Stakeholder Meeting on EPA's Development of New or Revised Recreational Water Quality Criteria June 14–15, 2011 – New Orleans, Louisiana

Meeting Overview

On June 14–15, 2011, the U.S. Environmental Protection Agency (EPA) held a multi-stakeholder meeting in New Orleans, Louisiana. In attendance were 50 stakeholders from state and local government, environmental groups, publicly owned treatment works, and industry. The purpose of the meeting was to provide an open forum for stakeholders to discuss EPA's development of the new or revised recreational water quality criteria; update stakeholders on EPA's evaluation, synthesis, summarization and statistical analyses of the research conducted; present options for the overall structure and content of the criteria; and seek stakeholder feedback on all of the above. This report summarizes the input and feedback received, and includes EPA's responses to clarifying questions from stakeholders. The meeting agenda and presentation slides are provided on this website: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/index.cfm.

General Direction of New Criteria

EPA clarified that it plans to have the draft criteria document externally peer-reviewed in summer 2011, following EPA's standard procedure for such scientific peer reviews. EPA will post the peer review charge on its website and share it with the stakeholder listserv. Stakeholders will not be asked to provide input on the charge. Regarding the availability of implementation guidance to accompany the criteria recommendations, EPA's current plan is to make draft implementation guidance available by December 2012. EPA also clarified that EPA does not promulgate water quality criteria under the Clean Water Act. EPA publishes recommendations that states consider in their development of new or revised state water quality standards. The BEACH Act, which amended the Clean Water Act, requires that states consider EPA's new recommendations within three years.

Epidemiological Studies

EPA addressed several clarifying questions regarding the National Epidemiologic and Environmental Assessment of Recreational Water (NEEAR Water) Study. For example, EPA clarified several assumptions and adjustments that are reflected in the NEEAR Study design, including the use of a broader definition of gastrointestinal (GI) illness that does not require fever as a symptom. Adjusting the previous illness rate of 8 per thousand by a factor of 4.5 (based on prior studies) leads to an estimate of 36 illnesses per thousand with the broader definition. EPA also explained that the level of water quality that was believed to be associated with a 19 per thousand rate of excess illness in marine waters in 1986 has now been determined

to more accurately correspond with an illness rate of 7 or 8 per thousand. This rate is similar to the current illness rate for freshwater sites.

Some stakeholders had questions about the NEEAR Water Study and EPA's interpretation of the results. A participant noted that the data from the 2009 epidemiological studies at Surfside and Boquerón beaches was being used by EPA in some analyses and not others. EPA responded that it will provide a more explicit and transparent rationale for this decision. Another participant expressed a desire for more investigation of sensitive subpopulations. EPA responded that the NEEAR study found a statistically significant relationship between illness and children at freshwater beaches but not at marine beaches; and that drawing additional conclusions based on analyzing other sensitive subpopulations would not be appropriate given the small number of individuals in those subpopulations.

Some stakeholders expressed confusion over EPA's current thinking to derive criteria values using a "water quality" approach rather than an "illness rate" approach. To more explicitly describe the advantages and challenges associated with each approach, EPA convened a special session over lunch. EPA described two goals in its current thinking regarding derivation of new criteria values. First, EPA would like to apply a uniform risk level across the various analytical methods that are recommended in the criteria. Second, EPA would like to derive criteria in a way that allows culture methods as well as the quantitative polymerase chain reaction (qPCR) method to be included in the criteria. EPA illustrated the challenges associated with deriving criteria values using the epidemiological and water quality data by offering examples. At the meeting, EPA stated that its thinking at the time was that the water quality approach provides a foundation for establishing qPCR-based and culture-based criteria for both fresh and marine waters. Stakeholder input included concerns about criteria based on the water quality approach because EPA would essentially be starting with a decision to continue protecting water quality at the levels represented by 33 and 35 CFUs for fresh and marine waters, respectively; a concern about using the 1986 data, which has its flaws, to derive a qPCR number; and preference for a range of illnesses over a single-point illness rate.

Analytical Methods

EPA described several benefits of qPCR, including enabling more rapid action to protect human health; enabling more rapid reopening of beaches once water quality has returned to appropriate levels; enhanced sensitivity to low levels of contamination, compared with culture methods; and compatibility with automated sample collection, which is typically not recommended for bacteria sampling, but can be used with qPCR because the DNA remains intact. EPA also clarified that the new criteria will continue to allow for methods such as Enterolert.

EPA provided the following clarifications about its analysis of data on the Enterococcus qPCR method:

- EPA found that three to six samples per day characterize water quality. In addition, qPCR samples collected in the morning have some predictive value throughout the day, although the relationship between morning and afternoon samples varies by beach. Influences can include weather—particularly ultraviolet radiation—and bather shedding.

- EPA stored filters by freezing and analyzed them a few weeks later. The researchers saw no evidence of significant degradation. By testing filter storage under a variety of conditions, EPA found that samples remain intact for up to a year when stored properly. However, results from longer-term storage suggest a possible relationship between age and degradation.

