

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



December 21, 2018

VIA EMAIL - COMMENTLETTERS@WATERBOARDS.CA.GOV

Ms. Felicia Marcus, Chair and State Water Board members
Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
P.O. Box 100, Sacramento, CA 95812-2000

Re: Comment Letter – Toxicity Provisions
Client-Matter No. 41395.00000

Dear Chair Marcus and Members of the State Water Resources Control Board:

On behalf of the City of San Bernardino Water Department (Department) and the San Bernardino Valley Municipal Water District (District), we submit the following detailed comments. The Department and District have been very engaged in this process since your staff began preparing a “Toxicity Policy” prior to 2008. We have carefully reviewed the most recent draft Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California; and Toxicity Provisions (Toxicity Provisions) and the Draft Staff Report, including the Draft Substitute Environmental Documentation (SED), for the Toxicity Provisions. We write to express our sincere disappointment that most, if not all, of our concerns expressed over the last 10 years, have still not been addressed. Because many of the State Water Resources Control Board (State Water Board) members were not present the last time this topic formally came before the Board, we have updated, expanded, and hereby resubmit our concerns in writing. We also provide a redline markup to and comments on the Toxicity Provisions document in **Attachment 1**.

I. The Proposed Toxicity Provisions Fail to Comply with Administrative Procedures Act and Clean Water Act Requirements

The State Water Board follows truncated requirements under both the Administrative Procedures Act (APA) and the California Environmental Quality Act (CEQA) when adopting statewide Water Quality Control Plans. However, under the APA, all such plans must be submitted to the Office of Administrative Law (OAL) and must be reviewed for compliance with the standards of Necessity, Authority, Clarity, Consistency, Reference, and Non-Duplication as set forth in APA section 11349.1. (See Gov’t Code §11353(a) and (b)(4).) In addition, all plans must be reviewed for compliance with requirements of the Federal Water Pollution Control Act (also known as the

Clean Water Act or CWA). (See Gov't Code §11353(b)(4) and (b)(7); Water Code §13372 (construe state law to ensure consistency with the requirements for state programs implementing the CWA); 33 U.S.C. §40 C.F.R. §131.6.) For the reasons set forth herein, the Toxicity Provisions cannot meet the applicable APA or CWA requirements.

A. The Toxicity Provisions Fail to Meet the APA Requirement for Necessity.¹

1. No Need has been Demonstrated to Alter Precedential Order Requirements.

For the last fifteen (15) years, most of the State of California has been following the multiple State Water Board precedential decisions that require dischargers under an NPDES permit with a demonstrated reasonable potential to cause or contribute to an instream exceedance for Whole Effluent Toxicity (WET) to have: 1) a *narrative* effluent limitation for chronic toxicity, along with 2) a *numeric* trigger that requires accelerated monitoring and a special study to attempt to determine the cause of any toxicity. While the proposed Toxicity Provisions mention *one* of these orders (Order No. 2003-0012), the Toxicity Provisions fail to discuss the holding in that and the subsequent, consistent State Water Board decisions. The holding in Order No. 2003-0012 was as follows (footnotes not included; emphasis added):

In reviewing this petition and receiving comments from numerous interested persons on the propriety of including numeric effluent limitations for chronic toxicity in NPDES permits for publicly-owned treatment works that discharge to inland waters, we have determined that this issue should be considered in a regulatory setting, in order to allow for full public discussion and deliberation. We intend to modify the SIP to specifically address the issue. We anticipate that review will occur within the next year. We therefore decline to make a determination here regarding the propriety of the final numeric effluent limitations for chronic toxicity contained in these permits. Pending modification of the SIP, we will ensure that the permits contain adequate narrative effluent limitations. The final numeric effluent limitations for chronic toxicity will be replaced by the following:

“There shall be no chronic toxicity in the effluent discharge.”

US EPA has also stated that if a narrative effluent limitation is used, the permits must also contain (1) numeric benchmarks for triggering accelerated monitoring, (2) rigorous toxicity reduction evaluation (TRE)/toxicity investigation evaluation (TIE) conditions, and (3) a reopener to establish numeric effluent limitations for either chronic toxicity or the chemical(s) causing toxicity. We find that the permits already contain a numeric

¹ “Necessity” means the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. (Gov't Code §11349(a).)

trigger of 1 TUc for conducting accelerated monitoring and rigorous TRE/TIE conditions, but there is a need for a reopener. We will make that revision to the permits.

The addition of an enforceable narrative effluent limitation for chronic toxicity, along with the existing TRE/TIE requirements and the reopener for a numeric effluent limitation for chronic toxicity, if necessary, will ensure that the requirements to perform a TRE/TIE and to implement it to eliminate toxicity are clear and enforceable. We also expect that where the TRE/TIE indicates a pollutant is causing the toxicity, the Regional Board will reopen the permit to include numeric effluent limitations for that constituent.

This Order as well as its companion, Order, No. 2003-0013, deleted the numeric chronic toxicity limits in the challenged permits and replaced them with the specified narrative effluent limitation, added a new reopener provision, and revised the Monitoring and Reporting Program to substitute “the trigger in Effluent Limitation A.12.c” for “the limitation,” where the trigger was set as an “exceedance of the 1 TUc effluent monthly median.” (*See accord* WQO 2003-0013 at pgs. 2-3.)

These narrative limits and triggers were carried over into the subsequent permits for the applicable Water Reclamation Plants, which were not objected to by the U.S. Environmental Protection Agency (USEPA). In fact, in 2007, USEPA wrote a comment letter not objecting to the draft Long Beach/Los Coyotes permits, that contained essentially identical toxicity provisions, confirming that “At minimum, the permits need to specify the WQBEL: “There shall be no chronic toxicity in the effluent discharge.” (USEPA Letter from Douglas E. Eberhardt, Chief of Clean Water Act (CWA) Standards and Permits Office to Deborah Smith, Los Angeles Regional Board (May 31, 2007).)

These precedential decisions were later upheld and followed in other, subsequent State Water Board orders, including WQO 2008-08 (City of Davis) and WQO 2012-0001 (City of Lodi). The most recent 2012 Lodi order at page 22 recognized that “[t]he Board previously addressed this issue in a precedential decision” and “concluded that a numeric effluent limitation for chronic toxicity was not appropriate in the permit under review, but that the permit had to include a narrative effluent limitation for chronic toxicity.” In the *Lodi* case, the State Water Board determined that because the discharge had the reasonable potential to cause or contribute to an excursion above the Basin Plan’s narrative toxicity objective, the Central Valley Water Board, on remand, was ordered to “amend Order No. R5-2007-0113 to add an appropriate narrative chronic toxicity limitation.” *See also* State Water Board WQO 2008-0008 at pgs. 5-7 (concluding that a numeric effluent limitation for chronic toxicity is not appropriate at this time).

The *City of Davis* Order also held the following (original footnotes not included, emphasis added):

The Permit includes several mechanisms to prohibit toxicity in the discharge.

Section IV.A.1 of the Permit (Effluent Limitations and Discharge Specifications) contains effluent limitations for all toxic pollutants that have the reasonable potential to cause or contribute to an exceedance of water quality standards, both numeric and narrative. These pollutant-specific limitations are intended to ensure that no known toxic pollutants are discharged. In addition to chemical-specific effluent limitations, the Permit includes Whole Effluent Toxicity (WET) requirements, intended to detect the effects of any other unknown pollutants, as well as any combined effects from various pollutants that may cause toxicity to receiving water organisms. Finally, Section V. 16 of the Permit (Receiving Water Limitations) states that the discharge shall not cause “toxic substances to be present, individually or in combination, in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life.”

The range of permitted survivability appropriately reflects uncertainty in existing test methods. All such test results are, at best, analytical estimates that are prone to some degree of inaccuracy, due to factors beyond practicable control. This is particularly true for WET tests because of their high inherent variability of test organisms and test environmental conditions, as well as other factors. In fact, the coefficients of variation for toxicity test results (acute and chronic alike) range from 14.8 percent to 67.6 percent. [*Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the National Pollutant Discharge Elimination System Program*, (EPA 833-R-00-003) June 30, 2000.] A permit limitation requiring 70 percent survival of test organisms in the test environment does not mean that it allows 30 percent mortality for aquatic organisms in the receiving water. Instead, the requirement reflects an established laboratory procedure.

The WET test is a tool to assess toxicity in the effluent under certain conditions, for a specific set of species that are used in such laboratory tests. In addition to the 70 percent survival requirement, there is also a 90 percent survival requirement as a median for three test results. The median requirement basically ensures that, in three tests, two of the results will show a survival rate of 90 percent or better. Among the permits issued in this state that have numerical acute toxicity limitations, all allow some degree of mortality of organisms during the tests. To account for the test variability, the U.S. Environmental Protection Agency’s (USEPA’s) “Guidance for NPDES Permit Issuance, February 1994” states the following:

Achievement of narrative criterion, as applied herein, means that ambient waters shall not demonstrate for acute toxicity: 1) less than 90 percent survival, 50% of the time, based on the monthly median, or 2) less than 70% survival, 10% of the time, based on any monthly median.

Thus, the USEPA guidance provides for a level of mortality in test results that is similar to the acute WET numeric limitations in this Permit. The Central Valley Water Board's use of a percentage for acute mortality is consistent with USEPA guidance. . . .

In Order WQO 2003-012, we stated that, pending adoption of a policy, it was not appropriate to include final numeric effluent limitations for chronic toxicity in NPDES permits for publicly owned treatment works, but that permits must contain the following:

1. A narrative limit such as: "There shall be no chronic toxicity in the effluent discharge;"²
2. Numeric benchmarks for triggering accelerated monitoring;³
3. Rigorous toxicity reduction evaluation/toxicity investigation evaluation conditions; and
4. A reopener to establish numeric effluent limitations for either chronic toxicity or the chemical(s) causing toxicity.

The regulatory process set forth in these precedential orders was reasonable and achieved the goal of getting to the root of any potentially toxic discharges and solving any toxicity problem without placing dischargers in unnecessary compliance jeopardy. Thus, additional, new objectives and implementation procedures to replace those that have been working for the last 15 years fail to meet the definition of "Necessity." In addition, these decisions went beyond the proposed Toxicity Provisions to require that effluent limits for the pollutant(s) causing toxicity be prescribed. Moreover, during this time, TMDLs for toxicity were undertaken, and the cause(s) of toxicity has been or is being addressed. No need exists or has been specified to justify a change from this clear, effective, and enforceable approach. In fact, this approach is not recognized as the current baseline. Instead, the Toxicity Provisions presume illegal permits, adopted contrary to these clear, binding precedential decisions, constitute the baseline.

² Narrative limits meet the statutory requirements for being an "effluent limitation" as it is a restriction on the discharge from a point source. 33 U.S.C. §1362(11); 40 C.F.R. §122.2. However, it is not clear whether these definitions actually apply to toxicity, since toxicity is not a constituent or "pollutant," but instead an effect. "Toxicity tests estimate the effects of discharges to surface waters on the survival, growth, and reproduction of aquatic species in the receiving water." Draft Staff Report at p. vii.

³ USEPA guidance acknowledges the use of triggers for additional monitoring to confirm the presence of toxicity. "EPA recommends that regulatory authorities evaluate the merits of a step-wise approach to address toxicity. This approach can determine the magnitude and frequency of toxicity and appropriate follow-up actions for test results that indicate exceedances of a monitoring trigger or permit limit." USEPA, *Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications under the NPDES System*, EPA 833-R-00-003 at p. 7-4 (June 2000); 65 Fed. Reg. 44528-9 (July 18, 2000) ("EPA recommends that NPDES permitting authorities implement the statistical approach as described in the TSD to evaluate effluent and to derived WET limits or monitoring triggers.")

2. The Toxicity Provisions fail the APA's Necessity Criteria by Not Meeting the Goal of Statewide Consistency.

If the State Water Board is concerned about statewide inconsistency under the program prescribed by its own precedential orders, then the most appropriate action would be to adopt consistent narrative objectives for chronic and acute toxicity statewide (which is *not* being proposed in the Toxicity Provisions), and to specify which of the promulgated toxicity testing methods set forth in regulation at 40 C.F.R. Part 136 should be utilized. Since USEPA has already specified a preferred method with the same Regulatory Management Decision (RMD) level of 25% effect selected in the Toxicity Provisions, namely the EC/IC 25 approach, the State Water Board should utilize this as the preferred regulatory option over the unpromulgated TST statistical approach that has been in litigation for years and continues to be challenged for its use as an underground federal regulation.

USEPA has sample narrative objectives that could be adopted, such as the following:

Toxic, radioactive, nonconventional, or deleterious material concentrations shall be less than those of public health significance, or which may cause acute or chronic toxic conditions to the aquatic biota, or which may adversely affect designated water uses.

(*See accord* 40 C.F.R. §131.35(f)(1)(ii)(G); (f)(2)(ii)(G); (f)(3)(ii)(G); (f)(4)(ii)(F).) Alternatively, one of the regional narrative objectives could be adopted for statewide use. As stated on page 32 of the Draft Staff Report, "all nine Regional Water Boards have a narrative objective for aquatic toxicity in their Basin Plans that is similar to the following language:

"All waters shall be maintained free of toxic substance in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life."

Failure to adopt uniform narrative criteria for toxicity is inconsistent with the Toxicity Provisions' stated goal of statewide consistency, and, therefore, Necessity.

3. Numeric Objectives and Limits for Chronic Toxicity are Not Necessary to Protect Water Quality.

As set forth in the Draft Staff Report, some regions have no toxicity at all. (*See* Table 4-2 – Toxicity Assessments of California Waters) The Santa Ana Region is listed as being 100% non-toxic, which begs the question of why additional regulatory tools are needed there. In other regions, the non-toxic waters range from a low of 33% to a high of 85%, showing that the problem is limited. Based on this now more than 10 year old data (from 2001-2008, some before the date of the 2002 Methods), the highest level of toxicity was seen in the Central Coast (at 28%). (*Id.*) However, the Staff Report explains that the sources of toxicity are known (namely

organophosphate pesticides chlorpyrifos and diazinon, and cationic metals. (*Id.* at p. 38). The causes can then be addressed by TMDLs and permit limits (*id.* at pp. 33-34); an important piece of the plan of implementation currently missing from the Toxicity Provisions. Clearly, the current approach is working and no evidence of need has been identified for making the major changes proposed in the Toxicity Provisions.

The CWA does not require numeric water quality criteria/objectives⁴ and generally only requires a permit to contain water quality based effluent limitations (WQBELs) in certain instances. (40 C.F.R. §122.44(d)(1).) The requirements for the inclusion of WQBELs for toxicity are set forth in the federal regulations specifically acknowledge narrative criteria for toxicity and limit the need for limits, as follows:

“Except as provided in this sub-paragraph, when the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, toxicity testing data, or other information, that a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative criterion within an applicable State water quality standard, the permit must contain effluent limits for whole effluent toxicity. Limits on whole effluent toxicity are not necessary where the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit, using the procedures in paragraph (d)(1)(ii) of this section, that chemical-specific limits for the effluent are sufficient to attain and maintain applicable numeric and narrative State water quality standards.”

(40 C.F.R. §122.44(d)(1)(v)(all emphasis added).)

This federal regulation acknowledges that toxicity limits are *not required* where chemical-specific limits for the pollutants most likely to be the cause of toxicity are included in the permits. (*Id.*) The most likely pollutants to cause toxicity are usually assigned effluent limitations within the permit (e.g., chlorine, ammonia, metals, etc.) such that WET limits are not required under 40 C.F.R. section 122.44(d)(1)(v). For instance, in the Los Angeles Region, ammonia was identified as the constituent responsible for nearly all of the historical incidences of Publicly Owned Treatment Works (POTW) toxicity. Numeric ammonia limits were incorporated into the NPDES permits for POTW facilities and treatment upgrades made to remove ammonia from the effluent were fully implemented more than ten years ago. As a result, numeric effluent limitations for toxicity are not necessary to protect water quality. The Toxicity Provisions fail to acknowledge and incorporate this review of permits to determine if likely sources of toxicity are already regulated through specific toxic pollutant limits.

⁴ The CWA recognizes that the goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife is limited to “*wherever attainable.*” (33 U.S.C. §1251(a)(2).) In addition, the CWA has a national policy that the “discharge of toxic pollutants in toxic amounts be prohibited,” but does not require regulation of toxicity as an effect, only regulation of *toxic pollutants.* (33 U.S.C. §1251(a)(3).)

The use of numeric toxicity limits to control for rare and sporadic incidences of chronic toxicity are not feasible for POTWs since proactive measures to address such incidences prior to observation are not possible nor are numeric toxicity limits necessary to protect beneficial uses. Where numeric limits are infeasible to comply with, non-numeric requirements and best management practices (BMPs) should be required instead. (40 C.F.R. §122.44(k)(3)-(4).)

Feasibility encompasses an inability to comply with numeric effluent limitations. *See City of Tracy v. SWRCB*, Statement of Decision at pg. 42, Case Number: 34-2009-80000392 (2011):

The State Board construes “infeasibility” to refer to “the ability or propriety of Establishing” numeric limits. (*See State Board Order WQ 2009-0015*, p.7; *State Board Order WQ 2006-0012*, pp. 14-16.) Thus, according to the State Board, feasibility turns on the ability and propriety of establishing numeric effluent limitations, rather than the ability of a discharger to comply. However, this argument is unfounded and is not supported by case law or by the Board's own Water Quality Orders. It will nearly always be possible to establish numeric effluent limitations, but there will be many instances in which it will not be feasible for dischargers to comply with such limitations. In those instances, states have the authority to adopt non-numeric effluent limitations.

Communities for a Better Environment makes clear that one factor a board may consider in determining whether a numerical effluent limitation is “feasible” is the “ability of the discharger to comply.” (*See Communities for a Better Environment*, supra, 109 Cal.App 4th at pp 1100.) The court expressly approved the regional board's consideration of this factor in upholding the determination that numeric effluent limits were not “appropriate” for the refinery at issue in that case. (*Id.* at p. 1105 [approving determination that numeric WQBEL was not feasible “for the reasons discussed above,” which included inability of discharger to comply.]

Likewise, in Water Quality Order 2003-0012, the State Board declined to impose numeric effluent limitations in a waste discharge permit because of a concern that numeric limitations would not be appropriate (State Board Order WQ 2003-0012.)

When the likelihood of false failures range from 14% to over 50% (*see California Association of Sanitation Agencies (CASA) comment letter submitted on the Toxicity Provisions and attached study*), consistent compliance is clearly impossible.⁵ For these reasons, numeric triggers, confirmatory testing, and TRE/TIE requirements continue to represent the most effective means to identify and ultimately control discharges of toxicity and provide full protection of water quality.

⁵ “The law never requires impossibilities.” Cal. Civ. Code §3531; *see also San Diego Cty. v. Milotz* (1953) 119 Cal.App.2d Supp. 871, 883 (“Where an act is impossible of performance, implied exceptions are recognized to mandatory requirements, but such exceptions are based upon impossibility.”).

4. No Need Exists to Save the State Money on Monitoring.

One of the issues raised by State Water Board staff at the workshops was the need to save the State money on monitoring by not requiring five concentrations. (See Draft Staff Report at p. 50 (“...would require these programs to conduct all toxicity tests with multiple concentrations (i.e., dilutions of the receiving water). This requirement would add additional cost to these programs.”).) However, this is a red herring “need” because the promulgated 2002 Methods (see **Attachment 2**, in section 2.2.4 and Section 8.11, and included below) specifically authorize receiving water samples to be run with just two treatments, while still encouraging the use of multi-concentration tests to estimate the degree of toxicity:

2.2.4 Receiving (ambient) water toxicity tests commonly employ two treatments, a control and the undiluted receiving water, but may also consist of a series of receiving water dilutions.

