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January 11, 2010

Linda Boornazian

Director

Water Permits Division

Office of Wastewater Management

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, MC 4203M

Washington, DC 20460

Via Electronic Mail

Dear Linda,

As you know, for more than a decade, NACWA has been working to ensure the use of whole effluent toxicity (WET) testing in Clean Water Act programs accounts for the inherent uncertainties in the test methods. While many of NACWA's concerns apply to the entire suite of WET methods and endpoints, the Association's primary focus continues to be on the use of chronic, sub-lethal endpoints, where permit compliance or "reasonable potential" may be more a function of the method itself, instead of effluent quality. In particular, NACWA has commented on the procedures for evaluating WET test results (i.e., hypothesis testing and point estimates) as a way of moderating some of the acknowledged uncertainties in the methods. Recently, NACWA was provided a draft guidance document detailing the test of significant toxicity (TST) for evaluating WET tests. Based on our initial review, the TST approach seems to address some of the issues with hypothesis testing, but it leaves many questions unanswered.

NACWA is continuing to evaluate the TST approach and understands that California is already pursuing its incorporation into the state's WET program, but we are primarily concerned that the TST approach only addresses hypothesis testing while most states, dischargers and even EPA have recognized that point estimates (EC/IC25 calculations) provide a superior approach. NACWA believes that EPA's resources would be better utilized improving point estimate approaches given the Agency's stated preference for them over hypothesis testing. There are limitations to using hypothesis tests in the reasonable potential (RP) calculations advocated by EPA that the TST approach or any other concept to refine hypothesis tests cannot adequately address. Point estimates are more appropriate for the EPA RP approach.



NACWA Comments on TST Approach

January 11, 2010

Page 2 of 4

NACWA believes that a more pressing need exists for EPA to develop comprehensive guidance on the implementation of WET testing requirements in the National Pollutant Discharge Elimination System (NPDES) program. Major issues remain in dealing with discharges with little or no dilution, unnecessary conservatism in the Technical Support Document for Water Quality-based Toxics Control (TSD) reasonable potential procedures, and in implementing chronic WET requirements in permits. While NACWA will formally comment on the guidance when EPA releases it for public review, NACWA's members have provided some initial reaction to the approach.

Initial Concerns with TST Approach

EPA is proposing a third analytical approach for evaluating WET test data called the "test of significant toxicity" (TST). The analytical procedures of this approach are nearly identical to previously published methods more commonly known as "bioequivalency" or "alternative null hypothesis testing".

The TST approach attempts to directly address the false negative error rate (calling a "toxic" sample "non-toxic") while also controlling the false positive error rate (calling a "non-toxic" sample "toxic"). In the draft TST document, EPA defined no toxicity as a 10% or lower effect. To control the probability of identifying a "non-toxic" sample as "toxic", EPA adjusted the alpha error up (not to exceed 0.25) or down until 5% (or less) of the tests with a 10% or lower effect were identified as "toxic". In more simple terms, chronic toxicity with the TST is defined as a 25% or greater effect and no toxicity with the TST is defined as an effect equal to or less than 10%. EPA would like the TST to identify at least 75% percent of the "toxic" tests as "toxic" and identify no more than 5% of the "non-toxic" tests as "toxic".

Due to the mathematics involved and the nature of the table or critical t-values, every sample exhibiting a 25% effect or more will be identified as "toxic" using the TST approach regardless of variability, number of replicates, or alpha selected. Therefore, the actual rate of identifying a "toxic" test as defined in the document (effects of 25% or larger) as "non-toxic" is zero (0). The probability of identifying a "non-toxic" test (a test with an effect of 10% or less) was adjusted to be no more than 5%. The frequency of identifying tests with effects between 10% and 25% as "toxic" or "non-toxic" will vary depending on replication, variability, and magnitude of effect. The greater the variability, the closer the effect is to 25%, and/or the fewer number of replicates conducted will result in more tests with effects between 10% and 25% being identified as "toxic". The lower the variability, the lower the effect, and/or the higher number of replicates conducted will result in more tests with effects between 10% and 25% being identified as "non-toxic". In reality, all (100%) of the tests with effects of 25% or greater will be identified as "toxic" and up to 5% of the tests with effects of 10% or less will be identified as "toxic".

