ANALYSIS OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY'S NON-COMPLIANCE WITH THE BEACHES ENVIRONMENTAL ASSESSEMENT AND COASTAL HEALTH ACT

Marylynn V. Yates
Professor of Environmental Microbiology
Department of Environmental Sciences
Univesity of California
Riverside, California 92521

Rachel T. Noble
Associate Professor
Institute of Marine Sciences
University of Carolina, Chapel Hill
Moorehead City, North Carolina

TABLE OF CONTENTS

INTRODUCTION

In 2000, the Beaches Environmental Assessment and Coastal Health Act ("BEACH Act") was signed into law. This act required EPA to perform studies to provide additional information for use in developing:

> (1) an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters, including nongastrointestinal effects;
>
> (2) appropriate and effective indicators for improving detection in a timely manner in coastal recreation waters of the presence of pathogens that are harmful to human health;
>
> (3) appropriate, accurate, expeditious, and cost-effective methods (including predictive models) for detecting in a timely manner in coastal recreation waters the presence of pathogens that are harmful to human health; and
>
> (4) guidance for State application of the criteria for pathogens and pathogen indicators to be published under section 1314(a)(9) of the Clean Water Act to account for the diversity of geographic and aquatic conditions.

The Act further required EPA, not later than five years after October 10, 2000, to 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 the studies described above for the purpose of protecting human health in coastal recreation waters.

To assist EPA in this process, EPA convened a formal workshop of forty-three national and international experts. This group met at the Airlie Center in Warrenton, Virginia from March 26 through March 30, 2007. The purpose of this workshop was "for EPA to obtain individual input from members of the broad scientific and technical community on the 'critical path' research and science needs for developing scientifically defensible new or revised Clean Water Act § 304a recreational ambient water quality criteria ("AWQC") in the near-term." (EPA, 2007a). The recommendations of these experts are presented in an EPA report titled "Report of the Experts Scientific Workshop on Critical Research Needs for the Development of New or Revised Recreational Water Quality Criteria" ("Experts Report," EPA, 2007b).

EPA solicited the guidance of these experts for the specific purpose of assisting EPA in the development of a "Critical Path Science Plan" ("CPSP"), which would set forth the studies and approach that EPA proposes to use in order to meet the statutory requirements of the BEACH Act. Specifically, "the purpose of the CPSP is to articulate the essential research and science that EPA will conduct between 2007 and the end of 2010 to establish the scientific foundation for new or revised recreational water quality criteria to protect swimming in waters designated by a State for that use . . . The CPSP represents an integrated approach to answering the key questions that EPA believes needs

to be addressed to ensure that the new or revised criteria are scientifically sound." (CPSP at p.1-1 – 1-2; EPA, 2007a). EPA published the CPSP on August 31, 2007.

As set forth in the discussion that follows, the CPSP will not meet its stated goal. As will be discussed, the studies set forth in the CPSP will not answer the key questions that need to be answered in order for EPA to meet the statutory requirements of the BEACH Act. The CPSP does not adequately address coastal marine beaches, and many of the expert panel's highest priority recommendations as set forth in the Experts Report are not reflected in the plan. This document will present in order 1) an annotated "Summary of Opinions" detailing the flaws with the CPSP and summarized recommendations for reconciliation of the flaws, 2) a listing of the flaws of the CPSP with detailed supporting technical information, along with the recommendations to address those flaws with associated detailed technical information, and 3) the references cited herein.

SUMMARY OF OPINIONS

The CPSP as written has serious shortcomings in that it will not allow for the accomplishment of the stated goals of the EPA. In particular, many of the highest priority recommendations provided by the Experts Report are not included in the CPSP. The shortcomings of the CPSP need to be overcome in order for the new or revised AWQC to have a sound, scientifically-defensible basis. The following document outlines the flaws in the CPSP that will need to be addressed for EPA to meet the requirements of the BEACH Act.

1. **EPA is studying a non-representative set of beaches, and it would be inappropriate to extrapolate the results from those locations to other locations for the purpose of criteria development. EPA must study a representative set of beaches in order to properly meet the requirement that it 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.**

    a. *EPA has studied, and proposes to continue to study, beaches that are the subject of "point source" discharges. The majority of marine beach use occurs at beaches that are subject to "non-point" sources (NPS) of pollution. EPA cannot make a full assessment of potential human health risks resulting from exposure to pathogens in coastal recreational waters without studying marine beaches subject to NPS pollution.*

        - ***Recommendation*:** Conduct epidemiological studies of marine beaches impacted principally by NPS pollution.

    b. *EPA is generally focusing on beaches from a single climatic zone (temperate climates). Because there are differences between beaches located in temperate, sub-tropical, and tropical locations, EPA must conduct studies at beaches located in these climatic zones.*

        - ***Recommendation*:** Future epidemiological studies need to be conducted at representative beaches from a range of climatic zones from temperate, sub-tropical, and tropical locations, such as those in California, Hawaii, and Florida.

    c. *Beaches in Florida, California, and Hawaii represent at least one-half of the total beach usage in the USA. However, the highest beach usage areas by the public (*e.g.*, CA, FL, HI) are not being well studied by EPA.*

        - ***Recommendation*:** Future epidemiology studies should be conducted in those locations where the most recreation occurs, as in the states of California, Florida and Hawaii.

d. *EPA has not studied, and does not propose to study, potential human health risks from exposure to pathogens from avian and other wildlife sources, which are likely to be the most common non-human contributors of pathogens present at marine beaches. EPA proposes to study only exposure to pathogens from one type of agricultural animal,* i.e.*, bovines. There are few, if any, high-use coastal marine beaches that are impacted by cattle. Absent the study of potential human health risks from exposures to pathogens from avian and other wildlife sources, EPA cannot make a full assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters.*

- ***Recommendation*:** Conduct epidemiological studies of NPS beaches and assess the importance of avian and other wildlife fecal contamination to human health.

2. **The CPSP focuses on a limited number of indicator organisms. EPA has failed to incorporate other indicators/methods that have shown great promise for assessing human health risks. EPA must expand the number of indicator organisms and methods being studied in order to properly meet the requirement that it perform studies to provide additional information for use in developing (1) appropriate and effective indicators of the presence of pathogens harmful to human health, and (2) appropriate, accurate, expeditious, and cost-effective methods to detect those pathogens.**

a. *The CPSP has placed too much emphasis on the use of* Enterococcus*. Others have already demonstrated in previous NPS-focused epidemiology studies (*e.g.*, Mission Bay Study) and in research that details bacterial regrowth in beach sand, that* Enterococcus *is not an effective indictor at those beaches, and therefore may not work well as an indicator at other NPS-contaminated beaches.*

- ***Recommendation*:** EPA needs to greatly expand their consideration of other potential organisms, as it is unlikely that *Enterococcus* will serve adequately as a single "magic bullet" indicator.

b. *The CPSP presently proposes to measure only a limited set of indicators/methods during their epidemiology studies.*

- ***Recommendation*:** EPA needs to greatly expand the suite of indicators measured in future epidemiology studies and archived epidemiology study samples. The approach used in the Avalon Epidemiology Study, in which more than 30 different indicators and pathogens are being measured, should be followed for future epidemiology studies. These include indicators that are specific to

human fecal contamination as well as indictors that are representative of the range of human pathogens (*i.e.*, viruses, bacteria, and parasites). The Experts Report details a list of indicators/methods for epidemiological studies that could potentially be used for future studies.

c. *Methods to detect indicators and pathogens that have been developed by scientists external to the EPA currently exist; EPA has provided no mechanism for including these technologies in many of their epidemiology studies. EPA has a limited view of available technology for water quality monitoring,* i.e.*, EPA generally only utilizes indicators/methods that have been developed at EPA and excludes from its studies analysis of a substantial range of methods currently being developed in academic and independent laboratories. There is no mechanism proposed whereby EPA can evaluate existing methods to be used in epidemiological studies in a standardized way.*

- ***Recommendation*:** EPA must develop a mechanism for including other indicators and methods in its studies. EPA should develop a relationship with (a) third party (ies) for development, evaluation, and standardization of potential indicators/methods.

d. *The CPSP does not detail a plan for inclusion of new indicators/methods in future epidemiology studies; especially needed are further details on how rapid methods will be assessed.*

- ***Recommendation*:** EPA needs to utilize a third party to conduct unbiased, performance-based testing of methods proposed for use in epidemiology studies and for water quality monitoring. Especially important is that side-by-side analyses of rapid molecular methods and existing culture-based methods be conducted.

