NACWA
A Clear Commitment to America's Waters

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U.S. Environmental Protection Agency
EPA Docket Center, Water Docket
MC 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Via Email: OW-Docket@epa.gov

Re: Notice of Availability of Draft Recreational Water Quality Criteria and Request for Scientific Views

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) *Notice of Availability of Draft Recreational Water Quality Criteria and Request for Scientific Views* (76 *Fed. Reg.* 79176; December 21, 2011). NACWA has for the past several years carefully tracked EPA's work on new studies and data collection efforts as part of revising the existing recreational water quality criteria (RWQC), last updated in 1986. Though these criteria are "intended as guidance to States and authorized Tribes in developing water quality standards", the Agency's criteria recommendations have a profound impact on a number of Clean Water Act (CWA) programs. Recognizing this impact, NACWA intervened in litigation over EPA's failure to meet its mandates under the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 (*Natural Resources Defense Council (NRDC) v. EPA*). One of NACWA's primary concerns in that litigation was ensuring that EPA had sufficient time to conduct the studies and collect the data it needed to make sound scientific decisions regarding any revisions to the criteria.

Given the complexity of the issue and the numerous variables involved in conducting large epidemiological studies, the schedule that EPA agreed to for conducting the studies and developing revised criteria was very aggressive. This aggressive schedule limited the number of studies EPA could conduct, limited EPA's ability to access external studies, prevented the Agency from conducting new studies where weather and other factors compromised results, and ultimately forced EPA to conduct studies designed to validate the use of a pre-selected indicator, rather than conduct studies to evaluate what indicator(s) might work best.

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With these limitations, EPA was still able to amass a significant amount of data and other information to use in its evaluation of the 1986 criteria and to determine what if any revisions are necessary. The new scientific information collected over the past several years supports maintaining the levels of public health protection established by the 1986 criteria and confirms that that the current criteria values are protective of human health. In fact, some of EPA's studies suggest that the current criteria for some waters are overly conservative. Results from several of the epidemiological studies suggest that higher levels of indicator bacteria could be permitted and still provide the intended level of protection.

NACWA understands EPA's rationale for maintaining water quality levels and generally supports EPA's draft RWQC. NACWA continues to have concerns and questions, however, over key elements of the criteria, the potential CWA-related impacts of the Agency's new rapid testing method and the implementation challenges that will arise if EPA does not develop timely guidance on implementing the draft RWQC. NACWA offers the comments and suggestions below for EPA's consideration as it works to finalize the RWQC.

General Comments

While EPA could have conducted more studies and addressed several of NACWA's major issues if it had been given more time, the Agency has, to date, met all of its obligations under the Consent Decree and Settlement Agreement developed pursuant to *NRDC v. EPA*. Some non-governmental organizations (NGOs) have incorrectly suggested that EPA has not met its settlement obligations because it has not made the criteria values more stringent and that EPA has lowered protection for swimmers, in part because the Agency has decided to broaden its definition of illness. These misstatements unfortunately stem from a lack of understanding of the underlying rationale that EPA is using. The science, as EPA explained in its January 25 webinar, simply does not support more stringent criteria values. The response curves from EPA's studies show no evidence that public health protection would improve if EPA lowered its criteria values. In reality, EPA is increasing the reach of its RWQC by applying the criteria to all waters designated for primary contact recreation, not just coastal recreation waters as mandated by the BEACH Act.

As discussed in the draft RWQC document, EPA and other experts acknowledge that these criteria become even more stringent when applied to flowing waters (see Comment 1 under "Other Comments" below). Application of these criteria to all primary contact waters, regardless of the frequency of use or site-specific conditions, has potentially major implications for state monitoring programs and for CWA compliance, as discussed in more detail below. In addition, EPA has for the first time made available a rapid test method for evaluating the presence of fecal indicator bacteria (FIB) as well as other tools which will provide beach managers and regulators with useful options to protect public health. EPA is also recommending that the statistical threshold value (STV) be used for beach notification purposes, even though this means that beaches may be closed more frequently than necessary as supported by the epidemiological-microbiological studies.

