematic since it is generally labor intensive and time consuming. However, advances in molecular biology have considerably improved the ability to detect pathogens and organisms that have public health significance.

Much debate over the use and application of the fecal indicator bacteria has been ongoing since they were first used as a substitute to determine pathogen presence. Several interesting papers were written in the late 1950's and 1960's to determine the occurrence of the total and fecal coliforms and enterococci in the environment. In an effort to establish the utility and acceptance of the coliform test for stream investigations or for surface water quality evaluations, the Division of Water Supply and Pollution Control, U.S. Public Health Service (now part of U.S. EPA) investigated the occurrence of coliforms, fecal coliforms, and streptococci in vegetation and insects (Geldreich et al, 1963). The debate was whether the coliforms and enterococci groups could multiply in the environment and therefore should not be used to measure water quality. The authors mentioned, *"The sanitary significance of a bacterial indicator of pollution is determined from accurate information on its probable sources and quantitative distribution in nature. Interpretation of this significance for the coliform group and the fecal coliform segment within the group has been, and currently is, a controversial subject. Much the same case can be made for the fecal streptococcus group. The coliform group and the fecal streptococcus group are composed of many species, of which some predominate in warm-blooded animal feces, and others may predominate in soil and on vegetation."* To determine if bacteria in water were derived from animals or plants, they examined 152 species of plants. Even though water and

animal samples were not included in the analyses, the authors concluded that since the fecal coliforms were not present on plants in numbers as high as other published studies, then they must be derived from animals. Therefore the coliforms detected in surface waters were largely derived from fecal pollution of animal origin. This confusing conclusion was one of the key papers used as the scientific basis for using fecal indicator bacteria for water quality monitoring and remains the culprit of the five-decade debate. It is interesting that the paper also established use of the “Completed Coliform Test” which was later approved by U.S. EPA for monitoring water samples. This situation seems very similar to the current pressure by U.S. EPA for using the enteroccci qPCR test.

Numerous studies throughout the world have evaluated the occurrence, seasonal variation, and survival of fecal indicator bacteria and pathogens in soil, water, biosolids, sands, and other matrices (Gallagher and Spino, 1968; Clark et al, 1982; Wright 1982; Parker and Mee, 1982; Zaleski et al, 2005; Van Donsel et al., 1967; Bonilla et al., 2007; Yamahara et al., 2007; Pettibone et al., 1987; Stuart et al., 1976, Santoro and Boehm 2007; Marzouk et al., 1980; Shiaris et al., 1987; Gerba et al., 1979; Mundt 1962). This list of references represents a fraction of the publications on this topic in the last 45 years. The overarching consensus of the studies is that the occurrence of fecal indicator bacteria does not reliably correlate with occurrence of pathogenic enteric bacteria, viruses, or protozoa in water or soils. Furthermore, early studies to evaluate the occurrence and usefulness of the streptococci/enterococci as fecal indicators concluded that while the organisms do survive longer in the marine environment, compared to fecal coliforms and *E. coli,* it is clear that they not only survive but they multiply. This attribute makes them unsuitable for use alone as a measure of water quality, particularly for evaluating storm water run off and ankle depth water samples.

Criteria listed in Table 6 were established to provide guidelines for the long time pursuit of the most ideal indicator organism (Bitton 2005).

Table 6. Criteria for an Ideal Indicator Organism (Bitton 2005).

The organism should be useful for all types of water
The organism should be present when enteric pathogens are present and absent when pathogens are absent
The organism should have a reasonably longer survival time than the hardiest enteric pathogen
The organism should not grow or multiply in water
The testing method should be easy to perform
The density of the indicator organism should have some direct relationship to the degree of fecal pollution
The organism should be a member of the intestinal microflora of warm-blooded animals

Unfortunately, no individual indicator organism meets all the criteria for all water quality monitoring applications. The fecal indicator bacteria have been used for almost 100 years even though it is commonly known that they have deficiencies as presented in Table 7.

Table 7. Deficiencies with the use of Fecal Coliform Bacteria as Indicators of Water Quality.

Regrow in aquatic environments, sand, and soil
Regrow in water distribution systems, catchments, & storm drains
Suppressed by high background bacterial growth
Not indicative of a health threat
No relationship between enteric protozoan and viral concentration

Environmental Detection

The evidence overwhelmingly suggests that the fecal indicator bacteria are normal endemic residents in the environment and survive and multiply in wet and dry sand and soils. Research from the 1960s, including the Division of Water Supply and Pollution Control, U.S. Public Health Services (currently part of U.S. EPA), evaluated the occurrence of coliforms, fecal coliforms, and streptococci on vegetation (flowers and leaves of plants, trees, ferns, and food crops in both agricultural and wild environments), soil, and insects. Studies showed that *Steptococcus fecalis* (now referred to as *Enterococcus fecalis*) constituted the majority of all strains isolated from vegetation and insects and that some of the strains were capable of hydrolyzing starch (indicative of the enteric *Enterococcus*) (Mundt 1962; Geldreich et al. 1963). Their work supported use of fecal coliforms and the "Completed Coliform Test" for identifying fecal pollution of animal origin and suggested that enterococci were ubiquitous in the environment.

