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Public Comment  
Toxicity Provisions  
Deadline: 12/21/18 by 12 noon



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December 20, 2018

Jeanine Townsend  
Clerk to the Board  
State Water Resources Control Board  
P.O. Box 100  
Sacramento, CA 95812-2000  
*Submitted Via Email: [commentletters@waterboards.ca.gov](mailto:commentletters@waterboards.ca.gov)*

**Re: Comment Letter – Toxicity Provisions in the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California and Accompanying Staff Report**

Dear Ms. Townsend:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the *Draft Toxicity Provisions* in the *Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California* (Draft Plan) proposed by California's State Water Resources Control Board (State Water Board), and the accompanying staff report.

NACWA represents the interests of 35 public clean water utilities in California and over 300 public clean water utilities across the country who are helping to ensure a sustainable clean water future and protect human health and the environment. NACWA's public clean water agency members fully support the adoption and appropriate implementation of water quality testing methodologies that provide reliable and accurate results as a tool for assessing water quality. For more than two decades, NACWA has been working to ensure the use of whole effluent toxicity (WET) testing in Clean Water Act (CWA) programs adequately recognizes and accounts for the inherent uncertainties and variabilities that are present when relying on a living test organism (e.g., *Ceriodaphnia dubia*) as an indicator of toxicity and a measurement of water quality more broadly.

NACWA, along with other water sector organizations and industrial groups, led the legal efforts that helped to shape the WET testing program to ensure at least some protections were in place for dischargers. This legal work ultimately led to additional study and the development of safeguards to give dischargers the "benefit of the doubt" and to protect against false positives and other issues caused by the inherent variabilities in the methods.

Since that time, NACWA has consistently raised concerns where implementation of the WET methods is done in a manner that does not reflect this additional study and need for safeguards.

Since first learning of EPA's interest in the test of significant toxicity (TST) for evaluating WET test results in 2009, NACWA has raised consistent and vocal objections to its use in the WET program (see attached comments on EPA's draft guidance document for the TST, which were submitted by NACWA despite the fact that EPA did not solicit public comments on the draft guidance document). Adding the TST to a WET testing regime as simply a new "data analysis approach," particularly in the manner proposed by California, erodes the safeguards EPA's inter-laboratory variability study demonstrated were needed and, if adopted, will set a troubling national precedent.

EPA Headquarters, EPA Region 9 and California are arguing that since the TST is merely a "statistical data analysis tool," it does not need to be subjected to the same standards of review as if it were part of a test method. But WET is defined by the methods and analysis tools used to measure it. As a method-defined parameter, changes in the way the results are analyzed can change the result returned by any particular test. "Tools" that can change the outcome of a particular WET test must be held to the same standards that courts have required for the suite of WET methods and endpoints that were promulgated in 40 CFR Part 136.

The TST has not been subjected to the same level of study as the other statistical approaches used in the WET program. Initial study of test results based on tests of control water suggests that the TST may produce higher false positive rates than expected. This not only will result in wasted regulator resources chasing false indications of toxicity, but it puts dischargers at an unlawful disadvantage. Most concerning, EPA has never given the regulated community an opportunity to formally review and comment on its use.

### **Additional Study of the TST is Needed Given the Unacceptably High False Positive Rate in Certain Analyses**

It is unacceptable for EPA (both Headquarters and Region 9) and now, California, to promote a testing methodology that may result in a higher frequency of false positive toxicity results than what was deemed acceptable when the WET methods were legally challenged. Reanalysis of data from EPA's inter-laboratory variability study indicates that the TST may conclude toxicity in clean blank samples at a rate greater than two times higher than that of the no observed effect concentration (NOEC) in the *Ceriodaphnia dubia* chronic test. EPA Region 9 is now trying to explain away those results – claiming that certain TST results should be invalidated – but those arguments fall flat when the Agency's own percent minimum significant difference (PMSD) criteria are applied properly.

As NACWA outlined in its initial feedback to EPA on the TST in 2010 (see attached), "false positives can represent effluent violations and are subject to enforcement action and citizen lawsuits...and put [dischargers] in the untenable position of being required to solve a problem that does not exist..." By applying the TST analysis – especially as proposed by California – municipal clean water utilities will face a higher likelihood of false positives and considerable cost in tracking down toxicity that may not exist. False positives will also lead to unwarranted impairment listings. The State Water Board must take steps to address the potential for a higher frequency of false positives before adopting and requiring municipal water agencies to implement the proposed TST analysis.