3. The studies EPA proposes to perform will not yield a definition of the appropriate level of risk on which the water quality criteria should be based.

a. *In the CPSP, EPA does not address the issue of the risk level on which the AWQC will be based.*

- ***Recommendation*:** EPA must justify the level of risk upon which any revised or new criteria are based.

b. *"Acceptable risk" has not been defined by any empirical studies. There has been no work conducted to assess what "acceptable risk" levels are truly acceptable to the public.*

- ***Recommendation*:** EPA should undertake a systematic process to define the appropriate level of risk, especially in the context of public perception.

c. *EPA has not addressed issues of statistical resolution associated with using lower "acceptable risk" levels. For example, if the currently used multiple tube fermentation-based* Enterococcus *methods are used and the "acceptable risk" level is reduced from 19 to 8 cases per 1000 persons, the statistical ability of the method to discriminate between zero cases of illness per 1000 persons and violation of the standard will be very low.*

- ***Recommendation*:** EPA should conduct research to demonstrate that economical and reliable detection methods are available to implement the accepted level of risk.

4. **The CPSP states that water quality criteria play a critical role in implementing a range of essential purposes and functions under the Clean Water Act, but the CPSP does not provide any further information on linkage of new or revised criteria to existing programs. Currently, Los Angeles County, as well as numerous other public agencies and publicly owned treatment works, are investing significant resources and public funds to comply with current criteria which may subsequently be revised by the EPA. The CPSP fails to provide any information on how EPA will provide guidance for state application of the current criteria for pathogens and pathogen indicators, given that EPA may develop new or revised criteria accounting for the diversity of geographic and aquatic conditions.**

a. *There is a lack of information in the CPSP regarding the linkage of new or revised criteria and the Total Maximum Daily Loads ("TMDLs") and National Pollutant Discharge Elimination System ("NPDES") permitting programs that are in various stages of development and implementation.*

- ***Recommendation*:** EPA must provide clear, concise guidance and include an outlined set of examples, possibly detailing phased approaches for TMDL implementation and new approaches for the NPDES permitting processes in consideration of newly developed criteria and clauses for re-evaluation of impaired water body status. EPA needs to provide scenarios for the adoption of new criteria and management approaches (such as the toolbox approach recommended in the Experts Report) for NPDES permitting.

b. The use of a tiered, toolbox approach in the new or revised criteria is not discussed.

- ***Recommendation*:** EPA needs to provide scenarios for the adoption of new criteria and management approaches (such as the tiered approach outlined by the World Health Organization ("WHO")) and discuss potential implementation strategies.

5. The CPSP proposes "epidemiology and/or Quantitative Microbial Risk Assessment (QMRA) studies" to establish new or revised criteria. This is not an appropriate way to delineate the studies that will be done to develop criteria.

a. QMRA is not a viable alternative to epidemiological studies. Appropriate data do not currently exist to conduct only QMRA studies for coastal recreational waters.

- ***Recommendation*: QMRA studies should not be used to supplant epidemiology studies, only to support them.**

OPINIONS

1. **EPA is studying a non-representative set of beaches, and it would be inappropriate to extrapolate the results from those locations to other locations for the purpose of criteria development. EPA must study a representative set of beaches in order to properly meet the requirement that it 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.**

The following matrix illustrates the range of climatic conditions and potential contamination sources at beaches used for recreation across the United States. The EPA is conducting, or has committed to conduct, studies only at temperate and subtropical beaches impacted by point sources of contamination.

	Climatic Conditions		
Contamination Source	Temperate	Subtropical	Tropical
Point Source	XXXX	XXXX	
Non-point Source			
Animal/Wildlife			

XXXX = EPA epidemiological study(ies) completed or in progress

a. *EPA has studied, and proposes to continue to study, beaches that are the subject of "point source" discharges. The majority of marine beach use occurs at beaches that are subject to "non-point" sources (NPS) of pollution. EPA cannot make a full assessment of potential human health risks resulting from exposure to pathogens in coastal recreational waters without studying marine beaches subject to NPS pollution.*

In the goals section (1.3) of the CPSP, "Assessment of Human Health Risks" was the first listed goal (EPA, 2007a). Although a section discussing human versus animal contamination is further laid out in ensuing sections, the CPSP does not adequately address the point source ("PS") vs. non-point source ("NPS") issues raised in the Experts Report. The majority of swimming activity occurs in NPS-contaminated waters as compared to PS-contaminated waters across the U.S. An example of the impact of NPS stormwater contamination on beaches is provided in a study conducted in southern California (Noble *et al.*, 2003). In that study, it was demonstrated that 60% of the shoreline exceeded indicator bacteria standards during wet weather, while only 6% of the shoreline exceeded the same criteria during dry weather, indicating that urban runoff (one type of NPS contamination) is a major source of indicator bacteria to the beaches. An excerpt from the EPA website on NPS pollution (http://www.epa.gov/nps/facts/point1.htm) states "The United States has made tremendous advances in the past 25 years to clean up the aquatic environment by controlling pollution from industries and sewage treatment plants. Unfortunately, we did not do enough to control pollution from diffuse, or nonpoint, sources. Today, NPS

pollution remains the Nation's largest source of water quality problems. It's the main reason that approximately 40 percent of our surveyed rivers, lakes, and estuaries are not clean enough to meet basic uses such as fishing or swimming". The usefulness of conducting the majority of the epidemiological studies for establishing criteria for recreational waters at PS-contaminated beaches is limited. Yet, EPA does not address this vital point.

Few epidemiological studies on the impact of non-point source-impacted recreational water have been published. A seminal study was conducted in 1996 at stormwater-impacted locations in Santa Monica Bay (Haile *et al.,* 1999). This work noted more than a decade ago that a major predictor of illness in recreational waters was distance to an outlet of NPS pollution in the form of urban runoff. This study also noted a relationship of illness to enteric viruses and to a low ratio of total coliform to fecal coliform bacteria. This study is not even mentioned in the CPSP. A subsequent study conducted at a marine beach impacted by NPS contamination was recently published (Colford *et al.*, 2007). In this study, it was found that traditional water quality indicators (*e.g., Enterococcus*, total coliforms, and fecal coliforms by culture-based methods) did not correlate with swimming-associated illness. In addition, *Enterococcus* measured by qPCR did not correlate with swimming-associated illness, in contrast to the findings of the EPA at two of the Great Lakes beaches (Wade *et al.*, 2006). The results of the Colford *et al.* (2007) study support the statement made by the experts at the Experts Workshop (EPA, 2007b) that "... the relationship between water quality indicators and health is different at non-point source-impacted sites since indicator levels may be high due to animal (*e.g.*, birds, other wildlife) or other sources that do not increase the risk of human illness." Therefore, it is critical to conduct studies at beaches impacted by non-point sources of fecal contamination.

The epidemiological studies that EPA has conducted to date, as well as the studies to which they have committed to conduct, have been carried out at beaches impacted by point sources of human fecal contamination (*i.e.*, wastewater from publicly-owned treatment works ("POTWs")). One epidemiological study or quantitative microbial risk assessment ("QMRA") in fresh or marine waters impacted by urban runoff (CPSP project P5) is also planned. However, the lack of commitment to conducting an epidemiological study (compared to QMRA) and the type of recreational water (*i.e.*, fresh vs. marine) is problematic. Non-point sources (of which urban runoff is one type) are an important contributor to fecal contamination at beaches. In California, for example, most water quality problems are attributable to non-point source contamination (Noble *et al.*, 2003; Schiff *et al.*, 2003a, Schiff *et al.*, 2003b); conducting only a single epidemiological study at either a fresh or marine water site will be inadequate to assess the applicability of water quality indicators to those conditions at all sites across the country that will be impacted by the ambient water quality criteria ("AWQC"). Indeed, the "Comparing Risk from Different Sources" group at the Experts Workshop stated that the highest priority for epidemiological studies is to "conduct studies at beaches impacted by different types of non-point sources of fecal contamination." (EPA, 2007b). There is a need for more than one epidemiological study to be conducted on NPS-contaminated beaches.

- ***Recommendation*:** Conduct epidemiological studies of marine beaches impacted principally by NPS pollution.

b. EPA is generally focusing on beaches from a single climatic zone (temperate climates). Because there are differences between beaches located in temperate, sub-tropical, and tropical locations, EPA must conduct studies at beaches located in these climatic zones.

