NACWA
A Clear Commitment to America's Waters

May 16, 2011

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Via Electronic Mail: *king.ephraim@epa.gov*

Dear Mr. King,

The National Association of Clean Water Agencies (NACWA) looks forward to participating in the upcoming stakeholder meeting on the U.S. Environmental Protection Agency's (EPA) work to develop new or revised recreational water quality criteria for coastal recreation areas and in particular those waters adjacent to beaches. As you know, NACWA was actively engaged in the settlement discussions held pursuant to *Natural Resources Defense Council* (*NRDC*) *v. EPA* that laid out the plan and schedule for the Agency to complete its obligations under the Beaches Environmental Assessment and Coastal Health Act (BEACH Act) and this issue continues to be a top priority for NACWA's public agency members.

In advance of the June 14-15 stakeholder meeting, NACWA wants to share its perspectives on the task that lies ahead for EPA based on the Association's preliminary review of the recently completed suite of studies required by the Consent Decree and Settlement Agreement developed pursuant to the BEACH Act litigation. Review of these studies is ongoing, but NACWA understands that EPA must soon make important decisions about the structure and content of the criteria in order to meet its deadline of October 2012 for publishing a notice of availability of new or revised recreational water quality criteria. NACWA's comments should both inform EPA's decision-making process and help to make the discussions during the June meeting more productive.

At this point NACWA has six main concerns or comments that EPA should address during the stakeholder meeting and criteria development effort:

1. EPA's rationale and methodology for developing new or revised recreational water quality criteria must be adequately vetted with the

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public and the upcoming stakeholder meeting must allow sufficient opportunity for public feedback;

2. The new studies have revealed no information to indicate that the current criteria used in Clean Water Act (CWA) programs are not protective and no changes are warranted;

3. Expanding the definitions of "illness" and "swimming" and the application of indicators developed for marine waters to fresh waters is inappropriate;

4. EPA must avoid a one-size-fits-all approach to recreational water quality criteria for beach monitoring and CWA purposes;

5. qPCR data should not be used for CWA purposes;

6. Scientifically defensible criteria that are protective of secondary contact uses are needed; and

7. EPA's criteria development effort must consider costs and benefits.

1. An Open Dialogue on EPA's Methodology is Needed

The stakeholder meetings EPA held in 2009 and 2010, as well as the meeting planned for June 2011, were key requirements of the Settlement Agreement. For the June 2011 meeting, the Settlement Agreement outlines that the focus of the workshop "will be to provide an opportunity for Plaintiff, Intervenors, and other interested stakeholders to comment on EPA's evaluation, synthesis, summarization and statistical analysis of the studies **and development of options for the overall structure and content of the recreational water quality criteria** (emphasis added)..." (Settlement Agreement, Paragraph 11). In order for the June 2011 stakeholder workshop to be successful, EPA must have an open dialogue with stakeholder participants not only on the scientific studies and how they might inform the final criteria, but also on the policy considerations that comprise the Agency's options for the overall "structure and content" of the criteria, including choosing levels of "acceptable" risk associated with the criteria. Providing additional information detailing the Agency's options for developing the criteria in advance of the workshop would better ensure a productive dialogue.

A key piece of information that will be essential to understanding how EPA's plan will meet its Consent Decree obligations and CWA mandates to develop effects-based criteria that reflect the latest scientific knowledge is the underlying scientific and policy rationale for developing the recreational criteria and associated "acceptable" risk levels. It will be critical for stakeholders to understand how EPA established the structure of the 1986 criteria and the associated risk levels, as outlined in *Health Effects Criteria for Marine Recreational Waters* (EPA-600/1-80-031, August 1983), and how any of the new information from the recently completed studies may dictate changes in the existing criteria and risk levels. Ultimately, EPA needs to subject the underlying studies, EPA's rationale for any new or revised criteria, including the scientific and policy analysis and support for any proposed modification to the current "acceptable" risk levels, and the criteria themselves to an independent, external peer review with ample opportunity for stakeholder involvement.

