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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

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APPENDIX A: CHARGE TO THE EXPERT WORKGROUP MEMBERS

PURPOSE

The purpose of the Pellston-type[1] Experts Scientific Workshop on Critical Research and Science Needs for the Development of Recreational Water Quality Criteria is 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 (CWA) §304(a) recreational water quality criteria in the near-term.[2]

BACKGROUND

An important goal of the CWA is to protect and restore waters for swimming. Section 304(a) of the Act directs EPA to publish "advisory water quality guidance on the effects of the presence of pollutants in water on health and welfare." These recommendations are referred to as §304(a) criteria. Under §304(a)(9) of the CWA, EPA is required to publish water quality criteria for pathogens and pathogen indicators to protect swimmers from illnesses associated with pathogenic microbes in coastal and Great Lakes waterbodies.

In adopting new or revised water quality standards, States must adopt criteria that are scientifically defensible and protective of the use, but they have flexibility to do so by adopting EPA's recommended criteria, adopting criteria to reflect site-specific conditions, or adopting other criteria that are scientifically defensible. In the case of criteria EPA publishes under §304(a)(9), States with coastal and Great Lakes waters are required to adopt EPA's new or revised criteria for pathogens and pathogen indicators into State Water Quality Standards (WQS).

Once adopted into State WQS, water quality criteria express the desired ambient condition of the water to protect a designated use. State WQS are used for various CWA purposes or programs that identify and address the sources of pollution with the goal of attainment of the criteria, including National Pollutant Discharge Elimination System (NPDES) permits, water body assessments to determine use attainment, and development of Total Maximum Daily Loads (TMDLs). In addition, these WQS used by States in beach monitoring and water quality notification programs.

[1] A workshop similar in organization and format to the Society of Environmental Toxicology and Chemistry (SETAC) Pellston Workshops where technical experts in a particular subject area are invited to participate and evaluate current and prospective environmental issues. A Pellston-type workshop brings together between 40 to 50 technical experts from academia, business, government, and public interest groups. Experts are sequestered for a week and expected to contribute to a summary report. Subject leaders are then responsible for consolidating, editing, producing, and distributing the workshop proceedings.

[2] Near-term requirements: in order for EPA to develop criteria in the near-term, the indicators/methods/tools upon which they are based must be currently available, have undergone scientific peer review and validation, and ready for day-to-day implementation in State public health/environmental laboratories within the next 2 to 3 years. New or revised criteria must be based on indicator/methods that are easy to use and interpret.

Historically, EPA's recommended criteria for protecting people who recreate in water have been based on fecal matter in recreational waters. In the 1960s, the federal government recommended using the indicator bacteria, fecal coliforms, as the primary contact recreational[3] criterion. In the late 1970s and early 1980s, EPA conducted public health studies evaluating several organisms as possible indicators, including fecal coliforms, *E. coli*, and enterococci. The studies showed that enterococci are a good predictor of gastrointestinal (GI) illnesses in fresh and marine recreational waters, and *E. coli* is a good predictor of GI illnesses in fresh waters. As a result, EPA published in 1986 revised criteria (*EPA's Ambient Water Quality Criteria for Bacteria – 1986*[4]*)* for primary contact recreation recommending the use of *E. coli* for fresh recreational waters (criteria set as a geometric mean of 126 colony forming units [cfu]/100 mL) and enterococci for fresh and marine recreation waters (criteria set as geometric means of 33/100 mL in freshwater and 35 cfu/100 mL in marine water). These recommendations replaced EPA's previously recommended bacteria criteria for fecal coliforms of 200 cfu/100 mL. EPA's criteria recommendations use "indicator" bacteria. Most strains of *E. coli* and all enterococci do not cause human illness (that is, they are not human pathogens); rather, they merely indicate fecal contamination, and the assumption is that pathogens co-occur with incidences of fecal contamination.

Since EPA issued its recreational criteria over 20 years ago, there have been significant scientific advances, particularly in the areas of molecular biology, microbiology, and analytical chemistry. EPA believes that these new scientific and technical advances need to be factored into the development of new or revised CWA §304(a) criteria for recreation. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 (which amended the CWA) required EPA to conduct new studies and issue new or revised criteria, specifically for Great Lakes and coastal marine waters.

