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REPORT OF THE EXPERTS SCIENTIFIC WORKSHOP ON CRITICAL RESEARCH NEEDS FOR THE DEVELOPMENT OF NEW OR REVISED RECREATIONAL WATER QUALITY CRITERIA

DRAFT
EXECUTIVE SUMMARY
BY WORKGROUP CHAIRS

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EXECUTIVE SUMMARY

The *Experts Scientific Workshop on Critical Research and Science Needs for the Development of New or Revised Recreational Water Quality Criteria* took place at the Airlie Center in Warrenton, Virginia, from March 26 to March 30, 2007. Forty-three U.S. and international experts from academia, numerous states, public interest groups, U.S. Environmental Protection Agency (EPA or the Agency), and other federal agencies, met to discuss the state of the science on recreational water quality research and implementation issues.

The purpose of the workshop was for EPA to obtain input from individual members of the broad scientific and technical community on the "critical path" research and related science needs for developing scientifically defensible new or revised Clean Water Act (CWA) Section 304(a) recreational ambient water quality criteria (AWQC) in the near-term. Near-term needs were defined as those specific research and science activities that could be accomplished over the next 2 to 3 years so that results would be available to EPA in time to support development of new or revised criteria. EPA would publish the new or revised criteria in roughly 5 years (2012).

Experts were assigned to one of seven workgroups to discuss the following seven topics essential for EPA's development of new or revised criteria: (1) approaches to criteria development; (2) pathogens, pathogen indicators, and indicators of fecal contamination; (3) methods development, (4) comparing risks (to humans) from different sources; (5) "acceptable risk"; (6) modeling applications for criteria development and implementation; and (7) implementation realities. The workshop proceedings dedicate a chapter to each of these seven topics.

Drafts of the seven chapters of the report were written by the experts at the workshop. Subsequently, the chairs of the respective groups worked with EPA to finalize each chapter and prepare this Executive Summary. Because the workshop's purpose was to obtain individual input from each expert, the report is necessarily a summary of individual views. Thus, commonalities and differences in expert opinion are acknowledged throughout the workshop proceeding. During their deliberations, experts were asked to consider the following four main applications and implementation issues associated with AWQC for recreational waters: (1) listing of impaired waters under CWA §303(d); (2) total maximum daily load (TMDL) calculations for impaired waters; (3) National Pollutant Discharge Elimination System (NPDES) permits; and (4) recreational water monitoring and notification.

Because of the diverse nature of watersheds throughout the United States, there was general agreement among experts that criteria that have flexibility are desirable. A common statement from a number of workshop participants was that a "one size fits all" criterion is inadequate for public health protection and the compliance applications under the CWA. Workshop participants agreed that EPA should develop implementation guidance, including monitoring protocols, concurrently with development of new or revised §304(a) AWQC, and that the criteria and implementation guidance should be released simultaneously. This would facilitate acceptance and adoption by States, Tribes, and Territories.

Various workshop participants suggested areas for EPA to improve lines of communication, including with state and local governments and the public, by means of clear implementation

guidance and timely risk communication and education activities. Experts also urged EPA to communicate with other researchers who are planning to conduct relevant studies in the near term; importantly, researchers who plan to conduct epidemiological studies of swimmers and adverse health outcomes during the summers of 2007 and 2008 to determine if any of the methods being used are appropriate for inclusion in EPA's planned summer 2007 studies. Whether a particular method or tool (e.g., indicator type, quantification assay, use of watershed and/or predictive models) is appropriate for addition to EPA's planned epidemiological studies could be judged based on whether that indicator or method is important for one or more of the four high priority research paths discussed below.

Summary of Critical Path Research

The workshop participants identified the following critical path research areas as high priority: (1) human health impacts from different sources of fecal contamination; (2) measurement issues: climatic, geographic, and temporal variability; (3) determining risk level and subpopulations of concern; and (4) indicators and methods for measuring fecal contamination.

