Pathogen Criteria White Paper
ASIWPCA Water Quality Standards Taskforce
November 4, 2005

The Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) has long expressed concern over the validity and implementation of bacteria criteria recommended by the US Environmental Protection Agency (EPA) in 1986. Outside of the enhanced study efforts in the Great Lakes states, little progress appears to have been made to clarify bacteria criteria and their implementation since publication of the original criteira document. Many of the issues raised by ASIWPCA in earlier correspondence to EPA are yet to be resolved, despite efforts by EPA to address bacteria criteria – the most fundamental measure of the sanitary quality of surface water.

Background

Fecal bacteria have a long history of use as indicators for the presence of pathogens in surface water, and subsequently a measure of the risk of illness associated with ingestion of contaminated surface water. Body contact with fecal contaminated water, primarily during recreation, can cause gastrointestinal, ear, or skin infections. Pathogens responsible for illness associated with surface water ingestion include bacteria, viruses, protozoa, fungi, or parasites inherent in feces of humans and other warm-blooded animals (EPA, 2003).

The National Technical Advisory Committee (NTAC) of the Department of Interior first proposed federal water quality guidelines for pathogen criteria in 1968. The NTAC's criterion was based on studies done by the U.S. Public Health Services in the 1940's and 1950's. The studies were conducted at bathing beaches located on Lake Michigan, the Ohio River, and on Long Island Sound. The NTAC concluded that fecal coliform bacteria should be used as the indicator organisms for pathogen contamination in surface waters and that primary contact recreation waters should not exceed a log mean of 200 colony-forming units (CFUs) per 100 milliliters of water (EPA, 1986).

After issuing their recommendations for bacteria limits, the NTAC was criticized over the validity of their data. However, in 1976, EPA recommended using the NTAC's data to set water quality criteria for bacteria (EPA, 1986). Consequently, most States adopted the EPA's recommendation of a fecal coliform bacteria criterion of 200 CFU's/100mL expressed as a geometric mean as their primary contact recreation standard.

The criticism directed towards the NTAC data initiated a series of studies by the EPA from 1972 to 1980 at freshwater and marine beaches. The studies were designed to determine if a relationship existed between different bacteria and swimming related illnesses. In 1984, EPA reported their findings in a document titled *Health Effects Criteria for Fresh Recreational Waters*. The report concluded that swimming associated gastrointestinal illnesses were directly linked to water quality impairments caused by sewage and that the illnesses were prevalent when concentrations of enterococci and *E. coli* bacteria were high. No such relationship with fecal coliform bacteria was found. The study also concluded the rate of illness in swimmers could be estimated when using either *E. coli* or enterococci as an indicator (Dufour, 1984).

In 1986, EPA published guidance titled *Ambient Water Quality Criteria for Bacteria* based on the findings from the *Health Effects Criteria for Fresh Recreational Waters* report and concluded that the newly recommended indicators, enterococci and *E. coli*, were superior to the fecal coliform group. The rationale was that a positive relationship existed between bacterial density and the number of observed illnesses for either of these indicators, while no such relationship was observed for fecal coliform.

It was suggested in the guidance that either enterococci or *E. coli* be used as fresh water indicators. The primary contact recreation criteria for enterococci of 33 CFU/100ml and 126 CFU /100mL for *E. coli* were recommended. The criteria were recommended based on an evaluation of a geometric mean of a minimum of five samples collected over a 30-day period, and were considered approximately equivalent to the 200 CFU/100mL criteria for fecal coliform bacteria (EPA, 1986).

Based on the 1986 guidance, EPA directed States to adopt the new enterococci /*E. coli* criteria during their next triennial review. However, there were still many questions posed by States on how to implement the recommended standards. For example, derivation of secondary (non-contact) recreation criterion, the plausibility of single sample criteria, wildlife impacts on bacterial water quality, etc. In order to address implementation questions, EPA determined that implementation guidance was needed for the recommended bacteria criteria. EPA published a draft implementation document in May 2002.

