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July 16, 2001

FILE NO: 58327.000002

Mr. Geoffrey H. Grubbs
Director, Office of Science & Technology
U.S. Environmental Protection Agency
401 M Street, SW (MC 4301)
Room W635E
Washington, DC 20460

Whole Effluent Toxicity Program

Dear Geoff:

On June 7, members of the WET Coalition[1] met with several EPA representatives to discuss the whole effluent toxicity ("WET") program. The meeting was held to discuss EPA's preliminary interlaboratory validation study, and future EPA actions under the WET Settlement Agreement. The event provided the Coalition an opportunity to highlight several WET concerns that warrant attention, and to emphasize the priority that needs to be placed on data quality as EPA attempts to address those issues.

We know EPA is committed to its "Agency-wide Mandatory Quality System" (see EPA Order 5360.1 A2, May 5, 2000) and the numerous data quality documents released in just the past year.[2] These documents must be utilized in the assessment of the WET method interlaboratory validation study preliminary report.

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[1] The WET Coalition consists of the following members: Alliance of Automobile Manufacturers, American Chemistry Council, American Forest & Paper Association, American Petroleum Institute, AMSA, Rubber Manufacturers Association, Utility Water Act Group, VAMWA, WESTCAS, Alcoa, General Electric, Kennecott Utah and Milliken Company.

[2] Guidance for Data Quality Assessment (July 2000); Guidance for the Data Quality Objectives Process (August 2000); Guidance for Preparing Standard Operating Procedures (SOPs) (March 2001); EPA Requirements for Quality Management Plans (March 2001); and EPA Requirements for Quality Assurance Project Plans (March 2001).

In short, a large percentage of the data points obtained from the interlaboratory study are derived from tests that deviated from mandatory quality control requirements. Those data quality problems are revealing. They arose under the ideal conditions that exist in a research-level testing program, and are likely to arise at least as often in the real world. The problems cannot simply be ignored in drawing conclusions from the study. Take as an example the test results for the chronic sheepshead minnow test, which by no means are the worst case. In the interlaboratory study, EPA concluded that *all* tests were completed successfully — notwithstanding the following number of tests that failed to meet the applicable test specifications:

- DO **(6 tests failed to meet)**
- reference toxicant control chart limits **(4 tests failed to meet)**
- salinity test limits **(10 tests failed to meet)**
- sample temperatures exceed 4C upon receipt **(2 tests failed to meet)**
- samples > 36 hours old at first use **(1 test failed to meet)**
- minimum # organisms/replicate **(1 test failed to meet)**
- temperature test limits **(4 tests failed to meet)**
- aeration not applied properly **(2 tests failed to meet)**

In the regulatory context, those data points would be rejected, and the permittee would be required to repeat the analyses (or might be subject to liability). Invalidation of these tests leaves 13 tests as valid, which results in a 41% test completion rate in contrast to the 100% reported by EPA. The attached comments provide more details regarding the data deficiencies in the study.

The WET litigation settlement agreement calls for EPA to propose a rule by September 24, 2001, to ratify, withdraw, or modify virtually all of the WET test methods in 40 C.F.R. Part 136. The content of that proposed rule, as it currently is described in the Settlement Agreement, will depend in large measure on the conclusions in the final interlaboratory validation report on which EPA is working. Our concern is that EPA may act prematurely in issuing the final interlaboratory study report and proposed rule without adequately addressing significant concerns associated with the conduct of the interlaboratory variability study, data collected and the analysis provided as part of that study, and the peer reviewers and petitioners' study-related comments. This could further delay resolution of the underlying controversy.

The meeting participants discussed options for addressing the key issues, including the substantial data quality concerns. Towards that end, the Coalition suggested a change in

"process" that would allow additional time for meaningful dialogue in the hope that resources could be used constructively to seek practical and reasonable solutions before the study report is finalized. The Coalition offered your staff a proposal, which we were asked to flesh out for your consideration. We have done so below.