Human Health Impacts from Different Sources of Fecal Contamination

There was broad support among the workshop participants for conducting research and including in the new or revised criteria provisions that account for differences in risks associated with human versus nonhuman sources of fecal contamination, and point versus non-point sources—regardless of the framework ultimately proposed for the criteria. The absolute risk levels and the magnitude of differences between animal and human waste associated risks are not well characterized and may vary greatly geographically and temporally. Point sources and non-point sources of fecal contamination also differ in risk and those differences are not well characterized. Workshop participants suggested enhancements to epidemiological studies, quantitative microbial risk assessment (QMRA), development of quantitative sanitary investigations, and models to aid in sanitary investigations to help characterize risks.

Epidemiological studies are the preferred approach to define and quantify human health risks from exposure to pathogens in recreational waters. Two principal study designs have been used in previous studies of recreational waters—randomized control trials and prospective observational cohort studies. Epidemiological studies have historically been used to assess human health risks at beaches impacted by point sources of fecal contamination. However, the need for additional epidemiological studies, especially at non-point source impacted beaches, is viewed as essential to better define risk and guide future criteria development. In future epidemiological studies, consideration should be given to enhanced study designs as well as use of both study designs simultaneously.

QMRA can be used to rank the relative risks of different exposure scenarios, such as recreational sites impacted by animal versus human fecal wastes, where no direct epidemiological information is available. QMRA can also supplement existing epidemiological data, such as has been done in a number of specific case studies in the United States and in other countries. QMRA has the ability to consider infectivity of specific pathogens from a variety of fecal sources and their fate and transport in waterbodies to estimate risk.

Quantitative sanitary investigations for watershed characterization could be used to classify water quality based on relative risk, with waters that are more likely to be impacted by human waste being assigned a higher risk. Some methods for watershed characterization include the following: methods for sanitary investigations, methods for fecal source identification, and modeling to determine which watershed characteristics are related to risk of illness. Quantitative sanitary investigations can address multiple concerns regarding the applicability of criteria, including the impact of different sources of fecal contamination. The details of how quantitative sanitary investigations can be designed and implemented on a national level have yet to be determined and were not substantively addressed by the workshop participants; in part because the process by which the details would be determined is likely to be lengthy and iterative, though the details will be important for implementation.

Related Key Near-term Science and Research Needs:
[bracketed numbers correspond to the report chapters in EPA 823-R-07-006]:

- Develop methods to quantify the difference in risk to human health from human versus animal fecal material in recreational waters. [1, 4, 7]
  - Conduct epidemiological studies at locations influenced by different types of animals but that are not influenced by treated sewage (wastewater) effluent or other human fecal sources. [2]
  - Identify data gaps and collect data that are important for conducting QMRA studies for estimating health risks from different sources of fecal contamination (e.g., humans, domesticated animals, birds, point, non-point), particularly when epidemiological data are not available. [4]
  - Conduct QMRA studies to estimate the risk of low probability/high impact illnesses from human exposure to animal waste in recreational waters. (Animals can harbor many bacterial and protozoan pathogens that pose a human health hazard and some of these pathogens, such as enterohemorrhagic *E. coli*, can cause serious, life-threatening illness in humans.) [4, 5]
- Determine potential exposure levels and the associated health risks to intermittent microbial pollution discharges, combined sewer overflows (CSOs), urban runoff, and concentrated animal feeding operations (CAFOs). One aspect of exposure includes whether swimmers are likely to be in the water during these events, and if so, collect appropriate data (e.g., for complementary QMRA studies). [7]
- Develop protocols for using simple, heuristic, statistical models that correlate watershed activities (presence of sewage treatment plant effluents, agricultural activities, domesticated animals) and attributes (slope, soil type, climate, soil moisture) to the susceptibility of a waterbody to exceed new or revised criteria levels. [6]
- Develop quantitative rather than qualitative sanitary investigation tools. A tiered assessment of the watershed, starting with traditional fecal indicators (conservative measures) and progressing to select a suite of indicators that provide source specificity and load information, was suggested as one possible approach. [1, 2, 7]

- Develop indicators and associated methods for differentiating between human and animal fecal contamination. These methods could be part of a second or third tier of steps in evaluating a watershed, regardless of what criteria approach is selected. [2, 3]