The EPA 2002 draft implementation guidance was intended to give States the necessary information to implement bacteria criteria set forth in EPA's 1986 guidance. EPA suggested a shift in indicator organisms from fecal coliform to *E. coli* or enterococci to better protect the public from water borne illnesses. EPA believed *E. coli* and enterococci to be better indicators of risk associated with gastrointestinal illness caused by the incidental ingestion of sewage contaminated water (EPA, 2002).

EPA's 2002 draft guidance expanded on the 1986 guidance by introducing the concept of differential risk-based criteria established as geometric mean and single sample maximum bacteria density. EPA proposed giving latitude to States in setting risk-based criteria to compensate for different frequency of recreation that may occur. The 2002 draft document also sought to respond to several implementation issues raised by States. ASIWPCA, as an organization, as well as several individual State members provided written comment on the draft guidance. The draft document eventually went through several iterations – each commented on by the ASIWPCA membership.

Subsequently, at the 2005 ASIWPCA Mid-Year Meeting, EPA officials stated the 2002 bacteria implementation guidance document would not be finalized, in part because of additional data expected from an on-going epidemiology study based in the Great Lakes region (personal communication, March 7, 2005). It was stated the epidemiology study report had an anticipated completion date of December, 2005.

Although an EPA-published copy of the study has not yet been released, the results of the study have been published online in Environmental Health Perspectives On-Line. The article titled *"Rapidly Measured Indicators of Recreational Water Quality are Predictive of Swimming Associated Gastrointestinal Illness"* summarizes the results of the EPA-funded epidemiology study on two Great Lakes swimming beaches (Wade et al., 2005). The report gives little indication as to what direction EPA is moving toward in development of companion implementation guidance for pathogen criteria.

On September 8, 2005, ASIWPCA membership received an email that had been forwarded from EPA announcing the first of four Co-Regulator Pathogen Workshops titled *Bacteria Criteria for Inland Waters* scheduled for November 17-18, 2005 in Philadelphia. Three other workshops are as yet unscheduled. A portion of each workshop is to be devoted to discussion on "how to use/interpret the 1986 bacteria criteria for inland waters."

States' Issues with the Current Status of Pathogen Criteria

Issue 1. The scientific validity of the 1986 criteria document

EPA has yet to address the continued and substantial State concerns regarding the scientific validity of the criteria. The criteria are now nearly 20 years old and the epidemiological data upon which they are based are even older. The recent study funded by EPA in the Great Lakes does little to expand the knowledge base for freshwater or marine criteria in other areas of the country. The study is as much a validation of a rapid test method for enterococci as it is an epidemiological study pertinent to inland freshwaters. While ASIWPCA agrees that a rapid test method has considerable value in protecting public health, we first need to reach consensus on which bacterial indicators are valid and at what concentrations they present a concern.

The Great Lakes Study had been promised by EPA as a definitive epidemiological study that would better refine and update criteria for inland freshwaters by October 2005 (letter from Denise Keehner to Sally Knowles, August 6, 2004). Apparently, the design of the study does not allow the data to be translated from the Great Lakes to other inland freshwaters. Therefore, the reliability of the epidemiology for inland freshwaters is still an unresolved issue. Moreover, there was no validation of the specific numeric criteria recommended in 1986.

Issue 2. The utility of the most recent Great Lakes epidemiology study for marine and inland freshwaters

The Great Lakes epidemiology study utilized a quantitative polymerase chain reaction cell equivalent (QPCRCE) method for quantifying e*nterococci* and *Bacteroides*. Of those two indicators, the study determined enterococcus was the only credible pathogen indicator. EPA's 1986 bacteria guidance document recommended the use of *E.coli* or enterococci as indicator bacteria (EPA, 1986). As late as the May 2002 EPA's Draft Implementation Guidance for Bacteria, EPA stated:

> "EPA believes the use of *E. coli* and/or enterococci are best suited to prevent acute gastrointestinal illness caused by the incidental ingestion of fecally contaminated recreational waterbodies."

