COUNTY SANITATION DISTRICTS
OF LOS ANGELES COUNTY

1955 Workman Mill Road, Whittier, CA 90601-1400
Mailing Address: P.O. Box 4998, Whittier, CA 90607-4998
Telephone: (562) 699-7411, FAX: (562) 699-5422
www.lacsd.org

GRACE ROBINSON HYDE
Chief Engineer and General Manager

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File No. 31-300.25

VIA ELECTRONIC MAIL
Ms. Jeanine Townsend
Clerk to the Board
State Water Resources Control Board
PO Box 100
Sacramento, CA 95812-2000

Dear Ms. Townsend:

Comment Letter – Toxicity Provisions

The Sanitation Districts of Los Angeles County (Sanitation Districts) appreciate the opportunity to provide comments on the State Water Resources Control Board's (State Water Board's) Draft Toxicity Provisions in the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Draft Plan) and the accompanying staff report (Staff Report). The Sanitation Districts are committed to effective and appropriate implementation of whole effluent toxicity (WET) testing as a tool to address uncertainties associated with chemical-specific monitoring and biological assessment. The Sanitation Districts also appreciate the significant efforts made by State Water Board staff to engage and work with stakeholders over the years to address significant issues and concerns identified by stakeholders in the previously released versions of the Draft Plan. However, several unresolved issues remain, as detailed in this comment letter.

Our overarching concern is that the *Ceriodaphnia dubia* reproduction endpoint, when analyzed using the Test of Significant Toxicity (TST), is not a reliable method for assessing NPDES compliance. The main study cited to justify the use of this test and statistical endpoint appears to contain multiple errors, and other studies indicate high error rates for non-toxic blank samples. Therefore, we strongly recommend that use of this *Ceriodaphnia* endpoint, when analyzed using the TST for regulatory compliance, be postponed until its reliability can be determined. In addition, the TST statistical approach has not gone through the formal promulgation process, nor has it been compared in acute toxicity testing to the LC50 (the only promulgated statistical approach for acute toxicity). Specific comments on the Draft Plan and Staff Report are detailed in the sections below.

COMMENTS ON THE DRAFT PLAN

1. **The "Test Drive" Study appears to contain numerous data errors and should not be used to support incorporation of the Test of Significant Toxicity (TST) statistical approach into the Draft Plan.**

To demonstrate that the TST statistical endpoint is equivalent to or superior to the promulgated no observed effect concentration (NOEC) endpoint, State Water Board staff relied heavily on the results of

the State Water Board Test Drive Study.[1] (Test Drive Study). Although stakeholders received only limited information from the Test Drive Study, numerous errors were identified, such as incorrect NOEC results, inclusion of WET tests that may have failed to meet minimum test acceptability criteria, and questionably low (and in some cases mathematically impossible) standard deviations reported for over 15% of the *Ceriodaphnia dubia* reproduction tests. Because of these errors, findings and conclusions from this study should not be considered until the errors are corrected or another study is conducted.

Incorrect Identification of Toxicity Using the NOEC

Facilities "J" and "K" from the effluent dataset (Test Drive Appendix A) correspond to the Sanitation Districts' Saugus and San Jose Creek Water Reclamation Plants. These facilities represent 30 of the 209 *Ceriodaphnia dubia* reproduction effluent and ambient tests evaluated in Appendix A. The Test Drive Study identified four of these 30 *Ceriodaphnia dubia* chronic tests as toxic using the NOEC. However, based on the Sanitation Districts' records of the results, three of these four tests that were declared toxic should have been identified as non-toxic with an NOEC of 100% effluent (Tests 1023833cdc, 1040235cdc, and 0816684cdc in Attachment 1). These three erroneous NOEC results represent half of the six test results in Appendix A where Test Drive Study reported that the NOEC identified toxicity and the TST did not. Although we were able to evaluate only the 30 tests conducted for our agency, we believe that the high error rate indicates that a comprehensive review is needed of the 1,095 *Ceriodaphnia dubia* chronic toxicity tests used in the study (combined number of tests in Appendices A and B).

Test Drive Study Ceriodaphnia Data Had an Unusually High Number of Tests that Exhibited a Low Standard Deviation

Nearly 40% of *Ceriodaphnia* reproduction tests in the CEDEN and SWAMP data set (Appendix B) reported a control standard deviation below the 1st percentile of National Values,[2] and nearly 22% of the tests reported a standard deviation of 0.000 in the control or instream waste concentration (IWC). To achieve a standard deviation of zero, each replicate would have needed to produce exactly the same number of offspring over the entire six to eight-day test. Several laboratories with experience conducting thousands, if not tens of thousands, of *Ceriodaphnia* tests stated that they had never observed such an occurrence. Beyond being extraordinarily unlikely, the majority of the tests that exhibited a standard deviation of zero also reported a non-integer mean reproduction response. If every replicate produced exactly the same number of offspring (and biologically, the *Ceriodaphnia* can't produce fractions of young), it is mathematically impossible to calculate a mean reproduction that is not a whole integer. These apparent errors in the data set clearly impact at least 22% of the *Ceriodaphnia* results. It is extremely unlikely that the actual standard deviations were as low as reported. Therefore, potentially up to 40% of the Ceriodaphnia data are compromised due to these issues, and a much more careful and thorough review of these tests is required before any of the findings and conclusions from this study can be considered valid.

