DRAFT FOR DISCUSSION AND INPUT BY STAKEHOLDERS

Pellston-type Expert Workshop on the Development of New or Revised Recreational Water Quality Criteria

BACKGROUND AND PURPOSE

An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of EPA's key roles is to recommend recreational water quality criteria (under Section 304(a) of the CWA)) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal government recommended a certain level of fecal coliform as the recreational criteria and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

It has been over 20 years since EPA last issued recreational criteria. Science - particularly molecular biology, virology and analytical chemistry - have advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. 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 BEACH Act provided EPA with an opportunity to conduct new studies and provided additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for Great Lakes and coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection over the 1986 criteria.

EPA is holding a Pellston-type Expert Workshop to confer with and obtain input from the broader scientific and technical community on the critical path for needed science and the approach EPA should follow in developing new or revised 304(a) recreational criteria in the near-term.

Stakeholder Input:

In addition, while the focus of the Workshop is on short-term research and implementation needs, EPA also welcomes input from the experts on scientific and policy considerations that could affect EPA's development of "next generation" water quality criteria. "Next generation" criteria refer to criteria EPA may publish in the longer term; that is, in approximately 10 years, pursuant to a provision in the Clean Water Act that EPA review and revise the criteria as appropriate every five years.

USES OF CLEAN WATER ACT SECTION 304(a) CRITERIA

Water quality criteria adopted by states into water quality standards are used for beach monitoring and notification programs, development of water quality-based effluent limits (WQBELs) for NPDES permits, water body assessments to determine use attainment, and development of Total Maximum Daily Loads (TMDLs), where needed. In addition, States covered by the BEACH Act use water quality standards in their beach monitoring and notification programs for coastal recreation waters (i.e., Great Lakes and coastal marine waters). Experts are asked to consider the availability of science to support the various purposes of criteria, factors that may affect implementation of a new or revised criteria for each of these purposes, and the approaches to criteria development that are more useful for each purpose.

OVERALL CHARGE TO THE EXPERTS

In providing input, EPA requests that experts assess whether EPA's current thinking on the path to follow to conduct research and develop criteria in the near-term is the best path to be on given the "state of the science". EPA welcomes input on the identification of critical path research that will lead to the ongoing near-term development of criteria that are scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection over the 1986 criteria. Experts are asked to help EPA define the critical path research needs, recognizing that research that cannot be completed within 3-4 years will not be helpful in EPA's near-term criteria development efforts.

Stakeholder Input:

Break-Out Group #1: Pathogens and Indicators of Fecal Contamination

Indicator Approach: EPA's current thinking is to develop criteria based on indicators of the potential presence of human pathogenic organisms; that is, based on indicators of fecal contamination. Other possible approaches are to develop criteria for separate, representative pathogens, or to combine the fecal-indicator approach with representative pathogens, or other.

> *Draft General Questions - Is the science there now to select an approach other than that of using an indicator of fecal contamination? If so, what is that science? If the science is not there, what are critical path research needs on indicators and can this research be completed in time to be used in criteria development in the near term?*
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> *Draft Specific Question - What are advantages and disadvantages of relying on indicators of fecal contamination, actual pathogens, representative pathogens, a combination of the above, or other?*

Stakeholder Input:

Choice of Indicator: If indicators of fecal contamination are the only type of indicators ready for "prime-time", there are several indicators that could be used as the basis for criteria, including enterococci, *E. coli*, and bacteroides. EPA's current thinking for developing criteria in the near-term is to base it on enterococci for all types of waters.

> *Draft General Questions - Is the science there now to select an indicator of fecal contamination other than enterococci,* E. coli*, or bacteroides? Which among these indicators (i.e., enterococci,* E. *coli, bacteroides, other) should EPA consider for criteria development? Should the same indicator be used for all types of waters? If the science is not there, what are critical path research needs and can this research be completed in time to be used in criteria development in the near term?*

Draft Specific Questions – What is the known relationship between the presence of individual fecal indicators and certain illnesses (GI or non-GI)? What are geographic and climate zone differences (e.g., tropical versus sub-tropical versus temperate, marine versus freshwater) that EPA should consider in selecting fecal indicators to develop criteria?

Stakeholder Input:

Break-Out Group #2: Methods Development

The 1986 criteria are based on a live culture method (method 1600) for the detection of pathogens in ambient waters. EPA's current thinking for developing the new or revised criteria is to develop criteria based on qPCR enterococci for beach notification and monitoring, and to further study the availability of other methods or tools for developing criteria applicable for the other CWA purposes that implement criteria.

Draft General Questions - Are there live culture methods other than method 1600 that EPA should consider? Is the science there now to select a molecular method other than qPCR enterococci (for beach notification and monitoring)? Are these other methods or detection technologies that are available to supplement and/or replace the qPCR method in an effort to develop new or revised criteria that can be used for the broad CWA purposes? If the science is not there, what are critical path research needs and can this research be completed in time to be used in criteria development in the near term?

Draft Specific Questions – 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? How important is time-to-results in method selection? 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)?

Stakeholder Input:

Break-Out Group #3: Approaches to Criteria Development

Single v "Toolbox" Approach: EPA's current thinking is that the new or revised criteria may consist of several "tools" to fulfill the variety of CWA needs. For example, as discussed above, using qPCR enterococci for beach monitoring and notification, and possibly other method-indicator combinations for other CWA uses. It may be possible to adopt a different method for different CWA uses, e.g., use qPCR for beach closings, and method 1600 for NPDES permitting, among others.