2. EPA Studies Indicate that No Criteria Changes Are Warranted

EPA's new studies have revealed no information to indicate that the current CWA criteria, and the levels of risk associated with them, are not protective of human health. Though EPA is obligated in the Consent Decree to publish "new or revised" criteria, NACWA does not believe this requires EPA to make changes to the existing criteria that are not supported by the science.

Recreational water quality criteria, though generally thought of as a number, really depend on several interrelated elements including: an indicator or indicators (the existing criteria rely on *E. coli* and/or E*nterococcus*), an acceptable level of risk (e.g., illness rate of 19 per 1000 bathers in marine waters for the existing criteria) that helps to establish the allowable level of the indicator, duration and frequency components, and the test method used to enumerate the indicator (e.g., culture based methods currently). The mandates in the BEACH Act sought to add scientific information to the policy debate on protecting public health in the nation's coastal recreation waters (in particular beaches), evaluate the appropriateness and effectiveness of indicators, and spur development of methods to enable beach management decisions to be made more quickly. The BEACH Act did not address or even contemplate the many other uses of EPA's water quality criteria.

When EPA initiated its work to complete the obligations laid out in the Consent Decree and Settlement Agreement, the Agency early on decided to focus on the values of two indicators, *Enterococcus* and *Bacteroidales*, enumerated using more rapid, DNA-based qPCR test methods in an effort to address the core concern of the BEACH Act – making quicker beach management decisions. Much of EPA's work has been focused on validating the test methods and determining whether correlations could be made between qPCR values and illness and whether comparisons could be made between the new qPCR data and data developed using the existing culture-based methods.

The recently completed studies largely reveal a lack of meaningful correlations between qPCR values and illness. The results also indicate that it is not possible to reliably predict outcomes of the culture tests using qPCR, and vice versa. NACWA plans to conduct a more thorough review of the available studies (some have still not been made available) in the coming weeks, but based on its initial review the Association does not believe EPA has sufficient scientific information to support any changes to the current recreational water quality criteria used for CWA programs.

3. Changes to Risk Levels, Indicator Use Are Inappropriate

EPA's recent studies provide no new information to support changes to the "acceptable" risk levels associated with the current criteria. Should EPA consider changes, it must ensure stakeholders have a thorough understanding of EPA's process for establishing the existing risk levels and its rationale for any changes to those levels.

Based on discussions at EPA's Beach Conference in March, EPA is considering a new, broader definition of illness that would include gastrointestinal illness when fever is not present. Presentations during the Beach Conference indicate that EPA may also consider broadening its definition of swimming to include non-contact recreation (limited body contact, e.g. shoreline activities). Expanding the definitions of illness and swimming (e.g., type and frequency of exposure) would make any changes to and the evaluation of the "acceptable" risk level even more problematic.

Discussions at the Beach Conference and previous stakeholder presentations indicate that EPA is considering application of indicators being developed for marine waters in fresh waters. Due to the numerous differences between coastal and fresh surface waters that impact the relationship between indicator bacteria densities and risk (Dorevitch et. al.[1]), NACWA strongly believes it is inappropriate to modify fresh water criteria based on results of studies performed in coastal waters pursuant to the Consent Decree and Settlement Agreement and BEACH Act.[2]

4. EPA Must Avoid One-Size-Fits-All Approaches

EPA must act carefully as it considers its next steps. The studies EPA has conducted were designed with the idea that a single tool could be used for CWA and beach management decisions. Based on previous EPA stakeholder meetings and Settlement Agreement updates, the Agency has acknowledged that qPCR may not be appropriate for use in CWA programs, but there are also questions over whether rapid testing will resolve the many issues associated with beach management decisions[3]. Since the BEACH Act was passed, there has been extensive work to evaluate different sampling and reporting approaches and the beach management community is just starting to zero in on the important issues and challenges. EPA should work with local authorities in the development of rapid testing methods. These local authorities can provide feedback to EPA on issues encountered such as field logistics, funding, equipment, certifications, human resource needs, and the overall extent of the consequences to the nation's beach programs.