OVERALL CHARGE TO THE EXPERTS

Experts are asked to provide their individual knowledge and insight that will help EPA define the critical path research and science needs, recognizing the "state of the science" and the reality that research that cannot be completed within 2 to 3 years will not be helpful in EPA's near-term criteria development efforts. Experts should focus their efforts at this Workshop on identifying near-term research and science needs that will allow EPA to publish new or revised criteria in roughly 5 years. (While EPA understands that experts may wish to offer perspectives on research and science needs for the development of future or "next generation" criteria, this is not the primary purpose of this Workshop.) "Next generation" criteria refer to criteria EPA may publish in the longer term; that is, in approximately 10 to 15 years, pursuant to CWA §304(a)(9)(B). Section 304(a)(9)(B) directs EPA to review and, as necessary, revise the §304(a)(9) criteria 5 years after EPA publishes the initial criteria, and every 5 years thereafter.)

[3] Primary contact recreation includes activities that could be expected to result in ingestion of water or immersion. These activities include swimming, water skiing, surfing, and other activities where contact and immersion in water is likely.

[4] US EPA. 1986. *Ambient Water Quality Criteria for Bacteria - 1986*. EPA440/5-84-002. Washington, DC: US EPA.

Although not the focus of this Workshop, EPA is aware of stakeholder concerns regarding implementation issues associated with the existing (EPA) 1986 criteria and the desire on the part of some stakeholders for EPA to address these issues in the interim (i.e., before EPA publishes a new or revised recommended criteria). In recognition of these concerns, experts in the "Implementation Realities" Workgroup are encouraged to identify aspects of the 1986 criteria which have been cited as problematic, and, to the extent that these issues can be remedied through new or revised criteria, offer individual input for EPA to consider in the criteria development efforts.[5]

The new or revised criteria must be scientifically sound, protective of the designated use, implementable for broad CWA purposes, and when implemented, provide for improved public health protection. By scientifically sound, EPA means that the criteria must be based on the science and peer reviewed studies available at the time the criteria are developed. By protective of the use EPA means that the criteria must establish the desired ambient condition of the water to protect the designated use (e.g., primary contact recreation) given to the waterbody. EPA's new or revised criteria must also serve the broad purposes for which CWA criteria are intended, including beach monitoring and water quality notification programs, development of water quality based effluent limits for National Pollutant Discharge Elimination System (NPDES) permits, waterbody assessments to determine use attainment, and development of total maximum daily loads (TMDLs), where needed. Lastly, the new or revised criteria, when implemented, should also provide for improved public health protection and States must be satisfied that the underlying science is sound and that the numeric values of allowed pollutant in recreational waters will achieve the desired environmental result.

On the last day of the Workshop, the chairs for the individual breakout topic groups will provide EPA with sections of a draft Expert Report. Each of these sections will summarize the individual input provided by the experts and collected by the Chairs throughout the week's discussions. The Chairs will be asked to summarize commonalities and differences in the input provided by participants, and list out the projects and activities that the individual experts identified as critical to the development of new or revised CWA §304(a) criteria in the near-term, recognizing that research that cannot be completed in 2 to 3 years will not be useful in near-term criteria development efforts. (The workgroup chairs may also summarize any research and science needs identified by the experts for developing "next generation" criteria.)

The draft Report will include a summary of expert views on the following topics: appropriate pathogens or pathogen indicators, along with available and appropriate methods; single versus "toolbox" criteria approach; implementation issues; and most importantly, identification of critical technical issues and uncertainties that could be addressed with near-term research.

EPA contractual support will be available to the Chairs during the workshop to provide assistance in preparing the draft Report. After the workshop, EPA contractual support will be available to the Chairs to finalize their component of the Report in 1-month's time. EPA will use

[5] To the extent that experts come to some conclusion on how to better implement the 1986 criteria, EPA intends to track these issues separately in order to not depart from the primary purpose of the meeting which is to obtain input on critical research needs for the development of the near-term criteria.

the Report as it develops a critical path science plan that will guide research activities over the next 2 to 3 years.

