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September 14, 2011

**Ephraim King**

Director, Office of Science & Technology

U.S. Environmental Protection Agency

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Washington, DC 20460-0001

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Dear Mr. King,

The National Association of Clean Water Agencies (NACWA) appreciated the opportunity to participate in the U.S. Environmental Protection Agency's (EPA) June 14-15 stakeholder meeting on the Agency's ongoing work to develop new or revised recreational water quality criteria for coastal recreation areas. In advance of the stakeholder meeting we wrote to you to express some concerns with the format and content of the meeting and we thank you and your staff for taking those concerns into consideration in the final agenda for the meeting.

The meeting was well organized and we appreciate EPA's willingness to share in detail its current thinking on the criteria. We understand that some stakeholders, including many from the public health and beach monitoring community, were not able to participate in the June meeting. As such, EPA's webinar planned for September 20, will provide a valuable opportunity for EPA to gather additional input. Given the evolving nature of this issue, it is critical that the discussion on September 20 reflect the current thinking of the Agency. NACWA understands that EPA's approach to establishing the criteria may have changed since the June meeting and EPA should highlight these changes during the September 20 webinar as they may significantly alter the final criteria. We urge EPA to focus less on background information regarding the research it has conducted up to this point and more on the current direction of the criteria during the webinar, including the scope and content of the peer review that is currently underway.

In advance of the webinar, NACWA wanted to share some of its reactions to the presentations at the June meeting. These are preliminary thoughts based on the material EPA presented and subsequent discussions. When additional details

become available about which studies EPA will use as the basis for the new criteria, how EPA used the results of the studies to derive the criteria, and how the criteria are intended to be applied, NACWA will provide more extensive comments and feedback.

### Timing of Implementation Guidance Critical

Our primary concern involves the timing for release of the final criteria recommendations and the planned implementation guidance. During the June stakeholder meeting, EPA staff indicated that the final criteria would be released before implementation guidance was ready, perhaps even before draft implementation guidance had been released for public comment. This is a major concern given the complexity of implementing these criteria and the added challenge of overlaying new criteria on existing programs based on the 1986 criteria.

It is essential that the final criteria recommendations be accompanied by final, detailed implementation guidance. Discussions at the June meeting highlighted a range of potential implementation issues that can only be addressed through guidance – this includes issues like the appropriate use of quantitative polymerase chain reaction (qPCR) testing, quantitative microbial risk assessment (QMRA), site-specific criteria and predictive modeling, as well as the proper use of the proposed statistical threshold value (STV) and geometric mean calculations, particularly for impaired beach determinations. Issuing the criteria without this guidance will only complicate roll-out of the criteria and create more confusion about the appropriate use of the 1986 criteria. Many of the proposed changes in the new criteria, including changes to the single sample maximum (SSM), are intended to address implementation issues with the old criteria. The lack of any implementation guidance for the current criteria, despite state and stakeholder requests for the Agency to develop such guidance, only underscores the importance of developing the guidance concurrently with the criteria.

An area where clear implementation guidance will be critical is the extent to which qPCR test information will impact Clean Water Act (CWA) programs. Data resulting from qPCR analysis should be used only for beach management purposes and, due to limitations in the method, only 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). Beach closures can and do result in 303(d) listings and beaches with only qPCR data could 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.

Maintaining the culture-based criteria and methods for use in CWA programs, as currently proposed, is essential. Though serious questions persist as to the new qPCR rapid test methods, as outlined in NACWA's May 16 letter to you, NACWA understands EPA's mandate and desire to provide an additional tool for evaluating beaches. However, it is critical for EPA to clearly outline the appropriate use of the new qPCR rapid test methods at the same time it releases the criteria.

### More Details Needed on EPA's Current Thinking

NACWA understands that EPA may have changed its current thinking on derivation of the new criteria values since the June stakeholder meeting. If this is the case, NACWA requests that EPA provide additional information on this new approach. The September 20 webinar will provide an opportunity to provide such information. In addition, NACWA requests that EPA make available all information that was provided to the

peer reviewers. NACWA requested additional information on the peer review process during the June stakeholder meeting, but was told that the charge questions and other information provided to the peer reviewers would not be available until after the peer review was complete. NACWA is requesting that EPA provide, in addition to the peer review findings, a listing of the peer reviewers, all of the documents provided to the peer reviewers, including the charge questions, and any additional presentations/analyses/discussion of data that have not been otherwise published including, but not limited to, the following:

- The new/revised criteria, as presented to the peer reviewers, and an explanation of the process used to develop the criteria values;
- Detailed description of the derivation of the *enterococcus* qPCR SSM/STV and geometric mean values;
- Information on the statistical models used and the assumptions applied in deriving relationships between the qPCR and culture values and the level of protection;
- Explanation of EPA's reasoning for changing existing risk levels to have the same value for both marine and fresh waters (8/1000); and
- Detailed explanation of the definitions of illness and swimming, why they were changed and how the proposed illness rate is as protective as the illness rates defined by the previous definitions.

In addition, based on discussions at the June meeting, NACWA seeks additional information on the following:

- The proposed STV and how it would be used for both culture and qPCR methods. Clarification on whether the STV would only be used for recreational water quality monitoring or if it would also apply for CWA compliance purposes;
- The suite of epidemiological studies EPA will rely upon when developing the new criteria and whether studies conducted by others (e.g., Southern California Coastal Water Research Project) may be included, and, if not, provide explanation for why other studies are not being considered; and
- The limitations of the National Epidemiological and Environmental Assessment of Recreational (NEEAR) water studies and the lack of positive relationships between elevated *enterococci* and increased illness at all beaches. EPA discussed how the NEEAR information was insufficient to derive an illness association over the range of observed water quality, but it was not clear how the dataset would be used to generate a water quality criteria value corresponding to an illness rate.

Following the September 20 webinar, NACWA would like to set up a meeting/teleconference with key members of your staff and some of the Association's members to further explore the technical issues raised during the June stakeholder meeting and the webinar.

Please do not hesitate to contact me should you have any questions.

Sincerely,



Chris Hornback  
Senior Director, Regulatory Affairs