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December 28, 1998

Stephen Sweeney
Office of General Counsel
United States Environmental Protection Agency
Room 513C
401 M Street Southwest, Mail Code 2355
Washington, D.C. 20460

Re: WET Settlement Dear Steve:

WESTCAS has some remaining concerns over the design of the interlaboratory variability study, as well as the Charge to Peer Reviewers. The focus of those concerns is contained in Attachment A hereto, a document which was prepared primarily by the WESTCAS consultants. In particular, WESTCAS wants to ensure that the interlaboratory studies are indeed “blind”. In a spirit of cooperation, WESTCAS has suggested a meeting of the litigants’ technical experts in order to ensure that the process remains “on course” in accordance with the Settlement Agreement.

In addition, WESTCAS would like to know if EPA is willing to release a copy of the comments submitted by the peer review panel once they are available. Once again, this will allow for an open line of communication and ensure that there are no future misunderstandings. Finally, I have not received a response to my correspondence of November 12, 1998, regarding the DMR certification question. I would appreciate a status report on this topic.

Sincerely,

Mark T. Pifher

MTP\me
cc: Tim Moore
Jim Egan
Steve Koorse

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“Attachment A”

Members of Westcas have had an opportunity to review the revised design for the proposed interlaboratory WET variability study. We appreciate the many changes EPA made based on our earlier comments.

There are still a few issues which continue to cause us great concern. In particular, we believe the research design is not adequate to assure that participating laboratories are “blind” to the true nature and composition of each test sample. This would violate the terms of the Settlement Agreement (Exhibit B, Paragraph 6).

Bioassay labs know to expect some random arrangement of toxic and non-toxic samples. Moreover, they also know that the samples will be a mix of industrial effluent, municipal effluent, and blanks. It is relatively easy to distinguish these matrices based on visual or Aromatic inspection. As such, it is also relatively easy to figure out which sample should be “non-toxic.”

Failure to properly “blind” the laboratories to the true answer undermines the representativeness and validity of all subsequent estimates of test variability. Some scientists recently criticized our own WET Method Blank Study for similar problems maintaining sample anonymity. We are concerned that EPA’s research approach address such criticisms by revising the methods as necessary to assure that participating laboratories cannot pre-judge sample toxicity or lack thereof. (On a related note, we certainly have no objection to a SETAC panel performing a peer review of our method blank study.)

We recommend that the Agency take several steps to restore adequate shielding to the study design:

1) Obscure the source of the samples so that participating laboratories do not know that these particular cubitainers are part of EPA’s study. Lift the veil only after results have been received. It would be best if each sample appeared to come from real-world NPDES permit holders. Westcas & AMSA members are prepared to assist in EPA’s effort to mask the true nature and composition of the samples by acting as “artificial origins” for the study samples.

2) Avoid special instructions which call attention to the unique nature of these samples.

3) Do not tell the laboratories exactly when each sample will be shipped/received. Commit the labs to a 90-day window.

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4) Do not send different sample matrices for simultaneous testing. This prevents labs from making direct visual or aromatic comparison between samples.

We are also concerned that the Charge to Peer Reviewers remains too vague. In our previous letter to Bill Telliard (dated 9/14/98) we provided detailed recommendations regarding the most critical questions to put before the Peer Review Panel. Since EPA has focused the study on assessing the precision of WET test methods, it is essential to provide peer reviewers with a quantitative objective for the study. For example:

> *"Is the study design, as proposed, capable of ascertaining whether x% of the labs will be within y% of the median estimate z% of the time?"*

Asking the peer review panel whether the proposed design is "appropriate," "scientifically credible," "useful," "adequate," or "acceptable" lacks an objective quantitative threshold for making the assessment. EPA has previously identified the essential data quality objectives by which methods must be evaluated. The DQO's are identified in the Agency's 304(h) Report to Congress. The peer reviewers should be given a copy of that document and asked whether the proposed study design will meet all of the relevant and required demonstrations.

Finally, we submitted several important questions to EPA as part of our comments on the original study design (copy attached). We noted that it was essential to know more about many critical elements in the research design in order to assess its scientific validity and provide meaningful recommendations to the Agency. Many of our questions were intended to focus EPA's attention on the need to establish objective decision-criteria before data collection begins. To date, we've received no response to our inquiries, and henc& we cannot evaluate whether the proposed approach is fully consistent with the requirements set forth in the Settlement Agreement.

There also appears to be considerable confusion concerning the relevance of the Settlement Agreement to current permitting activities. Several of our members say they've been told by regional EPA representatives that the variability study will have "no impact" on WET implementation. They've also been told that the Settlement Agreement "proves the validity of WET methods" and that there will "be no change in EPA's WET implementation strategy regardless of how the study turns out." Some of these same statements have been made to national trade journals and newsletters.

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We believe such comments greatly undermine confidence in the objectivity of EPA’s WET variability study. For that reason, an open dialogue on study issues between the Agency and the stakeholders would significantly reduce the likelihood that design deficiencies would become the basis for future litigation.

In the spirit of successful implementation of the Settlement Agreement, we suggest that EPA convene a meeting of technical experts from UWAG, Westcas and the agency to review the final study design. Because testing is scheduled to begin in March of 1999, it is urgent that such a meeting be held this coming January.