Test Drive Study Data May Include Tests that Failed Minimum Test Acceptability

Minimum test acceptability criteria for the *Ceriodaphnia dubia* chronic tests include a mean control reproduction of at least fifteen neonates per surviving female.[3] However, 25 of the 1095 *Ceriodaphnia dubia* chronic tests used in the Test Drive Study (Appendices A and B) exhibited a

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[1] 2011. Whole Effluent Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST). https://www.waterboards.ca.gov//water_issues/programs/state_implementation_policy/docs/tst_test_drive.pdf

[2] National Pollutant Discharge Elimination System Test of Significant Toxicity Technical Document: An Additional Whole Effluent Toxicity Statistical Approach for Analyzing Acute and Chronic Test Data. US EPA Office of Wastewater Management. EPA 833-R-10-004. June 2010.

[3] EPA Freshwater Chronic Toxicity Method (EPA-821-R-013), page 161.

mean control reproduction of less than fifteen neonates. Data not available to stakeholders could contain information that would allow the use of these results (e.g., 10% to 20% mortality in the control or male test organisms, which could yield acceptable results with the surviving females); however, given the other errors identified in the Test Drive data and the fact that these tests represent more than 2% of all the *Ceriodaphnia dubia* chronic tests used in the Test Drive Study, these results should be carefully reviewed to determine if they should be included or removed from the analyses.

2. **Comparability of the TST to the promulgated NOEC and Effective/Inhibition Concentration (EC/IC25) has not been demonstrated; in fact, the Test Drive Study and other studies have consistently found that the error associated with the *Ceriodaphnia dubia* reproduction endpoint will result in higher frequencies of toxicity detection in tests exhibiting effects below the 25% regulatory management decision (RMD) threshold. For this reason, the *Ceriodaphnia dubia* reproduction endpoint should be excluded from the draft Plan provisions.**

Inaccuracies in biological testing can result in false determinations of toxicity and unwarranted noncompliance with permits. This occurs when an effluent that is actually non-toxic is incorrectly identified as "toxic." As discussed below, the issues associated with inherently high variability are most problematic in the *Ceriodaphnia dubia* reproduction endpoint. *Ceriodaphnia dubia* reproduction in a non-toxic control can vary from 3 to 60 neonates but quality assurance provisions (such as minimum and maximum within-test variability criteria and minimum test acceptability criteria) typically limit variability in the control treatments to 15 to 45 offspring. Because the inherent variability for reproduction can commonly approach 300% in a non-toxic control, conclusively quantifying a difference in reproduction of 25% (the RMD threshold) in an effluent or receiving water treatment is extremely difficult.

To demonstrate that the TST statistical endpoint is equivalent to or superior to the NOEC, State Water Board staff relied heavily on the results of the Test Drive Study. In addition to the significant data errors in this study discussed above, the Staff Report contains several statements regarding the findings of this study that are inaccurate, unfounded, misleading, and/or oversimplified. For example, Section 5.3 of the Staff Report (page 58) misleadingly states *"The overall results from the TST Test Drive indicated the use of both the NOEC approach and the TST approach declared a similar percentage of tests as toxic and non-toxic."* This statement is true only when looking at all species and endpoints combined. When evaluating the *Ceriodaphnia dubia* reproduction endpoint specifically, the TST identified more tests exhibiting a mean effect less than 25% as toxic than the NOEC.[4] This discrepancy was clearly noted in a peer-reviewed publication[5] on the Test Drive Study results:

> *"Although most of the test endpoints or methods examined had either a similar or a higher percentage of tests declared toxic using the NOEC approach when the mean effect at the IWC was less than the toxic RMD, the Ceriodaphnia reproduction and the Pimephales [fathead minnow] survival and biomass endpoints exhibited a somewhat opposite pattern (Table 1).... [The] chronic Ceriodaphnia reproduction endpoint yielded the largest number of tests declared toxic using the TST when the mean effect in the effluent was less than the toxic RMD of 25% (13 of 29 tests or 45%; Table 2). Although this may be due in part to the relatively large number of Ceriodaphnia effluent tests evaluated in the study (209 tests), the proportion of Ceriodaphnia tests having this outcome is approximately twice the proportion observed in the entire study (45 vs 23%, respectively)."* The authors also identified *"relatively high within test variability observed in these tests (Table 2)"* as a possible reason for this observation.