Numerous studies have evaluated the occurrence of fecal indicator bacteria in the environment and it is well known that the organisms multiply in water, sand, and soils. An early study from the Federal Water Pollution Control Administration clearly showed evidence of "aftergrowth" of coliforms (referred by the authors as "non-fecal coliforms") in soil as a result of temperature and rainfall variations. They concluded that the aftergrowth contributed to the variations in bacterial counts of storm-water runoff, and said that there was no relation to the sanitary history of the drainage area (Van Donsel et al, 1967). The authors reviewed the literature and determined that fecal streptococci were ubiquitous in the environment, probably of no sanitary significance, and that they constitute a reservoir of organisms that find their way into storm water and cause misleading results. The authors also noted that the repeated aftergrowth of total coliform bacteria and apparent relationship with weather conditions makes it unreliable for use as an indicator of new contamination and stated that "total coliforms…are a poor indicator for water subject to storm-water contamination." However, the utility for use of total coliforms as an indicator in drinking water was still useful.

Recently, Stanford researchers reported *Enterococcus* bacteria in samples of beach sand from 50 of 55 beaches sampled along the California coast from Mexico border to Oregon border. *E. coli* were found at 34 of the 55 beaches (Yamahara et al., 2007). In an experiment at one specific beach in Monterey, they determined that the beach sand appeared to be a reservoir of *Enterococcus*. The researchers performed a mass balance calculation indicating that the bacteria in the sand were apparently entering the water at concentrations high enough to produce levels in the water above the single sample maximum criteria of 104/100 ml for enterococcus. Samples

collected 20 minutes apart for 24 hours presented tidally influenced bacteria levels with high tides washing the bacteria into the water column (Yamahara et al., 2007).

A two year study at three tropical beaches in south Florida found fecal indicator bacteria, including enterococcus, consistently present at higher levels in wet and dry sand than in the water column (Bonilla et al., 2007). Like the Boehm study, they found that both fecal indicator bacteria levels in sand and water were tidally influenced. Part of the study included a Prospective Cohort Study with 1491 participants to evaluate possible health effects with exposure to water, wet sand, and dry sand. Their study showed that illness rates in non-beach-goers were higher than in beach goers (15.3/100 and 8.5/100, respectively), regardless of whether the beach-goers swam or not. While an inverse relationship between coliphages and FIB was observed, somatic coliphage were more prevalent than the F+ specific coliphage, suggesting resident endemic coliphage and lack of evidence of human fecal pollution.

Indicator bacteria exceedences that lead to beach advisories and closings at the more than 400 beaches monitored in California and 307 beaches in Florida are predominately due to exceedences of bacteria "from unknown sources of contamination" (Dorfman and Stoner 2007). California advisories are mostly due to enterococci exceedences. It is notable that this indicator is ubiquitous in the sand water interface - including at the "ankle-depth" designated sampling location used throughout California (and many other states). The apparent ability of these bacteria to survive and grow in this environment calls in to question their value for assessing risk to swimmers.

Association Between Fecal Indicator Bacteria and Adverse Health Effects

Authors of the Santa Monica Bay Epidemiological Study report reviewed results of other studies and stated "*To date, the reported results trying to associate elevated indicator counts with health outcomes have been inconsistent*," (Haile et al., 1996). Their discussion asserts that the approach taken by Cabelli et al. in the U.S. EPA epidemiological studies that the 1986 criteria are based upon, was meant to answer the question if bacterial indicators, as commonly measured by health departments, do predict risk of adverse health effects. In theory, if the relationship is positive, then it would make sense to use the bacteria to develop criteria. However, the authors mention as seen in a number of comparison studies with respect to specific indicators and epidemiological studies that included water quality assessment with fecal indicator bacteria, significant correlation with increased illness is sporadic and appears to be more consistent only with high levels. For example, cutoff points showed some increased risk when the fecal indicator bacteria were >400 CFU fecal coliforms/100ml, >10,000 CFU total coliforms/100ml, and >106 CFU enterococcus/100ml (Haile et al., 1996). It should be noted that an author of the report indicated these data showed weak correlations and were significantly manipulated to produce these conclusions (personal communication).