8.11 RECEIVING WATER TESTS

8.11.1 Receiving water toxicity tests generally consist of 100% receiving water and a control. The total hardness of the control should be comparable to the receiving water.

8.11.2 The data from the two treatments are analyzed by hypothesis testing to determine if test organism survival in the receiving water differs significantly from the control. Four replicates and 10 organisms per replicate are required for each treatment (see Summary of Test Conditions and Test Acceptability Criteria in the specific test method).

8.11.3 In cases where the objective of the test is to estimate the degree of toxicity of the receiving water, a multi-concentration test is performed by preparing dilutions of the receiving water, using a ≥ 0.5 dilution series, with a suitable control water.

Therefore, the need to save the State the cost of running a full dilution series fails as a valid justification for the requirements contained in the Toxicity Provisions.

B. The Toxicity Provisions Fail to Meet the APA Requirements for Authority and Consistency.⁶

⁶ “Authority” means the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation. (Gov’t Code §11349(b).) “Consistency” means “being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions or other provisions of law.” (Gov’t Code §11349(d).)

The Clean Water Act clearly requires water quality criteria, where no numerical criteria guidance are available (as is the case with toxicity), to be “based on biological monitoring or assessment methods consistent with information published pursuant to section 1314(a)(8) of this title.” (33 U.S.C. §1313(c)(2)(B).) Section 1314(a)(8) required USEPA to “develop and publish information on methods for establishing and measuring water quality criteria for toxic pollutants on other bases than pollutant-by-pollutant criteria, including biological monitoring and assessment methods.” (33 U.S.C. §1314(a)(8) and (h).) These “biological monitoring and assessment methods” mentioned in both CWA sections above refer to the test methods found in 40 C.F.R. 136.

Despite this clear statutory mandate, along with the clear precedential orders discussed above that the State Water Board mandated to be followed, in the last 6 years, various regional water boards veered from these mandates, adopting permit limits and toxicity testing requirements that differed from and are inconsistent with those required under federal rules adopted under the Clean Water Act. (*See* Water Code §13370(c) (“It is in the interest of the people of the state, in order to avoid direct regulation by the federal government of persons already subject to regulation under state law pursuant to this division, to enact this chapter in order to authorize the state to implement the provisions of the Federal Water Pollution Control Act and acts amendatory thereof or supplementary thereto...”); §13372(a) (“This chapter shall be construed to ensure consistency with the requirements for state programs implementing the Federal Water Pollution Control Act and acts amendatory thereof or supplementary thereto.”))

Instead of reprimanding these rogue regional boards, the State Water Board now intends to adopt these divergent underground “rules” as its new statewide Toxicity Provisions. In fact, those illegal permits are now the baseline used by the State Water Board for both the environmental impact and economic analyses accompanying the Toxicity Provisions.

Although the State Water Board’s draft Toxicity Provisions are premised upon the allegation that the new approach, called the Test of Significant Toxicity or TST, complies with USEPA’s promulgated test methods for toxicity set forth in 40 CFR Part 136,⁷ this premise and allegation fails because the draft policy differs from and inconsistent with that binding legal authority in the following substantive ways:

⁷ USEPA’s first WET test methods were promulgated in 1995. 60 Fed. Reg. 53,529 (Oct.16, 1995). As a result of a legal challenge, these WET tests were modified pursuant to a settlement that required USEPA to re-promulgate chronic WET test methods for use in monitoring compliance with NPDES permit limitations after a formal national rulemaking process, in accordance with 40 C.F.R. Part 136. See 67 Fed. Reg. 69,952 (Nov. 19, 2002) (“2002 Methods”). The 2002 Methods specifically included two test methods, a hypothesis test based on the NOEC and a point estimate test based on the 25% Inhibition Concentration (“IC25”). The 2002 Methods constitute USEPA’s formally promulgated 40 C.F.R. Part 136 WET methods.

1. The Toxicity Provisions Unlawfully Modify the Promulgated Methods.

Whole Effluent Toxicity (WET) test procedures were promulgated and approved as standard test methods by EPA in 2002 as required by Section 1314 of the Clean Water Act. (67 Fed. Reg. 69,952 (Nov. 19, 2002).) The actual test procedures are described in a series of method manuals. (*Id.* at p. 69,971.) These manuals, and the related procedures for each WET test method, are now specified by rule at 40 C.F.R. §136.3, Table 1A, which as shown below specifies only “NOEC or IC25, percent effluent,” for chronic toxicity; not TST. Similarly, Table 1A only specifies “Toxicity, acute, fresh water organisms, LC50, percent effluent”; not TST.

TABLE 1A—LIST OF APPROVED BIOLOGICAL METHODS FOR WASTEWATER AND SEWAGE SLUDGE

Parameter and units	Method ¹	EPA	Standard methods	AOAC, ASTM, USGS	Other
11. Toxicity, chronic, fresh water organisms, NOEC or IC ₂₅ , percent effluent	Fathead minnow, <i>Pimephales promelas</i> , larval survival and growth	1000.0 ²⁷			
	Fathead minnow, <i>Pimephales promelas</i> , embryo-larval survival and teratogenicity	1001.0 ²⁷			
	Daphnia, <i>Ceriodaphnia dubia</i> , survival and reproduction	1002.0 ²⁷			
	Green alga, <i>Selenastrum capricornutum</i> , growth	1003.0 ²⁷			

²⁷Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA-821-R-02-013. Fourth Edition, October 2002. U.S. EPA.

WET is a “method-defined analyte” that cannot be independently measured apart from a prescribed test procedure. (*See* 67 Fed. Reg. 69,966 (2002) and USEPA’s Brief of Respondents in *Edison Electric Institute, et al v. USEPA, et al.* June 8, 2004 at pp. 45 and 78.) According to USEPA, “method-defined analyte means an analyte defined solely by the method used to determine the analyte.” (40 C.F.R. §136.6(a)(5).) Also according to USEPA, the “determinative technique means the way in which an analyte is identified and quantified.” (40 C.F.R. §136.6(a)(3) (emphasis added).) Federal regulations prohibit any modification of an EPA-approved Clean Water Act analytical method for method-defined analytes. (40 C.F.R. §136.6(b)(3).)

According to USEPA, the TST represents “an alternative statistical approach for analyzing and interpreting valid WET data.”⁸ Consequently, the TST provides a new and *different*

⁸ USEPA, National Pollutant Discharge Elimination System Test of Significant Toxicity Technical Document. EPA-833-R-10-004 (June, 2010) p. 60 (emphasis added) .

determinative technique for the way in which the analyte toxicity is identified and quantified despite the State Water Board's claim that the TST approach does not result in any changes to the WET test methods. (Draft Staff Report at pp. 12-13.) For method-defined analytes, the statistical technique used to determine the presence or absence of toxicity *is part of the method*. Any change to these techniques constitutes an impermissible modification to the approved method. Such modifications can only be authorized through a formal USEPA rulemaking process like the one used to promulgate the original WET test methods. (33 U.S.C. §1314(h); 40 C.F.R. §136.4.)

Federal regulations require that "those who develop or use a modification to an approved (Part 136) method must document that the performance of the modified method, in the matrix to which the modified method will be applied, is equivalent to the performance of the approved method. If such a demonstration cannot be made and documented, then the modified method is not an acceptable alternative to the approved method." (40 C.F.R. §136.6(b)(1).)

The Draft Staff Report for the proposed policy at page 127 acknowledges that "for a small number of tests, the TST approach may determine a *different outcome* than other statistical approaches." (Emphasis added.) If there were no difference in outcome, then there would be no reason for State Board staff to recommend using the TST in lieu of the promulgated statistical methods. However, the number of times the TST reaches a different outcome is not "small." In fact, data from the State Board's "Test Drive" study showed that the TST came to a different conclusion in about 8% of all *Ceriodaphnia dubia* reproduction tests (the single most common endpoint used to evaluate wastewater discharges to freshwater streams in California). In these tests, the TST was nearly twice as likely to label the sample "toxic" compared to the NOEC metric. Moreover, the TST is three times more likely to label the sample as "toxic" compared to the IC-25 procedure that EPA's method manual states is the preferred approach for NPDES permitting. (See 2002 Methods at p. 41, section 9.5.1 (**Attachment 2**)). Such discrepancies demonstrate that the TST does not provide performance equivalent to that of USEPA's promulgated methods and cannot be used to assess compliance with NPDES permit limits pertaining to toxicity.

a. Unauthorized Null Hypothesis deeming all water "Toxic."

Current law presumes that a water sample (either from a river/creek/bay or from a discharge) is *not toxic* until proven to be toxic as set forth in the promulgated methods. The State Water Board's new policy flips that presumption on its head. Under the proposed Toxicity Provisions, all tested water in reservoirs, bays, and rivers, and from drinking water pipes and recycled water discharges to receiving waters will be initially **presumed to be toxic**.⁹ This is 180 degrees

⁹ The Draft Staff Report at pg. 55 acknowledges the change in hypothesis from those in promulgated methods: "The TST uses a hypothesis testing approach *but in a different way* than traditional hypothesis testing. The TST hypothesis test restates the null and alternative hypotheses. The null hypothesis in the TST approach assumes that the test sample has an unacceptable level of toxicity until demonstrated otherwise (U.S. EPA 2010b)." (Emphasis added.)

opposite of the USEPA rule requirements, and contrary to law. The current “objective of aquatic toxicity tests with effluents or pure compounds is to estimate the ‘safe’ or ‘no effect’ concentration of these substances, which is defined as the concentration which will permit normal propagation of fish and other aquatic life in the receiving waters.” (See USEPA, *Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms*, Fourth Edition (October 2002), EPA-821-R-02-013 (2002 Methods) at Section 2.1.1 and 9.1.1.)

Flipping the hypothesis also flips the error percentage. The 2002 Methods determined a 5% alpha error rate (non-toxic water declared toxic),¹⁰ but did not specifically define a potentially higher beta error rate (toxic water not declared toxic), but this rate has been recognized to be “up to 20%.” (See *Edison Electric*, 391 F. 3d at 1272.) Under the Toxicity Provisions, the beta error rate of up to 20% flips to become the alpha error rate, which creates more potential liability for dischargers (from false Failures).¹¹ This “guilty until proven innocent” approach, and statistical guarantee to be in violation up to 20% percent of the time (if not more depending on test species used), when it is undeniable that proving a negative is difficult if not impossible, should not be the State Water Board’s discretionary policy selection. This would be the equivalent of deeming everyone to be a criminal until proven otherwise. There is no authority in United States law for such a presumption, particularly under a strict liability statute such as the CWA that ascribes civil and even criminal penalties and even potentially jail time for violations that at least one-fifth of the time could be wrong.

b. Unauthorized “Pass/Fail” hypothesis endpoint.

The EPA rules for hypothesis testing prescribe specific test endpoints (e.g., NOEC/LOEC). (See 2002 Methods at section 9.3.1.1 (“When hypothesis tests are used to analyze toxicity test data, it is not possible to express precision in terms of a commonly used statistic. The results of the test are given in terms of two endpoints, the No-Observed- Effect Concentration (NOEC) and the Lowest-Observed-Effect Concentration (LOEC).”) The Toxicity Provisions propose a *new* test endpoint of **Pass/Fail** despite USEPA discouraging the use of pass/fail. The 2002 Methods incorporated into 40 C.F.R. Part 136 state the following (emphasis in original):

¹⁰ USEPA determined that application of a relatively simple concentration-response evaluation procedure to chronic toxicity tests run using the NOEC hypothesis test analysis reduced the false positive rate among non-toxic blank samples from over 14% to less than 5%. USEPA, *Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule*, 67 Federal Register 69,963 (November 19, 2002).

¹¹ With the new “Pass/Fail” limits proposed, implemented using the two-concentration TST method, which is not approved under 40 C.F.R. Part 136 as a standard method, Permittees are more likely to be in violation of NPDES permits even when there is no real toxicity in the effluent due to a single test false Failure error rate estimated to be 14-20%.

2.2.3 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**.

Because Pass/Fail is not an authorized test endpoint, the State Water Board has no authority for adoption of Pass/Fail as a test endpoint,¹² or use of Pass/Fail as an effluent limitation is inconsistent with law. In fact, USEPA's 2002 Methods express concern that "single concentration, pass/fail, toxicity tests do not provide sufficient concentration-response information on effluent toxicity to determine compliance. It is the Agency's policy that all effluent toxicity tests include a minimum of five effluent concentrations and a control."¹³

Therefore, in order to maintain the procedural safeguards guaranteed by the 2002 Methods and *Edison Electric* case,¹⁴ the Toxicity Provisions must be modified to accurately reflect allowable and required 40 C.F.R. Part 136 protocol evaluation procedures that include the ability to conduct and utilize the results from multiple concentration tests and an appropriate concentration response relationship evaluation. Currently, as discussed below, the Toxicity Provisions direct that five concentrations be run, but the information gleaned cannot be utilized in determining the result.

Because of the general unreliability and inaccuracy of these biological tests, and the amplifying effects on the false Failure error rate imposed by the two-concentration TST method, strictly construed "Pass/Fail" effluent limits for toxicity are inappropriate, infeasible to consistently comply with, and should not be proposed.

c. **Unauthorized Statistical Approach.**

Instead of using one of Part 136's four specified hypothesis testing statistics, the new policy proposes the **TST statistical approach**, which was *not* included or incorporated by reference in USEPA's Part 136 test methods. Relying upon the one highlighted sentence in the EPA test methods set forth below, and ignoring the other context in the same paragraph, the policy

¹² The Toxicity Provisions only define the word "Endpoint" in Appendix A as "A measured RESPONSE of a receptor to a stressor. An endpoint can be measured in a toxicity test or field survey." This definition is of a BIOLOGICAL ENDPOINT, and should be defined as such (*see accord* Draft Staff Report at p. 11), while a TEST ENDPOINT represents the result of the test itself (NOEC/LOEC, EC/IC25, etc.). This currently does not comply with the requirement for "**Clarity**." (Gov't Code §11349(c).)

¹³ *See* USEPA, *Whole Effluent Toxicity: Guidelines Establishing Test Procedures for the Analysis of Pollutants - Supplementary Information Document* (SID) at pg. 28 (Oct. 2, 1995).

¹⁴ *Edison Electric v. EPA*, 391 F.3d 1267, 1272-1274 (D.C. Cir. 2004). In the legal challenge to the 2002 Methods, the court found that "[t]he ratified WET tests are not without their flaws" and cautioned that "[e]ven by EPA's calculations, WET tests will be wrong some of the time." *Edison Electric* at 1272-1274. However, the court upheld those methods because USEPA had provided adequate safeguards within those methods to protect against the concerns raised by the plaintiffs. One of these safeguards was the requirement to use a multiple-concentration test that includes a concentration-response evaluation.

attempts to justify use of an unpromulgated statistical approach. The entire section of the 2002 Methods states the following (highlighting and underlining added):

9.4.1.2 The statistical methods recommended in this manual are not the only possible methods of statistical analysis. 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. Among alternative hypothesis tests some, like Williams' Test, require additional assumptions, while others, like the bootstrap methods, require computer-intensive computations. Alternative point estimation approaches most probably would require the services of a statistician to determine the appropriateness of the model (goodness of fit), higher order linear or nonlinear models, confidence intervals for estimates generated by inverse regression, etc. In addition, point estimation or regression approaches would require the specification by biologists or toxicologists of some low level of adverse effect that would be deemed acceptable or safe. 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.

Thus, although the 2002 Methods realize other statistical procedures *exist*, USEPA selected the 4 specific statistical methods contained therein (namely (1) Dunnett's Test, (2) the t test with the Bonferroni adjustment, (3) Steel's Many-one Rank Test, or (4) the Wilcoxon Rank Sum Test with the Bonferroni adjustment) after due consideration for the four reasons specified. (67 Fed. Reg. 69964; *see also Attachment 2.*) Neither the TST nor any other statistical methods besides those specified in section 9.5.1 (underlining added; bold in original) and discussed in detail in Section 9.6 are authorized:

9.5.1. The recommended statistical analysis of most data from chronic toxicity tests with aquatic organisms follows a decision process illustrated in the flowchart in Figure 2. An initial decision is made to use point estimation techniques (the Probit Analysis, the Spearman-Karber Method, the Trimmed Spearman-Karber Method, the Graphical Method, or Linear Interpolation Method) and/or to use hypothesis testing (Dunnett's Test, the t test with the Bonferroni adjustment, Steel's Many-one Rank Test, or the Wilcoxon Rank Sum Test with the Bonferroni adjustment). **NOTE: For the NPDES Permit Program, the point estimation techniques are the preferred statistical methods in calculating end points for effluent toxicity tests.** If hypothesis testing is chosen, subsequent decisions are made on the appropriate procedure for a given set of data, depending on the results of the tests of assumptions, as illustrated in the flowchart. A specific flow chart is included in the analysis section for each test.

Neither the text of the 2002 Methods, nor the related flowchart (*see Attachment 2*), allow for the TST approach to be used in lieu of the promulgated statistical or point estimate approaches. The

Toxicity Provisions also contradict the June 18, 2010 USEPA Headquarters memo accompanying the TST Implementation Document, from James Hanlon, the Director of the USEPA Office of Wastewater Management, which stated: “The TST approach does not preclude the use of existing recommendations for assessing WET data provided in EPA’s 1991 Water Quality-based Technical Support Document (TSD) which remain valid for use by EPA Regions and the States.” The TST method was to be used for *additional* information, not for compliance determination purposes.

The 2010 USEPA guidance document, *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document*, EPA 833-R-10-003, introduced the TST protocol for analysis of chronic toxicity testing data. This guidance document made it clear in numerous places that the intent of the guidance was to introduce a new method of analyzing data collected during a valid WET analysis, not for permitting (emphasis added):

“This document presents TST as a useful alternative data analysis approach for valid WET test data that may be used in addition to the approaches currently recommended in EPA’s Technical Support Document (USEPA 1991) and EPA’s WET test method manuals.” (EPA 833-R-10-003 at p. 7)

“The TST approach is an alternative statistical approach for analyzing and interpreting valid WET data; it is not an alternative approach to developing NPDES permit WET limitations.” (EPA 833-R-10-003 at p. 60)

Therefore, the Toxicity Provisions go beyond even the intent and scope of the TST guidance. In sum, there is no authority for the State Water Board to utilize or expand upon an approach only found in federal guidance, and not authorized by federal rules. (See CWA, 33 U.S.C. §1314(a)(7)(requiring rules for establishing and measuring water quality) and §1314(h)(requiring promulgated test procedures). Such a proposal also lacks consistency with federal law and regulations.

d. Unauthorized Direction to Ignore Mandated Dose Concentration Response Curves and Other Safeguards.

Instead of requiring the quality assurance steps touted by a federal judge as reason for upholding the USEPA 2002 rules, the proposed policy removes the safeguards intended to reduce the likelihood that random “noise” in a biological test on live organisms will result in a false positive result. The new policy on the one hand still requires the cost and effort to conduct multi-concentration tests, but on the other hand forbids use of the important information that might be gleaned.¹⁵ The policy instead **relies on just two concentrations (the test sample and the**

¹⁵ While the Toxicity Provisions require that dischargers monitor the chronic toxicity of the effluent using five or more effluent dilutions (including 100% effluent and negative control), only the two-concentration TST result will be considered for compliance purposes. This conflicts with promulgated freshwater chronic toxicity test methods. The Draft Staff Report at pg. 60 acknowledges that there is no dose-response consideration: “Typically, using other

control), which is not allowed under USEPA rules without an approved Alternative Test Procedure (ATP) under Part 136. Therefore, a two-concentration compliance approach for effluent testing is not legal. The 2002 Methods state as follows:

2.2.2 Effluent chronic toxicity is generally measured using a multi-concentration, or definitive test, consisting of a control and a minimum of five effluent concentrations. The tests are designed to provide dose-response information, expressed as the percent effluent concentration that affects the hatchability, gross morphological abnormalities, survival, growth, and/or reproduction within the prescribed period of time (four to seven days). The results of the tests are expressed in terms of the highest concentration that has no statistically significant observed effect on those responses when compared to the controls or the estimated concentration that causes a specified percent reduction in responses versus the controls.