Draft General Questions - Could any of the above options regarding indicators, methods, geographical applicability (below) be combined in a "toolbox" approach to address the broad CWA uses of criteria? What are some factors EPA should consider in thinking about the "toolbox" approach in criteria development in the near term? What are critical path research needs and can this research be completed in time to be used in criteria development in the near term?

Draft Specific Questions - What are key elements needed for developing criteria that are protective of primary contact recreation and secondary contact recreation?

Stakeholder Input:

Geographical Applicability: Options for ensuring criteria are appropriate in a diverse range of recreational waters include having 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). EPA's current thinking is a "one-size fits all" criteria - one that would be the same for all geographical areas and all waters.

> *Draft General Questions - Is the science there now to select an approach other than the "one-size fits all" model? Is a "toolbox" approach appropriate for different geographical conditions? If the science is not there, what are critical path research needs and can this research be completed in time to be used in criteria development in the near term?*

Stakeholder Input:

Expression of Criteria: EPA is currently assessing the degree to which criteria should be expressed as the mean concentrations over a period of time (e.g. 30 days) and/or as a daily or instantaneous value. EPA's current thinking is that it is useful to have a value for long-term assessment (e.g., geometric mean) as well as a daily or instantaneous value (e.g., single sample maximum) for beach monitoring and notification.

> *Draft General Questions - Is the science there now to select another approach? If the science is not there, what are critical path research and can this research be completed in time to be used in criteria development in the near term?*

Stakeholder Input:

Break-Out Group #4: Risks to Human Health from Animal v Human Waste

EPA believes that the new or revised criteria should to be protective of waterborne pathogens from human and animal waste sources. EPA's current thinking is that if it develops criteria that protect human health from pathogens in human waste, that these criteria will also be protective of human health from pathogens in animal waste.

> *Draft General Questions – Is the science there now to support or rebut this assumption? Do we understand, based on available science, what the risk is to humans of swimming in waters that are contaminated with animal v human waste? If the science is not there, what are critical path research needs and can this research be completed in time to be used in criteria development in the near term?*
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> *Draft Specific Question – Based on the "state of the science", what conclusions or assumptions are reasonable to make about risks to human exposed to human fecal contamination, non-point source contamination from animal sources, and mixed sources (e.g., Combined Sewer Overflows and Storm Sewer Overflows)?*

Stakeholder Input:

Break-Out Group #5: Acceptable Risk

Population to be Protected: EPA is currently assessing the extent to which criteria should (and can) protect **all** vulnerable swimming populations against **all** types of waterborne diseases (GI and non GI) caused by **all** pathogens. For example, the extent to which criteria would protect all sub-populations (e.g., including immune-compromised individuals), against all types of waterborne diseases (e.g., would a criteria based on enterococci protect swimmers from Cryptosporidiosis). Additionally, whether other exotic animal microbes (e.g., hauntavirus) need to be considered. EPA's current thinking is that the science is not there to fully understand the degree of protectiveness for certain sensitive populations (e.g., immune-compromised), against all non-GI illnesses, and for all pathogens.

Draft General Questions - Is the science there now to select another approach? If the science is not there, what are critical path research and can this research be completed in time to be used in criteria development in the near term?

Draft Specific Questions – Should acceptable risk be individual- or population-based? What are pros and cons of various methodologies for determining acceptable risk? What are considerations for EPA in determining an acceptable risk level when using an indicator of fecal contamination? What information is available from other related examples of risk (e.g., drinking water, food), and can that information be used in this context?

Stakeholder Input:

Protection of Humans in Drinking Water and Fish and Shellfish Consumption: EPA is currently assessing the degree to which recreational criteria should (and can) protect from illness caused by drinking the water or consuming fish and shellfish found in recreational water. EPA's current thinking is that recreational criteria should be focused on protection of public health from swimming-related illnesses.

Draft General Questions - Is the science there now to characterize the degree of protectiveness for all these elements? If the science is not there, what are critical path research needs and can this research be completed in time to be used in criteria development in the near term?

Stakeholder Input:

Break-Out Group #6: Predictive Modeling

EPA is currently assessing the use of modeling as a core or supplemental tool for site-specific criteria setting. Presently, EPA is not addressing this aspect in its plans for new or revised criteria in the short-term.

> *Draft General Questions - Should EPA be addressing this aspect? What are critical path research needs and can this research be completed in time to be used in criteria development in the near term?*
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> *Draft Specific Question – What approaches are available for now-casing and fore-casing water quality based on various types of data, including monitoring and weather information? If EPA were to consider predictive modeling, what approaches should be considered in integrating this new monitoring with current monitoring regimes? What guidelines may be needed for waters that are not currently monitored?*
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> *Stakeholder Input:*

Break-Out Group #7: Implementation Realities

EPA requests that experts consider implementation realities when providing input to all general and specific questions throughout this document.

> *Draft General Questions - What are the pros and cons of available approaches for developing criteria in the near-term (e.g., the WHO Annapolis Protocol)? Which approach has the most potential for success in implementation when criteria are adopted into state water quality standards, and why? Is it necessary for EPA to develop secondary contact recreation criteria, or could an extrapolation be made from primary contact recreational criteria that could be scientifically valid?*
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> *Stakeholder Input:*

PROCEEDING REPORT

The last day of the Workshop, the leads for the individual break-out topics (or expert "leads") will deliver to EPA draft components of a Critical Path Research Plan that summarize the input collected. EPA contractual support will be available to expert "leads" during the workshop to provide assistance. After the workshop, EPA contractual support will be available to the expert "leads" to finalize those components in 1-month's time. EPA will use these components to plan research and criteria development activities over the next 3-4 years that will contribute to the development of criteria in the near-term.

Stakeholder Input:

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