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August 2, 2002

William Morrow
Assistant Branch Chief
Water Quality Standards Branch
U.S. Environmental Protection Agency (4305T)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Draft *Implementation Guidance for Ambient Water Quality Criteria for Bacteria* (May 2002 Draft); Request for Comments

Dear Mr. Morrow:

The Association of Metropolitan Sewerage Agencies (AMSA) is pleased to provide comments on the U.S. Environmental Protection Agency's (EPA's) draft *Implementation Guidance for Ambient Water Quality Criteria for Bacteria (Draft Guidance)*. Founded in 1970, AMSA represents the interests of over 270 of the nation's publicly owned wastewater utilities (POTWs). AMSA members serve the majority of the sewered population in the United States and collectively treat and reclaim over 18 billion gallons of wastewater every day. For decades now, AMSA members have worked to ensure their discharges are protective of both human health and the environment and have played an active role in shaping the national policies that affect the way they perform this vital function. Although the *Draft Guidance* is designed to provide additional clarification to states developing water quality standards for bacteria, the POTW community will be impacted by decisions made according to the guidance and by permit limits derived from the resulting water quality standards.

Over the past year, AMSA commented on two separate EPA actions that discuss issues addressed in the *Draft Guidance*. On October 1, 2001, AMSA commented on the Agency's *Draft National Beach Guidance and Performance Criteria for Recreation Waters* (66 *Fed. Reg.* 39510; July 31, 2001). AMSA's comments highlighted the need for additional study of *E. coli* and enterococci as

indicator organisms before any wholesale changes are made to water quality standards and noted a number of flaws in the studies cited by EPA to support the use of the new indicators.

On October 29, 2001, AMSA commented on EPA's proposal of test methods for the enumeration of *E. coli* and enterococci (August 30, 2001; 66 *Fed. Reg.* 45,811). EPA indicates in the proposal that the test methods were approved for ambient water quality monitoring purposes, not for evaluating effluent bacterial levels. AMSA commented that any change in indicator organism would be complicated by the lack of test methods to evaluate the new parameters in effluent. AMSA also noted that there is no evidence that POTWs meeting limits based on fecal coliform are causing any in-stream or downstream compliance, health, or environmental problems.

AMSA commends the Agency for addressing in the *Draft Guidance* those issues identified by states as impeding their progress towards adopting the *Ambient Water Quality Criteria for Bacteria* developed in 1986, which use *E. coli* and enterococci as indicators, and for providing added flexibility to states making the transition away from fecal coliform. However, many of our comments on the previous Agency actions mentioned above still apply. AMSA continues to call into question the Agency's complete reliance on *E. coli* and enterococci as indicators of bacteria contamination and is concerned with a number of other aspects of the *Draft Guidance*.

Additional Research Needed to Validate Criteria

AMSA continues to question the scientific validity of the 1986 *Ambient Water Quality Criteria for Bacteria*. The enterococci criterion, for example, was developed based solely on an extremely limited and highly polluted spatial representation of the United States coastal marine environment. This U.S. coastal sampling only looked at New York City, NY; Lake Ponchartrain, LA, and Boston Harbor, MA beaches. These data were further limited temporally to individual testing periods: 1973 to 1975 for New York City; 1977 and 1978 for Lake Ponchartrain; and, 1978 for Boston Harbor. The data focused entirely on known areas of pollution. No subsequent efforts have been reported that examine areas noted for uncontaminated, pristine swimming conditions. A random sampling program (random in distributions of geography and salinity, two important considerations) and the development of the true distribution for the bacteria and the measured illness are essential to achieving unbiased results.

A closer look at the individual studies used to support the 1986 criteria reveals additional concerns. Consider that nine testing periods were used for data collection and statistical comparison of the results at New York City beaches, but only two (22%) of these nine tests had a statistically significant difference in symptoms detected between swimmers and non-swimmers. In addition, determination of illness in all studies was the result of self-diagnosis of interviewed subjects. These subjects were frequently multiple members of the same family units which created a potentially strong conflicting bias, and self-diagnosis is often erroneous.

In the *Draft Guidance* EPA continues to affirm the scientific validity of the 1986 criteria, but the study results cited in support of the criteria are not as definitive as represented. For example:

*Cheung et al. (1990) conducted a study in Hong Kong and found a poor relationship between enterococci and symptoms of GI or HCGI illness. He also measured a much lower incidence of symptoms at corresponding bacterial levels than reported in the EPA 1986 criteria. Illness levels used for the development of the EPA geometric mean standard were 19 cases per 1000 individuals. Geometric means ranging from 40 to 250 enterococci were measured while corresponding GI symptom rates were only 4.5 per 1000 swimmers. The authors also summarized two beach studies in Egypt where to find a similar risk level of 19 cases of GI symptoms the predicted enterococci bacterial mean concentrations were 620 and 3400 cfu's/100 ml, respectively. It was concluded that this demonstrates the need for country (and we would contend regional) specificity in criteria development. **This study did not confirm or validate the EPA findings. In fact it contradicted the correlation claims of the EPA studies and identified a much higher level of enterococci associated with a much lower level of illness symptoms.***