The WET Coalition has developed three categories of "Action Items." Category One includes those Action Items from the Settlement Agreement that EPA can complete and include in a Part 136 proposal by September 24, 2001, without first having to resolve the data quality issues the Coalition believes must be addressed before the Agency can finalize the interlaboratory validation study report on EPA's WET methods.

Category Two includes the remaining Action Items from the Settlement Agreement, and integrally related items, that would be included in a subsequent Part 136 rulemaking proposal issued after the interlaboratory report is finalized.

Category Three includes Action Items involving issues that arose as a by-product of the new information resulting from EPA's various efforts under the Settlement Agreement, as well as issues the Agency already is aware of, but has yet to resolve (e.g., in the WET Implementation Strategy EPA initiated several years ago).

The Action Items for each Category are presented below. A proposed "process" to address the items also is included.

I. Category 1

A. Action Items

1. Delete *Holmesimysis costata* acute method from Part 136. (Due to lack of qualified laboratories.)

2. Delete *Champia parvula* (Method 1009.0) from Part 136. (Due to lack of qualified laboratories.)

3. Delete Silverside minnow sublethal endpoint (Method 1006.0) from Part 136. (Due to high CV.)

4. Delete *Selenastrum capricornutum* (Method 1003.0) from Part 136. (Due to unacceptably low completion rate and high CV.)

5. Delete the *Mysidopsis bahia* growth and fecundity endpoint (Method 1007.0) from Part 136. (Due to unacceptably low completion rate for fecundity and high CV for both endpoints.)

6. Amend 40 C.F.R. 122.22 to integrate EPA's memorandum (March 2000) on the inability to certify "accuracy" of WET test results on a discharge monitoring report.

The Coalition defines an unacceptably high CV as any greater than 40%, based on comments provided by the study's peer reviewers. Deleting the above WET tests is justified whether or not the invalid data points discussed earlier are included in the assessment. Taken at face value, the study confirms that the above methods are not adequately ruggedized or robust enough for common use as defined by EPA's Report to Congress entitled: "Availability, Adequacy, and Comparability of Testing Procedures for the Analysis of Pollutants Established Under Section 304[h] of the Federal Water Pollution Control Act," (EPA/600/9-87/030; September 1988).

B. Process

Segregating the action items in this manner would need to be agreed upon by the WET litigation Petitioners and EPA, because it involves a modification of the Settlement Agreement. Though the existing rule publication date would remain the same, the category of potential items covered by the September 24, 2001 rule proposal would be narrowed, excluding Category 2 and 3 items. The modification would specify that EPA will address the above action in a rulemaking, beginning with a proposed rule by September 24, 2001, and terminating with a final rule one year later.

II. Category 2

A. Action Items

1. Develop and include in the WET method manuals a Toxicity Reporting Level (TRL) for each method retained in Part 136. The TRL would perform the same

function as the Detection Limit defined in 40 C.F.R. 136.2. In the WET methods manuals, EPA states that the "detection limits of toxicity of an effluent or chemical are organism dependent," therefore, the TRL would be calculated using the Coefficient-of-Variation data EPA developed for each species-endpoint.

2. For purposes of evaluating the test methods to be ratified, withdrawn, or modified in 40 C.F.R. Part 136, recompute the true completion rate, and the CV for each method (and endpoint), based solely on tests that complied with the protocols defined in the study plan and test methods manuals.

3. Revise the Method Variability guidance (EPA, June 2000) to include test results from the Interlaboratory WET Variability Study (October 2000) deemed valid above. In particular, EPA should update the estimated Coefficient-of-Variation and Percent Minimum Significant Difference (PMSD) tables for each method.

4. For survival endpoints, EPA published only the CV for the LC-50 endpoint. The Method Variability guidance and Final Report for the Interlaboratory WET Variability Study must be revised to include the CV for the No Observed Acute Effect Concentration now used by many states.

5. Revise the test methods to make mandatory the revised test acceptance criteria adopted by North Carolina (as described in Section F.3 on page 5 of Appendix F in EPA's June 2000 WET Method Variability guidance).