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[4] State Water Board, Effluent, Stormwater and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST) (Dec., 2011) (see e.g., Chronic Freshwater results in Table E-1)

[5] Diamond et al. Evaluation of the Test of Significant Toxicity for Determining the Toxicity of Effluents and Ambient Water Samples. Environmental Toxicology and Chemistry, Vol. 32, No. 5, pp. 1101–1108, 2013

This higher frequency of incorrectly identifying non-toxic blank samples for the *Ceriodaphnia dubia* reproduction endpoint as toxic using the TST was subsequently corroborated in a reanalysis of data from EPA's interlaboratory variability study; the TST identified toxicity in clean blank samples at a rate up to three times higher than the NOEC.[6] Similarly high rates were observed in a Southern California Coastal Water Research Project (SCCWRP) study funded by the Stormwater Monitoring Coalition.[7] In this study, half of the non-toxic blank samples (laboratory dilution water) tested with *Ceriodaphnia dubia* were incorrectly identified as toxic using the TST. While recognizing that the reason for this observed toxicity has not been identified, they recommend that future studies should be conducted to "*confirm this anomalous result*" and "*conduct the experimental manipulations to identify the source of this inter-laboratory variability.*"

Although currently available information suggests that the other species and endpoints contained in Table 1 of the Draft Plan may be robust enough for application of numeric effluent limits using the TST, the *Ceriodaphnia dubia* reproduction endpoint, as currently measured using the EPA 2002 protocol (EPA-831-R-02-013), is not amendable to the TST statistical endpoint in the absence of a thorough blank study to quantify and correct any short-comings. Specifically, high within-test variability associated with the reproduction endpoint results in a higher frequency of toxicity detections when evaluated using the TST compared to the NOEC approach than that observed for the other species and endpoint points. Although this endpoint may be useful as a trigger for a toxicity reduction evaluation (TRE), any application of a numeric limit should not be considered until the problems identified by EPA and other researchers are confirmed and solutions are implemented into the method.

Recommended Solution:

This problem can be addressed without delaying adoption of the Draft Plan by removing "Reproduction" for the *Ceriodaphnia dubia* Chronic Freshwater Method in Table 1, page 6 of the Draft Plan. Alternatively, the Draft Plan can be amended to use the EPA recommended EC/IC25 for the *Ceriodaphnia* reproduction endpoint, as suggested within the method.[8] A third option would be to add a footnote such as the following to "Reproduction" for the *Ceriodaphnia dubia* Chronic Freshwater Method in Table 1, page 6: "Not to be used as a numeric limit but can be used as a trigger for additional testing and/or initiation of a toxicity reduction evaluation (TRE)." As a fourth option, the State Water Board could use the variance provisions in Section 5 of the Draft Plan to postpone the implementation of the Reproduction endpoint for *Ceriodaphnia dubia* on a statewide basis while a method blank study is implemented.

3. **The Staff Report contains incorrect or unsubstantiated statements suggesting that the TST is more accurate and/or provides more confidence in test results and that the TST represents an improvement compared to the NOEC since both the false negative and false positive errors are controlled.**

   Page 61 of the Staff Report - *"The TST approach provides high confidence in the test results as it incorporates both a false positive error rate and false negative error rate."*

   Page 62 of the Staff Report – *"The NOEC approach fails to incorporate a false negative rate (Type II error rate)."*

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[6] Larry Walker Associates, Inc. 2018. *Ceriodaphnia dubia* Short-term Chronic Reproduction Test: Understanding the Probability of Incorrect Determinations of Toxicity in Non-toxic Samples. White Paper prepared for California Association of Sanitation Agencies. November 2018 (attached).

[7] SCCWRP Technical Report 956. December 2016. Stormwater Monitoring Coalition Toxicity Testing Laboratory Guidance Document. Kenneth C. Schiff and Darrin Greenstein, Southern California Coastal Water Research Project.

[8] EPA Freshwater Chronic Toxicity Method (EPA-821-R-013), page 41.

Page 48 of the Staff Report - *"For those tests where the TST approach provided a different outcome than current statistical approaches, the TST approach appeared to perform better and provided a greater confidence in the outcome."*

It has not been established that the TST approach provides high confidence in test results. As discussed above, the TST, when applied to *Ceriodaphnia dubia* reproduction endpoint, identifies significantly more non-toxic blank samples and samples with responses below the 25% RMD effect threshold as toxic, compared to the NOEC. Furthermore, it is incorrect to assume that both the false negative and false positive errors are controlled using the TST. Only the false negative error is fixed, through the setting of alpha, while the false positive error will vary depending on within-test variability and replication. Lower within-test variability and/or greater replication will result in a lower false positive error rate while increased within-test variability and/or lower replication will result in a higher false positive error. This is very similar to the NOEC except that for the NOEC, the false positive error is fixed using alpha while the false negative error will vary depending on factors such as within-test variability and replication. However, the NOEC addressed and ultimately restricted increases in the false negative error by incorporating various required data review and data validation procedures. These include evaluation of the concentration-response, application of within-test variability caps for the sub-lethal endpoint, and recommendations on controlling variability.

4. Like the NOEC, EC/IC25, and LC50, the TST statistical approach should go through formal promulgation before being implemented for NPDES compliance assessment.

Table 1A in 40 CFR part 136.3 contains the list of currently approved biological methods for wastewater monitoring, including acute and chronic toxicity testing. In addition to the "method," the first column of Table 1A contains the approved parameters and units for each method. For the chronic toxicity methods, the approved parameter and units are the NOEC or IC25 in units of percent effluent. For the acute methods, the only approved parameter and unit is the LC50 in percent effluent. As discussed below, these parameters underwent rigorous analysis before their final promulgation; a similar process should be applied to the TST approach, to ensure its reliability.