The Toxicity Provisions require that multiple concentrations are tested, but that the results be ignored. This contradicts the 2002 Methods, which explicitly recognize that:

10.2.6.1. The concept of a concentration-response, or more classically, a dose-response relationship is “the most fundamental and pervasive one in toxicology” (Casarett and Doull, 1975).

In a challenge to the 2002 Methods, the federal court upheld those methods because USEPA had provided adequate safeguards within those methods to protect against the concerns raised by the plaintiffs. One of these safeguards was the requirement to use a multiple-concentration test that includes a concentration-response evaluation.¹⁶ “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%.” *Edison Electric*, 391 F. 3d at 1272.

The importance of the five-concentration test to meet test acceptability criteria was also recognized in an October 22, 2013 Memo from Robert Wood, USEPA Headquarters, to Alexis Strauss, USEPA Region IX (“as stated in the promulgated CWA WET methods and re-iterated in the ‘EPA’s National Pollutant Discharge Elimination System Test of Significant Toxicity

statistical approaches, after the data analysis step there could be a need to conduct an additional data interpretation review (U.S. EPA 2000 and 2010a). However, with the TST approach, there is no need to review and make an assessment of within-test variability nor to review the concentration response curve, as required for the traditional hypothesis approach, or when using a point estimate approach.”

¹⁶ *Edison Electric*, 391 F. 3d at 1273 citing 67 Fed. Reg. at 69,957-58 (holding that “exposing multiple batches of organisms to the effluent at various concentrations, as well as to a ‘control’ sample of pure water, and then aggregating the effects on each batch” followed by a statistical analysis “to ensure that any observed differences between the organisms exposed to a given effluent concentration and those exposed to the control blanks most likely are not attributable to randomness - that they are statistically significant” will be a “safeguard [that] addresses petitioners’ concerns.”)

Implementation Document,' these methods require a control plus five effluent concentrations under the methods' test acceptability criteria. As such, **the promulgated methods do not allow for only two concentrations for use in NPDES permits.**") (*See Attachment 3* (emphasis added). Thus, the unpromulgated TST guidance itself does not authorize failing to utilize the information gleaned from all five concentrations.

Other USEPA guidance, which addresses concentration-response evaluations, states that an "evaluation of the concentration-response relationship generated for each sample is an important part of the data review process that should not be overlooked."¹⁷ The same reference further concludes that "reviewing concentration-response relationships should be viewed as a component of a broader quality assurance and data review and reporting process." (*Id.*) This process includes data review, evaluation of test acceptability, evaluation of reference toxicant testing results, organism health evaluations, and test variability evaluation.

In addition, EPA's 2002 WET Method Manual describing the requirement to demonstrate adequate test sensitivity using the Percent Minimum Significant Difference (PMSD) metric. "The PMSD is the smallest percentage decrease in growth or reproduction from the control that could be determined as statistically significant in the test." (2002 Methods, section 10.2.8.2.1) This requirement was added to the 2002 Methods to reduce the risk of false negatives (e.g., a toxic effluent passes the WET test). If a test passes when the test sensitivity is poor then the test must be re-run (*see* 2002 Methods, section 10.2.8.2.4.2).

The Toxicity Provisions remove the USEPA required and judicially recognized quality assurance safeguards from the test methods. Prior to release of the Toxicity Provisions, the State Water Board sought USEPA's approval of an Alternative Test Procedure (ATP) authorizing the TST using the two-concentration test method, which compares an effluent sample at the instream waste concentration (IWC), which is set at 100% effluent where there is no dilution credit,¹⁸ to a control blank using the TST statistical test, and starts with the presumption that that the sample is toxic at the IWC.¹⁹ Although EPA Region IX inappropriately approved that ATP request,²⁰ the ATP was withdrawn as the result of litigation (*SCAP v. USEPA*, Eastern District Court, Case No.

¹⁷ USEPA, *Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing* (40 CFR Part 136), EPA 821-B-00-004 (July 2000) at p. 4-3.

¹⁸ Recent (December 2016) corrections made to the 2002 Methods documents (found at https://www.epa.gov/sites/production/files/2018-04/documents/wet-methods-errata_dec-2016.pdf) show that references to "100% effluent" were removed from the Methods manuals.

¹⁹ Even if USEPA's ATP approval was arguably proper, it is not clear that the any discharger can be *required* to use the two-concentration TST method. Dischargers or laboratories must request approval to use an ATP (40 C.F.R. §136.5), and analytical results obtained by using a non-promulgated method cannot be used for NPDES compliance determination purposes until that method has been incorporated into 40 C.F.R. Part 136. (*See accord* 40 C.F.R. §122.44(i)(iv), 40 C.F.R. §122.41(j)(4); 40 C.F.R. §122.21(j)(5)(viii))

²⁰ Background material on EPA's involvement in orchestrating the approval of the State's 2014 ATP is included in **Attachment 3**.

CV-01513-MCE-DAD) challenging that ATP approval.²¹ Without a valid ATP, there is no authority to modify the 2002 Methods.²²

The State Water Board is not a proper party to request an ATP under Part 136. Section 136.5(a) of the federal regulations states that “Any person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.” (40 C.F.R. §136.5(a).) However, “[w]hen the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, *the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority).*” (40 C.F.R. §136.5(b)(emphasis added).) The Director will then forward the application to the Regional ATP Coordinator or permitting authority with a recommendation for or against approval.” (40 C.F.R. §136.5(b).) In the case of a State-requested ATP, the State Water Board/permitting authority must send the ATP request to the Regional ATP Coordinator directly, bypassing a required step in the regulatory process for the requestor to send the ATP request to the State. While a lab or discharger may request use of the two-concentration TST as an ATP, the State Water Board may not. Without a valid ATP, no authority exists to utilize the two-concentration TST for regulatory purposes.

e. Different Compliance Approach.

1) Single Chronic Toxicity Tests Being Used for Compliance Determination.

²¹ See Draft Staff Report at p. 13, footnote 4, describing this history and stating: “As of the date of this writing, the state has not submitted a new ATP application. If USEPA indicates that a new ATP application is needed prior to approval or implementation of the Provisions, the state will submit a new ATP application.” This ignores the fact that NPDES permits are being written in California using the TST and two-concentration approach illegally without a valid ATP. As the Draft Staff Report at page 60 states, “roughly 20 percent of all active NPDES permits require the TST approach to analyze chronic toxicity data.” Instead of now retroactively authorizing this approach as proposed in the Toxicity Provisions, the State Water Board should have taken these permits up on their own motion and ruled that the use of the TST without an approved ATP was unlawful and contrary to binding precedential State Water Board decisions.

²² Pursuant to USEPA rules related to ATPs, a “limited use” ATP can apply to applications for single discharger, single laboratory facility uses, or to multi-discharger, multi-laboratory facility uses. (40 C.F.R. §136.5(d).) Nationwide ATPs can also be applied regionally. (40 C.F.R. §136.4(c)(2).) However, no ATP can be authorized for toxicity because EPA lacks an ATP protocol for toxicity:

“It should be noted that in its ATP program, EPA considers for review only those methods for which EPA has published an ATP protocol. Presently, EPA has published protocols for chemistry, radiochemical, and culture microbiological methods. EPA does not have ATP protocols for Whole Effluent Toxicity (WET) methods or genetic methods.”

75 Fed. Reg. 58,035 (emphasis added); see also **Attachment 3** (EPA Memo at p. 1 (Oct. 22, 2013)) (“we do not yet have guidance for requesting or evaluating WET ATP requests...”).

Contrary to USEPA regulations and guidance and precedential State Water Board orders (which prescribe a narrative toxicity limit), the Toxicity Provision prescribes a Maximum Daily Effluent Limitation (MDEL) for chronic toxicity that would result in an effluent limit and corresponding permit violation as a result of a single sample exceedance. Single sample violations for chronic toxicity analyses are inappropriate due to the variability and uncertainty inherent in testing biological organisms for non-lethal endpoints.

The preamble to the 2002 WET Rule says “EPA policy states that ‘**EPA does not recommend that the initial response to a single exceedance of a WET limit, causing no known harm, be a formal enforcement action with a civil penalty.**’” (67 Fed. Reg. 69968 (citing EPA memo entitled National Policy Regarding Whole Effluent Toxicity Enforcement (1995a) (emphasis added).) The appropriate response to a chronic toxicity test indicating the presence of toxicity is not to declare a violation, but to investigate the cause, starting with follow-up testing to confirm the initial result. (See *accord* 67 Fed. Reg. 69,968 (USEPA policy suggests additional testing is an appropriate initial response to a single WET exceedance); *see also* Los Angeles Basin Plan at 3-17 (recommending a TIE to identify cause of toxicity prior to imposing effluent limitation to implement the narrative Toxicity objective); *accord* State Water Board’s State Implementation Policy (SIP) at pp. 30-31 (requires TRE, and the failure to conduct required toxicity tests or a TRE results in establishment of chronic toxicity limits in the permit).)

Instead of relying on multiple tests to prove persistent toxicity that could realistically translate into potential instream impacts, the proposed MDEL allows a single test result to be deemed a violation, which is discouraged by USEPA. The Draft Staff Report even acknowledges that “[a] statistically significant difference may or may not be biologically significant.” (Draft Staff Report at p. 47.) A limit set on a single chronic toxicity sample result substantially increases the likelihood of violations for a false “Fail” result, which is anticipated to occur statistically at least 5%-20% of the time, and with certain test species such as *Ceriodaphnia dubia* may be much higher (>50%).

Chronic toxicity tests and subsequent statistical analyses included in the promulgated methods were developed to exhibit no more than a 5% single test false positive failure rate. However, the USEPA Interlaboratory Variability Study on non-toxic blank samples, conducted as a part of the test method promulgation process in 2001, showed a substantially higher single test false positive error rate (failing when there is no actual toxicity) for certain endpoints including the freshwater test species used to determine compliance in the Permits. (USEPA, *Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods*, Vol. 1; EPA-821-B-01-004 (Sept., 2001).) This places the regulatory usefulness of numeric limits for chronic toxicity in question and raises constitutional due process issues in the context of strict liability for permit violations. Even USEPA itself has determined that “the accuracy of toxicity tests cannot be determined.” (See *Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms*; EPA/600/4-91/002 at 139, 193, and 225 (July 1994).) Even if there is only presumed to be a 5% false failure level (as was stated to be statistically set for the TST, but was never verified through an actual study of known, non-toxic samples), this false indication of toxicity would constitute a violation subject to citizen

suits and discretionary Regional Board enforcement.²³ No reason exists to put permittees in compliance jeopardy unnecessarily when there is no real confirmed toxicity, or where the existence of actual, lingering chronic toxicity is not confirmed.

2) Use of a Daily Maximum Limit is Impracticable and Inconsistent with to Federal Regulations.

Where effluent limitations are authorized, federal regulations provide that for discharges from POTWs, all permit effluent limits shall, unless impracticable, be stated as average weekly and average monthly discharge limitations. (40 C.F.R. §122.45(d)(2) (emphasis added); *see also* State Water Board WQO 2002-12 at pp. 20-21.) Nevertheless, the Toxicity Provisions prescribe daily maximum limitations for chronic toxicity in NPDES permits, without making the requisite determination of impracticability, or without evidence to support its findings of impracticability (where made).²⁴ Without a valid and supported impracticability analysis, daily maximum limits are unlawful. (*See accord* Statement of Decision, *City of Los Angeles v. State Water Resources Control Board*, Los Angeles County Superior Court Case No. BS 060957 (April 4, 2001) and Statement of Decision, *City of Burbank v. State Water Resources Control Board*, Los Angeles County Superior Court Case No. BS 060960 (April 4, 2001).)²⁵

In addition to being contrary to federal regulations, imposition of an MDEL makes no logical sense when the test itself takes up to 9 days of exposure. Use of a daily maximum chronic toxicity limit to protect against a short duration event capable of exceeding the water quality objective for Toxicity makes no sense when a single freshwater chronic test itself typically consists of three (3) or more discrete samples collected over an exposure period of four (4) to eight (8) days, depending on the test organism. (*See* 67 Fed. Reg. 69953 (2002 Final WET Rule)(“short term methods for estimating chronic toxicity use longer durations of exposure (*up to nine days*) to ascertain the adverse effects of an effluent or receiving water on survival, growth

²³ Such a violation would be subject to discretionary enforcement, but would not be subject to Mandatory Minimum Penalties or “MMPs” (Water Code section 13385(i)(1)(D)) if there are any other toxic pollutant limits in the permit.

²⁴ Although there may be a cursory and general finding of impracticability and a statement that because such limits are in other permits they must be practicable (Draft Staff Report at p. 83), these findings are not specific to toxicity and are unsupported by evidence in the record to demonstrate practicability. Practicability or feasibility does not reflect the ability to calculate or impose the limit, but ability to comply with the limit. (*City of Tracy v. SWRCB*, Statement of Decision, Case Number: 34-2009-80000392 (2011)(Recognizing that federal regulations do not require numeric effluent limits where infeasible, which turns on the ability of the discharger to comply, not the ability or propriety of establishing the limit) .) Orders not supported by the findings or findings not supported by the evidence constitute an abuse of discretion. *See* 40 C.F.R. §124.8(b)(4); *Topanga Association for a Scenic Community v. County of Los Angeles*, 11 Cal.3d 506, 515; *California Edison v. SWRCB*, 116 Cal. App. 751, 761 (4th Dt. 1981). Without evidence to support the findings, the imposition of daily limits is unlawful.

²⁵ The State Water Board did not appeal the Superior Court’s decisions in the *City of Los Angeles* and *City of Burbank* cases with respect to the inclusion of daily maximum effluent limitations for POTWs. Thus, the Superior Court’s decision stands and binds the State Water Board. *See City of Burbank*, 35 Cal.4th 613, 623, n.6. (“Unchallenged on appeal and thus not affected by our decision are the trial court’s rulings that . . . the permits improperly imposed daily maximum limits rather than weekly or monthly averages...”).

and/or reproduction of the organisms.”) (*italics added*.) Therefore, the use of a daily maximum limit for chronic WET is itself impracticable and a chronic toxicity limit (as is recognized for other long-term chronic objectives²⁶) should be expressed only in narrative form of “There shall be no chronic toxicity in the effluent discharge,” interpreted as a monthly average, or a median monthly if the monthly average is demonstrated to be impracticable. (*See accord In the Matter of the Own Motion Review of City of Woodland*, Order WQO 2004-0010, 2004 WL 1444973, *10 (June 17, 2004) (“Implementing the limits as instantaneous maxima appears to be incorrect because the criteria guidance value, as previously stated, is intended to protect against chronic effects.” The limits were to be applied as monthly averages instead); *see also* WQO 2003-0012, WQO 2003-0013, WQO 2008-0008, and WQO 2012-0001; and USEPA Letter to Regional Board on Long Beach/Los Coyotes WRP Permits at pg. 4 (May 31, 2007)(“At minimum, the permits need to specify the WQBEL: ‘There shall be no chronic toxicity in the effluent discharge.’”).)

Another recent decision upheld the need for weekly, as opposed to daily limits, for POTWs because the USEPA Technical Support Document guidance cited by the Toxicity Provisions at pp. 83-84 cannot be used to *overrule* the express terms of the regulations. (*See accord California Sportfishing Protection Alliance (CSPA) v. Cal. Regional Water Quality Control Board, Central Valley Region*, Sacramento Superior Court, Case No. 34-2013-80001358-CU-WM-GDS, Ruling on Submitted Matter: Petition for Peremptory Writ of Mandate (Aug. 18, 2014)(Holding “To the extent that the applicable law does not represent a reasonable approach to establishing effluent limitations, the law may need to be changed, Until it is changed, however, that law unequivocally requires the establishment of a weekly limitation. Respondent [Regional] Board was obligated to do what the law required...”)) Thus, reliance on USEPA’s Technical Support Document guidance was overturned, and the permit was remanded. The Draft Staff Report’s similar reliance is misplaced as well.

For these reasons, a daily maximum limit for chronic toxicity fails to meet the requirements for Authority and Consistency.²⁷ MDELs also fail to meet the requirements for Necessity. MDELs are unnecessary to protect aquatic life because chronic toxicity, by definition, is neither “highly toxic” nor “short-term.” Chronic toxicity testing is meant to assess *long-term* impacts to biological communities of organisms in the ambient receiving waters, not the impact of a single day’s discharge. (*See accord* 40 C.F.R. §131.38(b)(1), *fn. d.*)

²⁶ Chronic toxicity can be compared to other chronic water quality criteria, such as the Criteria Continuous Concentration (“CCC”) under the California Toxics Rule and National Toxics Rule, which is defined as “the highest concentration of a pollutant to which aquatic life can be exposed for an extended period of time (4 days) without deleterious effects.” 40 C.F. R. §131.38(b)(1), note d; 40 C.F.R. §131.36(b)(1), note d. These criteria are not imposed as daily maximum limits in NPDES permits.

²⁷ The Monthly Median Effluent Limitation (MMEL) is also inconsistent with 40 C.F.R. §122.45(d)(2) as applicable to POTWs, since only weekly and monthly averages are prescribed, unless demonstrated to be impracticable. As currently proposed, the MMEL is not practicable because it may be impractical if not impossible to schedule 3 chronic toxicity tests within a calendar month. The State Water Board should consider the current requirements in San Bernardino’s RIX permit as a more feasible and practical alternative.

3) Numeric Limits Based on a Two-Concentration TST are Highly Problematic.

Reanalysis of actual WET test data, from a wide variety of real-world samples, demonstrates that the TST statistical hypothesis test consistently “detects” the existence of toxicity more frequently than the NOEC statistical hypothesis test, especially for freshwater test species. See State Water Board, *Effluent, Stormwater and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST)* (“State Board Test Drive”) (Dec., 2011)(see e.g., Chronic Freshwater results in Table E-1). However, one should not assume that greater statistical *sensitivity* equates with improved *accuracy* in WET testing.

Reanalysis of data from USEPA’s inter-laboratory WET variability study indicates that the TST statistical hypothesis test also “detects” toxicity in clean blank samples at a rate up to three times higher than the NOEC statistical test. USEPA. *Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods*, Vol. 1; EPA-821-B-01-004 (Sept., 2001). Blank samples are those comprised solely of laboratory dilution water that is known to be non-toxic before the test begins. Such inaccuracies demonstrate that the TST does not provide performance “acceptably equivalent” to that of the standard methods that were promulgated in 40 C.F.R. Part 136 in the 2002 Methods.

It has been suggested by USEPA and Tetra Tech that a more thorough review of USEPA’s blank study data revealed several previously undetected quality assurance and quality control issues that at least partially explains the presumed high false failure error rate associated with the TST. See Tetra Tech presentation at the August 22, 2011 State Board TST Workshop, slides 22 through 28, which can be found on the following website: http://www.swrcb.ca.gov/water_issues/programs/state_implementation_policy/docs/testdrive_presentation.pdf. However, the restrictions being imposed by requiring use of the two-concentration TST method will also restrict the ability of toxicologists to identify and address similar issues when interpreting compliance test results.

Neither the USEPA’s inter-laboratory WET variability study nor the State Board Test Drive evaluated the impact associated with incorporation of the two-concentration design, with no concentration-response evaluation, on the false failure error rate. The State Board Test Drive simply compared the results of NOEC and TST analyses on a large number of multiple concentration effluent tests incorporating a concentration-response evaluation and two-concentration receiving water tests. However, no evaluations comparing the multiple concentration TST method (with the concentration-response evaluation) to the two-concentration TST method have been conducted. In contrast, the USEPA did conduct an evaluation of the multiple concentration NOEC method with and without incorporation of a concentration-response evaluation and determined that incorporation of the concentration-response evaluation was responsible for reducing the false positive error rate from 14% to less than 5%. (67 Federal Register 69,964 (November 19, 2002).) Therefore, a similar improvement in the error rate in the TST statistical test would be expected with incorporation of a multiple concentration test design that included a similar concentration-response evaluation.