Presented in the following sections of this document are key questions on seven major overarching issues pertaining to criteria development and implementation. A threshold issue that impacts the deliberations of all groups is whether EPA should consider a fundamental change in its approach to recommending recreational criteria; for example, switch from a single criterion in all places to a diversified toolbox or tiered approach, using multiple criteria, or several tools supporting a single criterion, or some other combination.

Break-Out Group #1: Approaches to Criteria Development (See Chapter 1)[6]

Single versus "Toolbox" Approach: A single criterion and/or method may not adequately address all CWA needs. One approach for new or revised criteria may consist of several "tools" (i.e., indicators, methods, intrinsic geographic factors, etc.) to fulfill all of the specific CWA needs. For example, it could involve using molecular methods and rainfall models for beach monitoring and water quality notification, and possibly other method-indicator combinations for other CWA uses—provided that all criteria and methods are comparable in terms of level of protection provided. For example, the definition of an impaired recreational water in terms of the number of people that would get sick when the water is not in compliance cannot differ from the illness rate that triggers a beach advisory or closing.

The following set of questions is intended to guide a robust discussion among the experts in this group. The results of this discussion will improve the understanding of the advantages and disadvantages of various approaches to criteria development.

1. *What approaches exist currently for setting limits of pollutants that may be relevant for developing nationally recommended recreational water quality criteria? Consider approaches used for other kinds of pollutants in water, in other environmental media, and by other countries as well as approaches being implemented by States. What are the pros and cons of each of these approaches?*
2. *Which of these approaches is most applicable and appropriate for developing nationally recommended recreational water quality criteria in the near-term? Why is this approach on balance considered the most applicable and appropriate?*
3. *For those approaches identified as applicable and appropriate, what is the science that supports the approach? Is that science sufficient and of adequate quality?*
4. *Are there any critical research and science needs that should be addressed in developing or selecting an appropriate approach? Can this research be completed in time to be used in criteria development in the near-term?*
5. *Is a "toolbox" approach appropriate for developing new or revised recreational criteria in the near-term? Why or why not?*
6. *What are the pros and cons of selecting a "toolbox" approach?*

[6] Because breakout group numbers do not correspond to chapter numbers in these proceedings, chapter numbers are referred to for easier reference.

7. *What are desired features or characteristics that would make a "toolbox" approach appropriate?*
8. *Would a "toolbox" approach achieve additional public health protection as compared to another approach? Why or why not? If unknown, what science would need to be completed in order to determine whether a "toolbox" approach would achieve additional public health protection?*
9. *Criteria for secondary contact recreation could be part of a "toolbox." What approaches would be appropriate for developing criteria for secondary contact recreation? Would this approach be different from that used to develop primary contact recreation criteria? Why and why not?*
10. *What are critical research and science needs in developing or selecting an appropriate approach for secondary contact recreation? Can this research be completed in time to be used in criteria development in the near term?*
11. *What are the implementation considerations of the different approaches for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the use of an approach in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

Geographical Applicability: Options for ensuring criteria are appropriate in a diverse range of recreational waters include EPA recommending geographically different approaches, numbers, or indicators, applicable to different regions (e.g., fresh and marine waters, coastal and inland waters, tropical/subtropical and temperate waters) or types of waterbodies (e.g., lakes and flowing waters).

1. *Is a single criterion available that is applicable for the diverse range of geographic conditions? Why or why not?*
2. *Is a "toolbox" approach appropriate for different geographical conditions? Why and why not?*
3. *What would a "toolbox" that addresses geographical differences look like?*
4. *What are critical research and science needs in developing or selecting an approach that will appropriately factor-in diverse geographical conditions?*

Expression of Criteria: EPA is currently assessing the degree to which criteria should be expressed as the mean concentration over a period of time (e.g., 30 days) and/or as a daily or instantaneous maximum value.