Following initial promulgation of the WET methods on October 16, 1995, several parties challenged the rulemaking (Edison Electric Institute v. EPA, No. 96-1062 (D.C. Cir.); Western Coalition of Arid States v. EPA). As part of a resolution to litigation, EPA agreed to conduct an interlaboratory variability study; publish a peer-reviewed report on the results of this study (including a table of coefficients of variation), as well as a technical correction notice, method guidance document, and variability guidance document to address concerns regarding both false positive and false negative error rates; address pathogen contamination, propose specific technical method changes, and propose to ratify or withdraw WET test methods evaluated in the interlaboratory variability study.

The EPA inter-laboratory variability study indicated that some endpoints yielded a substantial single test false positive error rate (improper identification of a non-toxic laboratory blank sample as toxic).

- For the *Ceriodaphnia dubia* reproduction endpoint, four of the 27 non-toxic blank samples tested using the NOEC and/or EC/IC25 were initially identified as toxic, resulting in a false positive error of 14.8%.
- For the fathead minnow chronic toxicity test, three of 24 non-toxic blank samples were initially identified as "toxic," resulting in a false positive error rate of 12.5%.
- However, after application of EPA's concentration-response evaluation, three of the four *Ceriodaphnia dubia* samples and two of the three fathead minnow samples were correctly determined to be "non-toxic." Therefore, application of the concentration-response evaluation in this study decreased the false positive error from 14.8% to 3.8% for *Ceriodaphnia dubia* and from 12.5% to 4.2% for fathead minnows.

Based on these findings, the WET test methods were amended to include a requirement to evaluate the concentration-response relationship for all multiple concentration tests, clarifications on the generation of confidence intervals, guidance on dilution series selection, requirements regarding acceptable dilution waters, and incorporation of variability criteria to address concerns regarding both false positive and false negative error rates.

The court upheld the NOEC and EC/IC25 procedures because EPA had provided adequate safeguards within those methods to protect against the concerns raised by the plaintiffs. Two of these safeguards are the requirements to use a multiple-concentration test that includes a concentration-response evaluation and application of variability criteria. The court specifically stated, "*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%.*" In addition to specifically requiring a concentration-response evaluation for all multi-concentration toxicity tests and mandating the incorporation of variability criteria, the promulgated method strongly recommends against use of a single concentration "pass/fail" test design while recommending use of the IC25 point estimate approach for NPDES compliance determination:

> EPA Freshwater Chronic Toxicity Method (EPA-821-R-013), page 5 (emphasis not added): *"Use of pass/fail tests consisting of a single effluent concentration (e.g., the receiving water concentration or RWC) and a control* ***is not recommended.***"
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> EPA Freshwater Chronic Toxicity Method (EPA-821-R-013), page 41 (emphasis not added): ***"NOTE: For the NPDES Permit Program, the point estimate techniques are the preferred statistical methods in calculating end points for effluent toxicity tests."***

Unlike the NOEC and EC/IC25, the TST is a single concentration test design that incorporates a "pass/fail" response. Additionally, the TST is a hypothesis test like the NOEC, rather than a point estimate like the EC/IC25. However, the NOEC tests whether the control and sample are equivalent, and the TST approach for chronic toxicity evaluates whether the control and sample differ by no more than 25%. Functionally, the TST approach assumes that the sample is toxic (i.e., the difference between the control and the sample is greater than 25%) unless it can be statistically demonstrated otherwise. Therefore, the error associated with incorrectly identifying a truly toxic sample as non-toxic (commonly referred to as a false negative error) is fixed and set as "alpha" and the error associated with incorrectly identifying a truly non-toxic sample as toxic (commonly referred to as a false positive error) will vary depending on within-test variability and replication. As previously pointed out, the promulgation process for the NOEC and EC/IC25 caused EPA to conduct an inter-laboratory variability study that resulted in the promulgation of specific safeguards that control the error to acceptable levels (limiting false positive rates to at most 5%, while allowing false negative rates up to 20%).

Similar studies have not been conducted to evaluate how often the TST statistical endpoint incorrectly determines toxicity, and the specific safeguards (such as the evaluation of the concentration-response pattern) that are critical to maintaining acceptably low error rates for the NOEC have been removed or significantly restricted in the Draft Plan. State Water Board staff maintain that conducting a study that incorporates non-toxic blank samples is unnecessary, because the Test Drive Study included data from tests with a mean effect below 10 percent relative to the control[9]. Relying on such an assessment to quantify the frequency of incorrectly identifying a non-toxic sample as toxic would be sufficient if non-

[9] State Water Resources Control Board Response to Comments on the 2012 Draft Policy for Toxicity Assessment and Control, October 26, 2018. Comment 36.1)

toxic samples only exhibited effects of 10% or less. However, as detailed in the previous studies[10] that did include non-toxic blank samples, non-toxic samples were commonly observed to yield effects greater than 10% and up to nearly 70% effects.