Some NGOs are also expressing concern with EPA's new broader definition of illness. By defining illness more broadly than was done in the 1986 criteria, EPA has created the perception that the revised criteria are less protective than previously thought. EPA's use of the new definition of illness, however, is simply an effort to make EPA's studies and criteria more consistent with generally accepted practice within the epidemiology community. The levels at which the criteria are set are already pushing the limits of what the underlying science can support. NGOs are arguing that lower criteria values will improve water quality and reduce the illness rate. However, the response curves from EPA's studies – and other, non-EPA studies including work

conducted by the Southern California Coastal Water Research Project (SCCWRP) – show no marked change in the illness rate with more stringent (lower) criteria than those proposed by EPA. The relationship between bacteria concentration and risk is not linear and bacterial concentrations below a certain limit will not result in a significant reduction in risk of illness.

Criteria Values, Limitations Should be Clearly Explained

With the draft RWQC, EPA carried the same level of protection forward and adopted criteria values for the culture methods that are the same as the 1986 criteria values. NACWA understands and supports the rationale and science that this recommendation is based upon. However, EPA's rationale for maintaining the 1986 criteria values is not clear in the recommendations document. EPA should expand the explanation and rationale for keeping the 1986 values.

EPA should also strengthen its explanation for retaining the same level of protection for frequently used and less frequently used beaches and should mention the discrepancies between the results of the epidemiological studies. This is important because the EPA and other epidemiological study results were not consistently able to closely associate health risk with indicator occurrences, particularly at some beaches with historically high levels of FIB concentrations (Boqueron, Doheney, and Avalon). The data from these studies could not be used to obtain revised criteria standards because, despite higher illness incidence among swimmers at these beaches, the lack of correlation between health effects and indicator concentrations would have resulted in numeric endpoints that are less stringent than the current standards. In short, if all the epidemiological study data were used to derive new numeric endpoints for the indicators with the best correlations to health effects, those standards would be higher than the standards carried forth from the 1986 criteria. This finding suggests that the numeric endpoints for FIB that are expressed in the draft RWQC are likely very conservative and sufficient for making beach management decisions while maintaining at least the same level of protection as the previous criteria.

EPA should clearly explain that the new criteria recommendations were designed to provide flexibility for monitoring programs, because the use of bacteria indicator monitoring alone is not sufficient or appropriate at all beaches and for all water bodies. Instead, it is critical that agencies have the ability to tailor monitoring programs to be suitable for their particular waterbody. The use of FIB monitoring, including the use of rapid methods where appropriate, can provide a consistent and high level of public health protection in recreational water bodies. In some instances, however, the use of sanitary surveys and quantitative microbial risk assessment (QMRA) may be needed to fully assess exposure risk, particularly if the concern is over exposure to human sewage versus other sources of FIB.

Furthermore, although FIB predict human health risk at beaches with known contamination sources, the use of FIB monitoring alone for impairment determination has inherent limitations, which were demonstrated and clearly explained in the scientific reports provided by EPA as part of their studies and in other recent investigations (Bambic 2011; EPA 2005; EPA 2007; Harwood et al., 2011; Field & Samadpour 2007; Fleming 2008; Stoeckel & Harwood 2007). NACWA strongly believes that impairment determinations should be established with the use of well-established monitoring methods that assess living organisms.

EPA Should Develop Implementation Guidance as Soon as Possible

NACWA's top concern over the past year as EPA has worked to draft the new RWQC has been implementation and the timing of the release of implementation guidance. The Association has urged EPA to work to develop implementation guidance before it finalizes the criteria. In addition, NACWA has asked EPA to make it clear that test results from quantitative polymerase chain reaction (qPCR) monitoring programs do not have a direct impact on the CWA National Pollutant Discharge Elimination System (NPDES) permit program.

EPA has acknowledged the need for clear implementation guidance and has indicated that there are several guidance documents that will be developed throughout 2012 and after the release of the final RWQC in October. Again, NACWA urges EPA to accelerate the development of these documents and time their release to coincide with the finalization of the criteria. It is clear from initial feedback from state regulators that it will be difficult if not impossible for them to develop meaningful water quality standards and NPDES permit limits based on these criteria without this additional guidance. It is also important to allow a meaningful opportunity to comment on these guidance documents as they are developed. In addition to general implementation guidance, EPA should develop qPCR guidance with information on how to evaluate qPCR data, including guidance on sampling and calculation of geometric means.