6. Revise the chronic methods to require laboratories to include the results from all test organisms, regardless of whether the organism died during the test, when calculating sublethal endpoints. The common practice of assuming the weight or growth of all dead organisms equals "zero" introduces serious bias in the statistical analysis of sublethal endpoints. Alternatively, EPA can abandon the new "biomass approach" and return to calculating growth or weight based solely on the surviving test organisms.

7. Explain how the Coefficient-of Variation will be used when establishing WET criteria, developing WET translators, evaluating Reasonable Potential for WET, developing WET permit limits, or assessing compliance with WET limits in an NPDES permit. In particular, EPA should provide a working

definition and procedure for calculating the "Error Log Variance" as described in the Technical Support Document for Water Quality-based Toxics Control – Responsiveness Summary (1991).

8. Amend the test methods manuals to confirm that new statistical methodologies are acceptable.

9. Calculate 10^{th} and 90^{th} PMSD percentiles for all WET test endpoints used in the NPDES program.

B. **Process**

This also is a matter that would need to be resolved between the WET litigation Petitioners and EPA, because it involves a modification in the Settlement Agreement, as well as dialogue relevant to the deliverables in the Settlement Agreement. The modification would specify that EPA will take the above action in a rulemaking, beginning with a proposed rule by February 24, 2002, and terminating with a final rule one year later.

The Petitioners envision interaction with EPA along the lines of the following. EPA would prepare draft language for the Action Items within 45 days after the Settlement Agreement modification is signed. Petitioners and EPA would meet 30 days later and would schedule additional meetings and/or conference calls as appropriate prior to issuance of the proposed rule.

III. Category 3

A. **Action Items**

1. Identify a procedure to distinguish analytical variability from effluent variability when calculating Reasonable Potential using the methods described in the Technical Support Document for Water Quality-based Toxics Control (1991) as one resource.

2. State that point estimates are invalid unless accompanied by appropriate confidence intervals showing the likely range of variation around the point estimate and that confidence intervals must be reported with the test results.

3. Provide a detailed definition of the "step-wise approach" identified in the Recommendations section of the Method Variability guidance published in June 2000.

4. Publish general guidance describing the process used to account for influent toxicity and the remedies allowed (per the settlement agreement with Lone Star Steel).

5. Warn states that WET test methods may be inappropriate tools for characterizing some source waters (e.g., rain or groundwater due to naturally low pH or conductivity). At a minimum, EPA should describe methods to control for the test interference introduced by these confounding variables.

6. Explain that each method will produce a predictable number of false positives in a given number of tests. The Agency should publish a table or formula to assist permit writers in estimating the expected number of false positives likely to occur when performing the required number of WET monitoring tests over the life of a permit. These estimates will be used to interpret individual test results, in the context of the permittee's historical record, to determine compliance status and assess Reasonable Potential.

7. Explain how the ASTM *h* & *k* statistics can be used to identify outliers in the historical record when calculating Reasonable Potential for a specific discharge.

B. **Process**

EPA would establish a program to address the above Action Items (perhaps simply picking up where the Agency left off, with some updating, on its latent WET Implementation Strategy initiative). That effort would begin with a two-day workshop open to the public at which issues could be identified, discussed, and prioritized. EPA then would prepare a report for public comment proposing how it intends to address those issues, including a schedule for doing so, and the public participation

opportunities that would be available.

That program should be in place and the workshop scheduled for the third quarter of 2002.

Thanks again for your consideration of this most important matter. The Agency, states, and many stakeholders have invested considerable resources evaluating the WET program over the past several years. We have learned much to improve our confidence in many of the WET methods, but also have enhanced our knowledge about the many outstanding deficiencies that will lead to inappropriate regulatory decisions. As the states are evolving in their water quality programs, we have a unique opportunity to develop the technical support necessary for them to proceed in a scientifically defensible manner. The effort described above is intended to facilitate that result. We look forward to hearing back from you, and please feel free to contact Mark Pifher (303-861-1963) or me if you have questions.

Sincerely,

Steven J. Koorse

cc: Mr. Michael B. Cook
Ms. Sheila Frace
Stephen J. Sweeney, Esq.
Mr. William A. Telliard