Since Haile et al. (1996) reviewed epidemiological data, reported results remain inconsistent and an uncertainty remains about how reliable fecal indicator bacteria are for regulating water quality. U.S. EPA conducted a systematic review and meta-analysis of data from 27 epidemiological studies that included water quality measures and health outcomes (Wade et al., 2003). The reviewed studies included the Cabelli studies that the U.S. EPA 1986 criteria are

based on. Figure 1 shows the scatter plots for the results of the weighted regressions between (a) enterococci and (b) *E. coli* density and the natural log relative risk for GI illness in marine and fresh water, respectively. While the correlation (r) of relative risk and enterococci density was 37% (p=0.05), correlation for *E. coli* was 86% (p=0.63). The authors explained that enterococci had the only significant correlation among GI illness and the other fecal indicator bacteria evaluated, including fecal coliforms, *E. coli,* and total coliforms. They also mentioned that based on the epidemiological studies that they reviewed, no single indicator was consistently able to predict illness in all environments at all times. However, Wade did support the use of enterococci and *E. coli* as adequate indicators of GI illness in marine and fresh water, respectively (2003). Results of the comparison show a weak correlation and do not strongly support their conclusions. This is relevant since this study and the recent U.S. EPA epidemiological study at the Great Lakes beaches have been used to justify the use of enterococci and *E. coli* for recreational water monitoring (Wade et al., 2006).

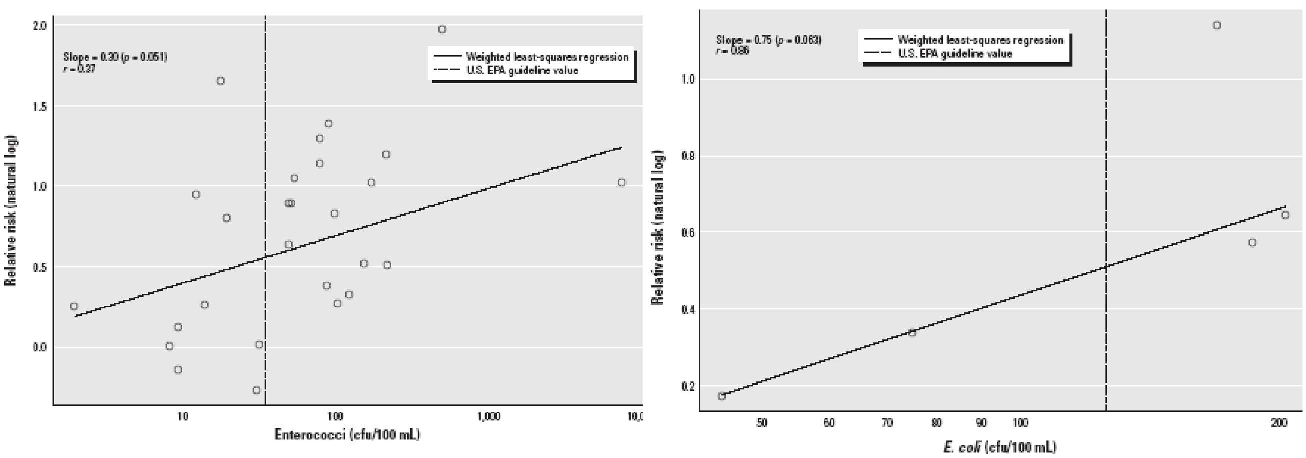

Figure 1. Scatterplot and weighted regression (weighted by the inverse of the standard error of the natural log relative risk) of natural log relative risks of GI illness from: a) marine water studies as a function of enterococci density; and b) freshwater studies as a function of *E. coli* density (Original figure published in Wade et al., 2003).

A recent epidemiological study at a beach with non-point source fecal contamination in Mission Bay, CA apparently found no increased risk of illness associated with elevated levels of enterococcus or other fecal indicator bacteria (Colford et al., 2007). Another epidemiology study at a beach impacted by a high volume of urban runoff in storm drains in Santa Monica, CA had weak correlation between the indicator bacteria occurrence and relative risk of illness (Haile et al., 1996).

Significant economic consequences have been realized in states and agencies implementing mitigation efforts to address spill events, combined sewer overflows, blending events and to meet TMDL requirements for storm water management. The potential for fecal indicator bacteria to survive and populate the sand and soil, particularly after sewage spills or other historical contamination events is an important issue that is not addressed in the literature. Neither is the relevance the information has for public health protection.

The Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) wrote a Pathogen Criteria White Paper describing the States' issues with the current status of pathogen criteria (ASIWPCA 2005 in Appendix D). The paper provides an excellent brief history and chronology of the criteria setting process for the use of indicators for pathogen presence. It also discusses six issues and a proposed plan of action for developing pathogen criteria and implementation guidance for the criteria. Issues include:

1. The scientific validity of the 1986 criteria;
2. The utility of the most recent Great Lakes epidemiology study for marine and inland freshwaters;
3. Substantial State implementation concerns;
4. State determination that other activities are "as protective as" adoption of the 1986 criteria document;
5. Need for U.S. EPA to provide more scientific data and information to States for implementation of bacteria criteria;
6. Need for U.S. EPA to provide more scientific information concerning the QPCRCE test method and its practical application.

