SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
Monitoring Workgroup
Teleconference: 1-270-400-1500/362592#
June 13, 2011; 11:30 a.m. – 12:55 p.m. EDT

The Environmental Laboratory Advisory Board (ELAB or Board) Monitoring Workgroup teleconference was held on June 13, 2011, to form a plan to address the EPA Recreational Water Quality Criteria Development and related beach monitoring issues. A list of teleconference participants is provided as Attachment A. Attachment B highlights the action items identified during the teleconference.

The Monitoring Workgroup assists the Board in dealing with a variety of matters under discussion and distributes the workload in information gathering for the Board's consideration. These minutes do not in any manner represent the full consensus of the Board. Significant discussions and outcomes from these minutes will be presented to the full Board for its consideration at a later date.

Ms. Judy Morgan, Monitoring Workgroup Leader, thought that the Board needed to provide input to EPA about the Recreational Water Quality Criteria Development prior to any formal publication by the Agency. Ms. Patsy Root agreed that it was necessary to be proactive. She had forwarded to Ms. Morgan a presentation give by Dr. Julie Kinzelman (Racine Health Department) entitled, "Preparing the Local Public Health Laboratory for qPCR." She thought that the Workgroup should define what is important from the perspectives of laboratories and assessors. What information is needed to accomplish this? What does the Workgroup want to know so it can advocate to the best of its ability? The answers to these questions will determine who the Workgroup should talk to first.

EPA has been working for several years on creating new water quality criteria, which will become water quality standards, which in turn the states will use to determine total maximum daily load. Per the Beaches Environmental Assessment and Coastal Health (BEACH) Act, a rapid method (i.e., 4–6 hours) must be associated with any new criteria and standards; therefore, it must be a qPCR-based test. The decision has not been made regarding what entity will be responsible for determining the rapid test. Will it be the states? Also, will the states decide which beaches will need the rapid test? How will the states make a decision? Will they receive guidance? Can they decide that none or all beaches receive the rapid test?

Ms. Morgan asked why qPCR is considered the ultimate method. Ms. Root explained that it is the only method that can perform the test as rapidly as required. Dr. Michael Wichman added that there also are issues with transport time. Ms. Root noted that another concern is that if the results are not known between 10 a.m. and noon, then public safety is not protected.

Ms. Morgan asked whether there has been an increase of problems on beaches that has prompted this effort. Ms. Root responded that there has not been that she is aware of, and she did not understand why Congress placed this requirement in the BEACH Act and held EPA responsible for implementation. This effort is Congress- and not data-driven. Ms. Morgan could not

understand why the requirements went from manageable and acceptable to this. Ms. Root explained that this has been in development for years.

Dr. Jim Pletl thought that it would make more sense to perform modeling of the beaches as well as to determine wastewater treatment plant (WWTP) releases, tide movement and so forth; models driven by data help define risk. qPCR will provide a quicker answer, but organism viability still is an issue. Ms. Root said that Mr. John Wathen (EPA), who is in Ms. Grace Robiou's group, spoke about beach modeling at a meeting the previous year and explained how the modeling helps translate into a better understanding of how and when beaches should be tested. The group continues to work on this topic and uses a software program for beach modeling. Another question is how EPA will consider historical data and understanding of the beaches as a result of testing; many beaches have been tested for years. EPA must consider data regarding how beaches are impacted by tides, waves, winds, bather load, industry and so forth. There is a wealth of knowledge that cannot be ignored, and Ms. Root was unsure how EPA would integrate this knowledge with the testing that it was going to recommendation.

Dr. Wichman asked whether results received by noon would be used to close the beach in case of a positive result. Ms. Root responded that this was the case. Dr. Wichman commented that the economic impact could be substantial. Ms. Morgan asked what is done about the exposure that has occurred up until that point. Ms. Root explained that fresh and salt water are very different. A positive test in saltwater does not necessarily mean a repeat positive test hours later, whereas fresh water generally still has positive results hours later. Ms. Morgan noted that there will be multiple impacts of positive results.

Ms. Root asked what is important from a laboratory or assessor perspective. What are the questions that the Workgroup needs to ask? Ms. Morgan thought that it was important because laboratories performing analyses will consider technology, technique and level of difficulty. At what point will the laboratory decide how much effort it will exert if there are many unanswered questions? If the ultimate goal of these criteria is protection and safety, then it should be the goal for the entire day. Ms. Root said that perhaps the question is about how a laboratory can manage its time schedules to best provide public health protection and safety. To attempt to obtain results by 9 a.m. is not feasible.