5. **Page 13 of the Staff Report incorrectly states that the "U.S. EPA neither recommends nor requires review of the concentration-response pattern for a multi-concentration test prior to or subsequent to running the TST approach." An evaluation of concentration-response relationships is required in 40 Code of Federal Regulations (CFR) Part 136, and the Draft Plan must not limit or restrict compliance with this requirement prior to application of the two-concentration TST statistical hypothesis test.**

Page 69963 of Federal Register Volume 67, Number 223 ((66 FR 49794) states that "*EPA is finalizing proposed method modifications to require the review of concentration-response relationships for all multi-concentration tests. Under this requirement, the concentration-response relationship generated for each multi-concentration test must be reviewed to ensure that calculated test results are interpreted appropriately. In conjunction with this requirement, EPA has provided recommended guidance for concentration-response relationship review.*" This requirement was implemented in Section 10.2.6.2 of the approved freshwater chronic toxicity method,[11] which states that the "concentration-response relationship generated for each multi-concentration test **must** be reviewed to ensure that calculated results are interpreted correctly" (emphasis added).[12]

Conducting multiple-concentration WET tests and evaluating the concentration-response relationship is a critical method-defined procedure for addressing variability and validating toxicity data. The concept of a dose-response/concentration-response relationship has been described by toxicologists as "*the most fundamental and pervasive one in toxicology.*"[13] The two EPA scientists most directly responsible for developing the current WET test methods have 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.*"[14] (emphasis added)

> "*The dose response curve is the basis for the validity of a toxicity test. The control serves as the starting point from which the dose response is evaluated. **If a dose response is not obtained, then toxicity cannot be inferred.***"[15] (emphasis added)

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[10] Larry Walker Associates, Inc. 2018. *Ceriodaphnia dubia* Short-term Chronic Reproduction Test: Understanding the Probability of Incorrect Determinations of Toxicity in Non-toxic Samples. White Paper prepared for California Association of Sanitation Agencies. November 2018 (attached).

[11] Short-Term Methods for Estimating the Chronic Toxicity of Effluent and Receiving Water to Freshwater Organisms, Fourth Ed., EPA-821-R-02-013. October 2002. Section 10.2.6.2, page 50.

[12] This section also states that "all WET test results (from multi-concentration tests) reported under the NPDES program **should** be reviewed and reported according to USEPA guidance on the evaluation of concentration-response relationships." (emphasis added) This apparently discretionary recommendation to follow USEPA guidance applies to interpretation of the promulgated NOEC and IC25 (not the TST), and does not relinquish an NPDES Permittee from complying with the requirement to conduct a concentration-response evaluation.

[13] Casarett, L.J. and J. Doull. 1975. Toxicology: the basic science of poisons. Macmillan Publishing Co., New York. [Exhibit 1]

[14] Dr. Donald Mount, National Effluent Toxicity Assessment Center, EPA Environmental Research Laboratory-Duluth, MN. NETACommunique, Jan., 1990

[15] Norberg-King, Teresa J., U. S. EPA Environmental Research Laboratory- Duluth, Memorandum to Rob Pederson, EPA Region X, Review of the Toxicity Results from West Boise and Landers Street POTWs (June 5, 1989).

Because toxicity testing assumes a causal relationship (i.e., that increasing pollutant concentrations cause an increasing organism response), evaluating concentration-response information is critical to associating any observed response to toxicity. Anomalies in this relationship reduce confidence in the test's ability to accurately estimate toxicity or, more specifically, the effects associated with pollutants or toxicants. As discussed above, the EPA determined that application of a relatively simple concentration-response evaluation procedure reduced the false positive rate among non-toxic blank samples from 14.8% to 3.8% for *Ceriodaphnia dubia* and from 12.5% to 4.2% for fathead minnows.[16] Although more challenging to quantify, evaluation of the concentration-response relationship is also expected to significantly reduce the false negative error rate as well.

As an example, results from one of the Sanitation Districts' toxicity tests are provided below. The control and in-stream waste concentration (IWC, or 100% sample) showed less than a 10% effect and were considered non-toxic, but the toxic effect increased as the concentration decreased. The concentration-response relationship in this test is clearly anomalous and not indicative of a non-toxic sample, but under the Draft Plan, the results depicted below would be identified as an unqualified "Pass."