EPA has committed to developing technical support material relative to establishing NPDES permit limits, but currently there is no timeframe for completing this work. This is a crucial piece of the puzzle that should be developed before states begin to adopt the criteria. It is difficult to provide meaningful comments on how the new criteria may impact NPDES permits until this document is available.
Again, because this is a critical issue for NACWA members, NACWA requests an opportunity for public review before release of any guidance on the new criteria, especially those documents relating to NPDES permitting.

New RWQC Will Present Implementation Challenges

NACWA is pleased that EPA recognizes the important role of the use attainability analysis (UAA) process (lines 1826 to 1828) and the concept of partial or time-limited uses – "WQS review could involve a use attainability analysis (40 CFR 131.10(g)) and subsequent modification of a designated use – for example, adoption of a partial or time-limited use for a defined period of time when primary contact recreation does not exist." Such tools are not currently used effectively and could help aid implementation of the new criteria, especially given the broader reach to inland waters designated for primary contact. NACWA is concerned, however, that the statement could be interpreted to mean that the only valid recreational UAAs are limited to "partial" or "time-limited" recreational uses, versus removing the use outright. In the past EPA has generally taken the position that even if it is unsafe to swim because of unsafe physical conditions (like flooding), the RWQC must still apply. EPA should clarify that 40 CFR 131.10(g) allows the complete removal of a recreational use if it is neither existing nor attainable.

EPA's decision to apply the new RWQC to all waters, not just coastal recreation waters, raises several concerns regarding existing criteria, total maximum daily loads (TMDLs), and NPDES permit limits. Many of these CWA programs have relied on indicators other than *E. Coli* and enterococci, such as fecal coliform and total coliform. As states work to adopt the new RWQC into their water quality standards, allocations and limits established based on these other indicators will need to be updated. NACWA expects that such adjustment can be addressed in criteria and associated load reduction revisions, based on monitoring to be done as part of adaptive implementation.

When EPA nationally promulgated the 1986 criteria for coastal recreation waters, it gave the states the option to use another indicator where equivalency could be demonstrated. It is unclear whether states will need to resubmit their justification for these alternative indicators. The use of different indicators is further complicated in interstate waters. Where one state uses fecal coliform and another state has adopted *E. coli* or enterococci, utilities have often had to compare the performance of infrastructure improvements using both indicators. National application of the same indicators for all waters could help to address this, but EPA should give clear direction to the states on how adoption of the new criteria will impact existing programs.

New Rapid Testing Methods and Implications for Clean Water Act Programs

NACWA strongly supports EPA's decision not to include qPCR values as a part of the RWQC. Given EPA's lack of experience with this method and the numerous issues that NACWA has raised in its previous letters to the Agency on this issue, supported by continued published findings of the limitations on the use of current qPCR methods at all beaches, a required inclusion of qPCR as a rapid method in the RWQC is not appropriate (Bae & Wuertz, 2012; Converse et al., 2012). The language on page 46 (lines 1988-1994) is clear that EPA's inclusion of supplementary information on the use of qPCR does not trigger the CWA section 303(i) requirement for state adoption.

Though EPA did not include qPCR as a part of the RWQC, states can develop site-specific alternative criteria (SSAC) that incorporate qPCR values into state standards. Such state action would mean that qPCR values will have real CWA implications, despite EPA's concerns with the method. It is likely that the release of guidance on how to develop and validate these site-specific criteria will not coincide with the release of the RWQC. EPA must quickly develop this guidance to ensure that the qPCR criteria that get adopted into state standards are appropriately derived and validated. Though the qPCR method will not directly apply to NPDES permitting (according to the recommendations document), waterbody assessments do have eventual impacts on permits if an impairment determination is made.