While some contend that the State Board Test Drive adequately demonstrated that the false failure error rate for the TST statistical test is comparable to the NOEC statistical test, such a conclusion is unfounded. The State Board Test Drive was not able to estimate the false positive error rate of the NOEC or false failure rate of the TST because the analysis was not conducted on known non-toxic blank samples. Tests used in the State Board Test Drive evaluation were performed on effluents and ambient waters whose actual or true “toxicity” was not known. Some of the tests that exhibited relatively high effects may have actually been “non-toxic,” while others that exhibited relatively small effects may have been truly “toxic.” Additionally, as discussed above, this analysis failed to examine the impact of eliminating the concentration-response evaluation on false positive error rates.

In the absence of any actual studies on the error rate of the two-concentration TST method, based on inference from the study referenced above, the single test false failure error rate for the two-concentration TST method is estimated to be 14-20% as was seen with the NOEC. Because of the general unreliability and inaccuracy of these biological test methods, and the amplifying effects on the false failure error rate imposed by the two-concentration TST method, strictly construed numeric (“Pass/Fail” or “% Effect”) effluent limits for toxicity are inappropriate, infeasible to comply with, and should not be imposed.

4) The Toxicity Provisions Fail to Include Authorized Regulatory Flexibility.

CWA Section 1312(b)(2) allows the Administrator (here, the State Water Board) to issue a permit that modifies the effluent limitations that otherwise would be required under the Act “if the applicant demonstrates at [a] hearing that there is no reasonable relationship between the economic and social costs [of the effluent limitations] and the benefits to be obtained (including attainment of the objective of [the Act]) from achieving such limitation.” (33 U S C §1312(b)(2).) By its terms, section 1312(b)(2) of the Clean Water Act does not apply to “toxic pollutants,” but to pollutants other than “toxic pollutants” and logically to toxicity which is not a pollutant at all, this section expressly allows consideration of economic costs to relax or modify water quality-based effluent limitations in a wastewater discharge permit. (*See accord City of Tracy v. SWRCB, supra.*) Here, because even if all available technology was installed at any cost,²⁸ the toxicity limits could still not be consistently attained, due to the sheer statistical likelihood that a violation will occur, the proposed limits (as well as the underlying objectives) must be modified to be attainable as well as reasonable. (Water Code §13300; §13241.)

2. Automatic Finding of Reasonable Potential Violates Federal Rules

For POTWs larger than 5 million gallons per day (mgd), the Toxicity Provisions propose to skip the important and federally required step of determining whether an effluent limitation is necessary, and automatically prescribes effluent limitations without this important information.

²⁸ In fact, reverse osmosis-treated water is likely to fail a toxicity test as the water is too clean to support aquatic life. Minerals and other constituents must be added back into that water to make it non-toxic.

This proposal is inconsistent with the CWA regulations' requirement to include effluent limitations only "where necessary to achieve water quality standards established under section 303 of the CWA, including State narrative criteria for water quality" (40 C.F.R. §122.44(d)(1)) and APA requirements of Necessity. Since the Santa Ana Region shows no toxicity in receiving waters, effluent limitations are wholly unnecessary despite the size of the POTW.

In addition to being contrary to law, the failure to conduct a reasonable potential analysis punishes good performers that would not otherwise receive an effluent limit where they have high quality effluent. POTWs over 5 mgd that have industrial dischargers to the sewer system all have pretreatment programs. Instead of making these systems more likely to have toxicity, they should be *less* likely to have toxicity since the industrial sources are well-regulated. (See USEPA, *Determining WET Reasonable Potential for NPDES Permitting*, at Module 5 ("if the facility has an advanced pretreatment and wastewater treatment system in place, the effluent may have less likelihood of being determined to have RP.")) All dischargers should be held to the same standard and all should be demonstrated to exhibit reasonable potential before an effluent limitation is prescribed for its discharge.

3. The Toxicity Provisions Violate State Law.

a. Failure to Include a Valid Program of Implementation.

In addition to be contrary to federal law, the proposed policy also violates state law by not setting forth a description of the nature of the actions necessary to meet the new toxicity objectives, or a plan for bringing the state's waterways that have exhibited some toxicity into compliance. The stated plan for compliance is to increase monitoring, which is not normally an action that would improve water quality or achieve compliance. However, under the TST approach, the outcome or toxic presumption can change merely by doing additional tests (replicates). How this additional testing can modify effluent or instream water quality defies logic.

An appropriate toxicity policy should be similar to the process for developing Total Maximum Daily Loads (TMDLs) for toxicity. Once confirmed and listed as impaired, the cause of toxicity is determined (where possible) and remedied. The proposed policy seems to focus more on placing dischargers in violation than seeking to remedy any actual water quality problem.²⁹ The current system of triggers for accelerated monitoring to confirm the existence of persistent toxicity, and then to determine the cause of toxicity represents a more reasonable approach, in accordance with Water Code section 13000, than to just have dischargers racking up violations

²⁹ The proposed policy also seems to be a solution without a huge statewide problem. The policy documents demonstrate that many regions of the state have very little toxicity and some seem to have none at all (Draft Staff Report at pages 35-39), yet the policy proposes a one-size fits all approach. That being said, the policy then proposes to exempt out several different categories of dischargers, which fails to achieve its statewide consistency goal, and will fail to solve any real toxicity problems. In addition, the policy goals appear to be set to only fit the TST approach, and this approach seems to be proposed to void any legal challenges to permits that were early adopters of this approach before it was blessed in this new policy.

and subjecting them to fines, penalties, and citizen suits over something that may not be chronic or toxic at all.

b. Unlawful Modification of Waste Discharge Requirements via Order.

The Proposed Toxicity Provisions state that certain permits' monitoring and reporting requirements may be modified to include requirements to use the TST. (See Draft Staff Report at page 21 ("For storm water and nonpoint source dischargers that are required to conduct toxicity testing with test methods described in Section IV.B.1.b of the Provisions, the Water Boards would issue Water Code section 13383 orders or 13267 orders within one year of the effective date of the Provisions. The orders would require toxicity testing, analysis, and reporting to be conducted in accordance with the Provisions commencing within one year from the date of the order.") Such a proposal violates state law.

Federal and state law prohibit modifying the terms of permits without public notice and comment and state law prohibits the delegating of authority to issue or modify waste discharge requirements (WDRs). (See *accord* 40 C.F.R. §124.5; Water Code §13167.5(a)(1); §13223(a)(2); §§13380-13381.) The Monitoring and Reporting Program (MRP) is an integral part of a WDR or NPDES permit in order to determine compliance with that permit. As such, modifications cannot be delegated to staff or made by an order separate from the permit itself. See *San Francisco Baykeeper v. SFRWQCB*, Order Granting Petition for Writ of Mandate and Statement of Decision, Consolidated Case No. 500527, Eighth Cause of Action (2003) (activities, such as approval of a monitoring plan containing monitoring requirements for a permit, cannot be delegated and would constitute "impermissible delegations of authority" under Water Code section 13223).

C. The Toxicity Provisions Fail to Meet the APA Requirements for Clarity.³⁰

The proposed water quality objectives for chronic and acute toxicity are unintelligible to the normal person. Although people can understand an objective of "10 milligrams per liter of copper," or "no toxics in toxic amounts," no one can easily understand the following proposed objectives:

2. Aquatic Toxicity Water Quality Objectives

a. Numeric Chronic Aquatic Toxicity Objective

The chronic aquatic toxicity water quality objective is expressed as a NULL HYPOTHESIS and an ALTERNATIVE HYPOTHESIS with a REGULATORY MANAGEMENT DECISION (RMD) of 0.75, where the following NULL HYPOTHESIS shall be used:

Ho: Mean RESPONSE (ambient receiving water) \leq 0.75 • mean RESPONSE (control)

³⁰ Clarity means "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them." (Gov't Code §11349(c).)

In general terms, the NULL HYPOTHESIS is the following statement: the ambient receiving water is toxic because the test organism RESPONSE (e.g., survival, reproduction, growth) in the ambient receiving water sample is less than or equal to 75 percent of the test organism RESPONSE in the control water sample.

And where the following ALTERNATIVE HYPOTHESIS shall be used:

Ha: Mean RESPONSE (ambient receiving water) > 0.75 • mean RESPONSE (control)

In general terms, the ALTERNATIVE HYPOTHESIS is the following statement: the ambient receiving water is not toxic because the test organism RESPONSE (e.g., survival, reproduction, growth) in the ambient receiving water sample is greater than 75 percent of the test organism RESPONSE in the control water sample.

Attainment of the water quality objective is demonstrated by conducting CHRONIC TOXICITY TESTING as described in Section IV.B.1.b and rejecting this NULL HYPOTHESIS in accordance with the TEST OF SIGNIFICANT TOXICITY (TST) statistical approach described in Section IV.B.1.c. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the chronic toxicity water quality objective. Failing to reject the NULL HYPOTHESIS (referred to as a “fail”) is equivalent to an exceedance of the chronic toxicity water quality objective.

b. Numeric Acute Aquatic Toxicity Objective

The acute aquatic toxicity water quality objective is expressed as a NULL HYPOTHESIS and ALTERNATIVE HYPOTHESIS with an RMD of 0.80, where the following NULL HYPOTHESIS shall be used:

Ho: Mean RESPONSE (ambient receiving water) ≤ 0.80 • mean RESPONSE (control)

In general terms, the NULL HYPOTHESIS is the following statement: the ambient receiving water is toxic because the test organism RESPONSE (e.g., survival) in the ambient receiving water sample is less than or equal to 80 percent of the test organism RESPONSE in the control water sample.

And where the following ALTERNATIVE HYPOTHESIS shall be used:

Ha: Mean RESPONSE (ambient receiving water) > 0.80 • mean RESPONSE (control)

In general terms, the ALTERNATIVE HYPOTHESIS is the following statement: the ambient receiving water is not toxic because the test organism RESPONSE (e.g., survival) in the ambient receiving water sample is greater than 80 percent of the test organism RESPONSE in the control water sample.

Attainment of the water quality objective is demonstrated by conducting ACUTE TOXICITY TESTING as described in Section IV.B.1.b and rejecting this NULL HYPOTHESIS in accordance with the TST statistical approach described in Section IV.B.1.c. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the acute toxicity water quality objective. Failing to reject the NULL HYPOTHESIS (referred to as a “fail”) is equivalent to an exceedance of the acute toxicity water quality objective.

The proposed null hypothesis’ presumption of toxicity lacks clarity since this is not a valid presumption. Further, mischaracterization of recycled water (or even drinking water since this policy applies to potable water discharges to surface waters) as “toxic” also harms the public by decreasing the acceptance and use of recycled water in times of drought.

II. The Proposed Toxicity Provisions Fail to Adequately Consider Alternatives.

Alternatives not considered in the proposed policy should be considered,³¹ such as enforcing the precedential orders, adopting a consistent statewide narrative objective (as was done in the Trash and Sediment Toxicity policies³²), and requiring a numeric trigger for confirmatory monitoring and toxicity identification/reduction. Once a toxicant is determined, then that constituent needs a numeric effluent limit - not chronic toxicity, which is not even a pollutant itself.³³

If the State Board is so enamored with the use of the TST, this approach could be used as the prescribed trigger, which would generate ample data so that the USEPA could promulgate the TST as an approved method for use in toxicity permitting and compliance in the future. Until that time, the State Water Board must utilize the mandated Part 136 methods and stop rewarding regional boards for adopting illegal permits (many of which have been appealed and have not been taken up by the State Water Board on its own motion to enforce its four valid precedential orders on chronic toxicity).

III. The Proposed Toxicity Provisions Violate CEQA.

In the case of *City of Sacramento v. SWRCB*, 2 Cal. App. 4th 960, 969 (3d Dt. 1992), the Court held that the purpose of CEQA is to “compel government at all levels to make decisions with environmental consequences in mind.” The proposed Toxicity Provisions fail to consider all potential environmental consequences.

The State Water Board’s conclusory statements on pages 182, 185, 191, 194-195, 198, 208-212, and 217 of the Draft Staff Report that the proposed requirements will have absolutely “no impact” is not supported by any substantial evidence, or any evidence at all, and is in direct contrast to California Environmental Quality Act (CEQA) requirements. (*Mountain Lion Coal. v. Fish & Game Comm’n* (1989) 214 Cal.App.3d 1043, 1047; *Laurel Heights Improvement Ass’n v. Regents of the University of California* (1988) 47 Cal.3d 376, 404, (Conclusory comments in

³¹ Downey Brand also submitted a proposal in January of 2011 and the State Water Board failed to respond to these comments that proposed an alternative policy. See **Attachment 4**.

³² The Trash Policy set standardized narrative water quality objectives for both the Ocean Plan and the ISWEBE Plan, which basically state that trash shall not be present in waters, along shorelines or adjacent areas in amounts that adversely affect beneficial uses or cause nuisance. As stated in the Final Staff Report for the Trash Amendments at page 71, “A narrative objective is as enforceable as a numeric objective.” Similarly, the Sediment Quality Provisions adopted a narrative sediment quality objective stating that “Pollutants in sediments shall not be present in quantities that, alone or in combination, are toxic to benthic communities in bays and estuaries of California. This narrative objective shall be implemented using the integration of multiple lines of evidence (MLOE)....” Implementation of this narrative objective includes requirements for monitoring and an iterative process to determine the cause of the biological effects and the responsible sources so that management actions are effective. No reason exists why surface water toxicity could not be regulated in a similar manner.

³³ See Draft Staff Report at p. 55 (“Toxicity is not an absolute quantity, but rather an effect that is determined relative to a control, when using a toxicity test.”)

support of environmental conclusions are generally inappropriate); *San Joaquin Raptor/Wildlife Rescue Center v. County of Stanislaus* (1994) 27 Cal.App.4th 713, 721.) A review of the Environmental Checklist provides no evidence to support the State Water Board's conclusion that the proposed Toxicity Provisions will not result in reasonably foreseeable physical changes to the environment through the need for different or additional treatment technologies. Such lack of information and resulting analysis does not comply with an agency's required good-faith effort to disclose the environmental impacts of a project to decision makers and the public. (CEQA Guidelines, Section 15151.) Accordingly, the CEQA Checklist fails to disclose the data or evidence upon which the conclusions of "no impact" rely. (*Citizens Association for Sensible Development of Bishop Area v. County of Inyo* (4th Dist. 1985) 172 Cal. App. 3d 151 (holding that an initial study must disclose the data or evidence relied upon)).

The conclusions of "no impact" are not only unsupported, they are also inaccurate. For example, on page 198, the Draft Staff Report states that the proposed project would have no impact related to "Conflict with any applicable habitat conservation plan or natural community conservation plan." However, the newly proposed Toxicity Objectives may actually adversely affect the ability to use recycled water in the San Bernardino Valley. Currently, public agencies are making significant investments aimed at developing more than 15 MGD of recycled water for our region. Much of that water can be used to provide instream flows for habitat conservation purposes. Given the potential for "false failure" test results for toxicity under the new policy, the result is likely to be an inability to proceed with these projects or an inability to use the recycled water as planned (and in some cases permitted) for habitat projects. These adverse impacts on the environment – either through the need to import additional water from other portions of California or the inability to fully use recycled water, which then creates further needs for additional imported water – were completely ignored.

Similarly, it is unclear how the State Water Board can conclude on page 194 that the Toxicity Provisions have no impact related to "Substantially deplete groundwater supplies or interfere substantially with groundwater recharge such that there would be a net deficit in aquifer volume or a lowering of the local groundwater table level...." If potential sources of reusable wastewater or storm water are not proposed for recharge due to now intermittently demonstrating toxicity, this could adversely impact groundwater recharge projects and lower groundwater levels. Because the CEQA analysis focused primarily on differences in MONITORING, and not differences in how water is characterized and addressed through regulatory programs and treatment, the analysis misses many potential environmental impacts.

In addition, because in some cases an assumption has been made that no impacts will exist, there has also been no attempt to estimate the aggregate number of projects that would be undertaken as a result of the proposed Statewide Plan amendments. (See CEQA Guidelines, Section 15151 (requiring good-faith effort to disclose environmental impacts); CEQA Guidelines, Section 15063; and *Citizens Association for Sensible Development of Bishop Area v. County of Inyo* (4th Dist. 1985) 172 Cal. App. 3d 151 (holding that an initial study must disclose the data or evidence relied upon).) The Water Board must examine the impacts of the proposed amendments under

review against the backdrop of cumulative conditions. (*Communities for a Better Environment v. California Resources Agency* (3rd Dist. 2002) 103 Cal. App. 4th 98 (holding that an agency may not employ a *de minimis* rationale when evaluating cumulative impacts).)

The Water Board also improperly uses what is currently occurring under the Regional Water Board's regulatory programs and permits using TST as the baseline since those regulatory programs are not based upon any adopted regulation and never underwent CEQA review. The fact that the new objectives allow for the use of objectives different than the current narrative water quality objectives contained in the Basin Plans and the requirements of precedential orders must be considered, not only under the Water Code's mandatory factors set forth in section 13241, but also under CEQA. The current narrative water quality objectives in the Basin Plans and the requirements of precedential orders are the baseline, not the unauthorized procedures that the Water Board now characterizes as standard practice.

In addition, the Toxicity Provisions inadequately address the findings significant impact and do too little to mitigate. Modification of the policy to mitigate impacts is not considered and all alternatives are not considered for whether or not those alternatives present fewer impacts.

Specifically, for the reasons described above, the "false failures" rate of between 14% and over 50% indicates that the use of the TST procedure constitutes "speculation" that is forbidden by CEQA. Such a false failures rate makes compliance with the standard little more than a coin toss; such a capricious analysis of impacts is not consistent with CEQA's requirement that the Lead Agency use the best scientific methods available, particularly in light of USEPA's non-promulgation of the TST methodology.

In addition, the foregoing discussion has identified a number of alternatives that could, if implemented by the State Board, simultaneously address the objectives for the proposal (as understood by the State Board) and also reduce the adverse impacts of the proposal on the environment (e.g., reducing the use of recycled water) by ensuring a more reliable testing regime. Under well-established principles of CEQA, where a Lead Agency has before it an alternative that will accomplish its purposes and reduce impacts on the environment, the Lead Agency *must* adopt that alternative. Here, continuing to rely upon the existing testing methods (with appropriate modifications as discussed above) constitutes the environmentally superior project and so must be adopted by the State Board. Any other action would violate CEQA.

For these reasons, the CEQA-related analyses require revision and the proposed amendment must be re-circulated once complete.

IV. The Proposed Amendments are Not Supported by Findings or the Findings Made are Not Based on Evidence in the Record.

All administrative actions must be supported by findings, and findings must be based on evidence in the record. Orders not supported by findings or findings not supported by evidence constitute an "abuse of discretion" (Cal. Code Civ. Proc., §1094.5(b)). An "agency which

renders a challenged decision must set forth findings to bridge the analytical gap between raw evidence and the ultimate decision or order.” *Topanga Ass’n for Scenic Community v. County of LA*, 11 Cal.3d 506, 515 (1974); 40 C.F.R. §124.8(b)(4); see accord *California Edison v. SWRCB*, 116 Cal. App.3d 751, 761 (4th Dt. 1981); see also *In the Matter of the Petition of City and County of San Francisco, et al.*, State Board Order No. WQ-95-4 at 10 (Sept. 21, 1995).