1. *Given the diverse needs of the CWA programs and the overarching goal of protecting and restoring waters for swimming, what protection is provided by establishing a 30-day "average" value as the criteria? What additional protection (if any) is provided by a daily or instantaneous maximum value? From a scientific standpoint, is one measure better scientifically than another for particular purposes (e.g., mean value for purposes of identifying impaired waters and daily maximum for beach monitoring and notification purposes)? Why?*

2. *What are pros and cons of expressing the criteria differently for the various CWA program needs?*
3. *What are the implications of instantaneous or daily values for public health protection? If we don't currently have a good understanding of this, what are the critical research and science needs to answer these questions?*
4. *If EPA were to set criteria at a mean concentration over 30 days and not recommend a single sample maximum, do we understand the illnesses that could occur on a single day (where the level would still lead to compliance with the 30 day average)?*
5. *If the science is not there, what are the critical research and science needs to answer this question?*
6. *What are the implementation considerations for CWA purposes of failing to address (and addressing) differences geographically in the criteria and failing to include (and including) a single sample maximum value for (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

Break-Out Group #2: Implementation Realities (See Chapter 7)

Although EPA wants the experts to consider implementation realities when providing input to all general and specific questions throughout this document, the following set of questions are intended to guide a robust discussion among the experts about implementation issues and how science and research could ease implementation.

1. *What are the essential implementation considerations as EPA develops new nationally recommended recreational water quality criteria for CWA purposes: (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs?*
2. *What are the major lessons learned in implementing the (EPA) 1986 criteria? What worked well and not so well? How could we avoid repeating past "mistakes" that lead to delays in adoption or difficulties in implementing these criteria?*
3. *Which approaches to criteria development have the most potential for success in implementation when new or revised criteria are adopted into State water quality standards? Why?*
4. *What are general features or characteristics that would make new or revised criteria easy to interpret and implement for states when adopted into State water quality standards? Why?*
5. *Would a "toolbox" approach be easier or more difficult to interpret and implement? What are desirable characteristics of a "toolbox" criterion from an implementation perspective?*
6. *If new or revised criteria are provided as a range of values instead of a single value, what implementation concerns are triggered (e.g., can a range of values be used when developing NPDES permit limits or TMDL calculations)?*

7. *What are critical path research and science needs that would enhance implementation of new or revised criteria in the near-term?*

Break-Out Group #3: Pathogens, Pathogen Indicators,[7] and Indicators of Fecal Contamination (See Chapter 2)

Indicator Approach: EPA previously developed criteria based on indicators of the potential presence of human pathogenic organisms; that is, based on indicators of fecal contamination. Other possible approaches such as pathogen index microorganisms and specific pathogens are discussed below.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs in the development of criteria based on pathogens, pathogen indicators or indicators of fecal contamination. It is essential that this group focus discussions on only those pathogens, pathogen indicators or indicators of fecal contamination where methods are ready now for day-to-day use in State public health and environmental labs or where methods will be ready for day-to-day use in these labs within the next 3 years.

A. Fecal matter indicators (as surrogates for gastrointestinal and non-gastrointestinal diseases):

1. *What are the benefits and shortcomings for continuing to implement the current fecal indicators (*E. coli *and enterococci) to meet each of the CWA §304(a) criteria uses (beach notification, TMDLs, NPDES permits, listing of impaired waters) to protect swimmers health from (a) gastrointestinal disease? (b) upper respiratory tract disease? (c) other diseases (skin, ear, eye disease)? Should other CWA §304(a) uses be tied to health outcomes?*
2. *Are there other microbial fecal indicator(s) that can be used to better meet each of the CWA §304(a) criteria uses and provide improved protection against diseases (e.g.,* Bacteroides *spp.,* Clostridium perfringens*, coliphages or other phages)? Why?*
3. *Are there any chemical biomarker fecal indicators (e.g., fecal stanols, detergents, whiteners, caffeine) that can be used to better protect public health and meet all CWA purposes than the current indicators of fecal contamination?*
4. *What critical research would improve or widen the selection of fecal indicators available for the criteria?*

B. Pathogens and their Index organisms (gastrointestinal and non-gastrointestinal disease):

1. *Would a specific pathogen or index microorganism approach present an improvement in health protection over fecal indicators for each CWA use if applied as §304(a) criteria? If yes, then see question #2. If no, what research could be done to support this*