The experts in the Pathogens, Pathogen Indicators, and Indicators of Fecal Contamination at the Experts Workshop discussed four main issues. One of the issues was application of the indicators "… for all categories of waters, climatology, and geographical considerations." (EPA, 2007b). Since the AWQC were established in 1986, it has been demonstrated that a single approach to assessing water quality for all waters in the U.S. is not feasible. For example, almost 20 years ago it was shown that fecal coliform bacteria could be isolated from pristine sites in Puerto Rico (Rivera *et al.*, 1988) and Hawaii (Fujioka *et al.*, 1988, Hardina and Fujioka, 1991). Other investigators have published findings from studies in Hawaii (Byappanahalli and Fujioka, 2004) and Florida (Desmarais *et al.*, 2002) in which they have found that fecal indicator bacteria can persist and replicate in the environment. The findings that some fecal indicator bacteria exist in non-fecally contaminated environments and are capable of replication in tropical and subtropical environments, calls into question their utility as indicators of human health risk in those environments.

In the CPSP, the EPA states that they are addressing the need for studies to develop guidance to account for the diversity of marine waters by "… conducting epidemiological studies along diverse locations on the east, west, and gulf coasts of the United States." (EPA, 2007a). The studies that EPA is conducting at marine beaches are all at sites impacted by POTWs, with the exception of the study in which they are participating at Avalon Beach on Catalina Island, California. They state clearly that they will not include an epidemiological study at a tropical site because "… indicators of fecal contamination for temperate and subtropical waters may not be suitable for tropical waters…", thereby acknowledging the findings of previous researchers. The EPA states that they will need to do a great deal of other work before they can conduct an epidemiological study at a tropical site, and thus cannot complete such a study within the timeframe of the CPSP. However, there has already been a great deal of work done at some tropical locations (*e.g.*, Hawaii), resulting in the identification of potential indicators for use in those environments. For example, Fujioka and Shizumura (1985) found that *Clostridium perfringens* is a reliable indicator of water quality in streams in Hawaii. EPA needs to examine the existing data and conduct epidemiological studies at sites that are representative of other climate zones in areas that are impacted by sources other than POTWs.

- ***Recommendation:*** Future epidemiological studies need to be conducted at representative beaches from a range of climatic zones

from temperate, sub-tropical, and tropical locations, such as those in California, Hawaii, and Florida.

c. *Beaches in Florida, California, and Hawaii represent at least one-half of the total beach usage in the USA. However, the highest beach usage areas by the public (*e.g.*, CA, FL, HI) are not being well studied by EPA.*

According to the National Oceanic and Atmospheric Administration ("NOAA") (http://marineeconomics.noaa.gov/NSRE/NSRE_V1-6_May.pdf), in 1999-2000, over 43 percent of the civilian, non-institutionalized population, aged 16 and over participated in outdoor marine recreation, which translates to over 89 million people. Florida had the most participants with 22 million, followed by California with 18 million; Hawaii adds another 4.5 million participants. Therefore, these three states alone account for one-half of all of the marine recreational participants. Yet, the EPA is not conducting any epidemiological studies in these states (with the exception of the participation in the collaborative study between EPA and the Southern California Coastal Water Research Project ("SCWWRP") at Avalon beach on Catalina Island, CA, which is not necessarily representative of other Southern California beaches).

- ***Recommendation:*** Future epidemiology studies should be conducted in those locations where the most recreation occurs, as in the states of California, Florida and Hawaii.

d. *EPA has not studied, and does not propose to study, potential human health risks from exposure to pathogens from avian and other wildlife sources, which are likely to be the most common non-human contributors of pathogens present at marine beaches. EPA proposes to study only exposure to pathogens from one type of agricultural animal,* i.e.*, bovines. There are few, if any, high-use coastal marine beaches that are impacted by cattle. Absent the study of potential human health risks from exposures to pathogens from avian and other wildlife sources, EPA cannot make a full assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters.*

The CPSP identifies "Assessment of Human Health Risks" as its first goal. The associated "Key Research Question" is "What is the risk to human health from swimming in water contaminated by human fecal material as compared to swimming in water contaminated with non-human fecal material?" (EPA, 2007a). The CPSP attempts to lay out a scheme for conducting research that will permit partitioning of the fecal indicator organisms detected in a recreational water body to specific sources of fecal contamination (*e.g.*, from humans vs. animals). However, it falls far short of that goal.

The experts at the Experts Workshop made a number of points with respect to the issue of human vs. animal fecal contamination. These include the following:

- It is widely believed that human feces pose a higher risk to humans than do animal feces
- The risk to humans from animal feces varies based on the specific animal that is the source of feces
- Animal feces are often deposited in water without any treatment.

However, as the experts also stated, there are few data to demonstrate whether animal feces pose a lower, higher, or equivalent risk to humans than human feces. The experts clearly stated that the only way to find out the health risk posed by animal feces is to conduct targeted studies.

The epidemiological studies to be conducted at two POTW-impacted marine beaches (CPSP projects P1 and P2) begin to address the task of understanding human illness associated with human fecal contamination. A criticism of these studies (already conducted or in the process of being conducted) is that they are not addressing a critical issue: that of NPS contamination and the linkage to human health, as discussed above. Still, relationships between treated human sewage and human illness are likely to be the most straightforward of the questions at hand, so these studies will likely yield some useful information. One study (CPSP project P3) is being conducted at Avalon Beach, a marine beach impacted by untreated or poorly treated human sewage, located on Catalina Island, California. The study is being conducted by EPA with SCCWRP. This study is one step in the direction of understanding the relationship of human illness to poorly treated human sewage; however, more work is needed.

In the CPSP, EPA states that little adequate research has been conducted to assess the public health risk associated with swimming in animal feces tainted waters. It is followed by a subsequent suggestion to conduct a literature review to try and understand the relative risks associated with swimming in human fecal contamination versus animal-derived fecal contamination. If little research has been done, however, the information to be derived from such a literature review is likely to be of little use. Once again, this issue needs to be specifically addressed with active research. Literature review will assist in conducting the research at appropriate locations and on appropriate scales, but should not be viewed as a replacement for active research in this area.

Clearly, it will be necessary to conduct literature reviews and beach reconnaissance in order to assess the most likely animals that are contributing to poor water quality (*e.g.*, birds, dogs and other domestic animals, and wildlife), but this information is likely already known. The information that must be obtained is what animals are the most important in which areas. A brief literature review should be conducted, but the most important information on this matter will come from requesting quantitative information from all water quality agencies conducting sanitary surveys.

EPA states that QMRA might be a potential tool that can be used to establish criteria for swimming in waters contaminated with animal fecal contamination. This approach is problematic because there simply is not the necessary quantitative, statistically rigorous literature available detailing the likelihood of illness specific to a

range of zoonoses[1]. The only way to understand the health risk to swimmers posed by animal feces is to conduct targeted epidemiology studies. This topic is discussed in more detail below, in item 5.

To address the animal vs. human fecal contamination issues, it is necessary to conduct epidemiological studies first. If EPA follows the epidemiological studies conducted in key locations with QMRA targeted for the same location, then it is possible that those QMRA results might be applicable to other locations. It is not acceptable for EPA to use QMRA as a substitute for epidemiological studies on beaches receiving NPS contamination. There is only limited information available to create QMRA scenarios appropriate for animal and animal/human mixtures of fecal contamination; the components and data requirements for QMRA simply will not permit an accurate study to be conducted for animal fecal contamination, especially without the ability to conduct human feeding studies. More than one study needs to be done to potentially validate the findings of the first study. Human populations have ranges of susceptibilities to zoonotic infections, so humans exposed to animal fecal contamination in one area may have much higher rates of illness than humans in another area (this issue is also cited by Reviewer 3 in the peer review comments).

In the section detailing work on animal sources of contamination, EPA states that the work will be conducted at a freshwater beach. Epidemiological studies addressing animal fecal contamination must be conducted at marine beaches as well.

EPA states that the animal work will focus on developing methods that can differentiate bovine fecal material from other animal fecal material. They also state that "Additional research to potentially differentiate between non-human sources of fecal contamination (*e.g.*, wildlife vs. agricultural animals such as cows) cannot be completed in the proposed timeframe." (EPA, 2007b). Cattle are likely not an important source of fecal contamination along our nation's high-use marine beaches, so the focus on cattle is short-sighted and will not provide the information necessary to develop AWQC.