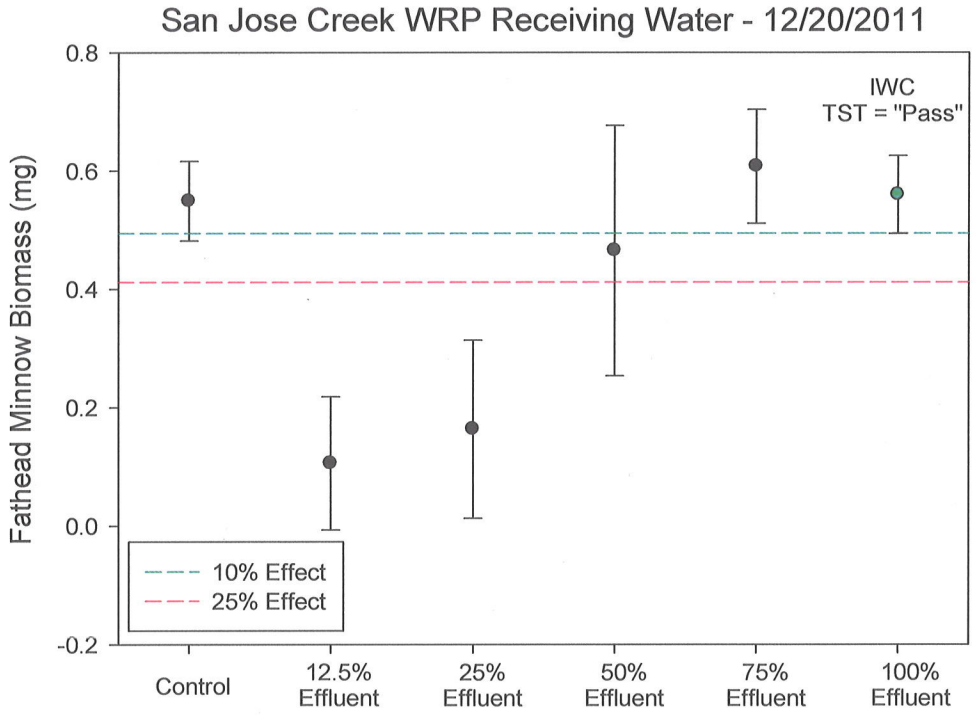

Figure 1. Dose-response pattern depicting a likely false negative error.

6. The numeric Water Quality Objective is inconsistent with numeric effluent limits and is expected to cause at least one third of non-toxic receiving waters to be listed as "impaired."

To determine compliance with numeric effluent limits, the Draft Plan incorporates the use of multiple-test TST failures, in an attempt to address issues of uncertainty and false determinations of toxicity associated with individual TST toxicity test results. However, similar provisions for addressing uncertainty are not incorporated into the numeric water quality objective. Failure to address this

[16] 40 CFR Part 136. Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule. Federal Register / Vol. 67, No. 223 / Tuesday, November 19, 2002 / Rules and Regulations. Page 69963.

shortcoming will cause a significant number of non-toxic receiving waters to be 303(d)-listed as "impaired."

The proposed numeric toxicity objective states that "attainment of the water quality objective is demonstrated by rejecting this null hypothesis in accordance with the statistical approach described in Appendix A." This provision indicates that a single TST failure in a receiving water toxicity test represents an exceedance of the numeric objective. Table 3.1 of California's 303(d) listing policy[17] specifies that if two or more of 24 measurements in a waterbody exceeds the water quality objective, the waterbody will be listed as impaired. The EPA interlaboratory validation study data indicated that the false determination of toxicity error rate for the single test TST is as high as 15%, and the State Water Board Staff estimated it to be 5% based on their interpretation of the Test Drive Study. The probability of listing a non-toxic water body under 303(d) (i.e., of observing at least two TST exceedances in 24 samples) is 89% using the EPA's error rate, and 34% using the State Water Board's error rate. This statistically-calculated high rate of incorrect identification will waste significant Water Board and stakeholder resources to unnecessarily respond and develop TMDLs in non-toxic receiving waters, with no benefit to aquatic life.

Recommended Solution:

The State Water Board should include instructions in the Draft Plan on the determination of 303(d) listings for toxicity, to address these uncertainties associated with the TST "pass/fail" approach (and these instructions should be amended into the 303d Listing Policy when that Policy is next updated). Specifically, the instructions should direct regulatory authorities to use a 66% TST "pass" rate among all toxicity tests conducted in a receiving water reach as evidence that the receiving water meets toxicity objectives. This "pass" rate is consistent with the two-out-of-three multiple TST test approach used for final effluent compliance to address uncertainty in the analytical and statistical methods. The current 303(d) Listing Policy could continue to be used to evaluate results for effects greater than 50%, which is consistent with the proposed final effluent maximum daily effluent limit (MDEL). Under these listing instructions, less than 1% of non-toxic waters would be erroneously listed as "impaired" (assuming a 5% false determination of toxicity error rate), and less than 2% would be erroneously listed if that error rate is 15%.

In the alternative, at a minimum, the Draft Plan should include language that would prevent regulatory authorities, when developing and implementing toxicity TMDLs, from imposing more restrictive toxicity limits than those proposed in the Draft Plan. This alternative solution will not reduce the number of statistically expected erroneous 303(d) listings, but will provide significant assurances that all potential numeric toxicity limits adequately address and account for uncertainty. This can be easily accomplished by adding the recommended edits (underlined below) to Section 2.e.i.(B) on page 22:

> ***Numeric Effluent Limitations in Permits***
> *The PERMITTING AUTHORITY shall include the following MMEL in the NPDES permits if REASONABLE POTENTIAL is demonstrated or if a TMDL derived waste load allocation for toxicity is warranted, for chronic toxicity in accordance with the provisions specified in Section IV.B.2.b. or if a POTW is authorized to discharge at a rate equal to or greater than 5.0 MGD:*

7. Studies comparing the TST to the promulgated LC50 have not been conducted.

For acute toxicity testing, the only promulgated endpoint is the 50% lethal concentration (LC50), and State Water Board staff did not compare the TST with the LC50. Because the TST uses a regulatory management decision that defines unacceptable toxicity as 20% mortality, compared to the LC50

[17] Water Quality Control Policy for Developing California's Clean Water Act Section 303(d) List. State Water Resources Control Board. Adopted September 2004.

threshold of 50% mortality, the two endpoints are unlikely to be comparable. The State Water Board should not adopt the proposed acute toxicity requirements using the TST statistical approach until and unless the proposed TST and the approved LC50 approach are demonstrated to be comparable.