[7] A specific pathogen belonging to a broader group of pathogens which would serve as a surrogate for the presence and/or health risks for that group (e.g., *Cryptosporidium* serving as a surrogate for all parasitic protozoa); or an indicator microorganism whose presence is correlated to the presence of a broad group of pathogens (e.g., spores of *Clostridium perfringens* serving as a surrogate for human or dog parasitic protozoa).

approach? (also for skin, upper respiratory tract, ear, eye disease criteria considerations)

2. *What are the advantages and disadvantages of this approach?*
3. *What might be the most appropriate pathogens or index organisms? Why?*
4. *What data support a dose-response relationship between a particular pathogen or its index in recreational water and any disease outcome?*
5. *The BEACH Act requires that EPA conduct research and develop new or revised water quality criteria for "Pathogens and Pathogen Indicators." The Act defines a pathogen indicator as a substance that indicates the potential for human infectious disease. How might the term "index microorganism" relate to the statutory term pathogen indicator?*
6. *What is the critical research to make the selection of pathogen/ index organisms available for the new or revised criteria and for the next generation criteria?*

Application of Alternatives: The following two sections present some possible applications of a mix of approaches that may increase the potential to improve monitoring, better express health risks from swimming exposures, and be more comprehensive in their use to meet all criteria needs and provide more efficient and cost effective procedures.

C. Application of fecal indicators, pathogen index organisms, and pathogens in combination for criteria:

1. *If none of the above three groups of surrogates can meet all CWA §304(a) criteria needs, is there any combination of the three that would provide an acceptable criteria approach?*
2. *What specific combined applications would have merit in meeting criteria needs?*
3. *Would the combined applications best utilize an analytical toolbox approach or a tiered analytical approach?*
4. *Would the criteria endpoint reflect a general gastrointestinal disease target or a dose response estimate base on more limited disease symptoms reflecting the metrics used?*
5. *What research is important to make the selection of combinations available for the new or revised criteria and the next generation criteria?*
6. *Can adoption of the WHO/Annapolis Protocol approach[8] that combines sanitary reconnaissance survey information along with microbial assessment to develop surrogates of fecal contamination (predictive modeling) on the day to manage water advisories provide improved health gains over current criteria? Are there sufficient examples of this approach to develop new/improved use of indicators/surrogates in the near term?*

[8] WHO (World Health Organization). 2003. *Guidelines for Safe Recreational Water Environments. Volume 1 Coastal and Fresh Waters*. Geneva, Switzerland: WHO.

D. Applications of all the above for all categories of waters, climatology, and geographical considerations:

1. *Will the choices of individual, combined, or tiered fecal indicators, index organisms or pathogen indicators, or pathogens selected from above be capable of working for each or all of the following:*
    a) *Freshwaters (flowing and lakes/ponds)? Marine waters? POTWs? TMDLs?*
    b) *Temperate waters? Tropical waters?*
    c) *High matrix waters (high in solids)? Special conditions?*
2. *What science or research is important in the near term to make the determination in Question D1?*

Break-Out Group #4: Methods Development (See Chapter 3)

The 1986 criteria are based on a culture method (EPA Method 1600) for the detection of fecal indicators in ambient waters. The Agency has been considering the use of newer methods, such as qPCR and faster culture-based methods, for inclusion in new or revised criteria. EPA is interested in input on what other methods or tools are available and should be considered for developing criteria/standards that would meet all CWA purposes.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs in the development of detection methods for the new criteria. It is essential that this group focus discussions on those methods (and pathogens, pathogen indicators or indicators of fecal contamination) that are ready now for day-to-day use in State public health and environmental labs or would be ready for day-to-day use in these labs within the next 3 years.