The ASIWPCA proposed plan of action is based on the States' frustrations with lack of guidance by U.S. EPA to develop and implement pathogen criteria. It includes a recommendation for dialogue between States and U.S. EPA to work with each other to resolve the matters. The short paper highlights much of the main concerns that were brought up in the GAO report and in this litigation.

4. Expert Opinions

4.1 State of the Science

It is my opinion that the proposed studies and schedules outlined in the U.S. EPA Critical Path Science Plan and Criteria Development Plan & Schedule are very ambitious, but I believe the proposed studies and research could be completed and the criteria could be revised or developed in the proposed schedules. However, I strongly believe that the proposed studies and schedules have the following fundamental fatal flaws that preclude revision of current criteria and development of new scientifically-sound, appropriately protective criteria:

1. U.S. EPA is basing all the studies on indicator organisms that do not adequately predict public health risk;

2. U.S. EPA is being requested to fit a new basis for evaluating and governing water quality directives into a strict schedule. This is impossible to accomplish since the results of studies may significantly change the direction of the research;

3. U.S. EPA did not build in off-ramps and access points for rejecting current methods, or considering new methods and approaches for inclusion in the proposed studies;

4. U.S. EPA's proposed schedules for studies and criteria development did not include interim goals, checkpoints, or contingencies. These steps are necessary to obtain stakeholder input and peer-reviewed guidance.

It seems as though U.S. EPA wrote the Science Plan and Schedule without considering the overarching problems associated with using fecal indicator bacteria as measures of water quality and evaluating risk. U.S. EPA's apparent assumption that the proposed studies will demonstrate a credible linkage between fecal indicator bacteria with human health risk is not supported by previous studies. If the Science Plan is approved in its current format, and U.S. EPA permits use of *Enterococcus* qPCR for reporting water quality monitoring data, one would predict a situation similar to the present one except we will know the results of testing faster. This will not resolve the fundamental issues that have been debated for over 20 years.

Through scientific advances and approximately 100 years of water quality research, we do have the tools we need to conduct appropriate studies that will allow adequate evaluation of all types of illness, pathogens, coastal waters, and sources of beach water pollution. Results of these studies should provide the necessary information for U.S. EPA to publish revised water quality criteria (including a revised list of test methods) for pathogens and pathogen indicators for use in coastal recreational waters. We have the ability to make necessary changes and overhaul the water quality monitoring program, but the Science Plan and schedule that U.S. EPA proposed will not accomplish this. Instead, it appears that if U.S. EPA accomplishes the proposed tasks, it will only provide justification for approval of one or two new rapid methods for detecting fecal indicator bacteria and possibly a coliphage.

Fecal indicator bacteria are 'indicators', and as the term suggests, merely indicate the possible presence of human fecal pollution. They can multiply in the environment and most are not pathogenic. The problem is that there is mounting evidence suggesting that the fecal indicator bacteria, particularly the enterococci, will take up residence in sand and soils and can contribute to exceedences at bathing beaches that may not be currently impacted by treated or untreated human fecal pollution.

Furthermore, decades of attempts to correlate pathogen and fecal indicator bacteria presence in water, soils, and sand have not been successful. Evidence to support use of fecal indicator bacteria for predicting adverse health outcomes has also not been well established.

Taken together, evidence suggests that the fecal indicator bacteria alone are not appropriate for indicating a health risk. Furthermore, various pieces of information make it increasingly difficult to accept the U.S. EPA guidance that *Enterococcus* is the single best indicator for determining health risk at coastal recreational beaches. Not only are there issues with the bacteria multiplying in the environment, but DNA based methods such as the proposed qPCR approaches, can only detect DNA. It is well established that DNA can be found in the absence of live, viable, and infectious organisms, and should not be used to measure the effectiveness of disinfection of treated wastewater. Considering that this particular group of organisms is the focus of the qPCR rapid method, and that method is based on DNA detection, it is highly possible to produce excessive erroneous results. In effect, it would be possible to unnecessarily

impact recreational activities at beaches from false positive results and also to underestimate the risk to swimmers due to false negative results. Much work still needs to be done to understand these issues and that work is not proposed in the Science Plan.

The purpose of the country's water pollution control programs is to determine if practices by clean water agencies are effective or not and whether there is a real risk of people becoming ill from pathogens that may be present. Evidence supporting the utility for using fecal indicator bacteria remains inconsistent and an uncertainty exists about how reliable they are for regulating water quality. It is difficult to support using a target organism that multiplies in the environment to assess risk or depend on it as the only measure for water quality. However, new rapid detection methods such as qPCR for enterococci, other fecal indicator bacteria, and pathogens could be very useful in a multiple tiered toolbox approach to model and monitor coastal recreational water quality.