Dr. Pletl said that he had recently received slides from a relevant EPA presentation; he will send the presentation to the Workgroup members. The U.S. Geological Survey National Water-Quality Assessment (NAWQA) Program has been following the issue closely. There is concern about many of the items that have been brought up. Based on the slides, the Agency probably is leaning toward culture-based methods for WWTP permitting. EPA is focused on using qPCR for the beach notification process and not National Pollutant Discharge Elimination System (NPDES) permitting. NAWQA has submitted comments to the Agency because, based on its and EPA's review of the data, a link between qPCR and human health was not observed that was strong enough to include in a legally binding document (e.g., NPDES permit). If the data are not used for Clean Water Act (CWA) activities, they may have some meaningful use, but there is a concern that CWA 303b listings are based partly on beach closings. If the use of qPCR will result in beach closings, which then are used in listings, the result will be that millions of dollars will be spent to control pathogens that have no relationship with qPCR. If EPA does not change

the Enterococci and *Escherichia coli* standards and only uses qPCR for beach monitoring, it is possible, but its use must be fairly limited and very qualified.

Ms. Root explained that criteria that have yet to be determined will be used by the states to determine which beaches must use qPCR; not all beaches will be required to use the rapid method. Dr. Wichman noted that states will have problems implementing the rapid testing. He noted that his understanding was that qPCR results do not indicate organism viability, which Ms. Root and Dr. Pletl confirmed. Dr. Wichman asked whether qPCR results would be confirmed with follow-up culture tests. Ms. Root said that they would not be and added that there were inhibition, contamination and preparatory issues that are of concern that have been discussed at the meetings that she has attended. These issues will make assessment of laboratories difficult for assessors. Ms. Morgan thought that the process sounded highly subjective. Ms. Root responded that if there inhibition is present, it is not known until very late in the assay, which then must be redone. Also, significant training is required to use this method. Ms. Morgan said that the testing is subject to a myriad of factors (e.g., water type). She asked what percentage of waters are expected to have these types of issues. Ms. Root explained that Dr. Kinzelman would be the best person to ask. Ms. Root reported that Dr. Kinzelman would be willing to attend a Workgroup conference call.

Ms. Morgan asked for confirmation that there are no other options for rapid testing. Ms. Root explained that culturing takes 24 hours; there is an available ATP test, but it takes a little longer and has not been verified through EPA's Environmental Technology Verification process as the two different qPCR methods have been. The Agency appears determined to use Enterococci and Bacteroides as its standards. Dr. Pletl said that his understanding is that EPA contract laboratories would be performing the drinking water work.

Ms. Morgan asked about the Workgroup's target for this effort. What should ELAB try to affect? Dr. Wichman thought that due diligence must be exercised in examining actual risk and health outcomes because there does not seem to be a clear link. What are the impacts? Gastrointestinal (GI) illnesses? Skin rashes? How will the impacts be documented and/or tracked? Does EPA possess relevant data? Ms. Root said that some data were available from epidemiological studies performed on the Great Lakes and in Puerto Rico and California. The data are available on the EPA Healthy Beaches website. Following the consent decree, EPA developed a proposed research program, which identified 39 initiatives that needed research. Data show a higher correlation with Enterococci and GI illness versus *E. coli* and other potential organisms. She did not know whether studies show an increase in events because the historical data are lacking. Perhaps it is a case of increased awareness rather than increased incidence. It may be a question to ask EPA, but the criteria, standards, and methods changes will move forward regardless.

Dr. Pletl noted that the Board's charter includes method validation to ensure that methods are scientifically rigorous, statistically sound, and generate representative measurements. There already are questions about whether the qPCR method meets these expectations. At a minimum, the Board should discuss these issues with EPA; regardless of the Agency's course of action from a beach water quality criteria standpoint, from a laboratory standpoint there is a standard that must be met for correct use of qPCR. Ms. Root agreed and stated that there are many questions: What will the proficiency tests look like? How will laboratories be assessed? On which criteria should assessors receive training? Dr. Pletl said that these issues are related to the

second part of the Board's charter regarding a national accreditation program. He thought that EPA had spent too much effort and funding into qPCR to change the method at this point. The question is how the method will be used. Dr. Wichman said that there still is issue of providing results between 10 a.m. and noon; he did not think it was possible. Dr. Pletl noted that the laboratories will have to be there very early. Ms. Root said questions to consider are: How many beaches will need the rapid testing? How many samples will be required? Distance of the beaches to the laboratories also will be need to be considered. Dr. Pletl said onsite laboratory capability also is important. Ms. Root said that this issue relates to the question of how many beaches will be required to use this method. Dr. Pletl asked whether rapid testing of inland water beaches also was being discussed. Ms. Root responded that it was but in the same context of marine water beaches; bather load, which affects the Great Lakes and marine water beaches, will be part of the criteria.