The TST approach does appear to reduce the false negative error rate for WET tests. This was one of EPA's stated intentions for pursuing the TST approach. Unfortunately, the TST approach does not reduce the existing false positive rate of 5 percent. In fact, by arbitrarily defining no toxicity as an effect equal to or less than 10 percent, the TST approach actually results in more "non-toxic" samples being identified as toxic than the current NOEC approach.

An unacceptable false positive error rate is troublesome for a number of reasons. For regulators, false positives divert enforcement resources away from "real" water quality violations. False positives in receiving waters lead to inappropriate impairment listings that ultimately consume regulatory resources through the development of

NACWA Comments on TST Approach

January 11, 2010

Page 3 of 4

unnecessary total maximum daily loads (TMDLs). For dischargers, false positives can represent effluent violations and are subject to enforcement action and citizen lawsuits. Dischargers are also put in the untenable position of being required to solve a problem that does not exist or attempt to unsuccessfully identify sources of toxicity in response to false positive results.

The draft EPA TST Implementation Document does not adequately address how the TST approach will fit into WET testing protocols. While stating that WET testing is to be conducted exactly as the current protocols require, there is no discussion of the issues discussed in EPA's July 2000 *Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing (40 CFR Part 136)*. Most pertinent are the discussions of nominal error rates, concentration-response relationships, dilution series, and acceptable dilution waters. Thus, assuming that the TST approach is implemented, it is not clear whether dischargers will have to first apply traditional statistical methods of evaluating the results of toxicity testing (including dose response), before applying the TST statistical tool. It is apparent that the TST approach can only be applied to tests that are "clean" and do not contain anomalous results, outliers, or non-uniform dose responses.

The EPA TST approach does not discuss the importance, if any, of testing effluent concentrations other than that of the In-stream Waste Concentration or IWC. The TST appears to assume that toxicity tests will result in monotonically increasing dose responses every time all of the time. This is rarely the case and it could make application of the TST problematic.

Other Specific Comments

NACWA also offers the following additional specific comments on the proposed TST approach based on its initial review of the document:

- Current Dunnett's approach uses all variability across the test to determine differences with the control (ANOVA). The TST does not. If the variability in the control and/or the IWC test concentration is not representative of the variability of the population that it represents the TST will result in erroneous conclusions.
- Dunnett's test must also be preceded by checks on normality of data and homogeneity of variances. The manuals have text addressing single concentration tests and they require statistical tests for these parameters before choosing a final statistical approach. NACWA did not see these types of checks in the TST guidance.
- This approach does not use all of the information available in a test like the IC25 or LC50. Even the Dunnett's test, although flawed in its own right, attempts to use information from the entire test.
- Like other hypothesis testing approaches, the TST requires transformation of percentage data (i.e. survival endpoints). However, no attempt is made to transform or appropriately adjust the "b" factor of 0.75 for chronic tests and 0.8 for acute tests. This results in a transformed effect and variance that is generally over-estimated compared to the observed effect and variance in tests with effects between zero (0) and 25%. This ultimately results in increasing the likelihood of identifying such tests as "toxic" using the TST.
- Unlike the other data analysis procedures, the TST is not promulgated. Changing the method of data

NACWA Comments on TST Approach

January 11, 2010

Page 4 of 4

analysis means you are changing the endpoint and since WET is a method-dependent parameter a change in data analysis essentially changes the water quality criteria. Given the implications of using a different analysis procedure, the review and comment associated with the promulgation of the new procedure is warranted.

- NACWA remains concerned that EPA continues to advocate an approach where one failed test equals reasonable potential. The impact of this is amplified by the fact that even if all tests pass by TST you still must have less than 10% effect at the IWC to avoid RP. So example #2 on page A-7 and example #3 on page A-8 with extra reps would both still be considered failed tests even though it passed by TST because the difference between the control and treatment is 20 percent.

Again, NACWA is offering this input based on its initial review of the document. Many of NACWA's members are also evaluating the TST approach by applying it to existing WET data. We hope to be able to share some of this information with the Agency when it formally seeks comments on the TST document.

Please contact me at chornback@nacwa.org or 202-833-9106 if you have any questions about these comments or would like to discuss any of these issues further.

Sincerely,



Chris Hornback
Senior Director, Regulatory Affairs