1. *Are there quantitative methods other than membrane-filtration/Most Probable Number (MF/MPN) methods that measure active organisms that EPA should consider for water quality criteria development?*
2. *Are there data to support other molecular methods for beach microbiological monitoring purposes? Which molecular methods are most fully developed in your view?*
3. *Are there data to support other methods targeting non-microbiological surrogates of beach fecal pollution? Which methods are most fully developed in your view?*
4. *How important is time-to-results in method selection from the perspective of public health protection?*
5. *What further work needs to be done to ensure that the qPCR method or other promising (molecular) methods are considered valid for all CWA purposes?*
6. *What are the pros and cons of the use of molecular methods in each of the CWA applications?*
7. *If some tools are available for certain CWA uses only (e.g., for beach monitoring and notification) how could other methods be "linked" to the qPCR method so that they are scientifically sound and easily implementable? If only qPCR has been validated through epidemiological studies to predict health effects, what other studies could be done to link qPCR to other methods/indicators that may be more appropriate for §304(a) uses?*

8. *Depending on the method used, how could contamination at the beach be linked to all potential fecal sources of contamination? If the source of the contamination was a treated point source, could the method be linked to the necessary source to address the contamination?*
9. *Current culture-dependent methods and qPCR are linked to health risks using epidemiological studies. How would future methods (resulting from rapid technical advances) be calibrated to health risks without new epidemiological studies?*
10. *What applications of water quality criteria would culture methods, including EPA Methods 1600 and 1603, be most suitable for and why?*
11. *What further work needs to be done to ensure that other culture methods are considered for CWA regulatory purposes? If the science is not there, what are the critical path science or research needs to be used in this aspect of criteria development in the near-term?*
12. *What new methods and analytical technologies may be useful to begin to investigate in order for these to potentially be available in the development of "next generation" criteria (i.e., 10 or more years in the future)?*
13. *Can other tools (e.g., models, sanitary surveys) be developed to enhance the insight provided by water quality indicators?*
14. *What characteristics of analytical methods are essential for the methods used in both wastewater and ambient water?*
15. *What are implementation considerations for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?*

Break-Out Group #5: Comparing Risks (to Humans) from Different Sources (See Chapter 4)

New or revised criteria should be protective of waterborne organisms that are pathogenic to humans whether the source is human waste or animal waste. The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs to better understand the relationship between the risks posed by exposure to human and animal wastes in recreational waters so that this may be considered in the development of new criteria.

1. *Is setting criteria based on a treated human point source such as a publicly (or privately) owned (sewage/wastewater) treatment work (POTW) protective, under-protective or overprotective of other potential sources of human pathogen? Why or why not? Are there data to support this conclusion?*
2. *Based on the "state of the science," what conclusions or assumptions are reasonable to make about risks to humans exposed to human fecal contamination, non-point source contamination from animal sources, and mixed sources (e.g., combined sewer overflows and storm sewer overflows)?*

3. *To what extent is it reasonable to apply risk estimates from POTW-influenced beaches to non-POTW beaches? Do we understand scientifically whether this would lead to overprotection? What science would be important to understanding this?*
4. *Assess whether there is a possibility of overprotection due to a compounding of risks from multiple factors (such as the current definition of GI illness [i.e., no fever]; more sensitive molecular methods; assuming that POTW risks = non-human source risks, etc.)*
5. *How should EPA evaluate risk that may have a low probability of occurrence but a significant risk, if it occurs?*
6. *What are the key data gaps and uncertainties needed to support criteria development in the near term?*

Break-Out Group #6: Acceptable Risk (See Chapter 5)

Population to be Protected: EPA is currently reassessing the extent to which criteria protect swimming populations, including some vulnerable subpopulations (e.g., immunocompromised individuals, elderly, and children) against various types of waterborne diseases (GI and non-GI) caused by pathogens.

The following set of questions is intended to guide a robust discussion among the experts toward the identification of critical research and science needs to better understand what protections new criteria would provide and for what populations/subpopulations.

1. *Is the science there now to understand the degree and extent of protection that nationally recommended criteria for the general population would provide to vulnerable subpopulations (e.g., immunocompromised individuals, elderly, and children)? Is the science there now to understand whether nationally recommended criteria (based on the types of epidemiological studies EPA and others have conducted to date) provide protection against all types of major waterborne diseases? If not, for which subgroups, pathogens, and waterborne illnesses is the science lacking? What types of studies would be needed to answer these types of questions about the degree of public health protection provided by nationally recommended criteria?*
2. *What methodologies or approaches for assessing human health risk or hazard should EPA consider as it develops new criteria? Why?*
3. *What are the pros and cons of using GI illness rates associated with differing levels of fecal contamination as the foundation for developing nationally recommended criteria?*
4. *Is there any scientifically-based reason to establish different "acceptable" risk levels for fresh water versus marine water?*
5. *Is the phrase "acceptable risk" from the (US EPA) 1986 criteria the best terminology or should we consider other terminology (e.g., tolerable or appropriate risk level)?*
6. *What science, if any, would be helpful to EPA in making decisions about what amount and type of human illness from recreation should be considered acceptable?*
7. *What is the level of human health protection provided by the implementation of the 1986 criteria? Is it really no more than 8 to 10 GI illnesses (with fever) per 1,000 in fresh water and 19 GI illnesses (with fever) per 1,000 in marine waters, or, are we really*