Ms. Root thought that a good place to begin would be to develop a list of questions to ask EPA and Dr. Kinzelman. She volunteered to develop the list and forward it to the Workgroup members for their input. Dr. Pletl seconded the idea. The Workgroup can examine these questions and issues to determine which are appropriate to the Board's charter and move those forward. Ms. Morgan thought that it would be good to include both questions and concerns because concerns lead to questions. The Workgroup members discussed a plan to develop the questions and meet via teleconference with Ms. Kinzelman. Dr. Wichman will forward the questions that were sent to the state laboratory managers to Ms. Root. Ms. Morgan said that the goal was to report to ELAB what the Board can accomplish within its charter about this issue by the August face-to-face meeting; the Workgroup should develop a plan and potentially a timeline. Ms. Root explained that she would be traveling for 10 days at the end of July and beginning of August and would not be available until the face-to-face meeting. Ms. Silky Labie reported that she would be gone during the same period. Ms. Morgan thought that the Workgroup would have a good draft by that time. The Workgroup agreed that Ms. Root would develop the list, the members would discuss it by e-mail, and Ms. Root would compile all of the responses.

The Workgroup discussed the February 2011 meeting minutes, which focused on the Workgroup's discussion about the laboratory greening efforts. Dr. Pletl asked whether the work could be developed into a recommendation for the Agency stating that there is a void that needs to be filled and providing ideas for EPA to consider. Ms. Morgan thought that this would be feasible and be a good effort for Workgroup to undertake. If the Workgroup is unable to provide the information on the ELAB website, the Board can at least provide a recommendation about what the stakeholder group thinks is missing and necessary. Dr. Pletl would like to use the prior work to make a recommendation so that the time and efforts of the Workgroup are not lost. As long as the recommendation falls within the charter, the full Board should approve it and forward it to the Agency. The Workgroup thought that it was important to pursue and that it should be brought forth to EPA. Ms. Morgan explained that the origin of the effort came from a suggestion made during a past face-to-face meeting. The Workgroup approved the February 2011 minutes and decided that its previous efforts and time spent on laboratory greening will result in a recommendation to EPA relevant to this issue. Ms. Morgan will draft a letter regarding the recommendation; because this is not a time-dependent issue, the timeline to draft the recommendation is not urgent.

Ms. Morgan thanked the participants for their time and contributions and adjourned the meeting at 12:20 p.m.

Attachment A

MEMBERSHIP LISTING AND GUESTS

ELAB Monitoring Workgroup

June 13, 2011; 11:30 a.m. – 12:55 p.m. EDT

Attendance (Y/N)	Name	Affiliation
Y	Ms. Judy Morgan (Group Leader)	Environmental Science Corp.
Y	Ms. Sylvia (Silky) S. Labie	Environmental Laboratory Consulting & Technology, LLC
Y	Ms. Patsy Root	IDEXX Laboratories, Inc.
Y	Dr. Jim Pletl	Hampton Roads Sanitation District
Y	Dr. Michael D. Wichman	University of Iowa Hygienic Laboratory
N	Ms. Lara Autry (DFO)	EPA/ORD
Y	Ms. Kristen LeBaron (Contractor)	The Scientific Consulting Group, Inc.

Attachment B

ACTION ITEMS

1. Dr. Pletl will send the relevant EPA presentation that he received to the Workgroup members.

2. Ms. Root will begin to develop a list of questions to ask the Agency and Dr. Kinzelman; once she has developed it, she will forward it to the Workgroup members for their input.

3. Workgroup members will provide input on the list of questions that Ms. Root will develop.

4. Ms. Root will compile all of the comments received from the Workgroup and finalize the list of questions.

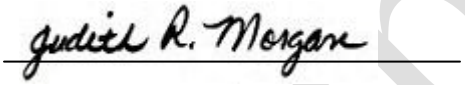
5. Dr. Wichman will forward the questions that were sent to the state laboratory managers to Ms. Root.

6. Ms. Morgan will, at some point in the future, draft a recommendation letter to the Agency about the laboratory greening issue.

7. Ms. Kristen LeBaron will finalize the February 2011 Workgroup meeting minutes and forward them to Ms. Morgan.

Attachment C

I hereby certify that this is the final version of the minutes for the Environmental Laboratory Advisory Board Meeting, Monitoring Workgroup held on June 14, 2011.



Signature Chair

Ms. Judith R. Morgan

Print Name Chair