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January 16, 2015

Cris Morris

Los Angeles Regional Water Quality Control Board

320 West 4th Street, Suite 200

Los Angeles, CA 90013

Sent via Electronic Mail to: losangeles@waterboards.ca.gov

Subject: National Association of Clean Water Agencies (NACWA) Comments on Tentative Permit for San Jose Creek Water Reclamation Plant

Dear Ms. Morris,

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide comments on the tentative permit for the San Jose Creek Water Reclamation Plant. NACWA is a national trade association representing 30 public wastewater utilities in California and nearly 300 utilities nationwide. NACWA has been working for nearly two decades to ensure whole effluent toxicity (WET) testing is appropriately used in Clean Water Act (CWA) programs and that any WET requirements imposed on public wastewater utilities adequately account for the variability inherent in the testing of biological organisms.

Our Association does not routinely comment on matters impacting individual treatment plants, but the tentative permit in question includes provisions that could have significant statewide and national impacts. To the extent that the terms related to toxicity being incorporated into this permit could be emulated by other regional boards, all of NACWA's members in California – and utilities beyond NACWA's membership – have a significant interest in the development and implementation of these permits. Based on the information it has, NACWA believes the toxicity provisions in the tentative permit, and the recently adopted permits for the Pomona and Whittier Narrows Water Reclamation Plants, are without precedent in any CWA permit in the country. Therefore, the decision to include these requirements could also have national implications. NACWA's three primary concerns with the draft permit are detailed below:

1. Mandating use of the Test of Significant Toxicity (TST), an approach that EPA has not approved or officially sought comment on, in a CWA permit is highly problematic. In 2010, NACWA reviewed and commented on a guidance document from the U.S. Environmental Protection Agency (EPA)

detailing the TST. Although EPA had not officially released the guidance for public review and comment, NACWA and several other stakeholders wrote to EPA to raise significant concerns with the use of the TST approach in CWA programs. Since that time, EPA has provided no additional information on the TST for public review and has done nothing to address the significant concerns raised by stakeholders in 2010. NACWA's comments from 2010 are attached for your reference. Compounding the issues with the TST in the case of the tentative permit for the San Jose Creek Water Reclamation Plant, are the restrictions the permit places on the use of the TST, mainly the prohibition on conducting multi-concentration tests and dose-response evaluations, discussed below.

2. Conditions imposed by the tentative permit improperly limit or restrict the use of data evaluation procedures either *required* or recommended by EPA in 40 Code of Federal Regulations (CFR) Part 136. Numeric limits based on a single effluent concentration chronic toxicity test using the TST, as prescribed in the tentative permit, are highly problematic and will inevitably lead to a substantially higher rate of false conclusions regarding the measurement of toxicity. Allowing a discharger to conduct multiple concentration tests and evaluate the dose-response relationship is one of the more critical and significant method-defined approaches to address variability within a test and validate data that have been acknowledged to be inherently variable. Interpretation of the 40 CFR Part 136 methods specifically calls for evaluation of the dose-response relationship to ensure that test results are interpreted and reported accurately. This cannot be done without multiple dilution testing.

The Board must also recognize that **the accuracy of whole effluent toxicity tests is unknown, and “cannot be determined in a meaningful way” according to EPA¹**. That is, it is unknown as to whether a laboratory conducted WET test will reflect what is observed instream at the effluent-receiving water interface. Additionally, the quality of WET tests and their respective results cannot be evaluated using tests of effluent samples of known toxicity like a test for a chemical parameter can be evaluated by testing samples of known concentration. The whole effluent testing paradigm, as established by EPA, simply does not make available the quality control tools commonly available in chemical parameter measurements (e.g., matrix spiking, matrix spike duplicates, calibration blanks, standards, laboratory control sample, limit of quantitation, limit of detection, internal standards, surrogate spikes, and initial precision and recovery requirements). This emphasizes the need for a permittee to collect as much data as possible for each sample analyzed when using WET tests to represent the quality of effluent samples.

Without multiple dilutions, permittees are left only with blanks (controls) and replication (for controls and one dilution) to evaluate the reliability of a WET test result. Even given these two quality control tools, there is no requirement that the variability of the controls or the single dilution tested meet a quality control maximum. EPA developed and implemented the Minimum Significant Difference (MSD) concept to address variability in WET tests, but these MSD requirements were developed based on a database of multi-dilution tests. MSD requirements for single dilution tests do not exist and have not been provided to allow proper qualification of test results for this permit. While reference toxicity

¹ EPA Memorandum, “Certification of ‘Accuracy’ of Information Submissions of Test Results Measuring Whole Effluent Toxicity”; From: Charles Sutfin, Office of Wastewater Management; Sheila Frace, Office of Science and Technology; Brian Maas, Office of Regulatory Enforcement; To: Regional Water Management Division Directors, Regional Enforcement Division Directors, Regions I-X, March, 3, 2000 (Attached).

test information is available, unlike other quality control tools where a failure results in effluent data being invalidated, a reference toxicity test that does not fall within quality control limits does not invalidate the associated effluent test.

This explains why EPA has routinely supported multiple concentration testing for all CWA WET compliance determination tests. If the Regional Board believes use of the TST is appropriate, the permit must be modified to include language that will specifically allow the permittee to assess the reliability of toxicity tests of the effluent using five or more effluent dilutions as well as utilize all 40 CFR Part 136 specified procedures. These are vital quality assurance/quality control procedures that must be available to permittees.