NACWA understands that some beach managers are highlighting the weaknesses of using any type of indicator-based approach or out-of-the-box water quality model as a solution. Many challenges are site- or region-specific and require intensive work on the ground to figure out site-specific solutions. Sanitary surveys to understand what is impacting beach water quality must be conducted, often using multiple indicators/methods to determine what type of evaluation method provides the timeliest information on whether to open or close a beach. In many cases, local regulatory authorities can use sanitary survey tools to make scientifically reliable determinations and take appropriate regulatory actions, including: 1) ongoing trends based on data collected from regular water monitoring and sample collection (often begun prior to the bathing season); 2) historical water quality data for the general ambient conditions, and probability distributions; 3) reports of pollution events from other regulatory agencies; and 4) practical knowledge of exogenous factors affecting the beach waterbody. Many regulatory agencies have this information available for contemporaneous evaluation.

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[1] Dorevitch et. al., "Meeting Report: Knowledge and Gaps in Developing Microbial Criteria for Inland Recreational Waters", Environmental Health Perspectives, June 2010.

[2] This approach would also seem to contradict EPA's *Health Effects Criteria for Marine Recreational Waters* (EPA-600/1-80-031, August 1983).

[3] According to the US EPA, "Microbial Source Tracking Guide Document" Office of Research and Development (EPA 600/R-05/064) there is no ideal source indicator and a combination of techniques are suggested. This approach has been referred to as a "toolbox" where a variety of indicators (not necessarily microbial) can be used. Even within the set of microbial methods, not any one fits all applications.

With the BEACH Act and during the *NRDC v. EPA* settlement negotiations, stakeholders asked for rapid testing, and EPA's work on qPCR over the past several years has been a response to that. But beach managers are realizing that even rapid testing will not resolve all of the challenges they face. In addition, EPA has not yet demonstrated in a compelling way that qPCR is any more accurate at predicting water quality or protecting public health than the older indicators and test methods. The original advantage was that qPCR was a rapid test, allowing for faster communication of risk and decision-making, but the extent of this benefit may still be limited. For example, while the test itself might be rapid relative to current methods, a rapid method to prepare the samples still has not been validated.[4] A case-controlled epidemiological study to assess qPCR and other indicators would have improved our understanding on these issues, but such work was not conducted by EPA.

The shortcomings of qPCR, particularly as the beach management community is coming to an improved understanding of the challenges and complexities of assessing and predicting water quality, speaks to the need for a suite of options, not a single management tool. It also further underscores the inherent differences between beach management and recreational criteria applications in CWA programs.

Even among the various CWA programs through which the recreational criteria are applied, there is a need to look at the different objectives and information needs. Evaluating ambient water quality, assessing CWA permit compliance, and managing stormwater, for example, all demand different considerations. While NACWA through this letter and in discussions with EPA at the June workshop will highlight concerns with the studies and the use of the qPCR approach, discussions about these more fundamental implementation issues are also needed.

5. qPCR Data Should Not be Used for CWA Purposes

NACWA agrees with EPA's current thinking that the new qPCR test methods should not be used in the CWA permitting context, and believes that other changes to the current criteria as they relate to CWA compliance obligations are not supported. NACWA believes, however, that a framework for more rapid notification and approach to managing beach closures using the new qPCR test methods EPA has developed, is one more tool in the toolbox for beach managers, and appears warranted where certain conditions are met. EPA can meet its obligations under the Settlement Agreement and the BEACH Act by addressing this need through a separate framework guidance document that does not result in any implications for existing CWA programs.