- ***Recommendation*:** Conduct epidemiological studies of NPS beaches and assess the importance of avian and other wildlife fecal contamination to human health.

2. **The CPSP focuses on a limited number of indicator organisms. EPA has failed to incorporate other indicators/methods that have shown great promise for assessing human health risks. EPA must expand the number of indicator organisms and methods being studied in order to properly meet the requirement that it perform studies to provide additional information for use in developing (1) appropriate and effective indicators of the presence of**

[1] A **zoonosis** is an infectious disease that can be transmitted from animals, both wild and domestic, to humans.

pathogens harmful to human health, and (2) appropriate, accurate, expeditious, and cost-effective methods to detect those pathogens.

a. *The CPSP has placed too much emphasis on the use of* Enterococcus. *Others have already demonstrated in previous NPS-focused epidemiology studies (*e.g., *Mission Bay Study) and in research that details bacterial regrowth in beach sand, that* Enterococcus *is not an effective indictor at those beaches, and therefore may not work well as an indicator at other NPS-contaminated beaches.*

Existing marine beach monitoring conducted by most U.S. coastal states focuses on the use of *Enterococcus*, as a result of the relationships observed between *Enterococcus* and public health described by Cabelli *et al.* (1982). Even though a significant relationship has been observed previously between *Enterococcus* and human health at point source, human sewage-contaminated beaches, this relationship is not likely to hold true for all beaches. In the few epidemiology studies conducted to date on NPS contaminated beaches, *Enterococcus* has not shown a significant relationship to human health (*e.g.*, Colford *et al.*, 2007). In epidemiological studies conducted at two Great Lakes beaches, EPA states that *Enterococcus* detected by qPCR was found to predict swimming-associated health effects (Wade *et al.*, 2006). However, when carefully examining the results of those studies, it is clear that the association between gastrointestinal illness and enterococci was statistically significant at only one of the two beaches. Importantly, the positive associations were found when the data from all three sampling periods during the day (taken at 8 a.m., 11 a.m., and 3 p.m.) were combined. The fact that the results from samples from all three time periods had to be combined in order for a statistically significant association to be found negates one of the positive aspects of using a rapid method.

Enterococcus may serve as an important indicator for some beaches (the idea of a tiered approach to monitoring is discussed under item 4b), but EPA should broaden its examination of potential indicators so as to include other organisms. There are more than 20 recognized species of enterococci known to reside in the guts of a variety of animals (*e.g.*, birds, horses, cows, and sheep) in addition to humans. The currently used methods for epidemiology studies (EPA 1600 and qPCR for *Enterococcus*) were designed to enable the detection of all known species within the *Enterococcus* genus (EPA 1600 method reference, EPA, 2006). Peer-reviewed publications have documented *Enterococcus* growing on grasses (Ott *et al.*, 2001), aquatic plants (Whitman *et al.*, 2003), and sediments (Fujioka *et al.*, 1999; Hartel *et al.*, 2005). If *Enterococcus* measurements at marine beaches include contributions from these types of non-fecal sources rather than human sewage, then the previously observed relationships between *Enterococcus* and human health might not hold.

- ***Recommendation*:** EPA needs to greatly expand their consideration of other potential organisms, as it is unlikely that *Enterococcus* will serve adequately as a single "magic bullet" indicator.

b. The CPSP presently proposes to measure only a limited set of indicators/methods during their epidemiology studies.

It is not likely that *Enterococcus* or *E. coli*, or any other single indicator organism will be the best indicator for all waters. The more widely accepted view is that a "toolbox approach" (discussed later in item 4b) is the preferred path. Since the number of epidemiology studies to be conducted is relatively low, and since the incremental cost of additional indicators to be measured is relatively small, a greater range of potential indicator organisms needs to be measured in each future EPA epidemiology study.

Several of the epidemiological studies being conducted or proposed to be conducted by the EPA involve or will involve the measurement of only a few indicators. In the description of the projects at the POTW-impacted marine beaches (CPSP projects P1 and P2) EPA indicates that they will conduct "… prospective cohort epidemiological studies designed to evaluate the ability of novel and rapid indicators of recreational water quality to predict swimming-associated illness at marine beach sites impacted by treated wastewater effluent discharge." However, the suite of indicators measured during these studies is too limited.

The suite of indicators/methods the EPA states they are using in these two studies (CPSP projects P1 and P2) conducted in summer 2007, is limited to quantitative polymerase chain reaction (qPCR) *E. coli*, qPCR *Enterococcus*, qPCR human-specific *Bacteroides*, qPCR general *Bacteroides*, EPA Method 1600 *Enterococcus* (membrane filtration method), and male-specific coliphages by antibody assay. As compared to the suite of methods included in the study (CPSP project P3) at Avalon, Catalina Island, CA, to which the EPA is contributing (there are more than 30 indicators/methods being tested in the Avalon study), the list of indicators to be measured during the EPA's POTW-impacted marine beaches studies (CPSP projects P1 and P2) is very short. The list of indicators utilized for the Avalon Study is lauded. Yet, the inconsistency among studies, and the suite of indicators employed is confusing and there is no scientific basis put forward by the EPA for the differences.

There are two major limitations with the list of methods employed in EPA's POTW-impacted marine beaches studies (CPSP projects P1 and P2): there are not enough alternate indicators being tested and there are not enough culture-based methods being employed. It is important to employ traditional culture-based methods for direct comparison with every rapid method that is tested (where possible). Culture-based methods for fecal coliforms, *E. coli* and *Enterococcus* are currently in use by all 50 states for management of recreational waters. The use of these methods stems from the relationships observed in relation to human health in past epidemiological studies. Although rapid methods are being examined for potential promulgation in the near future by EPA, it will take a long time for the methods to be implemented in most states. SCCWRP has conducted several culture-based vs. rapid methods equivalency assessments (*e.g.*, Griffith *et al.*, 2007), but there has not been enough research conducted in this arena to date. qPCR methods employed in epidemiological studies should, in all cases possible, be tested side by side with "traditional" EPA-approved

culture-based methods. This permits identification of the relationship of the qPCR method to human health effects, while also grounding the qPCR method in the equivalency demonstrated to existing methods. This step is vital for introduction of new methods, and an understanding of how utilization of new methods integrates into historical databases of fecal indicator bacteria measurements. All freshwater epidemiology studies should include culture and molecular based methods for *E. coli* to maintain a level of consistency with existing Clean Water Act ("CWA") §304 (a) guidance.

The approach used in the Avalon Epidemiology Study, in which more than 30 different indicators and pathogens are being measured, should be followed for future epidemiology studies. These include indicators that are specific to human fecal contamination as well as indictors that are representative of the range of human pathogens (*i.e.*, viruses, bacteria, and parasites). The Experts Report details a list of specific indicators/methods for epidemiological studies that could potentially be used for future studies.

One of the most important points about this issue is that EPA is not using a consistent approach to choosing indicators for its studies. The difference between the Avalon, CA and the Rhode Island/Alabama studies is perplexing. EPA needs to consistently use an expanded suite of indicators for effective criteria development.

- ***Recommendation*:** EPA needs to greatly expand the suite of indicators measured in future epidemiology studies and archived epidemiology study samples. The approach used in the Avalon Epidemiology Study, in which more than 30 different indicators and pathogens are being measured, should be followed for future epidemiology studies. These include indicators that are specific to human fecal contamination as well as indictors that are representative of the range of human pathogens (*i.e.*, viruses, bacteria, and parasites). The Experts Report details a list of indicators/methods for epidemiological studies that could potentially be used for future studies.

c. *Methods to detect indicators and pathogens that have been developed by scientists external to the EPA currently exist; EPA has provided no mechanism for including these technologies in many of their epidemiology studies. EPA has a limited view of available technology for water quality monitoring, i.e., EPA generally only utilizes indicators/methods that have been developed at EPA and excludes from its studies analysis of a substantial range of methods currently being developed in academic and independent laboratories. There is no mechanism proposed whereby EPA can evaluate existing methods to be used in epidemiological studies in a standardized way.*

Currently, EPA does not have a mechanism by which to evaluate existing methods developed both within EPA and outside of EPA for use in epidemiology studies. Most of the methods employed during EPA-conducted epidemiology studies are those developed in house at the EPA. This is a very important point, and EPA describes a methods project in the CPSP (project P17) which is intended to address the issue, but does not adequately do so. This need is also a major point discussed in the Experts Report, which states that "performance criteria for the method should be completed, and preferably before using the method in an epidemiological study" (EPA, 2007b). This need should have been clearly and prominently stated, rather than somewhat buried after the project to evaluate archived samples (page 3-9). The section of the CPSP that describes the studies needed to evaluate indicators and methods neglects some of the main activities that must be in place within EPA.