Measurement Issues: Climatic, Geographic, and Temporal Variability

There was broad support among the workshop participants for conducting research and including in the new or revised criteria provisions that account for differences in climatic regions and geographic areas. Workshop participants were in agreement that the current state of the science calls for the new or revised criteria to be based on indicators of fecal contamination. Experts also agreed that enterococci and *E. coli* are probably not appropriate indicators in all climatic regions (e.g., in tropical and subtropical climates) and geographic areas. Appropriate indicators that correlate with recreator illness rates in tropical and subtropical climates are needed. New or revised criteria need to be applicable in areas where currently accepted indicators of fecal contamination, such as enterococci, may not be strongly correlated with observed excess illness rates. The workshop participants felt 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).

Workshop participants agreed that the spatial and temporal variability evident in indicator data sets, as well as the delay in obtaining monitoring results using conventional culture-based methods, rendered the single sample standard impractical for routine water quality notification purposes. Simple statistical models that do not necessarily require an understanding of processes and mechanisms have the potential to be incorporated into the new criteria, particularly for beach monitoring and water quality notification purposes. These models relate water quality to environmental factors like wind speed, prior rainfall, and tide level. Models have been demonstrated to serve as valuable tools for making closure or advisory decisions while managers wait for laboratory results, thereby providing for improved public health protection for swimmers as compared to relying on bacterial indicator monitoring alone. Also, once a model is site-validated with a sufficient baseline of monitoring, further monitoring could be reduced and targeted to instances where the model predicts exceedences of the criteria. The Modeling workgroup members felt that due to time-lag notification errors and temporal variation known to exist in indicator data series, day-to-day water quality notifications should not be issued using a single sample standard in conjunction with a microbial assay that takes longer than a few hours.

Related Key Near-term Science and Research Needs:

- Identify and develop indicators and corresponding methods that are appropriate for use in tropical and subtropical recreational waters. Conduct epidemiological studies to link those indicators with illness at tropical and subtropical locations. [1, 2, 4, 5]
- Increase the diversity of climatic regions and geographic areas where epidemiological studies are conducted. Also include different types of recreational waters, such as flowing (inland) waters. [3, 7]

- Gain better understanding of temporal and spatial variability in environmental sampling using culture-based and non culture-based methods and the implications for their use in representing water quality. [2, 4]
- Conduct research to better understand the human health significance of regrowth and persistence of indicator bacteria in nutrient enriched surface waters and sand/sediments and how those impact water quality determinations. [5]
- Ensure that QMRA studies conducted for estimating health risks from swimming in recreational waters include parameters and assumptions that are applicable for temperate, subtropical, and tropical climates. [4, 5]
- Determine if data are sufficient to conduct QMRA studies for evaluating health risks from flowing waters and collect data if possible and necessary. [7]
- Develop, test, and validate water quality models for different water types with a wide range of fecal sources and locations to improve notification accuracy. [6]

Determining Risk Level and Subpopulations of Concern

Workshop participants felt that (1) risks to children should be considered as the basis for determining risk level associated with new or revised criteria, and (2) timely risk communication and education of the public are critical for future acceptance of new or revised criteria. Social sciences research is needed to inform risk communication strategies and to examine what the public considers to be an "acceptable" level of risk for swimming-related illnesses. However, the Acceptable Risk workgroup members agreed that the term "acceptable risk" is flawed and should be avoided during the process of developing new or revised recreational AWQC.

Workshop participants felt that the risks to children should be better characterized and that a better understanding of risks to children may help inform policy decisions regarding selection of the risk level that will be associated with new or revised criteria. Epidemiological data indicate that children can have a higher risk of illness than adults from swimming in fecal contaminated recreational waters. Two factors contributing to this difference are (1) increased exposure from ingestion of higher volumes of water, and (2) greater susceptibility due to immunological differences compared to healthy adults. Note, workshop participants agreed that criteria should not be established based on the susceptibility of immunocompromised individuals; rather, targeted risk communication and public health messages could be used to advise these individuals that they are at increased risk of illness and are advised not to swim.