The State Water Board must make findings based on evidence in the record and may not merely tick off statutory requirements and make claims without supporting evidence. See *City of Carmel-by-the-Sea v. Bd. of Supervisors*, 71 Cal.App.3d 84, 93 (1977) (holding that written findings of fact were insufficient as a matter of law because they were merely a recitation of the statutory language). In addition, the State Water Board may not rely on speculation in reaching a decision. Rather, it must be clear from the record that the State Water Board actually relied upon solid evidence to support its findings, and that this clearly identified and cited evidence supports the agency’s findings and ultimate conclusion.

Further, an agency must ensure that it “has adequately considered all relevant factors [here, CWA requirements along with Water Code sections 13000, 13241, 13242, etc.] and has demonstrated a rational connection between these factors, the choice made, and the purposes of the enabling statute.” *Cal. Hotel and Motel Ass’n v. Industrial Welfare Com.*, 25 Cal. 3d 200, 212 (1979). In this case, as discussed herein, the State Water Board’s action to adopt the proposed Toxicity Provisions is not supported by adequate or accurate findings, and/or the findings made are not based on evidence in the record.

The level of detail that must be included in the Board’s consideration must clearly demonstrate the “analytical route” contemplated under *Topanga*. See *Department of Corrections v. State Personnel Board*, 59 Cal.App.4th 131, 151 (1997). It is insufficient to simply cite to unsubstantiated findings without proof. Thus, the proposed Toxicity Provisions, if adopted, will constitute an abuse of discretion.

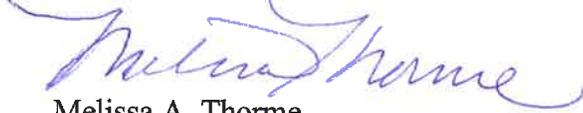
V. SUMMARY³⁴

The proposed Toxicity Provisions must be substantially revised to make them compliant with state and federal law. We believe that a compliant policy, acceptable to the stakeholders, is not only possible, but fairly simple if the State Water Board continues its currently binding precedential orders, proposes consistent statewide narrative objectives and effluent limitations for toxicity, and numeric triggers for additional confirmation of toxicity and identification of the source based on either promulgated point estimates or the TST (so long as the TST is not used for compliance determination purposes). We stand ready to assist in modifying the Provisions to meet this goal of consistency without placing dischargers and water/recycled water purveyors in compliance jeopardy.

³⁴ The Department and District also incorporate by reference consistent comments made by other dischargers, including but not limited to CASA, BACWA, SCAP, CVCWA, ACWA, and other discharger stakeholders.

Respectfully Submitted,

DOWNEY BRAND LLP



Melissa A. Thorne



David Aladjem

ATTACHMENT 1

DRAFT

**WATER QUALITY CONTROL PLAN FOR
INLAND SURFACE WATERS, ENCLOSED BAYS, AND
ESTUARIES OF CALIFORNIA**



OCTOBER 19, 2018

DIVISION OF WATER QUALITY

STATE WATER RESOURCES CONTROL BOARD

CALIFORNIA

ENVIRONMENTAL

AGENCY



PROTECTION



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Draft Water Quality Control Plan for
Inland Surface Waters, Enclosed Bays, and Estuaries of California

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I. INTRODUCTION

This Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Plan) was adopted by the State Water Resources Control Board (State Water Board) under authority provided by Water Code sections 13140 and 13170. Except as otherwise indicated, this Plan establishes provisions for water quality and sediment quality that apply to all INLAND SURFACE WATERS, ENCLOSED BAYS, and ESTUARIES AND COASTAL LAGOONS of the state, including both waters of the United States and surface waters of the state. These provisions do not apply to OCEAN WATERS, including Monterey Bay and Santa Monica Bay. In accordance with Water Code section 13170, except where otherwise noted, the provisions contained within this Plan supersede any Regional Water Quality Control Plans (Basin Plans) for the same waters to the extent of any conflict. All terms in capital letters are defined in Appendix A.

Commented [A1]: Section 13140 requires that state board policies "be adopted in accordance with the provisions of this article and shall be in conformity with the policies set forth in Chapter 1 (commencing with Section 13000)," which requires that water quality policies balance the different interests and are reasonable. For the reasons set forth in the attached comments, this policy fails to comply with Section 13140.

Commented [A2]: Section 13170 authorizes the State Board to adopt water quality control plans so long as "in accordance with the provisions of Sections 13240 to 13244, inclusive," which has not been adequately met, in particular section 13242.

Commented [A3]: Because regional boards are applying the TST approach to ocean waters, the State Board should reprimand the regional boards for doing so when not authorized by the Ocean Plan unless permittees have an approved ATP that would authorize use of the TST.

II. BENEFICIAL USES

Water body-specific beneficial use designations contained in the Basin Plans and other statewide plans, including future amendments to those plans, are incorporated by reference into this Plan.

Commented [A4]: Prospective incorporation of future changes is legally problematic and should not be included. On May 10, 1995, the Office of Administrative Law (OAL) issued a Notice of Approval and Disapproval, and Reasons for Approval and Disapproval of Parts of a Rulemaking Action on the 1994 Central Valley Basin Plan Amendments (OAL File No. 95-0328-01). This approval/ disapproval decision on the 1994 Central Valley Basin Plan determined that "[a] prospective incorporation-by-reference (one that automatically incorporates future changes to an incorporated document) is of dubious validity." *Id.* at pg. 10 (emphasis added).

III. WATER QUALITY OBJECTIVES

A. [Reserved]

B. Aquatic Toxicity

Aquatic toxicity is the adverse response of aquatic organisms from exposure to chemical or physical agents, and/or their synergistic effects in effluent or receiving water. Acute aquatic toxicity refers to adverse response (typically lethality) from a short-term exposure. Chronic aquatic toxicity generally refers to a longer term sub-lethal adverse response.

Commented [A5]: This recognizes that this is not an objective related to a pollutant, which is all that is required under the Clean Water Act. Because toxicity is different than a pollutant, the normal objective setting process should not apply.

Commented [A6]: How are these determined? This testing is not designed to address this – such as hardness, bacteria, viruses or other disease, temperature, etc.

1. Applicable Beneficial Uses

The following water quality objectives for chronic and acute toxicity establish minimum requirements to protect AQUATIC LIFE beneficial uses including, but not limited to, warm freshwater habitat (WARM), cold freshwater habitat (COLD), wildlife habitat (WILD), estuarine habitat (EST), preservation of rare, threatened, or endangered species (RARE), migration of aquatic organisms (MIGR), spawning reproduction and/or early development (SPWN), marine habitat (MAR), inland saline water habitat (SAL), and wetland habitat (WET). These objectives are not adopted to protect human health, groundwater, industrial, or recreation uses, such as municipal drinking water (MUN), groundwater recharge (GWR), industrial use (IND), process water (PRO), or recreation (REC1 or REC2).

Commented [A7]: This needs to be made more clear so people do not mistake these objectives as applying to broader use or to human health protection.

2. Aquatic Toxicity Water Quality Objectives

a. **Numeric** Chronic Aquatic Toxicity Objective

The chronic aquatic toxicity water quality objective is expressed as a NULL HYPOTHESIS and an ALTERNATIVE HYPOTHESIS with a REGULATORY MANAGEMENT DECISION (RMD) of 0.75, where the following NULL HYPOTHESIS shall be used:

H_0 : Mean RESPONSE (ambient receiving water) \leq 0.75 * mean RESPONSE (control)

In general terms, the NULL HYPOTHESIS is the following statement: the ambient receiving water is toxic because the test organism RESPONSE (e.g., survival, reproduction, growth) in the ambient receiving water sample is less than or equal to 75 percent of the test organism RESPONSE in the control water sample.

And where the following ALTERNATIVE HYPOTHESIS shall be used:

H_a : Mean RESPONSE (ambient receiving water) $>$ 0.75 * mean RESPONSE (control)

In general terms, the ALTERNATIVE HYPOTHESIS is the following statement: the ambient receiving water shall not exhibit chronic toxicity, defined as where because the test organisms' RESPONSE (e.g., survival, reproduction, growth) in the ambient receiving water sample is greater than 75 percent of the test organisms' RESPONSE in the control water sample.

Attainment of the water quality objective is demonstrated by conducting CHRONIC TOXICITY TESTING as described in Section IV.B.1.b using the IC25 point estimate method and rejecting this NULL HYPOTHESIS in accordance with the TEST OF SIGNIFICANT TOXICITY (TST) statistical approach described in Section IV.B.1.c. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the chronic toxicity water quality objective. Failing to reject the NULL HYPOTHESIS (referred to as a "fail") A receiving water not meeting the IC25 criteria in at least two consecutive tests is equivalent to an exceedance of the chronic toxicity water quality objective.

b. **Numeric** Acute Aquatic Toxicity Objective

The acute aquatic toxicity water quality objective is expressed as a NULL HYPOTHESIS and ALTERNATIVE HYPOTHESIS with an RMD of 0.80, where the following NULL HYPOTHESIS shall be used:

H_0 : Mean RESPONSE (ambient receiving water) \leq 0.80 * mean RESPONSE (control)

In general terms, the NULL HYPOTHESIS is the following statement: the ambient receiving water is toxic because the test organism RESPONSE (e.g., survival) in the

Commented [A8]: There is no requirement that these objectives be numeric, and other objectives for trash and sediment toxicity are narrative for reasons that would also apply to toxicity. As stated in the Final Staff Report for the Trash Amendments at page 71, "A narrative objective is as enforceable as a numeric objective."

Commented [A9]: Modifying the promulgated hypothesis is not authorized by federal law. Further, flipping the hypothesis also flips the alpha and beta error rates, limiting false passes to 5%, but increasing false failures (under TST) to 14-20%, which is not an acceptable error rate, particularly under a strict liability statute.

Commented [A10]: The Policy cannot modify the hypothesis in the 2002 promulgated methods without an approved ATP, which is not proper to be approved for a state permitting agency, only for dischargers and labs.

Commented [A11]: There is more than one test organism and control organism in each test. Original language implies a single organism for each.

Commented [A12]: This sets a statewide standard, using a promulgated method, that includes the RMD of 25%.

Commented [A13]: Failing to prove a negative is not acceptable standard.

Commented [A14]: Need to confirm failure and not waste resources where not confirmed as real toxicity.

Commented [A15]: The middle ground alternative, consistent with 4 precedential orders is narrative objectives paired with numeric triggers for additional monitoring and action.

~~ambient receiving water sample is less than or equal to 80 percent of the test organism RESPONSE in the control water sample.~~

~~And where the following ALTERNATIVE HYPOTHESIS shall be used:~~

~~H_a : Mean RESPONSE (ambient receiving water) > 0.80 * mean RESPONSE (control)~~

~~In general terms, the ALTERNATIVE HYPOTHESIS is the following statement: ~~t~~he ambient receiving water ~~is shall~~ not exhibit acute toxicity, defined as where because the test organisms' RESPONSE (e.g., survival) in the ambient receiving water sample is greater than 80 percent of the test organisms' RESPONSE in the control water sample.~~

~~Attainment of the water quality objective is demonstrated by conducting ACUTE TOXICITY TESTING as described in Section IV.B.1.b and rejecting this NULL HYPOTHESIS in accordance with the TST statistical approach described in Section IV.B.1.c. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the acute toxicity water quality objective. A receiving water Failing to reject the NULL HYPOTHESIS (referred to as a "fail") is equivalent not meeting the LC50 criteria equates to an exceedance of the acute toxicity water quality objective.~~

3. Interaction of Toxicity Provisions with Basin Plans and the SIP

In accordance with Water Code section 13170, ~~except where otherwise noted,~~ the TOXICITY PROVISIONS supersede any Regional Water Quality Control Plans (Basin Plans) for the same waters, ~~except for waters with an approved TMDL to the extent of any conflict.~~ The TOXICITY PROVISIONS supersede section 4 of the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (SIP).

The TOXICITY PROVISIONS in Section III.B.2 and Section IV.B, except as defined in this section, supersede Basin Plan toxicity provisions to the extent that:

- (A) ~~The Basin Plan toxicity objectives and provisions that specify methods of assessing compliance with any numeric or narrative water quality objectives for acute and chronic aquatic toxicity; and~~
- (B) ~~The Basin Plan provisions regard aquatic toxicity testing and/or interpretation of aquatic toxicity testing results; and~~
- (C) ~~The Any other Basin Plan provisions are in conflict with the TOXICITY PROVISIONS.~~

The TOXICITY PROVISIONS in Section III.B.2 and Section IV.B, notwithstanding the above, do not supersede:

- ~~(D) The narrative toxicity water quality objectives (e.g., "no toxic POLLUTANTS in toxic amounts"); and~~

Commented [A16]: EPA has already established a numeric RMD for acute survival. It is called the LC50 and EPA has also published easily-accessible software tools (such as Probit) to calculate the LC50 in order to assess compliance. It should be noted that many, if not most, of the numeric 304(a) water quality criteria were developed by EPA using the LC50 as the primary measure to chemical toxicity. Requiring effluent exposed organisms to demonstrate at least 80% of the survival rate shown by controls is a MAJOR change from the previous 50% threshold and cannot be construed as an "equivalent" method.

Commented [A17]: To meet the goal of statewide consistency, this Policy must supersede the 9 different regional objectives. Since the changes herein adopt new narrative objectives, the regional objectives would no longer be needed. In addition, if the State Board desires to use this Policy as authority to adopt effluent limitations for pollutants determined to be the source of toxicity, this Policy needs to include a narrative translator if any specific criteria other than those included in Basin Plans or the CTR are utilized to set effluent limitations.

~~(E) Any Basin Plan provisions regarding the application of narrative toxicity water quality objectives to derive chemical specific limits, targets, and other thresholds; and~~

~~(D) Any site-specific toxicity water quality objective established in a Basin Plan. In addition, the TOXICITY PROVISIONS in Section III.B.2 and Section IV.B do not apply to that water body; and.~~

(E) Any total maximum daily loads (TMDLs), including their implementation provisions, adopted by a Regional Water Board prior to the effective date of these TOXICITY PROVISIONS, remain in effect, and do not require reconsideration (for purposes of compliance with the TOXICITY PROVISIONS). Nothing in this section limits the Regional Water Board's authority to reconsider a TMDL and its implementation provisions.

4. Interaction of Toxicity Provisions with Narrative and Numeric Toxicity Water Quality Objectives

Section IV.B. includes a program of implementation for toxicity that shall be used to assess whether ambient receiving water meets the numeric aquatic toxicity water quality objectives, whether a PERMITTING AUTHORITY shall require aquatic toxicity effluent limitations for non-storm water National Pollutant Discharge Elimination System (NPDES) dischargers, and whether dischargers' effluent complies with applicable permit terms.

~~Compliance with narrative toxicity water quality objectives is determined by use of indicator species, analysis of species diversity, pollution density, toxicity tests or other appropriate method as specified by the PERMITTING AUTHORITY. The PERMITTING AUTHORITY may also consider all material and relevant information submitted by the discharger and other interested parties and 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 apply~~ narrative toxicity water quality objectives to derive chemical specific effluent limitations, receiving water limitations, targets, and other thresholds ~~as prescribed herein.~~

~~In addition to implementing the requirements of Section IV.B. using a species and endpoint identified in Table 1 of Section IV.B.1.b., the PERMITTING AUTHORITY shall have discretion regarding the application of narrative toxicity water quality objectives to derive effluent limitations for aquatic toxicity endpoints not addressed by any of the acute and chronic aquatic toxicity test methods identified in Table 1 of Section IV.B.1.b (e.g., endocrine disruption).~~

~~The PERMITTING AUTHORITY shall have discretion regarding the application of narrative or numeric toxicity water quality objectives to derive narrative effluent or receiving water limitations.~~

Commented [A18]: These need a narrative translator so better to have that be a consistent statewide policy as well.

Commented [A19]: TMDLs were properly adopted using promulgated methods and should be maintained.

Commented [A20]: These are not the listed requirements for an approved program of implementation. Section 13242 requires (a) a description of the nature of actions which are necessary to achieve the objective, including recommendations for appropriate action by any entity, public or private; (b) a time schedule for actions to be taken; and (c) a description of surveillance to be undertaken to determine compliance with the objectives. The Provisions fail to contain each of these items. By comparison, the additional tests to confirm persistent toxicity, determination of the pollutant(s) causing toxicity, and creating a plan to reduce those pollutants on a set time schedule complies with all 3 mandates.

Commented [A21]: Objectives will never be attained if all sources of toxicity are not addressed. The Draft Staff Report do not point to non-storm water dischargers as a major source of toxicity, so this focus is misplaced.

Commented [A22]: If numeric objectives are adopted, then there is no need for maintaining narrative objectives as this is duplicative and unnecessary, and therefore contrary to the APA. If narrative objectives are adopted, a more clear specification as to how narrative objectives will be translated into effluent limitations for the pollutant(s) causing toxicity needs to be better defined. For example, if there is a CTR criteria, then this should be the first criteria that should be considered unless demonstrated to be not stringent enough to avoid toxicity. Random criteria from other governmental agencies may or may not be appropriate and need to be demonstrated to be appropriate to address aquatic toxicity.

Commented [A23]: This does not meet the Provisions' goal of statewide consistency, or protect dischargers from being regulated differently just because of being located in a different region when the basic legal requirements are the same. The requirements for deriving effluent limits and receiving water limits, for which dischargers are liable, must be consistent statewide.

Commented [A24]: Only one limitation for toxicity is needed to prevent aquatic life toxicity. Other limits for particular pollutants with reasonable potential provide additional protection. The Provisions fail to justify need for additional toxicity limits.

Commented [A25]: What exactly does this mean? For reproduction, growth, and survival endpoints, or for NOEC/IC25 endpoints? The Provisions lack clarity on the definition of ENDPOINT, and need to define biological and test endpoints.

Commented [A26]: All discussion of discretion violates the goal of consistency. Further, there is no need for additional narrative limits besides limits included in the Provisions.

The PERMITTING AUTHORITY shall not include numeric effluent limitations for aquatic toxicity endpoints addressed by any of the acute and chronic toxicity test methods identified in Table 1 of Section IV.B.1.b to implement either the toxicity narrative or numeric water quality objectives except as indicated in section IV.B.2.e.

Commented [A27]: This seems to state that the 2002 Promulgated Methods cannot be used, in violation of federal requirements.

IV. PROGRAMS OF IMPLEMENTATION

A. [Reserved]

B. Aquatic Toxicity

The following sections shall be used to assess whether ambient receiving water meets the numeric aquatic toxicity water quality objectives, whether a PERMITTING AUTHORITY shall require aquatic toxicity effluent limitations for non-storm water National Pollutant Discharge Elimination System (NPDES) dischargers, and whether dischargers' effluent complies with applicable permit terms. Specific requirements for NON-STORM WATER NPDES DISCHARGERS, STORM WATER DISCHARGERS, and NONPOINT SOURCE dischargers are described, respectively, in Section IV.B.2, IV.B.3, and IV.B.4.

Commented [A28]: Again, this does not meet the requirements of Water Code section 13242.

1. Required Toxicity Testing Methods and Analyses

a. Toxicity Testing Sample and Location

To determine if ambient water meets the numeric aquatic water quality objective (non-specific to a discharger), the ambient water sample shall be a representative sample of the waterbody.

For compliance with a receiving water limitation for a specific discharger, the ambient water sample shall be from a location specified by the PERMITTING AUTHORITY.

Commented [A29]: This should be specified as not immediately end of pipe since that is not an ambient sample, but instead an effluent sample. Toxicity is not to cause receiving water to exhibit toxicity.

For compliance with an effluent limitation for a specific discharger, effluent samples shall be from a location specified by the PERMITTING AUTHORITY. Dilution and control waters should be obtained from an area unaffected by the discharge in the receiving waters. For rivers and streams, dilution water should be obtained immediately upstream of the wastewater outfall. Standard dilution water, as defined by the test methods, can be used if the above sources exhibit toxicity or if approved by the PERMITTING AUTHORITY.