protecting people from more than GI illness (with fever)? What science is needed to understand what protection is provided by the implementation of the 1986 criteria?

Protection of Humans from Drinking Water and Fish and Shellfish Consumption: EPA is currently assessing the degree to which recreational criteria can and should be developed to not only protect people from illnesses associated with recreation, but also to protect people from illness caused by drinking contaminated recreational water or consuming fish and shellfish found in contaminated recreational water.

1. *Will criteria that protect swimmers from swimming-related illnesses caused by pathogens also protect people who drink the water or eat fish or shellfish from the same water? Is the science sufficient to support a determination that recreational criteria will also protect drinking water uses and shellfish uses?*
2. *What additional science is needed to ensure that recreational criteria protect people from illnesses associated with recreation and also protect people from illnesses caused by drinking contaminated recreational water or consuming fish and shellfish found in contaminated recreational water?*
3. *Is the science there now to understand and characterize the degree of protectiveness for all these elements?*
4. *If the science is not there, what are the critical path science or research needs to address this?*

Break-Out Group #7: Modeling Applications for Criteria Development and Implementation (See Chapter 6)

Predictive modeling may be useful as a tool to help with the development of site-specific recreational water quality criteria, and the implementation of criteria. Presently, EPA is not considering models in its plans for new or revised criteria in the near-term. However, in recognition that some states and municipalities currently use models effectively in beach notification programs, EPA solicits input from experts regarding the potential use of models as tools to aide implementation of the new or revised criteria, and further requests input on critical research and science needs in this area for future criteria development.

1. *What potential role could estimating techniques (or models) play in criteria development? In the setting of site-specific criteria for recreational waters?*
2. *What potential role could estimating techniques (or models) play in implementing nationally recommended criteria for recreational waters?*
3. *What are advantages and disadvantages of using models, instead of direct measurement (monitoring), in water quality management? And in particular, in management of recreational waters?*
4. *What factors should be considered in integrating modeling with current monitoring regimes, or in changing monitoring regimes to include or support modeling?*
5. *What is the "state of the science" in modeling to support recreational water quality criteria development and implementation?*

6. *What model evaluation procedures are used to insure the quality of predictive models for recreational water quality?*
7. *How does uncertainty in modeling compare to uncertainty in monitoring? How can uncertainty be accurately represented and considered in risk analysis and public health decisions?*
8. *Do differences in the nature of the respective uncertainties inherent in modeling versus monitoring require different means of addressing these uncertainties? For instance, issue an advisory on the basis of modeled results, but clear the advisory only on the basis of sampling.*
8. *What models would be most useful for certain "uses" of criteria (i.e., beach notification, assessment, permitting, TMDLs)? How would modeling be used together with monitoring to cover all "uses" of criteria?*
9. *In models that are currently being used to predict levels of indicator bacteria, how are advisory/closure decisions being made using model results, and how are the results and/or the risk being communicated to the public? Do paradigms currently exist that would be applicable to the communication of modeled information on likely water quality?*
10. *Given the differences between fresh water and marine water environments in terms of physical predictive factors, what are the respective challenges of the two environments relative to developing predictive models? What are the differences in data requirements, likely effectiveness of models, and resources required to develop and implement useful models for the full range of intended purposes?*
11. *What are the critical path research and science needs EPA should pursue to further enhance the capabilities and effectiveness of models in the development/implementation of new or revised criteria? Why?*
12. *What critical path research and science needs EPA should pursue to consider modeling in the development of next generation criteria? Why?*