EPA needs to create a formal program for performance-based assessment of potential target microorganisms and methods for measuring those organisms prior to epidemiology studies. Currently, once methods (largely those developed in-house by EPA) that work in an accurate fashion have been identified, they go through EPA-specific performance-based testing. It would be optimal to conduct this performance-based testing outside of EPA by a third party, and to allow the results of the testing to determine which methods/indicators should be included in specific epidemiology studies with specific outlined goals.

In the immediate future, EPA could develop an approach similar to that used by SCCWRP for performance-based assessments of proposed methods for inclusion in the City of Avalon epidemiology study. They created blind samples and required research groups proposing to use different methods for the epidemiology study to analyze those samples, and report data back to SCCWRP officials. SCCWRP officials at that point unblinded the samples and confirmed the viability, reproducibility and accuracy of the proposed methods. Notably, this was all conducted (for a suite of more than 30 different methods) over the course of just 6 weeks.

- ***Recommendation*:** EPA must develop a mechanism for including other indicators and methods in its studies. EPA should develop a relationship with (a) third party(ies) for development, evaluation, and standardization of potential indicators/methods.

d. The CPSP does not detail a plan for inclusion of new indicators/methods in future epidemiology studies; especially needed are further details on how rapid methods will be assessed.

EPA needs to create linkages specifically to outside testing organizations to assess, validate and standardize new technologies that show promise for water quality monitoring including rapid methods. Some work similar to this is being conducted by Battelle as they have served as a partner with EPA in conducting the Environmental Technology Verification (ETV) program. The goals of the ETV program are to provide a venue for quality-assurance and assessments of the performance characteristics of the

technologies in question so that potential users and buyers can make informed decisions about those technologies. The ETV program addresses technologies for pollutants and natural species in source emissions, air, water, and soil. There appear to be plans to utilize the ETV program for assessment of rapid methods for recreational water quality monitoring by EPA. If this program is to successfully be used to evaluate technologies pertinent to recreational water quality, then Battelle must be brought to the table to interface with organizations such as SCCWRP, who have already conducted several studies to evaluate rapid methods (Griffith *et al.*, 2006) and beta-testing of new rapid technologies (Griffith *et al.*, 2007). The criteria used to assess the potential of new technologies must be established early and must be more specifically designed for recreational water quality needs, some of which are outlined in Noble and Weisberg (2006).

There are third parties that have developed new technologies (many of them rapid) for quantifying indicators and microbial targets that have not been brought to the forefront because of the lack of a competent mechanism within EPA. This is a vital component to the success of future epidemiological studies, as the studies are only as good as the indicators measured and the methods used to measure them. EPA should invite outside organizations to participate in assessment of their methods in order to determine the viability of specific technologies. Only a formal program will permit accurate, new technologies to be part of the evolution of criteria establishment. A formal program will make possible an "on ramp" for designers of future rapid technologies that may be potentially excellent and even more rapid than what is currently known, leading to the advancement of the water quality field at an appropriate rate.

Rapid methods for the detection of indicator microorganisms are being evaluated and validated within the EPA; some of this work is outlined in the CPSP. Rapid methods, whether specific to the currently recommended fecal indicator bacteria (*i.e.*, *Enterococci* and *E. coli*) or alternate indicators, have the potential to allow beaches to be managed more accurately because posting and closures can theoretically occur in a more timely fashion. With rapid methods for measurement of indicator organisms, a beach water quality sample can yield results within 2 hours, permitting recreational water users to know of contamination much more rapidly. However, potential promulgation of rapid methods, whether for early warning or for all beach monitoring purposes, raises a number of issues that have not been adequately addressed by the EPA.

As stated previously, and outlined in the Experts Report in the Methods Development section, there is a need to conduct work on rapid methods to relate rapid method results to health outcomes and for equivalency to existing EPA-approved culture-based methods. In addition, it is imperative that EPA begin to consider the resulting hurdles associated with promulgation of rapid methods. For example, phased promulgation, wherein the EPA permits agencies to choose whether or not to implement rapid methods, and the likely scenario whereby higher throughput monitoring laboratories (those responsible for thousands of recreational water quality sample assessments per annum) implement rapid methods immediately, and smaller laboratories continue with traditional culture based methods for a longer time period, must be

considered. Issues to be resolved include data management, data handling, QA/QC, standardization of approaches, data reporting, and public perception of rapid test methods. The EPA needs to clearly think about and discuss their strategy for promulgation of rapid methods with leaders in the field and garner feedback from key water quality agencies. While it is true that no rapid methods have yet been promulgated by EPA, it is necessary for these thought processes to occur now, rather than waiting for post-promulgation. There are water quality agencies across the country that are actively utilizing rapid methods to assist in accurate management of their recreational waters; there are many others that are actively waiting to utilize rapid methods, and a data management and guidance plan is necessary to have in place as these methods evolve and become subsequently used in real world applications.

- ***Recommendation:*** EPA needs to utilize a third party to conduct unbiased, performance-based testing of methods proposed for use in epidemiology studies and for water quality monitoring. Especially important is that side-by-side analyses of rapid molecular methods and existing culture-based methods be conducted.

3. The studies EPA proposes to perform will not yield a definition of the appropriate level of risk on which the water quality criteria should be based.

a. In the CPSP, EPA does not address the issue of the risk level on which the AWQC will be based.

The experts at the Experts Workshop (EPA, 2007b) clearly stated that there is "… no scientific rationale to support different risk level targets between geographic areas (*i.e.*, freshwater and marine water) or between climatic regions (tropical, subtropical temperate)." However, the CPSP does not comment on EPA's intentions regarding the approach to be taken with respect to establishing risk levels. Absence of the discussion of risk levels, and lack of justification for the differing levels currently in place in fresh and marine waters, is not acceptable.

The current ambient water quality criteria present different risk levels to recreators swimming in fresh water (8 illnesses per 1000 swimmers) compared to marine waters (19 illnesses per 1000 recreators). As stated by the EPA (1986), these risk levels are based on the historically accepted risk (dating back to at least the 1976 Quality Criteria for Water), which was arbitrarily set. Considering the advances that have been made in pathogen and indicator detection, and the focus on the establishment of risk-based criteria, EPA must take this opportunity to initiate a thorough and systematic process to consider what the appropriate levels of risk are, and establish the criteria accordingly.

There are a number of issues that must be considered when determining how the criteria should be set so that the risk levels are equal at all types of geographic and

climatic settings. This includes assessing the risks posed by different sources of fecal contamination, as well as the differences in risks posed by the nature of the contamination (*e.g.*, point vs. non-point source). The rationale for this is discussed more fully in the sections on human versus animal sources of fecal contamination and PS versus NPS contamination, items 1a and 1d. EPA must initiate the discussion of acceptable risk in order to successfully execute all other components of the CPSP. The stated risk level is directly related to the scientific and statistical design of the epidemiology studies, the required cohort group size, the potential methods to be used in the study, and statistical resolution of the methods to be employed.

Further, in the CPSP, EPA states that they will conduct a statistical analysis of the data to determine whether there is a significant difference in risk to children, who are considered a sensitive subpopulation (CPSP project P29). They do not however, describe the process they will use to determine whether the results of this analysis will be incorporated into any new or revised AWQC.

- ***Recommendation*:** EPA must justify the level of risk upon which any revised or new criteria are based.

b. "Acceptable risk" has not been defined by any empirical studies. There has been no work conducted to assess what "acceptable risk" levels are truly acceptable to the public.

In the Experts Report it is stated that there is a vital need for formal research to determine the "acceptable risk" for the public. The Expert Report suggests that "EPA should develop a policy that includes public interaction during the criteria development process". Currently, there is no proposed work to determine public perception of our nation's water quality. The Experts Report also makes a strong statement for EPA to include the public in the criteria development process, an issue that has not even been discussed in the CPSP. As outlined in the Experts Report, including public involvement in the criteria setting process would require research to establish

- what the public understands currently
- what does the public think of when one uses the term "acceptable risk"?
- how does the public interpret existing criteria and beach closures/advisories?
- how does EPA communicate this risk?
- what level of risk would the public accept?