The concern with the work proposed in the Science Plan and Schedule is the reliance on the continued use of fecal indicator bacteria for predicting health risk in coastal recreational water. The evidence clearly suggests that the fecal indicator bacteria are not adequate and should not be used as solitary components of future revised water quality criteria

4.2 U.S. EPA Critical Path Science Plan

The Report of the Experts Scientific Workgroup on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria was an excellent compilation and summary of the state of the science with regard to recreational water quality monitoring, regulation, and all the associated key issues. The Report identified the core research needs that would enable U.S. EPA to transition and make the changes necessary to update the coastal recreational water quality criteria. The Report suggested a route to obtain the necessary monitoring tools needed to achieve the goals of developing criteria that are based on sound scientific, legal, policy, and technical analyses that can efficiently and effectively be implemented and enforced to achieve public health protection. However, the U.S. EPA Critical Path Science Plan was not consistent with the Expert's Report.

The U.S. EPA Critical Path Science Plan acknowledged some of the key issues identified in the Expert's Report, but in general, ignored the Experts Report recommendations. It is possible that U.S. EPA focused on the basics to accomplish what needed to be done in a short time due to the litigation and that promulgation issues were anticipated. **However, the fundamental weakness of the Science Plan is that the U.S. EPA is basing all the work on fecal indicator organisms that are not proven to adequately predict public health risk.** This raises many implications for U.S. EPA since their Plan is based on the use of the *Enterococcus* qPCR rapid method for much of the proposed work.

The Science Plan continues to identify use of fecal indicator bacteria as exact measures for water quality, upholding the rationale that gastrointestinal illness is the most important endpoint and adverse health effect. The motivation for the use of fecal indicator bacteria are founded on studies conducted in the 1940's and 1950's including epidemiological studies at bathing beaches

known to be impacted by high levels of domestic sewage. Major progress in sewage and water treatment by clean water agencies has significantly improved the quality of our nation's waters since the 1970's when the Federal Water Pollution Control Act amendments and the Clean Water Act were passed.

In general, the Science Plan studies were vague and did not provide enough detail for a critical review. As such, the following is a summary of the weakness in four main areas of the U.S. EPA Critical Path Science Plan:

Epidemiological Studies:

- No tropical beaches were included in the epidemiology studies (CA, HI, FL);
- Studies focus mainly in Great Lakes regions and east coast;
- No stormwater runoff beaches included in the epidemiology studies;
- No small inland lakes included – focus is on extrapolating data, instead;
- Focus mainly on POTW impacted beaches with high visitation;
- Water quality analyses too narrow: focuses only on rapid qPCR methods, standard methods for point of reference not included, human specific pathogens & pathogen indicators not included;
- Externally developed water quality methods not considered;
- No bird impacted beaches included;
- No commitment to use external epidemiological study data for criteria development.

Methods Development and Validation Studies:

- Limited source studies (e.g. human or animal fecal discrimination);
- No studies to develop tiered toolbox for water quality evaluation;
- Quantitative sanitary surveys not used in epidemiological studies;
- Model studies in limited geographical area – need to include highest swimmer-day beaches;
- Not clear if sanitary surveys are included in models;
- Externally developed methods not considered and no apparent way to include them.

Risk Evaluation Studies:

- Justification for different risk levels and criteria for marine and fresh water is unclear;
- Proposing "epidemiology study or QMRA" in several studies - need to do both since QMRA should support the epidemiology studies and used for validating models;
- "Acceptable risk" should be clearly defined.

Selected Microorganisms/Analyses:

- Studies focus on limited analyses (e.g. *Enterococcus* qPCR);
- U.S. EPA is not using the Expert's Report recommended methods in the marine beach epidemiology studies – only bacteriophage by antibody assay and Enterococci by MF and qPCR;

- Regrowth and tropical environments should be addressed;
- Correlation of pathogen and indicator studies not clear and limited.

Several main issues about the proposed epidemiological studies in the Science Plan are listed below with more detail to explain my rationale for the comment:

1. The Science Plan describes conducting or supporting epidemiological studies at three marine beaches that are impacted by treated wastewater effluent discharge. The study design is nearly identical to the recently completed Great Lakes Study and will include water quality measures and compare health outcome to indicator occurrence in order to determine the correlation between the parameters. Proposed studies include the rapid method analysis of coliphage, enterococci, and *E. coli*. The proposed list of microbial water quality parameters is too narrow and does not include pathogens or traditional culture methods.