Commented [A30]: What if there is no upstream, or if there are other discharges immediately upstream. This does not consider those situations.

b. Toxicity Test Methods

CHRONIC TOXICITY TESTS shall be conducted using one or more of the test species in Table 1 selected by the PERMITTING AUTHORITY in accordance with the TOXICITY PROVISIONS, and shall follow methods identified in the Code of Federal Regulations, title 40, part 136 or included in the following United States Environmental Protection Agency (U.S. EPA) method manuals: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, Fourth Edition (EPA-821-R-02-013); Short-term Methods for Estimating

the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition (EPA-821-R-02-014); and Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms, First Edition (EPA-600-R-95-136).

Table 1. Bioequivalence Values (b), Test Species Tier Classification, and False Negative Rate (α error) for toxicity test methods.

EPA Toxicity Test Method	Bioequivalence Value (b)	Tier	False Negative (α Error)
Chronic Freshwater Methods			
<i>Ceriodaphnia dubia</i> (water flea) Survival and reproduction	0.75	I	0.20
<i>Pimephales promelas</i> (fathead minnow) Survival and growth	0.75	I	0.25
<i>Selenastrum capricornutum</i> (green alga) Growth	0.75	I	0.25
Chronic West Coast Marine Methods			
<i>Atherinops affinis</i> (topsmelt) Survival and growth	0.75	I	0.25
<i>Dendraster excentricus</i> (sand dollar); <i>Strongylocentrotus purpuratus</i> (purple urchin) Fertilization	0.75	I	0.05
<i>Dendraster excentricus</i> (sand dollar); <i>Strongylocentrotus purpuratus</i> (purple urchin) Larval development	0.75	I	0.05
<i>Haliotis rufescens</i> (red abalone) Larval development	0.75	I	0.05
<i>Mytilus</i> sp. (mussels); <i>Crassostrea gigas</i> (oyster) Larval development	0.75	I	0.05
<i>Macrocystis pyrifera</i> (giant kelp) Germination and germ-tube length	0.75	I	0.05
Chronic East Coast Marine Methods			
<i>Menidia beryllina</i> (inland silverside) Survival and growth	0.75	II	0.25
<i>Americamysis bahia</i> (mysid) Survival and growth	0.75	II	0.15
Acute Freshwater Methods			
<i>Ceriodaphnia dubia</i> (water flea); <i>Daphnia magna</i> (water flea); <i>Daphnia pulex</i> (water flea); <i>Hyalella azteca</i> (amphipod) Survival	0.80	I	0.10
<i>Pimephales promelas</i> (fathead minnow); <i>Oncorhynchus mykiss</i> (rainbow trout); <i>Salvelinus fontinalis</i> (brook trout) Survival	0.80	I	0.10
Acute Marine Methods			
<i>Atherinops affinis</i> (topsmelt) Survival	0.80	I	0.10
<i>Americamysis bahia</i> (mysid) Survival	0.80	II	0.10
<i>Menidia beryllina</i> (inland silverside) Survival	0.80	II	0.10

Commented [A31]: Does this mean false indications of toxicity (false fail) or false indication of non-toxic (false pass)? The concept of a false positive (violation when not toxic) reverses when the null hypothesis is reversed.

Notes: The false positive rate (β error) is set at 0.05 for all toxicity test methods. The bioequivalence value (b) is equivalent to the RMD.

ACUTE TOXICITY TESTS shall be conducted using one or more of the test species in Table 1 selected by the PERMITTING AUTHORITY in accordance with the TOXICITY PROVISIONS, and shall follow methods established in Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, Fifth Edition (EPA-821-R-02-012).

These methods specify a minimum number of REPLICATES. However, additional test REPLICATES may be conducted to increase test sensitivity and confidence in the results.

Test method selection is determined by salinity and tier classification (refer to Table 1 in this Section). Freshwater test methods shall be used for receiving waters in which salinity is less than 1,000 mg/L at least 95 percent of the time, and marine test methods shall be used for receiving waters in which salinity is equal to or greater than 1,000 mg/L at least 95 percent of the time. In all other instances, the PERMITTING AUTHORITY has discretion to choose either freshwater test or marine test methods for receiving waters. The PERMITTING AUTHORITY shall specify in the permit or monitoring requirements whether freshwater or marine test methods shall be used. The PERMITTING AUTHORITY may require use of freshwater test methods for dischargers that discharge freshwater effluent to marine waters. Tier I test species shall be used unless Tier I species are not readily available, in which case the PERMITTING AUTHORITY may allow the use of Tier II test species.

~~Test results shall be analyzed using the TEST OF SIGNIFICANT TOXICITY (TST) as described in Section IV.B.1.c. To the extent that U.S. EPA-approved methods require that observations should be made of organism RESPONSES in multiple concentrations of effluent or receiving water, the INSTREAM WASTE CONCENTRATION (IWC) shall be included as one of the selected concentrations, and the TST shall be conducted using the IWC and control as described in Section IV.B.1.c.~~

Commented [A32]: The TST is not an approved method and is inconsistent with the requirements of approved methods.

c. ~~Testing for of Significant Toxicity~~

Aquatic toxicity test data shall be analyzed using ~~the TEST OF SIGNIFICANT TOXICITY (TST)~~ EPA promulgated methods as described below in Steps 1 through 7. For any chronic toxicity test method with both lethal and sub-lethal endpoints, the sub-lethal endpoint data shall be used in Steps 1 through 7. For any chronic toxicity test method with more than one sub-lethal endpoint (giant kelp), the data for each sub-lethal endpoint shall be independently analyzed using Steps 1 through 7. ~~The TST is applicable for a data analysis of an IWC compared to a control. For assessing whether receiving waters meet the water quality objectives, the undiluted ambient water shall be used as the IWC.~~

Step 1: Conduct the aquatic toxicity test according to procedures in the appropriate test method manual, as described in Section IV.B.1.b.

Step 2: Determine if there is no variance in the ENDPOINT (i.e., determine if all REPLICATES in each concentration have the same exact RESPONSE).

If there is no variance in the ENDPOINT in both concentrations being compared, compute the PERCENT EFFECT, as described in Section IV.B.1.d.

If the PERCENT EFFECT ~~at the IWC~~ is \geq the RMD, the sample is declared toxic, ~~and the test result is "fail."~~ If the PERCENT EFFECT ~~at the IWC~~ is $<$ the RMD, the sample is declared non-toxic, ~~and the test result is "Pass."~~ Skip steps 3-7.

If there is variance in the ENDPOINT ~~in both concentrations being compared~~, follow Steps 3-7.

Step 3: Use the data to calculate the mean RESPONSE ~~for the control and IWC~~. If the data consists of proportions from a binary response (e.g., for survival, germination, and fertilization) transform the data using the arcsine square root transformation before calculating the mean RESPONSE for the control and IWC.

The arcsine square root transformation is used for such data to stabilize the variance and satisfy the normality requirement. To conduct the arcsine square root transformation, the response proportion (RP) for each REPLICATE (e.g., percent survival, percent fertilization), expressed as a decimal fraction (where 1.00 = 100 percent) for each treatment, is first calculated:

$$RP = \frac{\text{Number of Organisms with Response}}{\text{Number of Organisms Exposed}}$$

The square root value of the response proportion is then arcsine transformed before calculating the mean RESPONSE and analysis in Step 4. Note: Excel and most statistical software packages can calculate arcsine square root values.

If $0 < RP < 1$,
then the angle (in radians) = $\arcsin(\sqrt{RP})$.

If $RP = 0$,
then the angle (in radians) = $\arcsin(\sqrt{1/4n})$,
Where n = number of ORGANISMS used for each REPLICATE.

If $RP = 1$
then the angle (in radians) = $\arcsin(\sqrt{1 - (1/4n)})$,
Where n = number of ORGANISMS used for each REPLICATE.

Use the transformed data in the following steps.

Commented [A33]: The arcsine square root transformation is intended to "normalize" non-normally distributed data so that statistical tools (such as Welch's t-test) that rely on an assumption that the data is normally-distributed can then be used to complete the analysis. However, the transformation process can artificially inflate the measured variance and increase the risk of Type-II statistical error in the TST procedure (improper failure to reject the null) resulting in a larger number of false violations. The current methods provide for the use of non-parametric statistical tools when needed to analyze binary response data or non-normal or non-heterogeneous data. The proposed state policy fails to include similar modern statistical techniques for use with the TST. This, too, is a major change in the method itself.

Step 4: Conduct Welch's t-test (Zar 1996) using the following equation to obtain the calculated t value:

$$t = \frac{\bar{Y}_t - b \cdot \bar{Y}_c}{\sqrt{\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}}}$$

Where:

\bar{Y}_c = Mean RESPONSE for the control

\bar{Y}_t = Mean RESPONSE for the IWC

S_c^2 = Estimate of the variance for the control

S_t^2 = Estimate of the variance for the IWC

n_c = Number of REPLICATES for the control

n_t = Number of REPLICATES for the IWC

b = 0.75 for chronic tests; 0.80 for acute tests
(Note: b is equivalent to the RMD)

Note on the use of Welch's t-test: Welch's t-test is appropriate to use when there are an unequal number of REPLICATES between control and the IWC. When sample sizes of the control and treatment are the same (i.e., $n_t = n_c$), Welch's t-test is equivalent to the Student's t-test (Zar 1996).

Step 5: Adjust the degrees of freedom using the following equation:

$$v = \frac{\left(\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}\right)^2}{\frac{\left(\frac{S_t^2}{n_t}\right)^2}{n_t - 1} + \frac{\left(\frac{b^2 S_c^2}{n_c}\right)^2}{n_c - 1}}$$

Using Welch's t-test, the degrees of freedom is the value obtained for v in the equation above. When v is a non-integer, round v to the next smallest integer, and that number is used as the degrees of freedom.

Step 6: Compare the calculated t value from Step 4 with the critical t value in Table 2 using the test method-specific alpha values shown in Table 1 of Section IV.B.1.b. To obtain the critical t value, look across the table for the alpha value that corresponds to the toxicity test method and then look down the table for the appropriate degrees of freedom.

Step 7: If the calculated t value is less than the critical t value, the **NULL HYPOTHESIS** is **not** rejected, and the test result is "**fail-toxic**." If the calculated t value is greater than the critical t value, the **NULL HYPOTHESIS** is **not** rejected, and the test result is "**pass-non-toxic**".

d. Percent Effect

The PERCENT EFFECT ~~at the IWC~~ shall be calculated for each ENDPOINT in an aquatic toxicity test. Calculate the PERCENT EFFECT ~~at the IWC~~ using untransformed data and the following equation:

$$\text{Percent Effect at the IWC} = \frac{\text{Mean Control Response} - \text{Mean IWC Response}}{\text{Mean Control Response}} \cdot 100$$

Commented [A34]: References to the IWC should be removed since contrary to requirements to test 5 concentrations plus control and consider information derived from all 5 concentrations and dose response.

e. Reporting

Results obtained from toxicity tests shall be reported to the PERMITTING AUTHORITY ~~as either a "pass" or a "fail," and along with~~ the PERCENT EFFECT ~~at the IWC for each endpoint~~. The results and any required supporting data shall be submitted in the format ~~specified by the PERMITTING AUTHORITY~~.

Commented [A35]: EPA does not authorize pass/fail endpoints.

Commented [A36]: Again, this fails to meet the goal of statewide consistency.

Table 2. Critical values of the t-distribution; one-tailed probability is assumed.

Degrees of Freedom (v)	α Error				
	0.25	0.20	0.15	0.10	0.05
1	1	1.3764	1.9626	3.0777	6.3138
2	0.8165	1.0607	1.3862	1.8856	2.92
3	0.7649	0.9785	1.2498	1.6377	2.3534
4	0.7407	0.941	1.1896	1.5332	2.1318
5	0.7267	0.9195	1.1558	1.4759	2.015
6	0.7176	0.9057	1.1342	1.4398	1.9432
7	0.7111	0.896	1.1192	1.4149	1.8946
8	0.7064	0.8889	1.1081	1.3968	1.8595
9	0.7027	0.8834	1.0997	1.383	1.8331
10	0.6998	0.8791	1.0931	1.3722	1.8125
11	0.6974	0.8755	1.0877	1.3634	1.7959
12	0.6955	0.8726	1.0832	1.3562	1.7823
13	0.6938	0.8702	1.0795	1.3502	1.7709
14	0.6924	0.8681	1.0763	1.345	1.7613
15	0.6912	0.8662	1.0735	1.3406	1.7531
16	0.6901	0.8647	1.0711	1.3368	1.7459
17	0.6892	0.8633	1.069	1.3334	1.7396
18	0.6884	0.862	1.0672	1.3304	1.7341
19	0.6876	0.861	1.0655	1.3277	1.7291
20	0.687	0.86	1.064	1.3253	1.7247
21	0.6864	0.8591	1.0627	1.3232	1.7207
22	0.6858	0.8583	1.0614	1.3212	1.7171
23	0.6853	0.8575	1.0603	1.3195	1.7139
24	0.6849	0.8569	1.0593	1.3178	1.7109
25	0.6844	0.8562	1.0584	1.3163	1.7081
26	0.684	0.8557	1.0575	1.315	1.7056
27	0.6837	0.8551	1.0567	1.3137	1.7033
28	0.6834	0.8546	1.056	1.3125	1.7011
29	0.683	0.8542	1.0553	1.3114	1.6991
30	0.6828	0.8538	1.0547	1.3104	1.6973
inf	0.6745	0.8416	1.0364	1.2816	1.6449

Commented [A37]: This table is unnecessary and can be found at the back of any college statistics textbook.

2. Implementation for Non-Storm Water NPDES Dischargers

Commented [A38]: Inadequate justification has been provided for treating different discharges differently.

The PERMITTING AUTHORITY shall include the requirements specified in this Section (Section IV.B.2) for NPDES permits issued, reissued, renewed, or reopened after the effective date of these provisions for NON-STORM WATER NPDES DISCHARGERS.

a. Species Sensitivity Screening

i. Non-Storm Water NPDES Dischargers Required to Conduct Species Sensitivity Screening for Chronic Toxicity

All NON-STORM WATER NPDES DISCHARGERS shall conduct a SPECIES SENSITIVITY SCREENING for chronic toxicity either prior to, or within 18 months after the first issuance, reissuance, renewal, or reopening (to address toxicity requirements) of the permit after the effective date of these TOXICITY PROVISIONS, unless performed within the last 5 years (and in that case, the last analyses may be used). The PERMITTING AUTHORITY may require a SPECIES SENSITIVITY SCREENING for chronic toxicity prior to every subsequent issuance, reissuance, renewal, or reopening (to address toxicity requirements) of the permit. At a minimum, a SPECIES SENSITIVITY SCREENING shall be conducted no less than once every ten years unless the discharger is participating in a regional monitoring program approved by the PERMITTING AUTHORITY and the PERMITTING AUTHORITY determines that 1) the discharger has conducted a valid species sensitivity screening using test methods and statistical analysis required by these provisions and 2) the nature of the effluent has not changed-been reduced since the last species sensitivity screening.

Commented [A39]: If effluent cleaner due to treatment upgrades, that should not require another analysis, only if effluent is somehow reduced in quality.

ii. Non-Storm Water NPDES Dischargers Required to Conduct Species Sensitivity Screening for Acute Toxicity

Except for PUBLICLY OWNED TREATMENT WORKS (POTW) dischargers, all NON-STORM WATER NPDES DISCHARGERS shall conduct a SPECIES SENSITIVITY SCREENING for acute toxicity, either prior to, or within 18 months after the first issuance, reissuance, renewal, or reopening (to address toxicity requirements) of the permit after the effective date of these TOXICITY PROVISIONS. The PERMITTING AUTHORITY may require a SPECIES SENSITIVITY SCREENING for acute toxicity prior to every subsequent issuance, reissuance, renewal, or reopening (to address toxicity requirements) of the permit. At a minimum, a SPECIES SENSITIVITY SCREENING shall be conducted no less than once every ten years.

For POTW dischargers, the PERMITTING AUTHORITY may, in its discretion, should not require a SPECIES SENSITIVITY SCREENING for acute toxicity without specific demonstrated need. This determination of need must be documented in the NPDES fact sheet (or equivalent document).

Commented [A40]: Discretion fails to meet goal of statewide consistency. These changes provide more guidance and instruction to inform any exercised discretion.

iii. Type and Frequency of Testing in a Species Sensitivity Screening

A SPECIES SENSITIVITY SCREENING for chronic toxicity includes four sets of testing conducted within one year, each set of testing consisting of, at a minimum, one vertebrate, one invertebrate, and one aquatic plant/algae from Table 1 of Section IV.B.1.b. For CONTINUOUS DISCHARGERS, the four sets of testing shall be conducted over four consecutive quarters. For NON-CONTINUOUS DISCHARGERS, the four sets of testing shall be evenly distributed across the CALENDAR YEAR to the extent feasible.

A SPECIES SENSITIVITY SCREENING for acute toxicity includes four sets of testing conducted within one year, each set of testing consisting of, at a minimum, one vertebrate and one invertebrate from Table 1 of Section IV.B.1.b. For CONTINUOUS DISCHARGERS, the four sets of testing shall be conducted over four consecutive quarters. For NON-CONTINUOUS DISCHARGERS, the four sets of testing shall be evenly distributed across the CALENDAR YEAR to the extent feasible.

For dischargers granted a dilution credit or a MIXING ZONE for toxicity, the PERMITTING AUTHORITY ~~may-should not~~ direct that a higher concentration of effluent than the IWC be used for SPECIES SENSITIVITY SCREENING ~~to increase the likelihood that potential effects might be observed.~~

For seasonal and intermittent dischargers, testing in a specific SPECIES SENSITIVITY SCREENING can be conducted using effluent that is not discharged into surface waters (e.g., effluent discharged onto land because of summer prohibition on discharges into surface waters, etc.) as long as the effluent is representative of the effluent that will be discharged to surface waters.

iv. Determination of the Most Sensitive Species

~~The PERMITTING AUTHORITY has the discretion to choose how the MOST SENSITIVE SPECIES is selected from the SPECIES SENSITIVITY SCREENING.~~ The PERMITTING AUTHORITY should generally select the species in the SPECIES SENSITIVITY SCREENING exhibiting the highest PERCENT EFFECT ~~at the IWC~~ as the MOST SENSITIVE SPECIES. ~~If not species is clearly more sensitive,~~ The PERMITTING AUTHORITY shall indicate how the MOST SENSITIVE SPECIES is selected from the SPECIES SENSITIVITY SCREENING (e.g., species exhibiting highest percent effect, species with most number of “fails” etc.) in the NPDES permit.

The PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES ~~and IWC~~ in the NPDES permit. When the selected species cannot be used, including for example when the discharger encounters unresolvable test interference or cannot secure a reliable supply of test organisms, the PERMITTING AUTHORITY may specify a different species as the MOST SENSITIVE SPECIES. In such cases, the next applicable species shall be selected by the PERMITTING AUTHORITY as the MOST SENSITIVE SPECIES. The selection of the MOST SENSITIVE SPECIES must be documented in the NPDES fact sheet (or equivalent document).

Commented [A41]: This is artificial and unlikely to be replicated in the receiving water. The CWA requirements are not to cause instream exceedances.

When the SPECIES SENSITIVITY SCREENING is conducted within 18 months of the issuance, reissuance, renewal, or reopening (to address toxicity requirements) of the permit after the effective date of these TOXICITY PROVISIONS, then the PERMITTING AUTHORITY shall specify in the NPDES permit a species as the MOST SENSITIVE SPECIES until the SPECIES SENSITIVITY SCREENING is conducted. The NPDES permit shall indicate the method of determining the MOST SENSITIVE SPECIES from the SPECIES SENSITIVITY SCREENING, and a provision indicating that the Executive Director or Executive Officer may select and document the species determined to be the MOST SENSITIVE SPECIES from the SPECIES SENSITIVITY SCREENING test. When that species cannot be used, such as when discharger encounters unresolvable test interference or cannot secure a reliable supply of test organisms, the Executive Director or Executive Officer may specify the next applicable species as the MOST SENSITIVE SPECIES and document that determination.