Surprisingly, there was no mention as to why *E.coli* was excluded from the most recent epidemiologic study. Many States have adopted *E.coli* as their indicator for fecal contamination, plus *E.coli* was identified as one of two default freshwater indicators in EPA's November 16, 2004 promulgation of *Water Quality Standards for Coastal and Great Lakes Recreation Waters*. Regardless, this most recent study is mute on whether there is epidemiologic support for *E.coli* as an indicator. The lack of discussion concerning *E.coli* as an indicator is a major concern. Other concerns with the Great Lakes study include:

A. There is little, if any, discussion comparing the Great Lakes study findings to the conclusions that formed the foundation of the 1986 criteria guidance document. ASIWPCA was of the understanding the Great Lakes study was to be a validation of the numeric criteria presented in the 1986 Guidance. If that is the case, there should be a comparison of the 1986 recommended criteria to results of the Great Lakes study; realizing enterococcus is the only comparable indictor.

A major concern with the 1986 criteria has been the validity of the specific numeric criteria recommendations.

ASIWPCA's own analysis indicates that if the data from the Great Lakes study are used as the "gold standard", the 1986 criteria (as interpreted in the 2002 Draft Guidance) may have been somewhat liberal on the low end, and very conservative on the high end (Table 1). Our comparison could be flawed, however, since there is no discussion as to whether the "geometric mean density" from the 2002 Guidance is comparable to the "daily geometric mean" utilized in the latest study. Regardless, these types of questions need to be answered.

Table 1

	Enterococci Density Data (cfu/100 mL)		
Illness rate	**2002 (Geometric Mean)**	**2005 (Daily Geometric Mean)**	**% Difference (2005 vs 2002)**
8	35	NA	NA
9	42	15	-180%
10	54	38	-42%
11	69	85	+23%
12	88	170	+48%
13	112	350	+212%
14	144	600	+317%

B. There was no mention of any comparison of illness data to fecal coliform bacteria. Many States still use fecal coliform bacteria as their pathogen indicator. Again, if the main thrust of the Great Lakes study was to validate the 1986 study results, there should have been an analysis of fecal coliform data to confirm that fecal coliform bacteria are not a useful indicator of bacterial quality of recreational waters. ASIWPCA realizes that the 1986 study indicated an inverse relationship between fecal coliform bacteria and gastrointestinal illness (GI), however, we anticipated that finding would be tested for validity by the most recent study. It is interesting to note that even though the 1986 document did not recommend fecal coliform as an appropriate indicator organism, the document stated that the numeric criteria presented for *enterococci and E. coli* were comparable to the long-used fecal coliform values of 200 CFU/100ml.

C. There was no mention in the latest study if the QPCRCE method was compared to split samples using more conventional analytical techniques. Those data would be valuable in understanding the comparability of QPCRCE to membrane filtration and multiple tube fermentation methods. In addition, the data would assist in validation of the 1986 criteria.

D. The study confirms that teasing GI illness rates out of the data is tenuous. For instance, at one of the two beaches sampled, there was a greater chance of illness with body immersion but **no head immersion**. The opposite was true at the other beach. These types of findings further bear out that it is ill-advised to set criteria down to the individual cell count that will cause a specific illness rate when bacteria quality can literally change from minute to minute.

Issue 3. Substantial State implementation concerns

The ASIWPCA membership was operating under the assumption the most recent epidemiology study would form the basis of an implementation guidance document. At the 2005 ASIWPCA Mid-Year

Meeting, EPA stated the 2002 Bacteria Guidance Document would not be finalized, in part because of the additional data expected from the on-going Great Lakes study. The study notes the results are promising, but states **more** study is needed:

> "Because this is the first and only study to evaluate the ability of rapid water quality indicators to predict GI illness, **additional studies will be required to evaluate the generalizability of these findings** [emphasis added]."

Due to the fact the epidemiology is linked to a previously uncharted analytical method, it appears EPA is not ready to put forth the data for the Great Lakes or any other inland freshwaters without additional study. That decision will undoubtedly push implementation guidance back a year or more – guidance states have been expecting for over a decade. Key issues for which guidance needs have previously been identified include:

- Appropriate indicators for fresh waters
- Appropriate test methods for wastewater
- Relaxation of criteria in extreme high flow events
- Applicability of criteria in tropical and sub-tropical climates where *E. coli* and enterococci persist and grow
- Applicability of non-human sources