8. **The State Water Board should specify circumstances when acute toxicity provisions for dischargers might be appropriate, to facilitate the State Water Board's goal of statewide consistency for toxicity requirements and to avoid redundant and costly acute toxicity monitoring that provides no additional protection for aquatic life.**

Page 77 of the Staff Report states that "*given the nature of the influent, the dilution, and the treatment process associated with POTWs, a chronic toxicity test is generally protective of both chronic and acute toxicity.*" Chronic toxicity tests are expected to exhibit at least as much toxicity as acute toxicity tests, because chronic toxicity tests typically utilize a more critical and sensitive life-stage (e.g., larvae), have longer exposure durations, and incorporate more sensitive endpoints than survival, such as growth and reproduction. The Staff Report (page 77) describes several specific situations that could warrant inclusion of acute toxicity testing provisions, and the economic analysis (page 243) does not include acute toxicity testing for POTWs, indicating only chronic effluent limits as a default for POTWs. However, the language from the Staff Report indicating that chronic toxicity testing requirements are generally protective of both acute and chronic toxicity is not contained in the Draft Plan. This recommended language, while maintaining Permitting Authority discretion, is important to establish intent, ensure that the Plan is implemented consistently statewide by reducing the potential for misinterpretation by individual permitting authorities, and minimize costs and efforts associated with redundant and unnecessary acute toxicity testing.

Recommended Solution:

We request that the following underlined text, taken directly from the Staff Report, be added to Section IV.B.2.b.ii. of the Draft Plan, to clarify the application of numeric acute toxicity limits for POTW dischargers:

ii. Non-Storm Water NPDES Dischargers Required to Conduct Reasonable Potential Analysis for Acute Toxicity.

Section IV.B.2.b.ii

The PERMITTING AUTHORITY may require POTW dischargers to conduct a REASONABLE POTENTIAL analysis for acute toxicity, pursuant to the procedures in Section IV.B.2.b.iii, for review and approval by the PERMITTING AUTHORITY. Given the nature of the influent, the dilution, and the treatment process associated with POTWs, a CHRONIC TOXICITY TEST is generally protective of both chronic and acute toxicity. Factors that may warrant a REASONABLE POTENTIAL analysis for acute toxicity include, but are not limited to, discharges to water bodies inhabited by threatened and endangered species (if a chronic toxicity test surrogate does not exist), discharges with high dilution rates (as high dilutions may mask chronic effects), or a situation in which the CHRONIC TOXICITY TEST is not adequately protective of acute toxicity objectives in receiving water. The PERMITTING AUTHORITY shall document the decision whether to conduct a REASONABLE POTENTIAL analysis for acute toxicity in the NPDES fact sheet (or equivalent document).

9. **The State Water Board should clarify how the provisions in the Draft Plan will supersede certain existing Basin Plan provisions and all of the existing toxicity control provisions in the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (SIP).**

Section III.3 of the Draft Plan provides a high-level overview of what is superseded and what is not (see also page 9 of the Staff Report), and Appendix E of the Staff Report contains specific underline/strikeout of the sections and provisions of Basin Plans that would either be superseded or remain in effect. However, the Staff Report states that Appendix E provides an "indication of the language that would be superseded" by the provisions, which implies that the adoption of the Draft Plan does not automatically modify the Basin Plans. The State Water Board should clarify how and when the changes will be made: will the changes be considered administrative because they have already been considered in this rulemaking process, or will they be subject to full rulemaking processes (i.e., modification of the Basin Plans) in each Region in the future? If the latter, what discretion will the Regional Boards have in their decision-making process?

In addition, it is unclear exactly which portions of the Basin Plans and SIP would be superseded by the Draft Plan.

- Page 296 of Appendix E of the Staff Report provides "an indication of the language that will be superseded (in strikeout or underline)" but also states that "there may be sections of the Basin Plans that would conflict with the Provisions only when applied to aquatic toxicity that are not shown in strikeout below." This statement appears to apply to 11 sentences, which have the following footnote attached: "This sentence has been superseded to the extent that it is applied to aquatic toxicity." It would be far clearer to revise the Basin Plan provisions to indicate where the Provisions actually do apply, rather than to include the ambiguous statement that the sentence is superseded to the extent it is applied to aquatic toxicity. To what other conditions does it apply? How does it change the application of each of the affected Basin Plan's toxicity provisions?
- Page 296 of Appendix E also ambiguously states that "Other sections are not reflected below." Does this mean that "other sections" contained in existing Basin Plan toxicity objectives also have been determined to not conflict or overlap with the proposed Provisions, and that they will remain in effect and will not be superseded?