Workshop participants emphasized that clear and transparent communication with all stakeholders is important for the process of developing and implementing new or revised criteria. A tiered communication plan may be an effective approach for better informing the public about the criteria and how to interpret beach advisories and closings. Depending on the individual's level of interest or need, the information could be basic (e.g., a sign at a beach) or more detailed (e.g., pamphlets, websites). Workshop participants felt that EPA has a role in assisting State and local officials in developing risk communication strategies.

Related Key Near-term Science and Research Needs:

- Review existing recreational water-related epidemiological studies to evaluate risks to children. [1, 5]
- Include the ability to evaluate specific risks to children when developing new epidemiological studies. [1, 4, 5]
- Include some element of assessing acceptability of risk in the upcoming epidemiological studies, such as adding a sociological component. [5]
- Initiate studies to assess how impacted groups understand and perceive risks associated with recreational water use and what level of voluntary risk would be acceptable. [5]

Indicators and Methods for Measuring Fecal Contamination

Workshop participants felt that new or revised recreational AWQC should be based on fecal indicators. The level of occurrence and the types of pathogens in ambient waters vary greatly both temporally and spatially. Some pathogens are only present in very small concentrations, yet may present a public health risk. Because of these factors, methods to detect and quantify specific pathogens in ambient waters are not sufficiently developed at present to be practical for use in the near-term timeframe. Therefore, using suites of pathogens as the basis for new or revised criteria was not favored among workshop participants as a first "line of defense." However, pathogen monitoring may be useful as a subsequent tier for microbial water quality evaluation. For longer term research needs, further development of pathogen detection methods may result in a more important role.

There was broad expert support for new and/or improved methods for enumeration of fecal contamination and specific pathogens; however, methods need to be evaluated in the context of how they are going to be used for specific CWA applications. The workshop participants felt that rapid methods are needed in some but not all water quality management situations.

Future epidemiological study design efforts should integrate sanitary investigation and water quality modeling and incorporate characterization of the source of fecal contamination, including measurement of pathogens and indicators. The latter includes identifying the etiological agents in the source of fecal contamination and that cause illness in the subjects enrolled in the epidemiological studies.

Many of the enhancements of methods and tools discussed throughout these proceedings are likely to take longer than 2 to 3 years. Therefore, the further development of these methods and tools should be proactively pursued to facilitate future enhancements (beyond 2012). In situations where method and tool development proceed rapidly, then those methods and tools would become candidates for integration into new or revised criteria in the next 5 years.

Related Science and Research Needs:

- Evaluate and validate performance characteristics of methods that are linked to new or revised criteria and ensure that those methods are developed into official EPA Methods. [1, 2, 3]

- Develop and demonstrate the robustness of new methods for existing indicators (e.g., new ways of quantifying enterococci). [3]
- Develop new methods for new indicators, including but not limited to *Clostridium perfringens*, adenoviruses, coliphages, and *Bacteroides*, to either replace or augment the current bacterial indicators. [3, 4]
- Develop methods for enumeration of pathogens and indicators in wastewater. [1, 3]
- Develop methods for source identification to support watershed characterization activities. [3]
- Develop methods related to specific pathogens and fecal source identification for use in a second tier of tests to provide for a more refined assessment of risk of human illness. [1,3]
- Conduct fate and transport studies to determine relationships between current and new fecal indicators, index pathogens, and priority pathogens in treated effluents and in recreational water to better inform the applicability of those indicators and pathogens for specific CWA criteria uses. [2, 4, 7]

Summary

EPA would like to thank the workgroup chairs and other experts for their valuable contributions to the workshop deliberations, proceedings, and this Executive Summary, and on the state of the science of recreational water quality research and implementation issues. EPA intends to use these reports as it develops a critical path science plan that will help guide Agency research activities over the next 2 to 3 years in support of the development of new or revised recreational AWQC. These research activities could be a combination of Agency-sponsored studies, collaborative arrangements with external investigators and groups, or coordination of projects with external investigators to help supplement Agency efforts.