Commented [A42]: This seems very repetitive of the preceding page.

b. Reasonable Potential

~~If a REASONABLE POTENTIAL analysis is required pursuant to this Section, a~~ REASONABLE POTENTIAL analysis shall be conducted prior to every permit issuance, reissuance, renewal, or reopening (to address toxicity requirements).

Commented [A43]: This analysis is required under federal law, and thus under Water Code provisions requiring consistency with federal law.

i. All Non-Storm water NPDES Dischargers Required to Conduct Reasonable Potential Analysis for Chronic Toxicity.

~~Except for POTW dischargers authorized to discharge at a rate equal to or greater than 5.0 MGD, a~~All NON-STORM WATER NPDES DISCHARGERS shall conduct a REASONABLE POTENTIAL analysis for chronic toxicity, pursuant to the procedures specified in Section IV.B.2.b.iii, for review and approval by the PERMITTING AUTHORITY. ~~A REASONABLE POTENTIAL analysis for chronic toxicity is not required for POTW dischargers authorized to discharge at a rate equal to or greater than 5.0 MGD, because the PERMITTING AUTHORITY shall include an effluent limitation for these dischargers pursuant to Section IV.B.2.e.~~

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

Except for POTW dischargers, all NON-STORM WATER NPDES DISCHARGERS shall 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. 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. 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).

iii. Reasonable Potential Analysis

All toxicity test data generated within five years prior to permit issuance, reissuance, renewal, or reopening (to address toxicity requirements) that is representative of effluent quality during discharge conditions shall be evaluated in determining REASONABLE POTENTIAL. Data generated within those five years from a minimum of four tests using species specified by the PERMITTING AUTHORITY and selected from Table 1 of Section IV.B.1.b must be ~~conducted at the IWC and be analyzed using the TST used.~~ If this minimum data is unavailable and there is representative effluent, the PERMITTING AUTHORITY shall require the discharger to conduct additional toxicity tests ~~at the IWC,~~ using a species selected by the PERMITTING AUTHORITY from Table 1 of Section IV.B.1.b, and to analyze the results using ~~the TST EPA promulgated methods.~~ The PERMITTING AUTHORITY may also evaluate older toxicity test data to determine REASONABLE POTENTIAL.

A discharge has REASONABLE POTENTIAL to cause or contribute to an excursion above the chronic toxicity water quality objectives specified in Section III.B.2.a, if any of the CHRONIC TOXICITY TESTS result in a ~~"fail" at the IWC, or if any of the~~ CHRONIC TOXICITY TESTS ~~have with~~ a PERCENT EFFECT ~~at the IWC~~ greater than ~~or equal to 40-25~~ percent.

A discharge has REASONABLE POTENTIAL to cause or contribute to an excursion above the acute toxicity water quality objectives specified in Section III.B.2.b, if any of the ACUTE TOXICITY TESTS result in a ~~"fail" at the IWC, or if any of the~~ ACUTE TOXICITY TESTS ~~have with~~ a PERCENT EFFECT ~~at the IWC~~ greater than ~~40-20~~ percent.

Furthermore, other information or data, including, but not limited to, fish die off observation, lack of available dilution, or existing data on toxic POLLUTANTS ~~related to the discharge,~~ may be used by the PERMITTING AUTHORITY to determine if there is REASONABLE POTENTIAL to cause or contribute to an excursion above the toxicity water quality objectives specified in Section III.B.2.

For Non-Storm Water NPDES Dischargers that do not have an effluent discharge prior to permit issuance, reissuance, renewal or reopening (to address toxicity requirements) that is representative of the quality of the proposed discharge, the PERMITTING AUTHORITY may use non-facility specific monitoring data and other information to determine reasonable potential, consistent with 40 CFR 122.44(d)(1)(ii).

The PERMITTING AUTHORITY'S determination that there is or is no REASONABLE POTENTIAL must be documented in the NPDES fact sheet (or equivalent document).

If a REASONABLE POTENTIAL analysis indicates no REASONABLE POTENTIAL for either chronic or acute toxicity, the PERMITTING AUTHORITY may include a reopener clause in the permit authorizing the PERMITTING AUTHORITY to reopen the permit, reevaluate REASONABLE POTENTIAL, and add ~~MAXIMUM DAILY EFFLUENT LIMITATIONS (MDEL) and MEDIAN~~

Commented [A44]: 10 percent is not an appropriate value. RP is not done with lower numbers than the water quality criteria for toxic pollutants, and an RMD less than 25% should not be used here either.

Commented [A45]: Since the methods allow survival in the non-toxic control group to vary by up to 20%, we should not assume that there is reasonable potential for toxicity to exist until the observed effect in the effluent is at least greater than that (e.g. >20%). And, since we say the State proposes established an RMD of 25%, then there is no reason to infer reasonable potential until the measured effect is greater than the RMD. Anything less is purely arbitrary and undermines the Staff's claim that the TST provides an "unambiguous" conclusion about the presence or absence of toxicity in a given sample. Finally, RP has traditionally been based on a mathematical analysis of variability in historical sampling data. But, since the TST relies on a non-numeric "Pass/Fail" endpoint, it is not possible to calculate RP for WET in a manner consistent with EPA's TSD guidance. This shows the TST is, in fact, a different method altogether.

Commented [A46]: A fish kill wholly unrelated to the discharge should not be used to determine RP for a discharge.

~~MONTHLY EFFLUENT LIMITATIONS (MMEL)~~, if warranted, after the evaluation of new data and information.

If a REASONABLE POTENTIAL analysis indicates there is REASONABLE POTENTIAL for the discharge to cause or contribute to an exceedance of either the chronic or the acute toxicity water quality objective, then the PERMITTING AUTHORITY shall include the ~~corresponding MDEL and MMEL~~appropriate narrative effluent limitations and numeric triggers in the NPDES permit.

c. ~~MDEL and MMEL~~Effluent Limitation Compliance Monitoring

All NON-STORM WATER NPDES DISCHARGERS that demonstrate REASONABLE POTENTIAL for chronic toxicity ~~and all POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD~~ shall conduct monitoring for compliance with the chronic toxicity ~~MDEL and MMEL~~effluent limits. All NON-STORM WATER NPDES DISCHARGERS that demonstrate REASONABLE POTENTIAL for acute toxicity shall conduct monitoring for compliance with the acute toxicity ~~MDEL and MMEL~~limits. The compliance monitoring ~~for the MDEL and MMEL~~ includes ROUTINE MONITORING and ~~MMEL~~additional COMPLIANCE TESTS.

Commented [A47]: An automatic determination of RP for large POTWs fails to recognize the high level of effluent quality of these facilities due to regulations on industries and often higher treatment. This actually punishes good effluent quality instead of rewarding such results. This also adversely characterizes recycled water as presumptively toxic.

Toxicity tests of the MOST SENSITIVE SPECIES ~~conducted at the IWC and analyzed using the TST~~ shall be used to determine compliance ~~with the MDEL and MMEL~~. The PERMITTING AUTHORITY shall specify in the permit the specific type of testing (e.g. the MOST SENSITIVE SPECIES and the concentrations ~~used of~~including the IWC) that will be used to determine compliance with the chronic toxicity ~~MDEL and MMEL~~ and acute toxicity ~~MDEL and MMEL~~limits, as applicable. The toxicity test in ROUTINE MONITORING and ~~MMEL~~additional COMPLIANCE TESTS shall be the MOST SENSITIVE SPECIES toxicity test and shall be analyzed using ~~the TST at the IWC~~EPA Promulgated Methods.

The PERMITTING AUTHORITY shall specify the day of the month that corresponds to the start of a ~~CALENDAR MONTH~~SIX WEEK period, and the day of the month and the month(s) that correspond to the start of the CALENDAR QUARTER, AND CALENDAR YEAR in an NPDES permit ~~or Water Code section 13383~~Order.

Commented [A48]: In the current construct, it is very difficult to include 3 full chronic tests (which can take up to 9 days each) in one calendar month. Please consider other options, such as that included in the Santa Ana regional permits of approximately 6 week period instead of one month, or the 45 day geomean in the Bacteria Policy.

For dischargers that conduct ROUTINE MONITORING at a less than monthly frequency, the ~~CALENDAR MONTH~~SIX WEEK period begins from the initiation of the ROUTINE MONITORING test.

Commented [A49]: Permits cannot be modified by separate order.

ROUTINE MONITORING and ~~MMEL~~additional COMPLIANCE TESTS shall be conducted in accordance with this section. ROUTINE MONITORING and ~~MMEL~~ COMPLIANCE TESTS continue during any required TOXICITY REDUCTION EVALUATION (TRE), ~~and these tests may be used as part of the TRE~~. When there is no effluent available to initiate a ROUTINE MONITORING test or ~~MMEL~~ COMPLIANCE TEST(s), the test is not required and ROUTINE MONITORING continues in the frequency specified in the permit.

i. Routine Monitoring for Chronic Toxicity

(A) *Routine Monitoring Schedule for Chronic Toxicity*

For NON-STORM WATER NPDES DISCHARGERS authorized to discharge, at a rate equal to or greater than 5.0 MGD, the frequency of ROUTINE MONITORING shall be specified in the NPDES permit as follows:

“The discharger shall conduct at least one CHRONIC TOXICITY TEST every ~~CALENDAR MONTH~~SIX WEEK period during which there is expected to be at least 15 days of discharge. A sample for the ROUTINE MONITORING test shall be taken at a time that would allow ~~corresponding~~MMEL~~additional~~”

COMPLIANCE TESTS to be initiated within the same ~~CALENDAR MONTHS~~SIX WEEK period as the ROUTINE MONITORING test.”

For NON-STORM WATER NPDES DISCHARGERS authorized to discharge at a rate less than 5.0 MGD, the frequency of ROUTINE MONITORING shall be specified in the NPDES permit as follows:

“The discharger shall conduct at least one CHRONIC TOXICITY TEST each CALENDAR QUARTER during which there is expected to be at least 15 days of discharge. A sample for the ROUTINE MONITORING test shall be taken at a time that would allow corresponding MMEL COMPLIANCE TESTS to be initiated within the same ~~CALENDAR MONTHS~~SIX WEEK period as the ROUTINE MONITORING test.”

The PERMITTING AUTHORITY shall have the discretion to require NON-STORM WATER NPDES DISCHARGERS ~~with an MDEL and an MMEL in their permit~~ to conduct more frequent chronic toxicity ROUTINE MONITORING than that which is prescribed in this subsection with adequate justification set forth in the NPDES Permit Fact Sheet. The PERMITTING AUTHORITY may approve a reduction in the frequency of ROUTINE MONITORING in accordance with the requirements in Section IV.B.2.c.i.(B). At a minimum, a chronic toxicity ROUTINE MONITORING test shall be conducted at least once per CALENDAR YEAR. The rationale for requiring ~~more frequent or~~ reduced ROUTINE MONITORING must be documented in the NPDES fact sheet (or equivalent document) ~~or Water Code section 13383 Order~~.

Consistent with the required frequency, the PERMITTING AUTHORITY has ~~discretion to or not to~~ specify the exact dates or time period in which a sample for ROUTINE MONITORING shall be taken within the defined ROUTINE MONITORING period (e.g., a requirement to initiate test within five days of the start of the CALENDAR QUARTER, a requirement to sample between the 10th and the 15th of each month, etc.). To the extent feasible, ROUTINE MONITORING test shall be evenly distributed across the CALENDAR YEAR or period of seasonal or intermittent discharge.

Commented [A50]: Again, discretion voids goal of statewide consistency, and this language provides no guidance or guidelines for discretion.

(B) Reduced Routine Monitoring Schedule for Chronic Toxicity

The PERMITTING AUTHORITY may approve a reduction in the frequency of the ROUTINE MONITORING specified in Section IV.B.2.c.i.(A) for dischargers upon reissuance, renewal, or reopening (to address toxicity requirements) of an NPDES permit when during the prior five consecutive years the following conditions have been met:

- 1) The ~~MDEL and MMEL~~effluent limits as specified in Section IV.B.2.e have not been exceeded, or if there were no limits in previous permit cycle, there was no confirmed instances of toxicity;
- 2) The toxicity provisions in the applicable NPDES permit(s) have been followed.

The PERMITTING AUTHORITY may approve a reduced frequency ROUTINE MONITORING schedule from one CHRONIC TOXICITY TEST per CALENDAR MONTHSIX WEEK period, as required in Section IV.B.2.c.i.(A) to one per CALENDAR QUARTER. The PERMITTING AUTHORITY may approve a reduced frequency ROUTINE MONITORING schedule from one CHRONIC TOXICITY TEST per CALENDAR QUARTER, as required in Section IV.B.2.c.i.(A), to two CHRONIC TOXICITY TESTS per CALENDAR YEAR. In addition, the PERMITTING AUTHORITY may approve a reduced frequency of one CHRONIC TOXICITY TEST per Calendar year when the following conditions have been met: (1) the discharger has an initial dilution of at least 10:1, and (2) for dischargers authorized to discharge, at a rate equal to or greater than 5.0 MGD, the PERMITTING AUTHORITY requires additional monitoring in accordance with Section IV.B.1.

Commented [A51]: Few dischargers will meet this criteria.

Commented [A52]: This is "Required Toxicity Testing Methods and Analysis" and does not specify additional monitoring.

Commented [A53]: It is unclear how reduced monitoring is possible for large facilities. This language lacks clarity.

The PERMITTING AUTHORITY shall require dischargers on an approved reduced frequency ROUTINE MONITORING schedule to return to a ROUTINE MONITORING schedule, as described in Section IV.B.2.c.i.(A), if the requirements listed above cease to be met. The PERMITTING AUTHORITY may also require dischargers on an approved reduced frequency ROUTINE MONITORING schedule to return to a ROUTINE MONITORING schedule, as described in Section IV.B.2.c.i.(A), for other reasons including major changes to the treatment facility or changes to the quality of the influent frequent indications of toxicity. Upon returning to a ROUTINE MONITORING schedule described in Section IV.B.2.c.i.(A), dischargers will need to, once again, meet the two conditions listed in this section for at least a period of five years to be granted another discretionary chronic toxicity ROUTINE MONITORING reduction.

Commented [A54]: This should not be a trigger unless the treatment is LESS. Advanced treatment should not trigger more testing.

Commented [A55]: Influent is not monitored for many constituents and this should not be a criteria as it is treatment, not influent that would be important.

Commented [A56]: This is too long. What if they consistently met the criteria? Why would 5 years be needed in that case?

The PERMITTING AUTHORITY may also approve a temporary reduction in the frequency of the ROUTINE MONITORING specified in Section IV.B.2.c.i.(A) for dischargers conducting a TRE. When a discharger is conducting a TRE, the PERMITTING AUTHORITY may temporarily reduce the ROUTINE MONITORING frequency to two CHRONIC TOXICITY TESTS per CALENDAR YEAR. The PERMITTING AUTHORITY shall require dischargers under a temporary reduced frequency to return to a ROUTINE MONITORING schedule, as described in Section IV.B.2.c.i.(A), either at the conclusion of the TRE or one year after the initiation of the TRE, whichever occurs sooner. Upon returning to a ROUTINE MONITORING schedule described in Section IV.B.2.c.i.(A), dischargers will need to meet the conditions 1-2 listed in this section to be granted a discretionary monitoring reduction.

ii. Routine Monitoring for Acute Toxicity

If REASONABLE POTENTIAL is demonstrated for acute toxicity, in accordance with the provisions specified in Section IV.B.2.b, the discharger shall conduct acute toxicity ROUTINE MONITORING in addition to any other required chronic toxicity ROUTINE MONITORING.

The monitoring period shall be specified in the NPDES permit and be ~~at a frequency determined by the PERMITTING AUTHORITY but~~ no less than once per CALENDAR YEAR. A ROUTINE MONITORING test shall be initiated at a time that would allow corresponding ~~MMEL-COMPLIANCE TESTS~~ to be initiated within the same CALENDAR MONTH as the ROUTINE MONITORING test. The PERMITTING AUTHORITY ~~has discretion to or not to may~~ specify the exact dates or time period in which a sample for ROUTINE MONITORING shall be taken (e.g., a requirement to initiate test within five days of the start of the CALENDAR QUARTER, a requirement to sample between the 10th and the 15th of each month, etc.). To the extent feasible, ROUTINE MONITORING tests shall be evenly distributed across the CALENDAR YEAR or period of seasonal or intermittent discharge.

Commented [A57]: Discretion is contrary to goal of statewide consistency.

iii. Additional Routine Monitoring Tests for TRE Determination and Compliance

For NON-STORM WATER NPDES DISCHARGERS with a ROUTINE MONITORING frequency of less than monthly, an additional ROUTINE MONITORING test shall be required when ~~there is one violation of the MDEL or MMEL~~, but not two violations ~~occur~~ in a single CALENDAR MONTH. This additional ROUTINE MONITORING test is not required if the discharger is already conducting a TRE, or if the discharger is required to conduct ROUTINE MONITORING at or more frequent than a monthly frequency.

This additional ROUTINE MONITORING test is used to determine if a TRE is necessary. This additional ROUTINE MONITORING test is also used for compliance purposes, and could require ~~MMEL-COMPLIANCE TESTS~~.

This additional ROUTINE MONITORING test shall be conducted in the successive CALENDAR MONTH after the CALENDAR MONTH in which the ~~MMEL or MDEL~~ violation occurred.

When there is no effluent available to initiate this additional ROUTINE MONITORING test, this additional ROUTINE MONITORING test shall not be required, ~~ROUTINE MONITORING continues in the frequency specified in the permit, and the PERMITTING AUTHORITY shall have discretion to require a TRE.~~

Commented [A58]: This appears as though the Provisions merely seek to create violations instead of trying to find the root cause of any toxicity and solving that problem. Since toxicity is an effect, not a pollutant, the source must first be found before a solution can occur. Racking up violations does not encourage any different behavior where the source is unknown, only creates liability.

Commented [A59]: Why would a TRE be required if there is not effluent?

iv. MMEL-Additional Compliance Tests

If an acute or chronic toxicity ROUTINE MONITORING test results in a "fail" at ~~the IWC an indication of toxicity above the prescribed PERCENT EFFECT~~, then NON-STORM WATER NPDES DISCHARGERS shall conduct a maximum of two ~~MMEL-additional~~ COMPLIANCE TESTS. The ~~se~~ ~~MMEL-COMPLIANCE TESTS~~ shall be initiated within the same ~~CALENDAR MONTHSIX WEEK~~ period that the first ROUTINE MONITORING test was initiated that resulted in ~~the "fail" at the IWC toxicity~~. If the first chronic ~~MMEL-COMPLIANCE TEST~~ results in a "fail" at ~~the IWC toxicity above the prescribed PERCENT EFFECT~~, then the second ~~MMEL-COMPLIANCE TEST~~ is waived. For the purposes of ~~MMEL-the additional~~ COMPLIANCE TEST, for dischargers that conduct ROUTINE MONITORING at a

less than monthly frequency, the CALENDAR MONTH test period begins from the initiation of the ROUTINE MONITORING test.

When there is no effluent available to initiate an MMEL-additional COMPLIANCE TEST, the MMEL COMPLIANCE TEST shall not be required, and ROUTINE MONITORING continues in the frequency specified in the permit.

d. Mixing Zones and Dilution Credits

The PERMITTING AUTHORITY may shall grant MIXING ZONES and DILUTION CREDITS to dischargers in accordance with the provisions of this section. The allowance of MIXING ZONES for chronic aquatic toxicity is discretionary and shall be determined on a discharge-by-discharge basis. A PERMITTING AUTHORITY may consider allowing MIXING ZONES and DILUTION CREDITS for chronic aquatic toxicity only for discharges with a physically identifiable point of discharge that are regulated through an NPDES permit issued by the PERMITTING AUTHORITY. The following conditions must be met in allowing a MIXING ZONE:

Commented [A60]: Credits should be in accordance with this policy, that should not be discretionary.