Based on its review of the studies and EPA's own conclusions regarding correlation between rapid test results and swimmer illness, NACWA believes that only culture-based methods should be used for all CWA compliance programs, including 303(d), and that, given the issues outlined below regarding the new qPCR methods, qPCR should be used only for beach management purposes at a limited subset of beaches (i.e., high use beaches that have a history of bacterial standard exceedances, are located in proximity to a laboratory with qPCR capability, and that do not have qPCR inhibition issues).

[4] It is our understanding that a skilled technician can prepare about 12 – 15 samples in a day, not in four hours.

A point of conflict between these two systems is the link between beach closures and 303(d) listings. Beach closures can and do result in 303(d) listings and beaches with qPCR data only will potentially lead to listings that must then be reconciled with a permitting system that is based on culture methods. This issue should be addressed by clearly establishing a separate framework for beach notification and clearly precluding listing of waters under 303(d) based on qPCR data alone. Listing decisions would need to be confirmed or otherwise made using culture tests. States would need to maintain culture based methods in their state water quality monitoring programs to ensure that any beaches that are closed based on qPCR data are only listed under 303(d) if culture-based testing confirms impairment. Managers at high use beaches would still have the option to close beaches with qPCR data alone. Again, such a framework would satisfy the requirements of the Consent Decree and Settlement Agreement and the BEACH Act's mandates.

6. EPA Must Also Address Secondary Contact Recreation

In some cases, the highest attainable use may not be primary contact recreation, and a waterbody may be designated for secondary contact recreation. EPA's primary focus throughout its work on the BEACH Act studies has been on criteria for primary contact waters. There is, however, a real need for scientifically defensible criteria that are protective of secondary contact uses. There has been no discussion of secondary contact water by EPA and guidance is needed to assist states and others with these uses.

7. EPA Must Consider Costs and Benefits of its Criteria

Any changes to the current recreational water quality criteria must be considered in a cost-benefit context. Changes to the criteria will impact a wide swath of CWA programs including TMDLs, combined sewer overflow long-term control plans, stormwater, disinfection, and more. Selection of the "acceptable" illness rates, or levels of risk to which the criteria protect, is a policy decision. Fewer illnesses per 1,000 swimmers will carry with it cost implications for all of the CWA programs listed above. EPA generally asserts that federal criteria are 'recommendations' or guidance and therefore not subject to the same review as regulations. However, EPA uses these criteria as the regulatory threshold or minimum standard against which all other State criteria and standards are compared. Thus, simply put, State water quality standards must be as stringent, or more stringent, than EPA's criteria. These state standards then serve as the basis for permit limits and TMDLs, both of which have very real consequences for regulated entities. If state standards are to be subject to rejection based on federal criteria, then those criteria carry the weight of a regulation and are in essence being applied as a water quality standard. Therefore, the issue of attainability including the costs and benefits must be considered.

Though the BEACH Act applies to coastal waters that are designated by a state for swimming, bathing, surfing, or similar water contact activities, NACWA understands that EPA may also seek to revise criteria for inland waters. At the same time, throughout the EPA Regions, there is a continued pressure to assign 'fishable/swimmable' uses to more waters, even those that have not been historically designated that way by the state. Recent decisions involving heavily trafficked portions of the Mississippi River designed to make that water safe for swimming, in spite of barge traffic and current hazards that cannot be mitigated, combined with EPA's recent effort to amend its water quality standards regulations, asserting that waters must be designated to the highest attainable use, indicate that EPA will continue to push for fishable/swimmable designations unless the conditions in 40 CFR 131.10(g) can be met to EPA's satisfaction that such a use is not attainable. The

effects of this push will only be compounded should EPA increase the stringency, including the breath of application, of its already conservative recreational criteria.