2. The proposed epidemiological studies do not include pathogens or other alternative indicators that can provide relevant information to allow an adequate risk evaluation. The experts attending the Expert's Workshop were asked to identify near-term studies that U.S. EPA could complete in a reasonable amount of time and use for criteria development. The proposed studies in the U.S. EPA Science Plan were a fraction of those recommended in the Expert's Report and are based on the occurrence of a select small group of fecal indicator bacteria, using only the new rapid methods such as qPCR and antibody assay for detecting them. Standard methods that are currently used (and that could be used as points of reference) were not included in the suite of analyses and most of the Experts Report recommended methods for alternative indicators were not addressed (see Table 1).

3. The U.S. EPA proposes to conduct QMRA and/or epidemiological studies at only two other beaches; one at a fresh water beach impacted by agricultural animal fecal sources and the other is either in fresh or marine water impacted by urban runoff. Considering that the U.S. EPA's epidemiological studies have multiple weaknesses, it would be inappropriate to conduct the QMRA without the epidemiological data to back up the models. U.S. EPA should conduct QMRA and epidemiological studies **simultaneously** and include more parameters and analyses. Conducting QMRA without epidemiological studies to support the models is inappropriate.

4. It is disconcerting that the U.S. EPA has completed 4 epidemiological studies but has not released data from two of them. These studies were conducted from 2002 to 2003. Those epidemiological study designs did not include some existing indicator organisms (total and fecal coliforms or *E. coli* by membrane filtration) in suite of analyses and neither do the proposed studies.

5. U.S. EPA mentioned that the Avalon study and two other studies to be conducted by SCCWRP (Doheney and Malibu Beaches in CA) but did not mention that the data obtained from those studies will be used in developing criteria. They should commit to using data from scientifically robust studies.

6. The U.S. EPA focuses the epidemiological studies mostly on the Great Lakes regions at beaches that are not used year-round. Florida, California, and Hawaii have the most swimming days in the country and the Science Plan doesn't call for any epidemiological studies to be conducted in tropical environments. It is imperative to understand public health risks in all environments.

7. The Science Plan does not define terms of adopting acceptable risk levels. The term "acceptable risk" is confusing and there is much debate with regard to the application for the measurement of risk. It is also important to know what to expect for a significant correlation between indicator occurrence and outcome. The plan should outline the approach for determining the best predictive measure of adverse health outcome and address the health risk if spill events, CSOs, blending, accidental fecal release, etc., occurs, and pathogens are released. It should define how long the pathogens would survive in the environment and what health risk would be associated with those events. Finally, it should be able to define what is reasonable to use to measure impaired water and risk.

Other concerns include EPA's approach to addressing the proposed methods, their studies related to risk evaluation, and the selected organisms to use in the proposed studies. Also, public education and risk communication are key to disseminating the information about water quality at swimming beaches. These aspects should be included in the Science Plan or at least in long term goals for the program but it is not apparent that this type of mitigation is specifically addressed.

Finding the wrong organism faster is not the answer to the problem. The answer to the problem is that the fecal indicator bacteria should not be used as a sole measure of water quality. It is not a one-size-fits-all problem so no single organism or approach for water quality monitoring is sufficient. U.S. EPA needs to conduct studies to identify what the right approach is and what combinations of water quality parameters are sufficient to adequately measure water quality.

Molecular methods have already been developed for pathogens and indicator organisms and some of them are ready to be used routinely for water quality monitoring. However, even if the methods appear to be standardized in the lab that developed the method, other laboratories attempting to replicate the procedures will inevitably have problems. Also, different laboratories have different preferences for different reagents, instruments, and procedures, which makes standardizing the methods between laboratories difficult. It is important to include development of an implementation plan to ensure consistency, precision, and accuracy of data among and between laboratories.

The existing Science Plan could provide more tools for use in the interim. The currently accepted indicator microorganisms used alone do not provide the full potential for predicting public health risk and the overall approach for water quality risk evaluation should be overhauled. If providing the country with recreational water quality guidelines and criteria that are protective of public health is what is intended by the request to initiate and complete appropriate studies, then the current Science Plan is not appropriate, but a step in the right

direction – but only if human specific pathogens and a robust suite of analyses and outcomes are considered in the proposed epidemiological studies.

The Science Plan was written in a way that it could be a reasonable approach to finding an interim endpoint that could provide enough information to develop temporary revised proposed guidelines for assessing potential risk to human health (not criteria). These goals might be accomplished within 5 years IF U.S. EPA can complete the studies and IF they can expedite peer review and interim guidelines development. But, I believe there is much work still to be done to fully answer the questions and it will require a long term effort by U.S. EPA – much more than 5 or even 10 years. It is not possible for U.S. EPA to fulfill the expectation to find the perfect indicator, suite of indicators, develop and validate new methods, conduct epidemiological and quantitative microbial risk assessment studies with those methods, or determine risk, particularly for children, without doing more work than what is proposed.