The murkiness of implementation issues is epitomized by recent EPA guidance on 303(d) listings. EPA's current position regarding assessment of ambient data against existing State Water Quality Standards has re-emphasized the three components of a water quality criterion: magnitude, duration and frequency. Bacteria criteria have often been expressed as a geometric mean, typically taken from 5 samples collected over 30 days. Since most State monitoring protocols sample for bacteria at a far less intense frequency, the use of the geometric means is often moot. Alternatives have been introduced in State standards, such as a provision that no more than 10% of samples collected over a set timeframe exceed the criterion. This approach mirrors the commonplace 10% assessment rule employed by States in their development of 303(d) lists, which allows assessment of a set of individual samples collected over months to years. However, current EPA philosophy discounts this assessment rule, unless provisions for duration and frequency are explicitly defined in State Water Quality Standards. Hence, a single digression of bacteria levels over the criterion garners considerable weight in placing a water on the 303(d) list. Resource and logistical limitations preclude extensive use of geometric mean sampling, yet there has been neither guidance nor dialogue as to acceptable frequencies or averaging periods in which to assess single grab samples for bacteria. This knowledge gap invites the addition of multitudes of waters on 303(d) lists, and subsequently, no clear protocol to declare them compliant, with or without TMDLs.

In lieu of written guidance on these complex implementation issues, it appears EPA has scheduled *Co-regulator Pathogen Workshops*. ASIWPCA believes this method of providing implementation guidance is problematic. First, it requires considerable expense for most States to travel for a two day workshop. Second, verbal dissemination of information at four separate workshops will lead to varying interpretation of EPA's guidance by States and Regional Offices, leading to more confusion and inconsistency in implementation of 1986 criteria.

Issue 4. State determination that other activities are "as protective as" adoption of the 1986 criterion document

EPA needs to adhere to its long-established policies with regard to States' adoption of recommended water quality criteria for toxics to ensure that the same flexibility will be used throughout its dealings with all States in all Regions with regard to this determination. At this time, we do not believe EPA's data from 1986 were verified by the subsequent Great Lakes study. We now have two studies that indicate a relationship between GI illness rate and indicator bacteria, but neither, apparently, can be used to confirm the other. Each study still requires additional follow up studies to confirm its findings. Therefore, ASIWPCA does not believe there is a sound case for disapproving any State standard that is based on any of the previously accepted indicators for inland freshwaters - fecal coliform, *E. coli*, or enterococci bacteria. Nor do we believe there is reason to challenge individual State standards that may be more stringent based on recent, local epidemiological data that demonstrates a relationship between the levels of bacteria indicators and increased health risks.

As long as States have bacteria criteria in place and aimed at providing some assurance of sanitary conditions in recreational waters, those criteria should be honored by EPA.

Issue 5. EPA needs to provide more scientific data and information to States for implementation of bacteria criteria

States have concerns regarding the effectiveness of existing treatment capabilities on new indicator organisms. Millions of dollars have been spent providing for disinfection of point source effluent using both ultraviolet (UV) and chlorine-based technologies. Many of those technologies (particularly UV) were designed to meet a permit limit based on fecal coliform bacteria. In switching to enterococci or *E. coli* as an indicator, there is concern those designs may not meet permit limits based on the new indicator criteria. There is evidence based on the relationship between fecal coliform bacteria and other indicators that permit limits based on a new indicator may be difficult to meet under all conditions. This is problematic since there is no confirmed increase in human health risk associated with a failure to meet limits set using new indicators. This issue needs to be addressed by EPA so that the State programs will have consistent, valid, and, scientifically defensible responses when these concerns are raised during the implementation of the new standard. Addressing this issue will necessarily require other branches at EPA become involved in the standards process to assess the impact on existing programs.

Issue 6. EPA needs to provide more scientific information concerning the QPCRCE test method and its practical application

ASIWPCA understands the QPCRCE test method quantifies all bacteria in a sample – not discriminating between viable, inactive, and dead cells. This understanding is apparently confirmed in the previously referenced article titled "*Rapidly Measured Indicators of Recreational Water Quality are Predictive of Swimming Associated Gastrointestinal Illness*" where it is stated:

> "Because QPCR relies on DNA to quantify organisms, viable organisms are not necessary for measurement. As a result, indicators measured by QPCR may differ in their sensitivity to some environmental conditions. For example, we did not see a reduction in QPCRCE over the course of the day, an effect that as been observed for culture-based indicator organisms as a resulting from die-off caused by ultraviolet radiation."