AMSA recommends that EPA conduct additional research on the validity of *E. coli* and enterococci as indicator organisms. Under the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000, EPA must perform an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters. To meet the requirements of the BEACH Act, EPA states in the *Draft Guidance* that they are "planning to conduct additional epidemiological studies that may be used to revise and develop new water quality criteria for pathogens and pathogen indicators." Ideally these studies should be completed before states make wholesale changes to water quality standards and discharge permits. However, this information is unlikely to be available before April 2004, when states with coastal recreation waters are required to have in place criteria as protective as EPA's criteria.

Effective Test Methods for Wastewater Not Available

The lack of approved analytical procedures in 40 CFR Part 136 for enumerating *E. coli* and enterococci has been one of the primary roadblocks to state adoption and use of these indicators in a regulatory context. As states strive to meet the April 2004 deadline for developing bacteria water quality standards that are as protective as EPA's, POTWs and other point sources will begin receiving permit limits for *E. coli* and enterococci. Regulated entities will need procedures for assessing compliance with their permit limits. The *Draft Guidance* does reaffirm that permit writers, in accordance with 40 CFR 122.41(j)(4), have the authority to specify methods that are not contained in 40 CFR Part 136, and refers to several EPA-approved methods that may be used in permits. However, these methods, which EPA proposed to add to 40 CFR Part 136 on August 30, 2001 (66 *Fed. Reg.* 45,811), are only approved for ambient water quality monitoring purposes. EPA has determined and noted in the text of the methods that these procedures are not acceptable for evaluating other matrices, such as POTW or other point source effluent.

In fact, there has been at least one study that indicates the Colilert test for *E. coli* used for wastewater matrices can result in false positives due to the presence of other organisms that react in the same way as *E. coli*. It is our understanding that one major issue is the moderate incubation temperature used for *E. coli* as part of this test procedure. At least one AMSA member

has found that different enumeration methodologies for enterococcus give radically different results when used for treated wastewater, and that EPA Method 1600 (24-hour) yields significantly lower enterococci numbers in chlorinated and dechlorinated wastewater than an older method (48-hour). AMSA recommends additional study of appropriate test methodologies to ensure that accurate, representative test results can be obtained in complex wastewater/effluent matrices.

Many POTWs currently operate with effluent limits for fecal coliform bacteria. Regulators will seek to establish *E. coli* and enterococci limits that are equivalent to existing requirements. However, the effectiveness of disinfection, as currently practiced, on *E. coli* and/or enterococci is uncertain. Without approved test procedures for enumerating *E. coli* and enterococci in effluent, POTWs and regulators will have no reliable means to assess effluent quality with respect to the new water quality criteria.

AMSA recommends that EPA add to the *Draft Guidance* a discussion of how the lack of approved test methods should be addressed by permitting authorities and permittees as they transition away from fecal coliform.

Specific Comments on Draft Guidance

As mentioned above, AMSA appreciates the Agency's efforts to provide states with additional guidance to aid in the transition from fecal coliform to *E. coli* and/or enterococci. The following are AMSA's specific comments on the *Draft Guidance*:

Criteria Values

AMSA questions the use of two different, acceptable rates of gastroenteritis, per 1000 swimmers, depending on whether the exposure occurs in marine or fresh water. The *Draft Guidance* suggests that the values are an approximation of the protection afforded by the fecal coliform criterion. However, a closer look at EPA's 1986 criteria document reveals that the primary reason EPA used the new indicators was the lack of correlation between fecal coliform concentrations and illness rate (*Ambient Water Quality Criteria for Bacteria – 1986*, Table 2, "Correlation Coefficients for Swimming-Associated Gastroenteritis Rates Against Mean Indicator Densities at Marine and Fresh Water Bathing Beaches"). It is unclear how these numbers were calculated given the lack of correlation; whether EPA has new data that suggest a good correlation; what confidence levels surround these numbers; and what safety factors were used.

While the *Draft Guidance* states that it would be appropriate for states to protect marine waters at approximately the same level as fresh waters, it does not allow States and Tribes to correct the inequity without severe consequences. By limiting freshwater criteria to no more than 14 illnesses per 1000 swimmers, parity could only be achieved by lowering the marine criteria to that level (or lower if the freshwater standard were lower). In doing so, the marine mean indicator density for enterococci would be reduced from the proposed 35 to 13. To protect at a level of 8 per 1000 in marine waters, the criteria would be reduced from 35 to 4. It is unlikely that any urban beach could meet either criterion on a regular basis.