Regardless of its decision on whether or not to revise the current recreational water quality criteria for CWA programs, EPA should make every effort to support designated uses that best reflect the population, industrial and agricultural changes throughout the country since passage of the CWA in 1972. Doing so would demand a new approach to designating uses and more importantly assessing the attainability of water quality standards, or at the very least, better utilization of existing regulatory provisions governing use attainability analyses (UAAs) and other tools, such as the development of wet weather water quality standards. NACWA agrees that waterbodies should be designated for the highest-attainable use, but disagrees with EPA's apparent presumption that every waterbody, even those that are generally unsafe for recreational activities, can attain the Act's "fishable and swimmable" goals at all times. Deciding what is attainable is key, as are clear and reasonable UAA guidelines.

Specific Concerns with EPA's Studies

EPA Should Examine Non-EPA Studies for Inclusion in its Criteria Development Process

Paragraph 7 of the Settlement Agreement required EPA to provide technical assistance on study design and analysis for an epidemiological study that was being proposed by the Southern California Coastal Water Research Project (SCCWRP). That study is now complete, as is another study conducted in Miami. NACWA strongly encourages EPA to consider the results of these studies as it determines possible changes to its criteria. Another study, conducted in Orange County California[5] provides valuable lessons on the use of qPCR tests for beach monitoring and NACWA encourages EPA to consider the results of this study.

Concerns Remain with EPA Rapid Test Methods and Implementation

To meet its obligations under Paragraph 12 of the Settlement Agreement, EPA must "validate and publish a rapid test method for the new or revised criteria". Again, EPA can meet this obligation without applying these rapid methods for use in determining CWA compliance. The detailed comments below outline some of NACWA's initial reactions to the methods and provide some recommendations for improving implementation of the methods. Given these issues, implementation guidance for use of the methods will be critical.

Implementation Considerations

- With limited funding available, use of rapid methods such as qPCR (costing approximately three times as much as traditional culture-based methods) should be limited to locations where the only benefit of using the method, the speed by which method results are obtained, justifies the added cost.

- Until the inhibition and QA/QC issues are resolved, the new qPCR-based rapid methods should not be required for inclusion in monitoring programs, but should instead be optional.

[5] Southern California Coastal Water Research Project (SCCWRP) - http://www.sccwrp.org/ResearchAreas/BeachWaterQuality/RapidIndicators/RapidMethodsDemonstration.aspx (last accessed April 29, 2011)

- The more expensive rapid methods should only be recommended at beaches where the benefits of the rapid test have been clearly established and the beach meets certain criteria such as: 1) high attendance; 2) frequent exceedances; 3) proximity to a laboratory such that results can be received in time to post same-day beach closures; and 4) an absence of compounds that inhibit the methods.

- Rapid methods should not be required for inland surface waters with low recreational usage (cost has not been justified) and/or significant input from POTWs with full-time disinfection (due to the inability of DNA-based methods to distinguish between live and dead pathogens).

- No time limit should be set on obtaining results from rapid methods (i.e., noon on the day of sampling) unless any such limit addresses the time needed to collect samples from multiple locations, transport the samples to a laboratory, prepare the samples for analysis, conduct the analysis, verify the results, and report the results. Any time limit should also be based on scientific evidence that notification at or prior to this time would result in decreased incidence of illness.

- Guidance needs to be provided not only as to whether it is appropriate to use rapid methods, but also as to monitoring frequency and reporting goals. This document should be based on an EPA survey of end-user concerns.

- EPA should conduct and/or sponsor qPCR training programs.

- EPA should investigate and publish the estimated costs associated with qPCR laboratory start-up and operation, including various qPCR platforms and the degree of technical staff expertise required[6].

- EPA should recognize that many laboratories provide multiple fecal indicator bacteria analyses to meet overlapping water quality monitoring programs (e.g., shellfish harvesting, bacterial TMDLs, MS4 permits, and NPDES permits).