Further, the Board needs to implement multi-dilution WET tests in this permit so that the Board can be sure that conclusions regarding WET measurements associated with the discharge are reliable. Limiting the ability of a permittee to utilize the appropriate promulgated chronic toxicity testing protocols is inappropriate and NACWA is not aware of any other state that is limiting permittees in this manner. Contrary to the proposed permit action, the collection of more data (more dilutions, more replicates) in each test should be encouraged by the Board. This approach is in the best interests of the permittee, the Board, and the aquatic life of the receiving water.

3. Toxicity is not a pollutant, but an effect which indicates that additional investigation is needed to determine what is causing the effect. NACWA strongly believes that the toxicity identification evaluation/toxicity reduction evaluation (TIE/TRE) process is the best approach for a discharger to investigate and ultimately identify the underlying issue. Requiring TST results to be reported as effluent compliance monitoring during the accelerated monitoring that follows a toxicity event and initiation of the TIE/TRE is inappropriate, counterproductive, and should not be included in the tentative permit. NACWA understands that State Water Board staff and numerous stakeholders are working to develop a statewide toxicity plan that would mandate accelerated testing and/or TIE/TRE implementation after an initial toxicity violation. This is an approach that NACWA has advocated for on the national level as well, and commends the state for considering this approach. During this time of accelerated monitoring and investigation, however, further violations should not be incurred provided that the permittee is conducting all of the required and appropriate actions to address the exceedance.

A permittee cannot identify the causes of toxicity – the purpose of the TIE/TRE – without toxicity being present and measured. It is counterproductive to penalize a permittee for reporting toxicity when the permittee has not been provided the opportunity to identify the cause of the toxicity and remove it. The approach taken in the permit is not constructive and will result in resources being redirected to dealing with the violation rather than solving the toxicity problem. Efforts conducted after an identified exceedance should focus on identifying the cause of the exceedance and addressing it. Continued routine monitoring during accelerated testing and/or TIE/TRE plan implementation will only serve to increase reported violations that could subject the discharger to liability without contributing anything toward actually identifying and controlling toxicity.

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NACWA appreciates the opportunity to comment on the tentative permit. The precedent these problematic provisions could set will undermine much of the progress the clean water community has made over the past 20 years in addressing the variability of WET tests. NACWA has worked with EPA to develop tools to address the uncertainty in WET testing, but these tools will not work without data for multiple dilutions.

Please contact me at 202/833-9106 or chornback@nacwa.org should you have any questions or wish to discuss our comments further.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback", written in a cursive style.

Chris Hornback
Senior Director, Regulatory Affairs

ATTACHMENTS

ATTACHMENTS

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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 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

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

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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



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR - 3 2000

MEMORANDUM

SUBJECT: Certification of "Accuracy" of Information Submissions of Test Results
Measuring Whole Effluent Toxicity

FROM: Charles S. Sutfin, Director
Water Permits Division (4203)
Office of Wastewater Management
Office of Water

Sheila E. Frace, Director
Engineering and Analysis Division (4303)
Office of Science and Technology
Office of Water

Brian J. Maas, Director
Water Enforcement Division (2243A)
Office of Regulatory Enforcement
Office of Enforcement and Compliance Assurance

TO: Regional Water Management Division Directors, Regions I-X
Regional Enforcement Division Directors, Regions I-X

In litigation challenging EPA rulemaking to standardize analytic testing procedures for whole effluent toxicity, questions arose regarding the significance of certification requirements for information submissions when the person signing the information submission certifies to the "accuracy" of that information. Confusion has arisen over use of the term "accuracy," which is a term of art to describe a performance characteristic of a measurement system. The purpose of this memorandum is to clarify that the Agency's intent is that a certification of "accuracy" in information submissions is a certification that the information provided is "accurate" as the layperson uses the term, rather than "accurate" as that term is used to describe the quantifiable performance of a measurement system.

Regulations implementing the National Pollutant Discharge Elimination System ("NPDES") permitting program require that, for various information submissions required by the regulations (e.g., permit applications, discharge monitoring reports, etc.), the person submitting the information sign a certification statement to accompany the information submission. The person signing a document must make the following certification:

I certify under penalty of law that this document and all attachments were prepared under my supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information submitted is, to the best of my knowledge and belief, true, *accurate*, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations 40 C.F.R. 122.22(d) (emphasis added).

The purpose of the certification requirement is primarily to ensure that the person submitting the information certifies the veracity of statements made in the forms and acknowledges liability for false statements. 43 Fed. Reg. 37078, 37079 (Aug. 21, 1978)

In EPA documents associated with testing procedures for measuring whole effluent toxicity, the Agency stated that the "accuracy" of toxicity tests cannot be determined in a meaningful way. "Accuracy" in that context is a specialized, scientific term (a term of art) used to describe a performance characteristic of a measurement system. Recognizing that accuracy as a performance characteristic to describe whole effluent toxicity testing cannot be quantified, however, does not diminish the value of a document certifying to the accuracy of information submissions pursuant to 40 C.F.R. 122.22(d). When a person certifies the accuracy of an information submittal as described above, that person does not certify the accuracy of the measurement system. When a person certifies that the submission of WET testing information is "accurate" to the best of their knowledge and belief, the person certifies that the results obtained using the WET testing procedures are faithfully and truthfully transcribed on the information submission, and that the results were, in fact, results that were obtained using the specified testing procedures.

cc: Laura Phillips
Marion Thompson
Alan Morrissey
John Fox
Stephen Sweeney