The question then becomes, why not allow States and Tribes to raise the freshwater illness protection threshold to 19 (the marine waters threshold)? The guidance indicates that the epidemiological data would not support such a change, because the data used only ranged up to 14 illnesses per 1000 swimmers and does not support extrapolation (Section 1.4). Criteria should not be dictated by limitations in the study design.

The proposed geometric mean density associated with each of these protection levels highlights the significance of shifting from 8 to 14 or 19 illnesses per 1000 swimmers. For *E. Coli*, the calculated limits for each of these levels are 126, 547 and 1863 respectively. Therefore, a small change in the allowable potential illness rate results in a large change in the proposed criteria. EPA needs to prioritize the development of data to allow for the setting of criteria at levels higher than 14 illnesses per 1000 swimmers. Until those studies have been completed, EPA should propose interim criteria for the 15, 16, 17, 18 and 19 gastroenteritis rate for freshwater enterococci and *E. Coli*. At a minimum, an interim objective at the 19 potential illnesses level should be considered.

Other Comments by Section

Section 4.4.1 – Section 4.4.1 discusses when it is appropriate to modify a primary contact recreation use to reflect high flow situations (i.e., wet weather flows). Specifically, the *Draft Guidance* states that an intermittent recreation use (e.g., a high flow cutoff) may be appropriate when the water quality criteria associated with primary contact recreation are not attainable for all wet weather events. EPA “anticipates that the use of high flow cutoffs will be primarily applicable to flowing waterbodies and still waters impacted by flowing waterbodies, where high flows are accompanied by high levels of indicator bacteria that can not be controlled without substantial and widespread economic impact.”

The *Draft Guidance* lists several issues that should be addressed if a high flow cut off is to be adopted. Included in that list is the completion of a use attainability analysis (UAA), which has shown that additional controls would have “substantial and widespread economic impact.” AMSA recommends that EPA outline in the *Draft Guidance* what a state should, at a minimum, have to show to satisfy the UAA requirements for setting high flow cutoffs. AMSA understands that EPA is working to develop guidance to clarify the UAA process, but believes that additional information is needed now specifically for the primary contact recreation scenario.

Section 4.3 – Section 4.3 discusses the problem of indicator bacteria persisting in the environment in tropical climates resulting in high bacterial concentrations that do not correlate with human health risks. Recent work by Dr. Richard Whitman of the U.S. Geological Survey has indicated that this same phenomenon is occurring in wet sand on beaches of the Great Lakes, a temperate climate situation. AMSA recommends that EPA review the recent scientific literature on this topic, and acknowledge that a similar problem may be occurring in temperate climates.

Section 5.1 – AMSA is troubled by the statement in Section 5.1 that a “lack of data should not delay states’ and authorized tribes’ adoption of *E. coli* and/or enterococci.” Before states adopt water quality criteria and develop water quality standards based on those criteria, they must

consider whether those criteria and associated uses are appropriate and attainable. Developing water quality standards without supporting data and without regard to attainability, will only force states to back-track through the UAA and total maximum daily load (TMDL) process. Over the past 30 years we have learned how difficult it is to deal with water quality standards that were developed with little or no data. Compliance with bacteria TMDLs will pose significant challenges for municipalities in wet weather events, making it even more important that bacteria criteria are based on sound footing. EPA does suggest a period of overlap, where states would have criteria for fecal coliform and *E. coli*/enterococci, generally one triennial review cycle, and at the same time collect data on *E. coli* and enterococci. EPA also suggests the adoption of a delayed effective date to allow for more time in which to collect data. Nevertheless, EPA should not recommend blanket adoption of criteria in the absence of adequate data.

Section 5.2.2 and 5.4 – AMSA agrees with EPA's recommendation that states use only the geometric mean component of the criteria for National Pollutant Discharge Elimination System (NPDES) water quality-based effluent limits. However, the guidance also states that attainment decisions and TMDLs are to consider both the 30-day geometric mean and the single-sample maximum standards, and details how waste load allocations would be calculated to achieve attainment of both the 30-day and the single-sample standards. AMSA is concerned with the inconsistency between these statements and the Agency's recommendation for using the geometric mean component of the criteria for setting permit limits.

Section 5.5 – Section 5.5 of the document specifies the mTEC method as being the recommended analytical method for determining *E. coli* (see also discussion above on lack of approved test methods). AMSA members who have used the Quanti-Tray method believe it performs better than or at least as well as the mTEC method for *E. coli*. AMSA recommends that EPA consider the Quanti-Tray method as an acceptable alternative. Round robin validation studies of both methods would also be beneficial.

We appreciate the opportunity to comment on the *Draft Guidance*. If you have any questions about our comments, please do not hesitate to call me at 202/833-9106 or via email at chornback@amsa-cleanwater.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback". The signature is fluid and cursive, written over a white background.

Chris Hornback
Director, Regulatory Affairs