- Several studies have shown poor overall comparisons between qPCR cell equivalents and cultural numbers. The variability between the qPCR and cultural data, coupled with the lack of robust epidemiological evidence correlating enterococci qPCR numbers to disease incidence, indicate that applying current public health action limits to the qPCR assay could lead to erroneous beach management decisions and thus, result in the expenditure of additional limited local agency resources to address non-public health concerns as well as additional stress to the recreating public. Therefore, implementation of the assay should be limited to carefully defined situations. Additional work is needed to establish public health action limits in regards to qPCR data. If the assay is to be

[6] States currently audit for Enterococcus by culture. In the case of California, the requirement would be for the Environmental Laboratory Accreditation Program (ELAP) to include qPCR in their audits. ELAP must be willing to do so. Accreditation requires that there are proficiency samples available for the labs. EPA requires that proficiency sample providers meet ISO 17043. It is unclear whether there are any providers for this service. It appears that the infrastructure to support the use of this analyte does not currently exist.

promulgated without this work, current action limits should be retained until sufficient scientific data are presented that validate the methods and approach.

- On a site-specific basis, states should be permitted to implement alternate criteria based on different indicator or pathogenic organisms that may correlate better to various levels of risk (i.e., type and degree of recreational exposure) than enterococcus, and/or on QMRA and sanitary surveys. Any new or revised criteria that EPA may issue must make it clear that development of site-specific criteria offers the opportunity for improved public health protection and is encouraged.

Compliance assessment

- Only culture-based methods should be used for CWA purposes.

- Different criteria should be set for different levels of exposure (i.e., full body contact versus indirect or lesser exposure).

Sampling and analytical issues

- An updated guidance document should be developed to address qPCR output metrics, reagents, standards, and acceptable levels of end user assay variability (intra/inter-laboratory). In this document, EPA should recommend the use of commercially available qPCR reagents, standards and calibrators from manufacturers that meet EPA specified criteria. The update should be based on a robust statistical analysis of results.

- Method must be validated by demonstrating it meets appropriate data quality and measurement quality objectives.

- EPA should develop a means of certifying reagents and standards.

- EPA should develop a means of certifying laboratories, personnel, and/or methods.

- EPA should standardize qPCR output metrics.

- A guidance document should be developed to address procedural considerations. This document should include a requirement to validate each specific site for inhibition. If validation of the internal control fails due to inhibition, then the qPCR method should be considered inappropriate for use at that site. The guidance should also specify a minimum of three replicates per sample, with necessary controls, blanks, and calibrators also prepared in triplicate.

Policy Issues

- In assessing the cost/benefit of using rapid methods, lost revenue to local merchants associated with unnecessary closures, which may occur due to unreliability of rapid methods, and impacts to "consumer surplus" due to false positive results need to be considered. "Consumer surplus" is the non-market value placed on a resource by society beyond what it costs to enjoy that resource, or more simply the value of consumer enjoyment. Also included should be costs associated with laboratory startup (e.g., equipment, reagents), additional personal with appropriate technical expertise, validation of the

method within the laboratory, certification of the method by the appropriate entity (e.g., ELAP in California), and on-going QA/QC.

- Although they provide results more quickly, it appears that, based on studies to date, newer methods such as qPCR are not more robust at predicting public health impacts than the more traditional fecal indicator bacteria (FIB) methods.

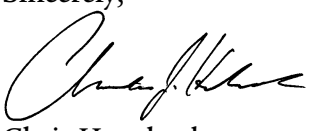
- Use of rapid methods to provide same-day beach closures requires an extensive, coordinated effort that may not be sustainable by many communities.

Future Research Recommendations

- No studies have been conducted that indicate an actual benefit to public health from use of rapid methods to post same-day beach closures. Studies to determine any public health benefit should be conducted in association with any implementation of rapid methods.
- Other promising rapid methods (<1 hour) should be identified and investigated.

We look forward to a productive dialogue in June and request that EPA prepare to address these comments at the stakeholder meeting. Please contact me at 202/833-9106 if you would like to discuss further before the stakeholder's workshop.

Sincerely,



Chris Hornback
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cc: Grace Robiou, EPA
Jon Devine, NRDC