More broadly, before it is used in a regulatory context, the TST must be subjected to the same testing and study that the courts directed EPA to conduct before it finalized its suite of WET test methods. At the direction of the courts, EPA's eventual promulgation of the methods was based on the results of the EPA inter-laboratory variability study that evaluated the frequency of identifying toxicity in non-toxic blank samples using the NOEC and EC/IC25. The court upheld the NOEC and EC/IC25 methods because EPA had provided adequate safeguards within those methods to protect against the concerns raised by the plaintiffs. These safeguards included the requirement to use a multiple-concentration test that includes a concentration-response evaluation and the application of variability criteria. The court in *Edison Electric Institute v. EPA* specifically justified its decision by stating, "EPA also offered an additional safeguard by designing the tests to give permittees the benefit of the doubt, limiting false positive rates to at most 5%, while allowing false negative rates up to 20%."<sup>1</sup>

Similar study of the TST has not been conducted and, in the case of California, specific safeguards identified as being critical to maintaining acceptable error rates have been removed or significantly restricted.

### California's Draft Plan Removes Key Protections, Penalizes Dischargers

EPA never formally sought public comment on its *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document* and finalized the guidance document without ever responding to the numerous comments and concerns that were submitted to the Agency after a draft copy of the document was informally circulated.

As EPA, in particular Region 9, continued to express an interest in using the TST in a regulatory context, California, at the urging of Region 9, attempted to use the Alternative Test Procedure (ATP) provisions of 40 CFR Part 136 to circumvent the requirement to test five effluent test concentrations and a control (and thus remove the critical safeguard of conducting a concentration-response evaluation to ensure the test was valid). With legal challenges mounting, the ATP request was withdrawn, and California looked to EPA's Methods Update Rule to remove the five-concentration minimum requirement.

In an exchange detailed in EPA's response to comments document on the Methods Update Rule, California requested that EPA change the 'test concentration' requirement in the toxicity method manuals to state that five effluents and one control sample were the minimum for LOEC and NOEC endpoints and point estimates, but that only one effluent and one control sample were the minimum for TST. EPA rightly directed California to the ATP process if it wanted to reduce the number of test concentrations. EPA responded by stating that:

*The TST can be used consistently with the current EPA WET test methods, as long as the permittee continues to meet the required condition in the Part 136 WET test methods to test five effluent test concentrations and a control – even though the TST statistical analysis uses the data from only one of those effluent concentrations plus the control.*

It is our understanding that the push to remove this key tenet of the use of WET tests in the NPDES program – the five-concentration minimum plus a control – was being promoted within EPA Headquarters as a potential cost savings measure for dischargers. In other words, a safeguard intended to protect the discharger from erroneous results, potentially costly violations, and expended resources trying to track down the source

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<sup>1</sup> Edison Elec. Inst. v. EPA, 391 F.3d 1267, 1275 (D.C. Cir. 2004).

of a false positive, was being described as a cost burden for those same dischargers. Contrary to all of this is the fact that the TST guidance itself endorses the use of more replicates per test concentration, which will not reduce the cost.

This is where it becomes most obvious that use of the TST is inconsistent with the basic tenets of the WET program. The TST is designed to give results using only a single test concentration and a control. It is not possible to develop a meaningful dose response curve with only one point of reference – the control response. The value of the dose response curve is that it provides another reference point to judge the reliability of the test. An accuracy quality objective does not exist for WET tests – one cannot compare a WET test result with a “known” in the same manner as a chemical test. This shortcoming of WET testing demands that review and test conclusions must include a dose response reference. In stressing the importance of dose response, the lead EPA scientist responsible for standardizing the WET test methods stated:

*A predictable dose-response curve is one of the mandatory requirements for a valid toxicity test. We would never accept analytical results from an instrument producing an abnormal standard curve. The predictable dose-response curve, that is increasing toxicity with increasing concentration, is the analogue of the analytical standard curve and is of equal importance in toxicity testing.*

Dr. Donald Mount, National Effluent Toxicity Assessment Center, EPA Environmental Research Laboratory - Duluth, MN, NETA Communique (Jan. 1990).

Faced with the fact that the requirements in 40 CFR Part 136 remain unchanged, the State Water Board is proposing an absurd policy that requires the discharger to conduct a suite of five test concentrations and a control, but that also requires the discharger to ignore the information from four of the concentrations. The proposed policy does not allow the discharger to use the information from the other four concentrations to understand the dose response relationship that EPA itself sees as critical to any valid toxicity test.

As with other aquatic toxicity approaches defined in 40 CFR Part 136 for WET tests, test interpretation depends on the dose-response of the organisms tested (as well as other factors like the PMSD). Dose-response and the PMSD are both determined by analyzing *all of the data* from a multi-concentration WET test. Simply put, data from a control treatment and one concentration of effluent cannot determine the acceptability and, hence, the regulatory reliability, of a WET test and its associated result.

California has created a double penalty for the discharger – being required to pay for and run replicates for five concentrations, but not being allowed to use all of the data to reliably analyze the test results, potentially resulting in additional cost to deal with erroneously detected toxicity.