The tiered toolbox approach to monitoring and water quality assessment as well as use of real-time water quality prediction models that include land based observational data in addition to microbial water quality data appear to be the most applicable and relevant tools that could be developed and implemented in near term. This was clearly identified in the Expert's Report and was mentioned in the Plan. My opinion is that this is the best approach for finding fast (near or real-time) evaluation of water quality.

In summary, the following recommendations could be helpful to improve the Science Plan and provide necessary information to achieve the goals to improve recreational water quality.

1.) Include more parameters in the epidemiological studies that include multiple symptoms and multiple potential indicators and pathogens as recommended in the Expert's report;

3.) Conduct epidemiological studies with water quality models that predict real time water quality while also including expanded symptoms and indicators;

4.) Develop multiple tiered toolbox approach for criteria that includes sanitary survey, water quality information, guidance for states;

5.) Conduct comparison of pathogen and indicator occurrence and survival studies in various water matrices to understand the relationship between them;

6.) Improve and standardize sample collection procedures for use with molecular methods;

7.) Develop guidance for agencies to implement new methods.

4.3 U.S. EPA Criteria Development Plan & Schedule

The U.S. EPA Criteria Development Plan & Schedule (Schedule) is highly ambitious and does not consider contingencies in case set backs are encountered. It also does not include a clear path with checkpoints to conduct and finish the necessary research first. For instance, if studies

show a big risk from non-human feces, the direction of the research will have to be changed. These weaknesses were also noted by U.S. EPA's own peer reviewers (USEPA 2007d). Hurricane Katrina-like events or other major setbacks could occur during the time period of the proposed studies. This would set back the schedule in both time and resources and this should be accounted for. U.S. EPA should also consider alternative studies if the planned studies do not provide appropriate information.

The following necessary schedule and input issues were not accounted for in the Schedule and are integral to the success of the criteria development process:

1.) Public input;
2.) Policy decisions;
3.) Stakeholder input;
4.) Inter-agency reviews;
5.) Intra-agency reviews.

Following completion of the proposed research and studies, U.S. EPA should conduct an interim stakeholder meeting to review results of studies and literature surveys to assess the current status of research efforts. As studies are completed, stakeholder meetings should be convened and input considered prior to proceeding. If studies show a clear correlation between adverse health outcomes and various pathogens and/or indicator occurrences, then it will expedite the process. However, if there is indication that particular indicators do not correlate with health risk, trouble with validating methods, or if confounding evidence suggests that the qPCR methods for *E. coli* and enterococci cannot give reliable information about the microbial water quality for organisms of public health significance, then the research plan will need to be reevaluated.

Given the additional studies I believe need to be done, the proposed time frame for the Schedule is too short to be reasonable. Three years to complete the studies and 2 years to complete the criteria does not provide enough time to make significant acceptable revisions to the criteria, which include adopting a new approach for monitoring recreational water quality. The Schedule is not going to achieve the goal of evaluating all types of illnesses, pathogens, coastal waters, and sources of beach water pollution within five years.

It would be more appropriate to define a long-term Criteria Development Plan & Schedule. The first step in such a plan would be to amend the current criteria with interim guidelines. Near term goals should be included, with a main goal to establish a water quality monitoring toolbox. It is essential to have multiple lines of evidence to make an accurate assessment of water quality since determining a single perfect indicator/predictor/measure of water quality and risk is not likely. But it is possible that a holistic management strategy can be developed that would be protective. On a longer term, a goal of the Schedule should be to refine the toolbox as validated methods are developed and information becomes available.

Public education and risk communication were not included in the Schedule. Since these are key factors to disseminate water quality information, they should be included in the U.S. EPA goals.

4.4 Opinion Summary

U.S. EPA has spent a great deal of time and effort into developing the criteria, implementing them, reporting information, and understanding it. The result is a much improved national monitoring program which is a great accomplishment and direct result of the BEACH Act. As a result of this improved monitoring program, we are better able to identify *potential* health risks in recreational waters, regardless of the source, and post appropriate warnings. Mitigation efforts will eventually resolve the impaired beaches when contaminant sources can be identified. Despite the shortcomings, it looks like the BEACH Act was a big success and a good beginning to improving the overall coastal recreational water quality in the nation.

However, as discussed above, it is my opinion that U.S. EPA cannot develop credible recreational water quality criteria based upon the proposed studies and schedules outlined in the U.S. EPA Critical Path Science Plan and Criteria Development Plan & Schedule. U.S. EPA should:

1. Expand the proposed studies in accordance with my recommendations in Section 4.2;

2. Complete the expanded studies in three years;

3. Provide for sufficient time for scientific and public review of the results of each study and U.S. EPA's findings as each study is completed;

4. Develop interim guidelines (not criteria) with revised list of methods including implementation guidance for states;

5. Determine whether the data are sufficient for development of new criteria or whether additional studies are needed;

6. Provide an updated schedule for developing new criteria or conducting the requisite additional studies after adequate scientific and stakeholder review and input.