- EPA tested qPCR with a variety of different types of water, including challenging matrices such as an algae-covered lake and water with high turbidity. Different waters showed different levels of qPCR inhibition, with highly turbid samples tending to show more inhibition. However, the data are insufficient to allow EPA to make broad statements about the types of waters where qPCR will or won't work well. EPA plans to continue researching this issue to support the implementation guidance.

- The results suggest that culture and qPCR methods detect similar levels of contamination in raw sewage and primary treated wastewater, but the results diverge for secondary treated wastewater. This divergence occurs because qPCR detects DNA from both living and dead cells; thus, because secondary treatment involves disinfection, the resulting effluent will contain dead cells that are detected by qPCR but not by culture methods.

Regarding indicators, EPA explained that the NEEAR Water Study did not test *E. coli* as an indicator in marine waters because *E.coli* is known to lyse in salt water. In addition, no qPCR method was available for *E. coli* when the NEEAR study began in 2003. Further, although EPA found a relationship between *Bacteroidales* and gastrointestinal illness in marine waters, the version of the fresh water assay used in the early studies did not allow a similar relationship to be developed.

Most stakeholder comments related to challenges in implementing the Enterococcus qPCR method. Concerns related to cost, logistics and timing.

- **Cost.** A pilot study found that qPCR required a startup cost of $100,000 per laboratory plus 0.5 full-time equivalents of additional labor. The equipment costs $50,000 per laboratory. One stakeholder explained that her state has three labs and $300,000 in annual funding for beach monitoring, so it would take half of a year's funding to purchase qPCR equipment for all three labs.

- **Logistics.** Although a pilot study found that it was possible to collect samples in the morning and post results by noon, this study required an early morning start and more personnel. Some states have hundreds of sites and long distances to transport samples

back to a laboratory. By the time the morning samples have been analyzed and the results incorporated into a beach advisory press release, the day might be over.

- **Timing.** The weekend—the time when beaches receive the heaviest use—is also the time when laboratories are least likely to be open and available to process samples. Also, because of the short recreation season in many parts of the country, some states could find themselves equipping and staffing a laboratory for just a few months.

Stakeholders suggested solutions to each other's problems. For example, states might be able to use qPCR lab capacity to deal with other needs during the non-recreation season, such as total maximum daily loads (TMDLs) monitoring and analysis, potable water analyses, and other microbial studies. Others might find it useful to hire and train students to run qPCR analyses during the summer.

At least one stakeholder urged EPA to provide states with additional funding to help them set up and maintain rapid qPCR monitoring programs. One stakeholder voiced support for letting states decide when and where to use rapid methods, if at all. In contrast, another stakeholder expressed disappointment that EPA is not mandating the use of qPCR, given the public health benefit of rapid analysis. Others cautioned that qPCR is not a perfect solution because it is still not instantaneous—i.e., it may not provide results in time to inform people who go to the beach in the morning—and if a state only tests the water once a week, the public health benefits of rapid analysis will only extend to that single day.

Predictive Models

EPA explained that developing a good predictive model requires at least two years of data, and the cost depends on the number of independent variables and the extent to which data can be obtained from sources such as the National Weather Service rather than collected from scratch. One researcher has estimated the cost at around $20,000 per model. EPA also explained that predictive models can be improved by accounting for seasonality. Some beach managers might find it beneficial to create multiple models—for example, wet season and dry season models in certain tropical or sub-tropical areas.

Several stakeholders expressed interest in the use of predictive modeling to reduce monitoring frequency and to determine when and where monitoring is most needed. Some stakeholders also requested guidance regarding the extent to which predictive models can be regionalized. One stakeholder cautioned EPA not to let predictive modeling become an excuse not to monitor beaches. One stakeholder noted that it would be ideal to have a model that could output a risk of illness instead of just a risk of exceeding the water quality standard. EPA explained that an illness estimate would require a broader risk assessment strategy that considers other factors such as susceptibility.

Site-specific Criteria and Incorporation of New Technologies

In response to a question about the Agency's QMRA studies, EPA clarified that the studies considered all human sources, including the influence of bather density and shedding. EPA also addressed a number of questions about differences in sources and the corresponding indicator-to-pathogen ratios. EPA's studies focused on POTWs as a worst-case scenario, but other studies have found that any human influence—even if it contributes just a small percentage of the overall contamination—will tend to drive risk. In addition, EPA's QMRA studies found that cattle sources have a similar risk profile to human sources, and other studies have detected norovirus in runoff from undeveloped forest land. Thus, it is not necessarily safe to assume that all nonhuman sources pose a lower risk than human sources. In EPA's current view, these findings justify the use of a single national standard as a default. If states want to develop different criteria, EPA's current thinking is that they should use a sanitary survey coupled with to use QMRA or an epi study to characterize their actual sources on a site-specific basis.