A more informed and communicative path for decision making is critical to future acceptance of these new or revised criteria.

- ***Recommendation:*** EPA should undertake a systematic process to define the appropriate level of risk, especially in the context of public perception.

c. *EPA has not addressed issues of statistical resolution associated with using lower "acceptable risk" levels. For example, if the currently used multiple tube fermentation-based Enterococcus methods are used and the "acceptable risk" level is reduced from 19 to 8 cases per 1000 persons, the statistical ability of the method to discriminate between zero cases of illness per 1000 persons and violation of the standard will be very low.*

An important component of criteria development is to determine "acceptable risk", as described in 3b. Since the risk level in place for freshwaters is 8 cases per 1000 persons, a possible scenario that has been discussed is to reduce risk level for marine waters to be equivalent. If one creates a hypothetical scenario by which the current *Enterococcu*s standard is reduced by half (for simplicity assuming that the relationship between risk and *Enterococcus* density is linear), the new water quality standard for a single sample would be 52 *Enterococcus* colony-forming units or most probable number per 100 ml. At this lower density of *Enterococcus*, use of currently approved methods such as multiple tube fermentation would become problematic given their statistical variability, the false positive rates of the test in question, and presence/absence format. Following a scientific discussion of "acceptable risk", EPA must address the relevance and statistical resolution of "traditional" and proposed methods in the framework of any newly established risk levels.

- ***Recommendation*:** EPA should conduct research to demonstrate that economical and reliable detection methods are available to implement the accepted level of risk.

4. **The CPSP states that water quality criteria play a critical role in implementing a range of essential purposes and functions under the Clean Water Act, but the CPSP does not provide any further information on linkage of new or revised criteria to existing programs. Currently, Los Angeles County, as well as numerous other public agencies and publicly owned treatment works, are investing significant resources and public funds to comply with current criteria which may subsequently be revised by the EPA. The CPSP fails to provide any information on how EPA will provide guidance for state application of the current criteria for pathogens and pathogen indicators, given that EPA may develop new or revised criteria accounting for the diversity of geographic and aquatic conditions.**

   a. *There is a lack of information in the CPSP regarding the linkage of new or revised criteria and the Total Maximum Daily Loads ("TMDLs") and National Pollutant Discharge Elimination System* (*"NPDES") permitting programs that are in various stages of development and implementation.*

There is a lack of attention in the CPSP to the direct linkage between new or revised AWQC to implementation in the form of 1) water quality assessments, 2) TMDLs, 3) NPDES permitting process, 4) NPS programs, and 5) recreational water

quality monitoring and notification. The CPSP does not provide a discussion of and timeframe for the linkage between development of the new or revised criteria and how the criteria will be applied to each program, how the new criteria might alter the existing program, the timeframe within which implementation by water quality monitoring agencies is expected, and guidance as to how implementation will dovetail with existing implementation. The latter is especially important for TMDL and NPDES programs, as enactment of a multi-tiered approach for criteria establishment will be vastly different from the current measurement of a single indicator. All of these components are extremely important to water quality stakeholders in the United States. Specifically, the County of Los Angeles has active TMDL and NPDES programs and they need applicable and timely guidance now as to how the evolution of establishing new criteria will impact their current work. For example, the County is currently charged with compliance of water quality standards for summer, dry weather conditions, and is further charged with compliance of winter, dry weather conditions by 2012. Given that revised criteria are to be in place by 2012, the County of Los Angeles would benefit from guidance as to implementation modifications to meet the needs of all stakeholders. The County currently invests millions of dollars in TMDL and NPDES permit compliance, so an important reason for the process to be better delineated is to prevent wasted resources.

- ***Recommendation*:** EPA must provide clear, concise guidance and include an outlined set of examples, possibly detailing phased approaches for TMDL implementation and new approaches for the NPDES permitting processes in consideration of newly developed criteria and clauses for re-evaluation of impaired water body status. EPA needs to provide scenarios for the adoption of new criteria and management approaches (such as the toolbox approach recommended in the Experts Report) for NPDES permitting.

b. The use of a tiered, toolbox approach in the new or revised criteria is not discussed.

One of the main recommendations of the experts at the Experts Workshop was that EPA should utilize a toolbox approach in the implementation of the new AWQC. In the CPSP, however, EPA has neglected to incorporate this recommendation.

A toolbox approach would allow for the use of a "toolbox" of several indicators, methods and approaches to providing public health protection rather than reliance on one indicator or method in all environmental settings. As set forth in the Experts Report, for criteria that must be implemented nationwide and in a wide range of geographic, meteorologic, and hydrologic settings, a toolbox approach is appropriate, as it allows for "… greater flexibility increased options for implementation in selecting situationally-appropriate indicators/methods …" (EPA, 2007b).

The toolbox approach is "a set of assays that could be employed alone or in certain combinations to protect and restore the use of recreational waters." An example

of the use of the toolbox approach would be to use both quantification of enteric human pathogenic viruses and determination of the presence of *Bacteroides* human-specific marker in order to confirm the presence of human fecal contamination in a high priority recreational use area. Often, researchers in the field prefer to use multiple lines of evidence to create a snapshot of the types of fecal contamination present in a sample, instead of using only single measurement approaches. In addition, a combination of qualitative and quantitative measures of sources of fecal contamination can provide additional statistical confidence in the presence and quantity of human fecal contamination present in a sample (*e.g.*, Noble *et al.*, 2006).

The Experts Report also clearly recommends examination of a multi-tiered approach to water quality management in the United States. An example of a tiered approach is that currently in place for management of recreational waters as outlined by the World Health Organization (WHO, 2003) and discussed at length in the Experts Report. The Experts Report includes a table excerpted from the WHO (2003); it has been reproduced below. In this tiered approach, a water body is classified into a tier (the Sanitary Investigation Category) based on its susceptibility to fecal contamination. Based on the concentration of intestinal enterococci detected in the water, the water body is then designated as having "Very good" to "Very poor" water quality. In this tiered approach, two water bodies having the same concentrations of intestinal enterococci could be designated as having different water qualities, because they have different susceptibilities to fecal contamination.

		Microbial Water Quality Assessment Category (95th percentile intestinal enterococci/100 mL)				
		A	B	C	D	Exceptional
		≤40	41-200	201-500	>500	Circumstances
Sanitary	Very Low	Very good	Very good	Follow up*	Follow up*	
Investigation	Low	Very good	Good	Fair	Follow up*	
Category	Moderate	Good#	Good	Fair	Poor	Action
(susceptibility to	High	Good#	Fair#	Poor	Very poor	
fecal influence)	Very High	Follow up#	Fair#	Poor	Very poor	
	Exceptional Circumstances		Action			

From a criteria establishment standpoint, the Experts Report suggests that a "tiered approach" be considered, similar to those implemented by the European Union ("EU") and outlined by the WHO for management of bathing water quality. It is not suggested that the EPA adopt the full EU or WHO classification schemes, but there are components of the two approaches that make sense for consideration by the EPA. Formalization of the "sanitary investigation" process outlined in the Experts Report is one such example. A second example is sample discounting (elimination of some samples from the analysis, based on a pre-established set of criteria), which might be potentially useful in areas that are actively contributing to stormwater mitigation and

restoration efforts. A third example specific to the WHO Guidelines is the development of a recreational water quality reclassification scheme. The WHO approach utilizes a classification matrix (seen in the Table above) created by *Enterococcus* density crossed with sanitary investigation results. The *Enterococcus* concentrations represent the 95th percentile measured at the target beach. An asterisk (*) denotes that non-fecal source of *Enterococcus* may be influencing measurement and this should be verified using scientifically defensible methods. A pound sign (#) indicates that there is a possible discontinuous source of *Enterococcus* (from an ephemeral signal such as stormwater). The Experts Report states that the sanitary investigation component of the tiered approach may be most useful and consistent with the CWA and development of new criteria. The sanitary investigation component of the WHO approach provides a means for considering risks associated with contamination stemming from a range of sources. It is foreseeable that a "tiered toolbox monitoring approach" such as that outlined in the Experts Report will work in the following manner:

- For a tier one assessment, the use of the appropriate indicator organism would be allowed. For example, a water quality manager in the Great Lakes could utilize *E. coli*, a water quality manager in Waikiki Beach, Hawaii could use *Clostridium perfringens*, and a manager in Jones Beach, New York City could use *Enterococcus* sp.
- The next tier of the toolbox approach might include specific quantitative or qualitative measurements for pathogens of concern (*e.g.*, pathogenic viruses, *Salmonella*, *Campylobacter*, etc.), genetic markers specific to certain types of fecal contamination (*e.g.*, ESP gene specific to human fecal contamination), or speciation of specific fecal bacteria (*e.g.*, quantification of *Enterococcus faecalis*). This second tier might have several roles:

    - to facilitate the process of partitioning sources between human and animal fecal contamination, thereby permitting an assessment of relative risk,
    - to permit identification of sources of contamination,
    - to identify dynamics of source contributions over the course of events such as storms.