This raises several questions:

- How does QPCRCE data correlate with gastrointestinal illness? We assume pathogens have to be viable to cause illness.
- If disinfection of wastewater effluent is effective in providing a measure of protection to public health, how can QPCRCE data confirm that disinfection is taking place when inactive and dead cells are included in the test results?
- If the level of QPCRCE reported material in a sample is independent of disinfection of wastewater effluent, is it possible to use QPCRCE as an analytical method for wastewater effluent?

ASIWPCA Proposed Plan of Action

Numerous resources have been expended to develop pathogen criteria and implementation guidance for those criteria, yet definitive guidance continues to languish. ASIWPCA believes EPA shares in the States' frustrations in developing and implementing inland freshwater pathogen criteria and recognizes the need to definitively establish criteria and implementation guidance for this most basic measure of the sanitary quality of surface water. Therefore, in order to bring forth both short and long term solutions to the bacteria criteria/implementation issue, ASIWPCA puts forth the following plan of action:

1. Until such time EPA completes epidemiology studies validating the 1986 bacteria criteria, States will maintain their current recreational bacteria criteria and indicators. Changing criteria or indicators will be at the States' discretion. EPA will approve State criteria and indicators if they fall within the range of previously accepted criteria for fecal coliform, *E. coli*, or enterococci bacteria. There is no statutory requirement to force adoption of the 1986 bacteria criteria for waters other than coastal recreational waters.

2. A subgroup from the ASIWPCA/EPA WQS Workgroup will meet with EPA to discuss the States' needs for epidemiologic studies validating recreational bacteria criteria. Those needs will include indicators, test methodologies, applicable waters, potential pollutant sources, treatment process removal efficiencies, etc. The needs requirements will be utilized as the basis for developing a quality assurance project plan (QAPP) for future epidemiologic studies. ASIWPCA and EPA should be able to reach consensus up front regarding the format of the studies and the data output for any studies utilized to establish criteria.

3. Epidemiology studies validating the 1986 bacteria criteria will follow the accepted QAPP.

4. Final bacteria guidance will be based on results of the validating study(s) and present criteria in terms compatible with identified State implementation needs.

ASIWPCA proposes a dialogue be initiated immediately between States and EPA, as partners, on how to deal with each of the matters identified in this White Paper. Until these issues are resolved, doubt will continue to be cast on the validity of EPA's bacteria criteria and their implementation.

References

Dufour, Alfred P. (1984). Health effects criteria for fresh recreational waters. EPA-600/1-84-004. Office of Research and Development, USEPA, Washington, DC.

Available online at http://www.epa.gov/waterscience/library/wqcriteria/healtheffects.pdf

EPA. (1986). Ambient water quality criteria for bacteria-1986. EPA/440/5-84-002. Office of Water Regulations and Standards, USEPA, Washington, DC.

Available online at http://www.epa.gov/waterscience/beaches/1986crit.pdf

EPA (2003). Bacterial water quality standards for recreational waters (freshwater and marine waters) status report. EPA-823-R-03-008. Office of Water, USEPA, Washington, DC.

Available at http://www.epa.gov/OST/beaches/local/statrept.pdf

EPA (2002). Implementation guidance for ambient water quality criteria for bacteria. – May 2002 draft. EPA-823-B-02-003. Office of Science and Technology, USEPA, Washington, DC.

Available at http://www.epa.gov/ost/standards/bacteria/bacteria.pdf

Wade, T.J., Calderon, R.L., Sams, E., Beach, M., Brenner, K.P., Williams, A.H., & Dufour, A.P. (2005). Rapidly measured indicators of recreational water quality are predictive of swimming associated gastrointestinal illness. Environ Health Perspectives doi:10.1289/ehp.8273 available via http://dx.doi.org/ [Online 1 September 2005].

Available at http://ehp.niehs.nih.gov/members/2005/8273/8273.pdf