## **EPA Ignores Basic Administrative Procedures Act Requirements in Allowing Use of the TST**

Rather than go through the full process of modifying 40 CFR Part 136 by seeking comment from the public to propose to include the TST for use in the WET context, EPA (Headquarters and Region 9) and the State

Water Board are now arguing that the TST is simply a “data analysis approach,” not part of the methods, and therefore requires no action to use in a regulatory context.

This argument, as noted above, contradicts the very foundation of toxicity testing – that the interpretation and analysis of test data directly defines the test result. EPA has recognized for decades that WET is a method-defined parameter. How one conducts and interprets the test defines the result. Each test result, defined by a specific data analysis and interpretation approach, stands on its own and cannot be readily equated to other conclusions using other statistical approaches.

This is why EPA, in its WET interlab study completed in 2000, assessed ten WET test methods based on specific test effect measures that included the LC50, IC25, and NOEC. This interlab effort did not include a review of the reliability and performance of the TST. Further, EPA has not conducted a study of the TST in any way comparable to that used to confirm the reliability and performance of other test effect measures specifically defined in 40 CFR Part 136. This is particularly true for tests with waters that are known to be not toxic (blanks).

The interlab study completed in 2000 resulted in EPA releasing two guidance documents that were needed to ensure that WET tests were conducted, interpreted and implemented correctly. Again, application of the TST to WET tests was not addressed in these guidance documents and, therefore, permittees do not have guidance of comparable quality to use in interpreting test results relative to the TST. The TST must be held to the same standard as the other test effect measures in this respect before being specifically referenced in Part 136 and/or subsequently used in a regulatory context.

Furthermore, a plain reading of the EPA's WET freshwater method manual and of 40 CFR 136 makes it abundantly clear that the TST is not approved for use in the NPDES program. EPA's WET freshwater method manual contains the following statement in section 9.4.1.2: *The statistical methods recommended in this manual are not the only possible methods of statistical analysis.* EPA appears to be using this rationale when explaining its position on the TST.

However, this statement cannot be used to justify allowing the TST, because the statement has clearly been taken out of context. Section 9.4.1.2 goes on to say, “*Many other methods have been proposed and considered. Certainly there are other reasonable and defensible methods of statistical analysis for this kind of toxicity data....The statistical methods contained in this manual have been chosen because they are (1) applicable to most of the different toxicity test data sets for which they are recommended, (2) powerful statistical tests, (3) hopefully "easily" understood by nonstatisticians, and (4) amenable to use without a computer, if necessary.*” When taken as a whole, section 9.4.1.2 makes it clear that only certain methods were chosen for adoption into the NPDES program, and these methods do not include the TST.

Additionally, the section 9.4.1.2 statement about other possible statistical methods is not found in the individual method documents (e.g., EPA Method 1002.0 for *Ceriodaphnia Dubia* survival and reproduction). 40 CFR Part 136 discusses the need to follow and report the methods and EPA went to great lengths to develop a specific method and method number for each WET method. These individual methods include specific statistical approaches not including the TST and do not include language providing for the use of other statistical methods. The individual methods do not provide any flexibility in the use of statistics

and are written to only support the development and reporting of three specific metrics (LC50, NOEC, IC25).

EPA was even more explicit in 40 CFR Part 136 where it only lists certain statistical approaches in Table 1. Only the LC50, NOEC and IC25 are identified in this table. These are the only statistical approaches that the public had an opportunity to comment on during adoption of these regulations. Use of the TST in the Draft Plan, or in a permitting context based on the Draft Plan without a change to 40 CFR Part 136, runs afoul of the Administrative Procedures Act and the CWA regulations relating to delegated state implementation of the NPDES permitting program.<sup>2</sup>

When EPA realized that many of its analytical methods did not include a number of essential QA/QC elements, they included these QA elements in a method update rule under 40 CFR Part 136.7. These elements affect the reliability and utility of data, just as the TST affects these same aspects of WET tests. It seems inconsistent to hold a change in QA elements – critical to data interpretation – to this standard of review and not do the same for the TST, which is similarly critical to the interpretation of test data.

Even if other statistical methods can be used, as EPA asserts, the TST has not been held to the same standard of review as other statistical methods that are used in an NPDES context. EPA established the standard of review with the WET interlab study in 2000 and the TST should be subjected to the same level of scientific rigor and public review.

NACWA appreciates the opportunity to comment on the Draft Plan. NACWA also fully supports the more detailed comments submitted by its Member Agency the Sanitation Districts of Los Angeles County.

Sincerely,



Chris Hornback  
Deputy CEO

cc: Andrew Sawyers, Office of Water, EPA Headquarters  
Deborah Nagle, Office of Water, EPA Headquarters

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<sup>2</sup> 40 CFR Section 122.41(j)(4) and 40 CFR Section 136.1.