EPA needs to revise the RWQC to indicate that impairment assessments must be supported by data generated from culture methods or other validated methods. Even though EPA is not recommending incorporating the qPCR criteria into state standards without a site-specific evaluation, EPA is recommending that the qPCR criteria be used where possible to make rapid assessments for beach monitoring. In addition, there are other potential tools for states to use in beach assessments (e.g., predictive models, QMRA, etc.). Closures of these beaches based on qPCR data will likely result in an impairment determination. EPA states on page 42 (lines 1854 – 1856) that "...water quality attainment determinations would include water quality monitoring data collected as part of a beach monitoring program, as well as information regarding beach closures and advisories." The potential outcome of this statement is that impairment determinations will be made based on methods/criteria that have not been validated. This could ultimately impact an NPDES permittee.

New Approach Needed for Criteria Duration and Magnitude

EPA has changed the assessment period for the criteria to 30 to 90 days, but has not provided a scientific rationale for capping the assessment period at 90 days. EPA has clarified that although its studies were based on data from a full recreation season, they believe the 30 to 90 day period is a valid tradeoff between accuracy (improved with increased number of samples and longer periods) and timeliness (best informed by reviewing data on a shorter period). The geometric mean (GM) is the appropriate measure of the acceptable number of

illnesses. The duration and frequency describe the number of samples collected, and thus the confidence intervals about the GM. Therefore it would appear that for assessment purposes, using all of the data in the recreation season would provide the best representation of the GM and the STV. The STV could still be used on a daily basis for appropriate notification of the public of potentially unsafe conditions.

Most states have designated nearly all of their water bodies as suitable for primary contact recreation and meeting the duration and sampling requirements will be impractical for non-beach primary contact waters that are typically monitored at a lesser frequency and over a longer duration than beaches. The RWQC document specifically states that a state would need to evaluate both the GM and the STV independently to determine if a water body meets the designated use (lines 1848 – 1850). For waters that are sampled at a lesser frequency, this can have the effect of making the criteria much more stringent, because only one sample may be available to calculate the GM. The GM criteria therefore become de facto single sample limits, which is not consistent with how the criteria were derived. This is particularly troublesome because waters that are less frequently sampled are usually those that are used less frequently, or sometimes almost never, for recreation. Having more stringent criteria in these lesser used areas could mean that resources are incorrectly prioritized to address these lesser used water bodies instead of appropriately focused on higher used areas.

The RWQC guidance should also retain discretion for states and authorized tribes to implement multiple use intensity values. Within an appropriate range of risk levels, protections for a highly public swimming beach versus a remote stream with no existing recreational use is a matter of public policy best addressed by the appropriate state agency. NACWA concurs with EPA's draft 2003 bacteria criteria guidance that "it is appropriate for states and authorized tribes to exercise their risk management discretion when protecting recreational waters." Per this prior guidance, multiple states have already structured bacteria criteria on multiple use intensity values with no apparent negative impacts on public health. Removal of this flexibility for the sake of "national consistency" and "equivalent public health protections" (lines 263-264) does not justify undermining the ability to make this public policy decision at a more local level.

EPA should also add back the flexibility provided in the 1986 criteria that allowed states to calculate a site-specific standard deviation for calculating STV values, particularly for inland waters. The STVs in the 2012 RWQC assume the same distribution of water quality exist for all bodies of water. This distribution is based on log standard deviations observed during EPA's beach studies and reported in the 1986 criteria document (0.4 for freshwater *E. coli* and enterococci; and 0.7 for marine water enterococci). These studies are largely based on data collected from coastal and Great Lakes freshwaters and are not representative of all waters. Water body variability is highly site-specific depending on type (e.g., marine or lake vs. flowing freshwater), local hydrology, and other factors. EPA appropriately accounts for this issue in the 1986 criteria document by recommending that "[e]ach jurisdiction should establish its own standard deviation for its conditions which would vary the single sample limit" (i.e., STV).

qPCR Reporting Limits

The draft RWQC document includes contradictory information as to which reporting unit to use for the qPCR data: calibrator cell equivalents (CCE) or target sequence copy numbers. The EPA's qPCR method specifically recommends ***against*** the use of CCEs but the RWQC recommend expressing qPCR action limits in CCEs. This creates confusion as to which unit should be used. Specifically, *EPA Method A: Enterococci in water by TaqMan qPCR Assay* states, in Section 12.3.1 (in reference to CCE), "While the use of this reporting unit is no longer

recommended because of the false impression it creates concerning the cell concentration detection limit of the qPCR method…". Additionally, Section 12.5 states, in regards to reporting results, "Report the results as *Enterococcus* (large subunit ribosomal RNA gene) target sequences per volume of water sample filtered".