It will be important in the future for beach managers to have an approach that will permit them to determine if the cause of their poor water quality is from a human or animal source. It was specifically noted by the experts at the Experts Workshop that a "magic bullet" or single microbial marker or target will not be applicable to all sites. The toolbox approach will likely permit improved indicator/illness rates in subtropical and tropical waters to be determined and would reduce the inappropriate listing of waters as impaired under the CWA. The toolbox approach will also be an important component of management if indeed this approach could be successfully used to potentially allow for discounting of waters (as within the WHO 2003 approach) with no human fecal contamination loading, thereby also reducing the inappropriate listing of waters.

The Experts Report clearly recommends examination of a multi-tiered approach to water quality management in the United States. As mentioned above, this concept is different from the 'toolbox approach", but it is envisioned that the two together would provide an integrated strategy for successful, implementable criteria development.

Areas that are simultaneously conducting multiple indicator monitoring (*e.g.*, California), TMDL implementation, and sanitary investigations may be able to serve as test beds for successful application of WHO or EU management components, thereby serving as important sources of information for new criteria implementation. In order to make it possible to implement the WHO framework, it is necessary for research to be conducted to assess how different indicator/method combinations for CWA §304 applications relate to each other and to ensure that they provide equivalent levels of protection. This is especially important for States such as California that proactively conduct monitoring for multiple fecal indicator bacteria groups. Also immediately necessary are determining the appropriate metric for reporting water quality criteria (*e.g.*, upper percentile or geometric mean) and developing a well-described approach to "sanitary investigation".

- ***Recommendation:*** EPA needs to provide scenarios for the adoption of new criteria and management approaches (such as the tiered approach outlined by the WHO) and discuss potential implementation strategies.

5. **The CPSP proposes "epidemiology and/or Quantitative Microbial Risk Assessment (QMRA) studies" to establish new or revised criteria. This is not an appropriate way to delineate the studies that will be done to develop criteria.**

    a. *QMRA is not a viable alternative to epidemiological studies. Appropriate data do not currently exist to conduct only QMRA studies for coastal recreational waters.*

For the freshwater beach impacted by bovines and freshwater or marine beach affected by urban runoff studies (CPSP projects P4 and P5), EPA indicates that it will conduct epidemiological **and/or** QMRA studies [emphasis added]. The experts at the Experts Workshop indicated that the preferred approach for defining and quantifying human health risks from exposure to pathogens in recreational waters is to conduct epidemiological studies.

Epidemiological studies should be the primary means of proceeding. In contrast to epidemiological studies, it is not clear that the necessary data currently exist in order to conduct accurate QMRA for recreational waters. Also, given the data available in the literature, although the Experts Workshop experts suggested that QMRA might at some time be an alternative to epidemiological studies, it is strongly felt that QMRA should currently serve only as an adjunct or precursor to epidemiological studies.

EPA has proposed a project (CPSP project P7) to determine the data needed for QMRA applications. However, in the project description, the types of data that EPA indicates might be needed are the volume of water ingested by the recreators and the critical etiologic agents. This description of the manner in which a QMRA would be performed appears to differ considerably from what was viewed by the experts at the Experts Workshop as being the appropriate manner to conduct such an assessment.

The experts described the process that would need to be used. First, a suite of sentinel pathogens would have to be chosen – this would include representative viruses, bacteria, and protozoa. The next step involves calculation of the exposure to the organisms. One piece of information that would be needed is the volume of water that would be ingested by the recreators. However, according to the experts at the Expert Workshop, information on the "… origin, quantity, and fate and transport of wastes deposited on a land surface and into waterways is of prime importance in determining the distribution of pathogens in the water that is subsequently ingested or inhaled." In order to obtain this information, extensive experimental studies would have to be performed; EPA has not proposed conducting such studies. Other major limitations of QMRA for recreational waters are suggested in Medema and Ashbolt (2007), that "the large variability of pathogens in source waters and the limited availability of data ... are important issues to take into consideration in QMRA" and "pathogens selected for QMRA should be detectable in source waters with reliable analytical techniques.

According to the experts, "QMRA can be used to rank relative risks of different exposure scenarios … where no direct epidemiological information is available." (EPA, 2007b) Similarly, it is stated in Eisenberg *et al.* (2006) that "risk assessments can be used to specify the conditions in which future trials (epidemiology studies) are justified. Risk assessment can also provide information on where are the important data gaps". Therefore, there may be occasions when QMRA studies might have to be performed in *lieu* of epidemiological studies. For example, it may be necessary to use QMRA when calculating risk of infection, rather than risk of illness. In addition, when calculating the risk of high impact, low occurrence illnesses, QMRA may be necessary. An example of such a situation is determining the risk of illness from exposure to *Naegleria fowleri*. This organism is responsible for a few cases of illness (generally less than 5) every year in the United States; however, the illness most often results in the death of the infected individuals. It wouldn't be possible to conduct epidemiological studies to assess the occurrence of such a low frequency event. Absent these circumstances, however, epidemiological studies rather than QMRA should be used.

In the CPSP, EPA also stated that, based on an assessment of source and site characterization activities, and "… an evaluation of the preliminary results of the Doheny, CA, SCCWRP study, EPA will decide whether the potential differences in risk can be assessed through QMRA activities or an epidemiological study is needed" (EPA, 2007a). EPA must provide information on the process they will use to determine exactly when epidemiological studies are needed, and when QMRA can be substituted for them to develop scientifically-based AQWC.

- ***Recommendation:*** QMRA studies should not be used to supplant epidemiology studies, only to support them.

6. Other Flaws in the CPSP

The CPSP also suffers from the following flaws:

a. EPA states that the data from the Avalon study "**could potentially be combined** [emphasis added] with EPA-conducted studies for future analysis". The CPSP does not state that these data will in fact be used to formulate criteria, nor does it describe the process that will be used to determine if these data will be used.

b. EPA states that, if the results of the studies at the two POTW–impacted marine beaches (Goddard, RI and Fairhope, AL) "do not yield sufficient statistical power or if the results between these studies … are not consistent, then an additional epidemiological study on POTW-impacted marine water (P6) will be conducted." No information is provided on what constitutes "sufficient statistical power" or "consistency". Nor does EPA address how they will proceed if an additional study is performed and they still do not have "sufficient statistical power" or consistency among studies. EPA must provide information on the process they will use to determine exactly how many epidemiological studies are needed, and the required level of statistical significance that is needed for them to develop scientifically-based AWQC.

c. Studies are being conducted using methodologies that are very similar, if not identical in many respects, to the studies conducted by the EPA. Because EPA has limited resources (both financial and personnel), it is critical that EPA develop a procedure by which it will determine how the results of these and other studies (such as the Chicago[2] epidemiological

[2] Metropolitan Water Reclamation District Collaborates with UIC for Epidemiological Study about Environmental Exposures and Water Recreation. The Metropolitan Water Reclamation District of Greater Chicago (District) and the University of Illinois at Chicago (UIC), School of Public Health, are embarking on a three-year collaborative study about the health effects of water exposure during recreational use of the waterways. Prior studies of water recreation and health have focused on the health risks faced by swimmers. This research will be the first US study to address the health of individuals who engage in limited contact water recreational activities, such as boating, fishing, canoeing, kayaking, and rowing. http://www.mwrd.org/press_releases/07-27-2007-UIC.htm, Epibathe is a consortium of European research institutions carrying out an EC-funded project to explore the relationship between microbial indicators and health outcomes in order to define appropriate guideline levels. From http://www.who.int/water_sanitation_health/bathing/epibathe/en/index.html

study, the Epibathe and Virobathe studies being conducted in the EU) can be incorporated into the criteria development process.