The basis for this opinion is the fact that a credible linkage between new fecal indicator bacteria data and human health risk is highly unlikely. U.S. EPA's apparent assumption that the proposed studies will demonstrate a credible linkage between fecal indicator bacteria with human health risk is not supported by previous studies.

Expand and Complete the Proposed Studies

U.S. EPA needs to expand its proposed studies to include pathogens and other alternative indicators listed in Table 1 and implemented in the Avalon Beach epidemiological study; this will require additional funding but should allow the studies to still be completed within U.S. EPA's proposed schedule. This would also make U.S. EPA's studies consistent with the study designs of the Southern California Coastal Water Research Project (SCCWRP). Membrane filtration of fecal coliform and *E. coli* should also be included for comparison with previous studies.

U.S. EPA studies should be expanded to address a multi-tiered toolbox approach to monitoring and water quality assessment as well as use of real-time water quality prediction models. These are the two best approaches for finding fast (near or real-time) evaluation of water quality. These approaches will provide multiple lines of evidence to provide increasingly higher orders of precision, as needed, for determining the risk and possible sources of contamination. Data for the models should include input from clean water agencies such as spills, bypass, or disinfection system problems to issue advisories or beach closures. Together, the tools have inherent flexibility for multiple applications and water matrices.

The molecular tests (e.g., qPCR) for fecal indicator bacteria may provide more information about the source of the fecal contamination and provide results faster than current methods. However, I do not believe that molecular methods, used alone, will provide an improvement to the current regulatory approach or satisfy the complaints in the litigation. The studies need to be expanded to gather the data necessary to validate the multi-tiered toolbox approach that was recommended in the Experts Report (U.S. EPA 2007b). Studies should also address more illness endpoints rather than just the gastrointestinal related illness that is the focus of the proposed U.S. EPA studies.

Provide Sufficient Time for Scientific and Public Input

Because of the evolving nature of the microbiological methods, the inherent variability associated with measuring fecal indicator bacteria and pathogens and distinguishing between human and non-human sources, the difficulty in correlating fecal indicator bacteria and pathogens and multiple illness endpoints, and the difficulty in extrapolating data to missing beaches from selected study sites, U.S. EPA must provide adequate time for peer review and scientific input. U.S. EPA should make all of the data associated with the epidemiological studies publicly available and obtain adequate peer review of the findings of each study before it is considered for use in developing new criteria.

Conversion of epidemiological studies into criteria requires definition of “acceptable” risk, which is a policy decision. U.S. EPA has two different acceptable risk guidelines based on whether the beach is a freshwater (8 illnesses out of 1,000 swimmers) or a marine (19 illnesses out of 1,000 swimmers) beach, but there is no rationale for how the two different guidelines were derived. U.S. EPA should describe the process by which they will define “acceptable” risk, and should include consultation with an informed public and the use of real data from a robust dataset. This policy decision will have significant implications for people recreating at a beach as well as informing an emerging national debate about appropriate levels of wastewater treatment for plants discharging to areas that have potential to affect drinking water supplies.

Provide an Updated Schedule for Developing New Criteria

Expanding the current scope of the proposed studies may still not result in a robust enough data set for developing national criteria. This is because the outcome of scientific investigation cannot be determined a priori. Additionally, the results of the planned studies may not result in definitive relationships between fecal indicator bacteria, pathogens, and multiple endpoints for

illness. U.S. EPA should commit to incorporating ongoing epidemiological studies and other pertinent information into the criteria development process and provide for off-ramps in the criteria development plan in case additional information is required.

U.S. EPA should commit to evaluating and integrating, if appropriate, related study results from California, Chicago, Europe, China, and other countries in developing new national criteria. In particular, U.S. EPA should consider beaches impacted by stormwater and nonpoint sources alone (i.e., agricultural runoff, wildlife) since the vast majority of beaches are not affected by wastewater treatment plant discharges. This is particularly important for assessing the potential of contribution of regrowth of fecal indicator bacteria to beach water quality problems. U.S. EPA should also complete studies in tropical environments and consider additional studies at beaches with the most swimming days per year.

U.S. EPA appears to consider the primary basis for future criteria development as quantitative microbial risk assessment (QMRA) and proposes to conduct "…QMRA and/or epidemiological studies…". It is difficult, at best, to review the document since this language is not clear. QMRA is not the most appropriate tool for use without epidemiological data to support the models. QMRA can assess infection and does not assess illness, meaning that it is better suited for high effect/low probability pathogens (such as *Nagleria* infections which are unrelated to wastewater discharges). U.S. EPA should develop studies to collect epidemiological information to validate the results of QMRA for a minimum of one beach and preferably several.

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