In contrast, the draft RWQC Section 4.0 states, "For states interested in adopting a value for enterococci using EPA's *Enterococcus* qPCR method A into their WQS, EPA recommends a GM criterion of 475 CCE per 100 mL and an STV criterion of 1,000 CCE per 100 mL in freshwaters and marine waters based on its epidemiological study data".

Conversions between CCE and target sequence copy numbers are not always consistent and can depend on several factors including the method chosen to titer the bacteria used in the CCE determination, i.e., direct counts vs. plating vs. spectrophotometer readings. As such, the EPA should recommend a single reporting unit to avoid confusion and allow qPCR criteria to be standardized. If the CCE reporting unit is chosen, the EPA should recommend a single procedure for enumerating the calibrator bacteria.

Tools for Alternate Water Quality Criteria

NACWA supports the use of tools for states and tribes in managing recreational waters and for considering alternate water quality criteria. NACWA especially applauds the recommendation for use of real time predictive monitoring models and the potential ability to develop alternative criteria based on novel indicators or new analytical methods, without site-specific epidemiological studies. It is important to be able to use tools such as QMRA or epidemiological studies to assess the relative significance of regularly elevated FIB concentrations at locations known to have natural sources of bacteria reservoirs and for areas with existing best management practices in place. We understand that technical support materials on how to use the tools are forthcoming. However, it is not clear how the EPA intends to use the output of the tools, such as a gastrointestinal (GI) risk estimate from a QMRA study, or how the these tools can be used to develop statewide water quality standards. NACWA suggests adding clarification to the criteria regarding the development of site-specific criteria, particularly when background bacteria indicator levels are high and for areas where the risk from exposure to pathogens and illness incidence is low.

Other Comments

1. Page 3, lines 231-234 – EPA's RWQC recommendations for all surface waters as stated includes both inland and coastal waters designated for primary contact recreation use. The limitations of *E. coli* and/or enterococci as indicators of fecal contamination for two different water types were raised in general at a 2007 EPA Experts Workshop (EPA 2007) and summarized further in a peer-reviewed publication (Boehm, Ashbolt et al. 2009). A subsequent expert panel noted that the general limitations of indicator bacteria may be accentuated in inland waters due to factors such as turbulence and a relatively high ratio of the sediment boundary layer to surface water (Dorevitch, Ashbolt et al. 2010). NACWA is concerned that the 2012 RWQC are recommended for use in both water body types.

2. The criteria recommendations document consistently refers to "waters". EPA should more clearly explain that the criteria are intended for use with waters that are designated for primary contact recreation. EPA is silent on the issue of secondary contact recreation, but it should clarify that the recommended criteria are not applicable to secondary contact recreation waters:

a. Page 2, lines 202 & 205 – It is misleading to express the RWQC in terms of illness per 1000 **"recreators".** This could imply that the criteria apply to both primary and secondary contact recreation. It should be made clear that the criteria apply as "illnesses per 1000 primary contact recreators or swimmers".
b. Page 3, line 210 states, "[The NEEAR study] Section 3.3 discuses subpopulations that participated in ***recreational*** activities". The NEEAR study compared "swimmers and non-swimmers". Again, it should be made clear that the recreational activities are primary contact activities (i.e., swimming).
c. Page 6, lines 347-372 – Past studies described here refer to fresh and marine **waters** in general. It should be made clear that the 1986 criteria recommendations were for fresh and marine water **designated for primary contact recreation**.
d. Page 6, line 363-364 – It should be made clear that the EPA recommendations for the protection of people using bodies of water such as swimming, bathing, surfing, or similar **primary** water contact activities. Similar water contact activities will be misleading as it will indicate also the secondary contact activities.

3. Page 41 – EPA should clarify its intent on the use of the more stringent derivation values between GM and STV for NPDES permits.