d. In the Great Lakes studies (Wade et al. 2006), *E. coli* should have been measured by both culture-based and qPCR-based methods, as the current indicator for freshwater recreational waters is *E. coli* measured by culture-based methods. The lack of *E. coli* measurements in these epidemiological studies reflects a major shortcoming of EPA's study design. Archived samples from these epidemiological studies should be subjected to qPCR testing for *E. coli* as soon as possible, and future studies should include analysis for *E. coli* using both approaches.

e. A drawback of the qPCR-based assays is that the method targets DNA, so it will detect both living and dead organisms in a water sample. The relative proportions of living vs. dead organisms will vary from site to site, and at different sampling times at a given site. This issue is further discussed in Griffith *et al.* (2007). A stated research need in both the Experts Report and EPA CPSP is to understand the relationship of qPCR methods vs. culture-based method results in the context of chlorinated wastewater. The research approach could be more clearly explained.

f. In the CPSP, EPA indicates that predictive modeling is an important part of their future research program. The current work on predictive modeling is being conducted using the *E. coli*-specific method, EPA Method 1603, using modified mTEC agar. Yet, epidemiological studies in similar freshwaters are not being conducted with *E. coli* as an indicator (for example, *E. coli* measurements were not made during the Great Lakes epidemiology studies). In order to provide consistency and to be able to utilize the suggested predictive studies to protect public health and to help assess the variability of the indicator signal dependent upon environmental conditions, it is imperative for *E. coli* to be measured in all studies.

Virobathe is a 2.8M EU (DG-RTD)-funded project aimed at the rapid detection of viruses in recreational waters. http://www.virobathe.org/.

REFERENCES CITED

Bay, S. M., B.H. Jones, K.C. Schiff, and L. Washburn. 2003. Water quality impacts of stormwater discharges to Santa Monica Bay. *Marine Environ. Res.* 56:205-223.

Byappanahalli, M and R. Fujioka. 2004. Indigenous soil bacteria and low moisture may limit but allow faecal bacteria to multiply and become a minor population in tropical soils. *Wat. Sci. Technol.* 50 (1): 27-32.

Cabelli, V.J., Dufour, A.P., McCabe, L.J., and Levin, M.A. 1982. Swimming-associated gastroenteritis and water quality. *Am. J. Epidemiol.* 115: 606-616.

Colford, Jr., J.M., T.J. Wade, K.C. Schiff, C.C. Wright, J.F. Griffith, S.K. Sandhu, S. Burns, M. Sobsey, G. Lovelace and S.B. Weisberg. 2007. Water quality indicators and the risk of illness at beaches with nonpoint sources of fecal contamination. *Epidemiol.* 18:27-35.

Desmarais, T.R., H.M. Solo-Gabriele, and C. J. Palmer. 2002. Influence of soil on fecal indicator organisms in a tidally influenced subtropical environment. *Appl. Environ. Microbiol.* 68 (3): 1165-1172.

Eisenberg, J. N. S., A. Hubbard, T.J. Wade, M. D. Sylvester, M. W. LeChevallier, D. A. Levy, and J. M. Colford Jr. 2006. Inferences Drawn from a Risk Assessment Compared Directly with a Randomized Trial of a Home Drinking Water Intervention. *J. Environ. Health Perspectives* 14 (8):1199-1204.

EPA. 1986. Ambient water quality criteria for bacteria – 1986. EPA440/5-84-002. Washington, DC.

EPA. 2007a. Critical path science plan for the development of new or revised recreational water quality criteria. Office of Water and Office of Research and Development.

EPA. 2007b. Report of the experts scientific workshop on critical research needs for the development of new or revised recreational water quality criteria. Office of Water.

Fujioka, R.S. and L.K. Shizumura. 1985. Clostridium-perfringens, a reliable indicator of stream water-quality. *J. Wat. Pollut. Contr. Fed.* 57 (10): 986-992.

Fujioka, R.S., K. Tenno, and S. Kansako. 1988. Naturally-occurring fecal coliforms and fecal streptococci in Hawaii's fresh-water streams. *Toxicity Assessment* 3 (5): 613-630.

Fujioka, R., C. Sian-Denton, M. Borja, J. Castro, and K. Morphew. 1999. Soil: the environmental source of *Escherichia coli* and enterococci in Guam's streams. *J. Appl. Microbiol.* Symp. Suppl. 85:83S–89S.

Griffith, J.F., D. Moore, C. McGee and S.B. Weisberg. 2007. Beta testing of rapid methods for measuring beach water quality. Southern California Coastal Water Research Project. Costa Mesa, CA.

Griffith, J. and S.B. Weisberg. 2006. Evaluation of Rapid Microbiological Methods for Measuring Recreational Water Quality. Southern California Coastal Water Research Project. Westminster, CA.

Haile, R. W., J. S.Witte, M. Gold, R. Cressey, C. McGee, R.C. Millikan, A. Glasser, N. Harawa, C. Ervin, P. Harmon, J. Harper, J. Dermand, J. Alamillo, K. Barrett, M. Nides, and G.Y. Wang. 1999. The health effects of swimming in ocean water contaminated by storm drain runoff. *J. Epidemiol.* 10 (4):355-363.

Hardina, C. M and R. Fujioka. 1991. Soil: the environmental source of *Escherichia coli* and enterococci in Hawaii's streams. *Environmental Toxicology & Water Quality* 6 (2):185 – 195.

Hartel, P.G., K. Rodgers, J.A. Fisher, J.L. McDonald, L.C. Gentit, E. Otero, Y. Rivera-Torres, T. L. Bryant, and S. H. Jones. 2005. Survival and regrowth of fecal enterococci in dessicated and rewetted sediments. http://gwri.ce.gatech.edu/GAConf/Proceedings/Papers/2005/HartelPG_GWRCpaper.pdf

Medema, G. and N. Ashbolt. 2007. QMRA. Its value for risk management. MicroRisk. European Commission Fifth Framework Program. http://217.77.141.80/clueadeau/microrisk/uploads/microrisk_value_of_qmra_for_risk_management.pdf

Noble, R.T., S.B. Weisberg, M.K. Leecaster, C.D. McGee, J.H. Dorsey, P. Vainik and V. Orozco-Borbon. 2003. Storm effects on regional beach water quality along the southern California shoreline. *J. Water and Health* 1:23-31.

Noble, R.T., J.F. Griffith, A.D. Blackwood, J.A. Fuhrman, J.B. Gregory, X. Hernandez, X. Liang, A.A. Bera and K.C. Schiff. 2006. Multitiered approach using quantitative PCR to track sources of fecal pollution affecting Santa Monica Bay, California. *Appl. Environ. Microbiol.* 72:1604-1612.

Ott, E.-M., T. Muller, M. Muller, C.M.A.P. Franz, A. Ulrich, M. Gabel and W. Seyfarth. 2001. Population dynamics and antagonistic potential of enterococci colonizing the phyllosphere of grasses. *J. Appl. Microbiol.* 91 (1):54-66.

Rivera, S.C., T.C. Hazen and G.A. Toranzos. 1988. Isolation of fecal coliforms from pristine sites in a tropical rain-forest. *Appl. Environ. Microbiol.* 54 (2): 513-517.

Schiff, K. C., J. Morton, and S.B. Weisberg. 2003. Retrospective evaluation of shoreline water quality along Santa Monica Bay beaches. *Marine Environ. Res.* 56:245-253.

Wade, T. J., R. L. Calderon, E. Sams, M. Beach, K. P. Brenner, A.H. Williams, and A. P. Dufour. 2006. Rapidly Measured Indicators of Recreational Water Quality Are Predictive of Swimming-Associated Gastrointestinal Illness. *Environ Health Perspect.* 14(1): 24–28.

Whitman, R.L., Shively, D.A., Pawlik, H., Nevers, M.B. & Byappanahalli, M.N. 2003. Occurrence of *Escherichia coli* and enterococci in *Cladophora* (*Chlorophyta*) in nearshore water and beach sand of Lake Michigan. *Appl. Environ. Microbiol.* 69(8):4714-9.

World Health Organization (WHO). 2003. Guidelines for safe recreational water environments. Volume 1. Coastal and freshwaters. Geneva, Switzerland. ISBN: 92 4 1545801. The document can be found in full at: http://whqlibdoc.who.int/publications/2003/9241545801.pdf