While several stakeholders supported the idea of giving states the flexibility with detailed guidance to develop site-specific criteria, one expressed concern that this approach is not necessarily protective, especially in complicated cases such as a high-use beach in an urban watershed with a diverse array of sources. This person felt that QMRA might be useful to inform sanitary surveys, but that the QMRA techniques are not mature enough to support the development of site-specific water quality criteria.

Several stakeholders expressed concern about whether the data support extending a single set of criteria to waters that were not well-represented in EPA's studies, including:

- Waters with human influences other than POTWs—particularly nonpoint sources such as urban runoff—and waters influenced by nonhuman sources such as livestock or wildlife. Stakeholders voiced concerns that if POTW-impacted waters are a worst-case scenario and represent a minority of water bodies, then the new national criteria could be overprotective for the majority of waters. Additionally, stakeholders commented that the new criteria could affect a large number of Municipal Separate Storm Sewer System (MS4) permits and TMDLs. Perhaps more so today than in the 1980s, many states see that a significant portion of their impaired waters are listed as such because of fecal indicators. Hence, fecal standards are a major driver of TMDLs and costs. Also, that even if a POTW is doing its best to eliminate pathogens from its effluent, the receiving water body still might exceed EPA's criteria because of other sources.
- Tropical and subtropical waters. To this concern, EPA clarified that two of the beaches in the NEEAR Water Study were located along the Gulf of Mexico in a subtropical zone.
- Unique cases, such as episodic events and inputs that are dominated by wastewater during dry periods and where bacterial regrowth may be a particular concern.

Overall, stakeholder opinions on flexibilities were split. Some supported a conservative single-standard approach as the most protective of public health, especially considering the lack of comprehensive data to characterize the risk posed by non-POTW and nonhuman sources. However, other stakeholders encouraged EPA to build more flexibility into the criteria. These stakeholders argued that a flexible standard will allow states to focus their resources on the most important waters, those with the most contamination and the highest potential for human exposure.

Expression of the Criteria

EPA clarified that under the new criteria, individual samples would be compared with a statistical threshold value (STV) for the purpose of beach advisories. In contrast, attainment with standards would be determined by looking at the data collected over a full recreation season and comparing the geometric mean and the 75th percentile (i.e., no more than 25% of samples can exceed the STV), with the recommended geometric mean and STV, respectively.

A few stakeholders expressed concern with the shift from the Single Sample Maximum (SSM) in the 1986 criteria recommendations, to the STV in which 25% of samples can be exceeded, specifically in states and localities where the SSM is being used currently as a value not-to-be-exceeded. Another participant suggested that EPA specify a minimum frequency of monitoring. Another participant suggested that if EPA is going to mandate the new criteria, the Agency should consider retaining the use intensity categories to allow some flexibility that is built into the criteria for waters that have little or no human sources, possibly with tiered criteria and monitoring frequency, reserving the most protective criteria and most frequent sampling for the most heavily used beaches.

Additional Stakeholder Feedback

At least one stakeholder expressed concern that EPA is "backsliding." In response, EPA explained that the new criteria would be as protective as the Agency's 1986 criteria—in fact, the availability of a rapid method would enhance public health protection where it is used. However, some states have established their own standards that are already more stringent than EPA's new criteria. States have the ability to be more stringent than federal standards (if their state law does not prohibit it). On a related note, a few stakeholders urged EPA to be careful not to imply that states with more protective criteria than the 1986 EPA criteria were confused about the proper implementation. In reality, EPA gave states flexibility and worked with them to set their own standards.

Stakeholders identified several types of support that might help states implement the new criteria recommendations more effectively: financial support and technical assistance; guidance for source characterization; monitoring guidance; guidance on effective risk communication. Stakeholders requested that EPA address several outstanding questions through implementation

guidance; for example: what constitutes "primary contact recreation"; how many times can a beach be closed before it must be added to the impaired waters list; can a waterbody be listed as impaired – and a TMDL developed – based solely on qPCR results.

Stakeholders also suggested several areas for further research, including:

- Advancing EPA's understanding of different types of waters that have not been strongly represented in the studies, including non-POTW-influenced waters, tropical waters, and waters influenced by episodic events.
- Developing assays and dose-response curves for pathogens—particularly norovirus—rather than indicators that are not the actual cause of illness.
- Determining a scientifically sound adjustment factor for secondary contact.
- Developing human source markers to help states determine whether waters are impacted by human sources.
- Testing qPCR with a broader sample of POTWs, including locations with recycled water, tertiary treated effluent, and rivers dominated by disinfected effluent.
- Expanding QMRA studies to examine fate and transport of fecal pathogens with a greater variety of soil types and other conditions.
- Harmonizing with FDA's shellfish monitoring program, which allows the use of fecal coliform as an indicator—although EPA cautioned that FDA's criteria are much more stringent than EPA's recreational water quality criteria.