4. Beach monitoring, especially when done with limited local resources, may involve shallow-water sampling. Many factors such as kids playing nearby, waves, etc. can heavily influence concentrations of FIB. qPCR-based findings should be used only for beach advisory/closure and not for NPDES permitting or CWA-related programs (e.g., wet weather programs or consent decree obligations).

5. It is not clear in the current draft of the document how a state might utilize other indicators and/or test methods.

6. Based on the utility of *E.coli* as a fecal indicator for freshwater, the qPCR *E.coli* method should be studied and validated to provide a rapid option for protection of public health in freshwaters.

7. For culture methods, 1603 and 1600 or "equivalent" methods are specified. EPA should clearly indicate what is considered "equivalent". There is no clear link for approval of IDEXX methods.

8. If samples are taken in duplicate or triplicate, how is the STV value determined?

9. The colony counting procedure for EPA 1600 was modified in the 2006 version of the method to exclude colonies <0.5 mm in diameter. Was data evaluated for the potential differences in enterococci values due to the different colony counting procedures after the method change?

10. Page 6, line 380 – Check – "designed for swimming". This should be changed to designated for swimming.

11. Page 25, Table 2 – The NEEAR culture based *E. coli* and illness rate for each of the seven beaches as described in Table 2 is missing from the document. This comparison will be helpful when comparing the fresh water and marine swimming associated illness for culture based *E. coli*.

12. EPA in its site-specific criteria flexibility to states should allow for a fecal coliform bacteriological standard and not require a supplemental *E. coli* test in addition to fecal coliform for fresh water inland waters. This was discussed during the January 25, 2012 webinar during the Q&A session.

13. EPA in its criteria document should acknowledge or at least reference the Chicago Health, Environmental Exposure, and Recreation Study (CHEERS) conducted in Chicago. There are many wastewater utilities interested in ensuring the science on this waterbody which is designated for secondary contact recreation. The CHEERS study has collected a large database on this challenge and the study is useful to water quality professions around the globe. The following study articles have been peer-reviewed and published:

    - Dorevitch S, et al. 2011. Water ingestion during water recreation. Water Res. 2011 Feb; 45(5):2020-8. Epub 2010 Dec 13. PMID: 21227479.

    - Aslan, A, S. Dorevitch. et al. 2011. Occurrence of adenovirus and other enteric viruses in limited-contact freshwater recreational areas and bathing waters Journal of Applied Microbiology ISSN 1364-5072. doi:10.1111/j.1365-2672.2011.05130.x

    - Dorevitch S, et al. 2011. A comparison of rapid and conventional measures of indicator bacteria as predictors of waterborne protozoan pathogen presence and density. † J. Environ. Monit. 2011, 13, 2427.

    - Dorevitch S, et al. 2011 Health Risks of Limited-contact Water Recreation. Environ Health Perspect. http://dx.doi.org/10.1289/ehp.1103934

Concluding Thoughts, Issues for the Future

NACWA continues to have concerns about using beach management criteria to develop NPDES effluent limitations. What is needed is a true measure of whether disinfection of publicly owned treatment works (POTW) effluent or a combined sewer flow has been effective. It is likely that there is a long list of indicators including non-microbial ones (e.g., chlorine residual) that are superior to those currently used for beach management. It is not clear whether the new RWQC could acknowledge this and allow states to use other indicators to measure disinfection effectiveness, but it remains an issue for further discussion.

Sincerely,

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REFERENCES

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Fleming, L.E., Solo-Gabriele, H., Fleisher, J.M., Elmir, S., Sinigalliano, C., Plano, L., and Wang, J. 2008. Final Report on the Pilot Epidemiologic Assessment of Microbial Indicators for Monitoring Recreational Water Quality in Marine Sub/Tropical Environments. The NSF NIEHS Oceans and Human Health Center, University of Miami.

Harwood, V.J., K.V Gordon, & C. Staley. 2011. PATH3C09 Validation of Rapid Methods for Enumeration of Markers for Human Sewage Contamination in Recreational Waters. Water Environment Research Foundation, Alexandria, VA and IWA Publishing, London, UK.

Stoeckel, D.M. & V.J. Harwood. 2007. Performance, Design, and Analysis in Microbial Source Tracking studies. Appl. Environ. Microbiol. 73(8): 2405-2415.