Changes to Basin Plans should be clearly identified and explained, and the public should have an opportunity to review and comment on the changes, both as they relate to the adoption of these Provisions and as they will be implemented in the future (i.e., to the extent they are not superseded). In short, this information provided in the Draft Plan and Staff report is both unclear and confusing, and appears to violate the California Administrative Procedures Act (APA) by fostering duplicative and/or overlapping regulation.[18]

10. Section III.4 of the Draft Plan is intended to address the interaction of these Toxicity Provisions with narrative and numeric toxicity water quality objectives. The State Water Board should specify how narrative toxicity objectives will be translated into effluent limits and permit requirements, as required by U.S. EPA's water quality standards regulations to implement the Clean Water Act.

The proposed provisions in Section III.4 of the Draft Plan allow broad discretion to Permitting Authorities to evaluate compliance with narrative toxicity water quality objectives. These provisions essentially allow a Permitting Authority to select a value for a water quality objective from any identifiable source and derive a chemical-specific effluent limitation from it, without any notice-and-comment regulatory process:

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[18] California Government Code §§11349 and 11349.1. The APA requires that an agency proposing to amend or adopt a regulation must identify any state or federal statute or regulation which is overlapped or duplicated by the proposed regulation and justify any overlap or duplication. "Nonduplication" means that a regulation does not serve the same purpose as a state or federal statute or another regulation.

- "*The Permitting Authority may consider numerical criteria and guidelines for toxic substances developed by the State Water Board, the California Office of Environmental Health Hazard Assessment, the California Department of Health Services, the U.S. Food and Drug Administration, the National Academy of Sciences, the U.S. EPA, and other appropriate organizations, to evaluate compliance with narrative toxicity water quality objectives.*"
- "*The Permitting Authority shall have discretion regarding the application of narrative toxicity water quality objectives to derive chemical specific effluent limitations*," among other things.

These provisions preclude interested parties, including permittees, from understanding the nature of how they will be regulated, which is at odds with the APA standard for clarity.[19]

In addition, the Draft Plan lacks clear implementation provisions, including translator procedures explaining how these effluent limitations, receiving water limitations, targets and other thresholds, will be selected and/or applied as chemical specific effluent limitations. The Clean Water Act requires that States adopt numeric criteria for all toxic pollutants for which Section 304(a) criteria have been adopted by EPA.[20] EPA regulations allow States to adopt narrative, rather than numeric, criteria to protect beneficial uses as long as the State provides "information identifying the method by which the State intends to regulate point source discharges of toxic pollutants on water quality limited segments based on such narrative criteria.[21]" This "narrative translator" procedure is intended to ensure "acceptable scientific quality and full involvement of the public and EPA.[22]" Furthermore, EPA guidance documents, such as the Water Quality Standards Handbook (2nd Edition, EPA-823-B-12-002) and the Technical Support Document for Water Quality-Based Toxics Control (March 1991) say that States must adopt implementation procedures to address "all mechanisms" used by the State to ensure that narrative criteria are attained, and these procedures should describe things such as the methods the State will use to identify those pollutants to be regulated in a specific discharge; an incremental cancer risk for carcinogens; methods for selecting appropriate hardness, pH, and temperature variables for criteria expressed as functions; design flows to be used in translating chemical-specific numeric criteria for aquatic life and human health into permit limits; and other methods and information needed to apply standards on a case-by-case basis[23]. None of these requirements for a translator mechanism as applied to narrative toxicity objectives have been included in the Draft Plan.

Finally, with respect to the implementation of the narrative objectives, Section III.4 states that "the Permitting Authority shall have discretion in deriving chemical specific limits, targets and other thresholds." This statement is not sufficient to demonstrate compliance with Water Code Section 13242, which requires inclusion of the following elements:

a. A description of the nature of actions which are necessary to achieve the objectives, including recommendations for appropriate action by any entity, public or private;
b. A time schedule for the actions to be taken;
c. A description of surveillance to be undertaken to determine compliance with objectives.

Recommended Solution:

To achieve a consistent approach to narrative toxicity objectives, we recommend that a Statewide Program of Implementation, in compliance with Section 13242 and consistent with federal regulations, be included in the Draft Plan.

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[19] Under the APA, "clarity" means "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."
[20] 33 U.S.C. §1313(c)(2)(B)
[21] 40 CFR §131.11(a)(2)
[22] 57 Fed. Reg. 60853 (1992)
[23] Water Quality Standards Handbook (2nd Edition, 2012, EPA-823-B-12-002) at §3.5.2 & Ex. 3-3; Technical Support Document for Water Quality-Based Toxics Control (EPA, March 1991), p. 31-32 and Box 2-1.

In conclusion, the Sanitation Districts thank the State Water Board for this opportunity to provide input into the Draft Plan and appreciate the efforts by State Water Board staff to work with our staff and other stakeholders over the years to address issues related to these toxicity provisions. If you have any questions about these comments or require additional information, please feel free to contact Phil Markle at (562) 908-4288, extension 2808, or by email at pmarkle@lacsd.org.

Very truly yours,

Ann T. Heil
Section Head
Reuse and Compliance

AH:MT:ep