A MIXING ZONE shall not:

- 1) compromise the integrity of the entire water body;
- 2) cause acutely toxic conditions to AQUATIC LIFE passing through the MIXING ZONE;
- 3) adversely impact biologically sensitive or critical habitats, including, but not limited to, habitat of species listed under federal or state endangered species laws; or
- 4) overlap a MIXING ZONE from different outfalls unless demonstrated not to cause any of the above.

Commented [A61]: This is unclear; when would this happen?

If a PERMITTING AUTHORITY allows a MIXING ZONE and DILUTION CREDIT, the permit shall specify the method by which the MIXING ZONE was derived, the DILUTION RATIO calculated, the IWC granted, and the point(s) in the receiving water where the applicable objectives must be met. The application for the permit shall include, to the extent feasible, the information needed by the PERMITTING AUTHORITY to make a determination on allowing a MIXING ZONE, including the calculations for deriving the appropriate receiving water and effluent flows, and/or the results of a MIXING ZONE study. MIXING ZONE studies may include, but are not limited to, tracer studies, dye studies, modelling studies, and monitoring upstream and downstream of the discharge to that characterize the extent of actual dilution.

When a MIXING ZONE and DILUTION CREDIT is granted by the PERMITTING AUTHORITY, the IWC is the concentration of effluent in the receiving water after mixing as determined by the PERMITTING AUTHORITY. When a mixing zone is granted, the IWC is the inverse of 1 plus the DILUTION CREDIT or $IWC = 1/(1+D)$, where D = DILUTION CREDIT. The PERMITTING AUTHORITY may set the IWC at a concentration of effluent greater than the inverse of 1 plus the DILUTION CREDIT in order to protect beneficial uses, or because of site-specific conditions. For the purpose of toxicity tests, in no case shall the Permitting Authority set the IWC at less than the inverse of 1 plus the DILUTION RATIO. For completely mixed discharges

the dilution credit may be equivalent to the dilution ratio. If no DILUTION CREDIT is granted for toxicity, then the undiluted effluent shall be used as the IWC.

The dry weather DILUTION RATIO shall be determined using the parameters specified in Table 3. A wet weather DILUTION RATIO may be granted if justified in the NPDES Permit Fact Sheet based on available data provided in the permit application.

Commented [A62]: This provides no consideration of seasons. Either the objectives should have seasonality or the dilution ratio should reflect seasons since there is more available dilution during wet season. Failure to include this makes the requirements more stringent than necessary to protect the beneficial uses and water quality.

Table 3: Parameters for Calculating a Dry Weather Dilution Ratio

In Calculating A DILUTION RATIO For:	Use the Critical Low Flow Of The Upstream Receiving Water Of:	Use the Discharge Effluent Flow Of:
Acute Toxicity Objective	Lowest flow that occurs for one day with a statistical frequency of once every 10 years	Maximum daily flow (i.e., the maximum flow sample of all samples collected in a calendar day) during period of discharge.
Chronic Toxicity Objective	The average low flow that occurs for seven consecutive days with a statistical frequency of once every 10 years.	Four-day average of daily maximum flows (i.e., the average of daily maximums taken from the data set in four-day intervals.) during period of discharge.

e. Effluent Limitation Provisions

i. Chronic Toxicity Effluent Limitations and Numeric Triggers

(A) Chronic Toxicity ~~MDEL~~

~~“There shall be no chronic toxicity in receiving waters (outside any allowable mixing zone) as a result of the discharge.” Except when the MOST SENSITIVE SPECIES does not include the survival ENDPOINT the The PERMITTING AUTHORITY shall include the following MDEL-effluent limitation in the NPDES permit if REASONABLE POTENTIAL is demonstrated 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:~~

~~“No (MOST SENSITIVE SPECIES) CHRONIC TOXICITY TEST shall result in a “fail” at the IWC for the sub-lethal ENDPOINT measured in the test and a PERCENT EFFECT for the survival ENDPOINT greater than or equal to 50 percent.”~~

~~If the MOST SENSITIVE SPECIES CHRONIC TOXICITY TEST does not include the survival ENDPOINT, then the PERMITTING AUTHORITY shall include the following MDEL:~~

~~“No (MOST SENSITIVE SPECIES) CHRONIC TOXICITY TEST shall result in a “fail” at the IWC for any sub-lethal ENDPOINT measured in the test and a PERCENT EFFECT for that sub-lethal ENDPOINT greater than or equal to 50 percent.”~~

In addition, all NPDES permit shall specify a numeric monitoring trigger (which may include a DILUTION CREDIT).

The PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES and the IWC numeric trigger in the NPDES permit. Exceedance of a numeric trigger requires additional COMPLIANCE TESTS. A More than one exceedance of a numeric trigger in a SIX WEEK period MDEL violation may require the implementation of a TRE in accordance with the provisions of Section IV.B.2.f.

~~(B) Chronic Toxicity MDEL~~

~~The PERMITTING AUTHORITY shall include the following MDEL in the NPDES permit if REASONABLE POTENTIAL is demonstrated 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:~~

~~“No more than one (MOST SENSITIVE SPECIES) CHRONIC TOXICITY TEST initiated in a CALENDAR MONTH may result in a “fail” at the IWC for any ENDPOINT.”~~

~~The PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES and the IWC in the NPDES permit. A MDEL violation may require the implementation of a TRE, in accordance with the provisions of Section IV.B.2.f.~~

ii. Acute Toxicity Effluent Limitations

~~(A) Acute Toxicity MDEL~~

THE PERMITTING AUTHORITY shall include the following MDEL in the NPDES permit if REASONABLE POTENTIAL is demonstrated for acute toxicity:

~~“There shall be no acute toxicity in receiving waters (outside any allowable mixing zone) as a result of the discharge. No (MOST SENSITIVE SPECIES) ACUTE TOXICITY TEST may result in a “fail” at the IWC for the survival ENDPOINT and a PERCENT EFFECT for the survival ENDPOINT greater than or equal to 50 percent.”~~

The PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES and the IWC percent survival in the NPDES permit in accordance with EPA Promulgated Methods. A ~~MDEL~~ violation may require the implementation of a TRE in accordance with the provisions of Section IV.B.2.f.

~~(C) Acute Toxicity MDEL~~

~~THE PERMITTING AUTHORITY shall include the following MMEL in the NPDES permit if REASONABLE POTENTIAL is demonstrated for acute toxicity in accordance with the provisions specified in Section IV.B.2.b: "No more than one (MOST SENSITIVE SPECIES) ACUTE TOXICITY TEST initiated in a CALENDAR MONTH may result in a "fail" at the IWC for the survival ENDPOINT."~~

~~The PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES and the IWC in the NPDES permit. An MMEL violation may require the implementation of a TRE, in accordance with the provisions of Section IV.B.2.f.~~

f. Toxicity Reduction Evaluation

A TRE is required when a NON-STORM WATER NPDES DISCHARGER has any combination of two or more ~~MDEL or MMEL violations~~ numeric trigger exceedances within a single ~~CALENDAR MONTH SIX WEEK period~~ or within two successive CALENDAR MONTHS. In addition, if other information indicates toxicity (e.g., results of additional monitoring, fish kills as a result of the discharge, or intermittent recurring ambient water column toxicity due to the discharge, etc.), then the PERMITTING AUTHORITY ~~shall have discretion to may~~ require a TRE.

The discharger shall conduct a TRE in accordance with a TRE Work Plan as approved by the PERMITTING AUTHORITY. When TREs are required of multiple dischargers, the dischargers may coordinate the TREs with the approval of the PERMITTING AUTHORITY. ROUTINE MONITORING, as specified in Section IV.B.2.c, shall continue during a TRE, although may be at a reduced interval.

Commented [A63]: Where does it say this is required. This should be specified as part of the Provisions – what must be included, what type of actions should be taken, etc.

g. Flow-Through Acute Toxicity Testing Systems

The PERMITTING AUTHORITY may require additional toxicity compliance provisions in the NPDES permit specific to FLOW-THROUGH ACUTE TOXICITY TESTING SYSTEMS, including but not limited to additional effluent limitations or additional monitoring requirements. For existing flow through systems that are not amenable to use of the TST, the PERMITTING AUTHORITY shall specify the statistical analysis and ENDPOINT (e.g., fail/pass, no observed effect concentration (NOEC), IC25, etc.). These additional requirements do not substitute for the toxicity provisions in Section IV.B.2.

Commented [A64]: This lacks clarity. What type of additional limits or monitoring? This fails to meet the statewide consistency goal.

~~If the PERMITTING AUTHORITY requires monitoring with FLOW THROUGH ACUTE TOXICITY TESTING SYSTEMS constructed after the effective date of these TOXICITY PROVISIONS, these FLOW THROUGH ACUTE TOXICITY TESTING SYSTEMS shall be designed to facilitate analysis of results using the TST, and the PERMITTING AUTHORITY shall require analysis of results to be conducted using the TST.~~

Commented [A65]: TST is not an authorized method or statistic unless the discharger or lab obtains an ATP.

h. Additional Monitoring

In addition to effluent limitation compliance monitoring and monitoring specific to FLOW-THROUGH ACUTE TOXICITY TESTING SYSTEMS, the PERMITTING AUTHORITY has the discretion to require dischargers to conduct additional toxicity testing. This testing can include, but is not limited to the following, special studies, additional test species, testing with additional dilutions or higher concentrations of effluent than the IWC where dilution available, or using test species not included in Table 1 of Section IV.B.1.b. ~~The PERMITTING AUTHORITY can require this testing in an NPDES permit or a Water Code section 13383 Order.~~ The rationale for requiring additional monitoring must be documented in the NPDES fact sheet (or equivalent document) ~~or Water Code section 13383 Order.~~

Commented [A66]: Again, all discretion violates goal of statewide consistency.

Commented [A67]: Permits cannot be modified by outside order that do not follow requirements for permit modification.

The PERMITTING AUTHORITY shall specify in the permit the specific type of testing (e.g. the MOST SENSITIVE SPECIES and the concentration of the IWC) that will be used to determine compliance ~~with the MDEL and MMEL.~~ To the extent any of the additional monitoring described above requires the use of receiving water, different species, different effluent concentrations than the IWC, or different test methods, that monitoring cannot be used to determine compliance with the toxicity effluent limitations specified in Section IV.B.2.e.

i. Violation Reporting

All toxicity tests of the MOST SENSITIVE SPECIES at the IWC shall be used for determining compliance with any toxicity ~~MDEL or MMEL numeric triggers~~ contained in the discharger's permit. NON-STORM WATER NPDES DISCHARGERS shall notify the PERMITTING AUTHORITY of any ~~exceedance violation~~ of a toxicity ~~MDEL or MMEL trigger~~ as soon as the discharger learns of the ~~violation-exceedance~~, but no later than 24 hours of the discharger receiving the monitoring results.

j. Exceptions

i. Small Disadvantaged Communities

The PERMITTING AUTHORITY is authorized to exempt POTWs only serving SMALL DISADVANTAGED COMMUNITIES from some or all of the provisions of Section IV.B.2 if the PERMITTING AUTHORITY makes a finding that the discharge will have no REASONABLE POTENTIAL to cause or contribute to an exceedance of the toxicity water quality objectives. The REASONABLE POTENTIAL conclusion necessary to exempt SMALL DISADVANTAGED COMMUNITIES need not be based on the REASONABLE POTENTIAL analysis methods set forth in Section IV.B.2.b. For POTWs only serving SMALL DISADVANTAGED COMMUNITIES that do not have an effluent discharge prior to permit issuance, reissuance, renewal, or reopening (to address toxicity requirements) that is representative of the quality of the proposed discharge, the PERMITTING AUTHORITY is authorized to require only monitoring, and make this determination and exempt the POTW only after the first year of effluent discharge.

Commented [A68]: Who would this apply to when the RP test is set at 10% effect, which is much more likely to not be actual toxicity. RP should be the same as the compliance determination point as to percent effect. There is no justification for a lower percentage for RP determination.

If exempt, the PERMITTING AUTHORITY shall include the water quality objectives in Section III.B.2 as a receiving water limitation in the NPDES permit and the PERMITTING AUTHORITY shall have the discretion to assign ROUTINE MONITORING as necessary. ROUTINE MONITORING schedules for POTWs only serving SMALL DISADVANTAGED COMMUNITIES shall not exceed the applicable frequency specified in Section IV.B.2.c for the discharger's authorized rate of discharge.

ii. Insignificant Discharges

The PERMITTING AUTHORITY is authorized to exempt certain NON-STORM WATER NPDES DISCHARGERS, including water reclamation plants (even those over 5 MGD) from some or all of the provisions of Section IV.B.2 if the PERMITTING AUTHORITY makes a finding that the discharge will have no REASONABLE POTENTIAL to cause or contribute to an exceedance of the toxicity water quality objectives. The REASONABLE POTENTIAL conclusion necessary to exempt INSIGNIFICANT DISCHARGES need not be based on the REASONABLE POTENTIAL analysis methods set forth in Section IV.B.2.b.

If exempt, the PERMITTING AUTHORITY shall include the water quality objectives in Section III.B.2 as a receiving water limitation in the NPDES permit and the PERMITTING AUTHORITY shall have the discretion to assign ROUTINE MONITORING as necessary. ROUTINE MONITORING schedules for INSIGNIFICANT DISCHARGES shall not exceed the applicable frequency specified in Section IV.B.2.c for the discharger's authorized rate of discharge.

3. Implementation for Storm Water Dischargers Regulated Pursuant to NPDES Permits

The PERMITTING AUTHORITY shall have discretion to require toxicity monitoring using any EPA promulgated test method. ~~For all STORM WATER dischargers with existing chronic or acute toxicity monitoring requirements with test methods described in Section IV.B.1.b, the PERMITTING AUTHORITY shall issue Water Code section 13267 or 13383 Orders within one year of the effective date of these TOXICITY PROVISIONS that requires the statistical approach, percent effect, and reporting to be conducted in accordance with Section IV.B.1.c, IV.B.1.d, & IV.B.1.e commencing within one year from the date of the Order.~~

If after the effective date of these TOXICITY PROVISIONS, the PERMITTING AUTHORITY issues new or reissued chronic or acute toxicity monitoring requirements with test methods described in Section IV.B.1.b, then the PERMITTING AUTHORITY shall require the statistical approach, percent effect, and reporting to be conducted in accordance with Section IV.B.1.c, IV.B.1.d, and IV.B.1.e.

The PERMITTING AUTHORITY shall have discretion to require test methods not described in Section IV.B.1.b, except as required by federal law. This determination must be documented in the NPDES fact sheet (or equivalent document) ~~or Water Code section 13267 or 13383 Order~~. Multi-concentration testing is not required except to the extent required by federal law or specified by the PERMITTING AUTHORITY.

Commented [A69]: Permits cannot be modified by separate order, and previously issued permits that improperly included TST should not be authorized post hoc by this policy.

Commented [A70]: Again, promoting inconsistency contrary to one of the main goals of the policy.

Commented [A71]: For non-receiving water tests, five concentrations plus a control are required.

4. Implementation for Nonpoint Source and Other Non-NPDES Dischargers

~~The PERMITTING AUTHORITY shall have discretion to require toxicity monitoring using any test method. For all NONPOINT SOURCE and other non-NPDES dischargers with existing chronic or acute toxicity monitoring requirements with test methods described in Section IV.B.1.b, the PERMITTING AUTHORITY shall issue a Water Code section 13267 Order within one year of the effective date of these TOXICITY PROVISIONS that requires the statistical approach, percent effect, and reporting to be conducted in accordance with Section IV.B.1.c, IV.B.1.d, and IV.B.1.e, commencing within one year from the date of the Order.~~

Commented [A72]: Discharges to land do not require toxicity testing. Discharges to surface waters should be consistent with other dischargers.

Commented [A73]: WDRs must be modified to make these changes as WDRs cannot be modified by separate order.

~~If a~~ After the effective date of these TOXICITY PROVISIONS, ~~if~~ the PERMITTING AUTHORITY issues new or renewed chronic or acute toxicity monitoring requirements with test methods described in Section IV.B.1.b, then the PERMITTING AUTHORITY shall require the statistical approach, percent effect, and reporting to be conducted in accordance with Section IV.B.1.c, IV.B.1.d, & IV.B.1.e.

~~The PERMITTING AUTHORITY shall have discretion to require test methods not described in Section IV. B.1.b, except as required by federal law. This determination must be documented in the WDR (or equivalent document) or Water Code section 13267 Order. Multi-concentration testing is not required except to the extent required by federal law or specified by the PERMITTING AUTHORITY.~~

5. Variances and Exceptions to the Toxicity Water Quality Objectives

a. Waters of the U.S.

The PERMITTING AUTHORITY may, in compliance with CEQA, and subsequent to a public hearing, grant a variance to the ~~numeric and narrative~~ water quality objectives for toxicity. Water quality standard variances are subject to review and approval of the U.S. EPA, in accordance with Code of Federal Regulations, Title 40, section 131.14. {Note: This paragraph or similar provision may be added as part of an earlier amendment to the ISWEBE.}

Commented [A74]: Need to specify if a variance is needed for the Aquatic Herbicide/Pesticide Permit.

b. Waters of the State That are Not Also Waters of the U.S.

The PERMITTING AUTHORITY may, after compliance with CEQA, allow ~~short-term or seasonal~~ exceptions from meeting ~~numeric and narrative~~ water quality objectives for toxicity if determined to be necessary to implement control measures for resource or pest management (e.g., vector or weed control, pest eradication, or fishery management) conducted by public entities.

Commented [A75]: This needs to be described with clarity.

Commented [A76]: Seasonality should be included in the objectives and/or dilution credits.

The discharger shall notify potentially affected members of the public and governmental agencies. Also, the discharger shall submit to the PERMITTING AUTHORITY all of the following:

- 1) A detailed description of the proposed action, including the proposed method of completing the action;

- 2) A time schedule;
- 3) A discharge and receiving water quality monitoring plan (before project initiation, during the project, and after project completion, with the appropriate quality assurance and quality control procedures);
- 4) CEQA documentation;
- 5) Contingency plans;
- 6) Identification of alternate water supply (if needed); and
- 7) Residual waste disposal plans.

Additionally, upon completion of the project, the discharger shall provide certification by a qualified biologist that the receiving water beneficial uses have been protected and/or restored. A qualified biologist is a biologist ~~who has~~with the knowledge and experience in the ecosystem where the resource or pest management control measure is implemented ~~so that he or she can~~to adequately evaluate whether the beneficial uses of the receiving waters have been protected and/or restored upon completion of the project.

Commented [A77]: Why is this specified when this is not a human health concern? This confuses the different beneficial uses.

APPENDIX A: Glossary

ACUTE TOXICITY TEST: A test to determine an adverse effect (usually lethality) on a group of test organisms during a short-term exposure (e.g. 24, 48, or 96 hours).

Commented [A78]: This should be specified for consistency. Usually, this is 96 hours.

~~ALTERNATIVE HYPOTHESIS: A statement used to propose a statistically significant relationship in a set of given observations. Under the TST approach, when the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, indicating a relationship between variables and an acceptable level of toxicity.~~

AQUATIC LIFE: Aquatic life refers to aquatic organisms.

CALENDAR MONTH(S): A period of time from a day of one month to the day before the corresponding day of the next month if the corresponding day exists, or if not to the last day of the next month (e.g., from January 1 to January 31, from June 15 to July 14, or from January 31 to February 28).

CALENDAR QUARTER: A period of time defined as three consecutive CALENDAR MONTHS.

CALENDAR YEAR: A period of time defined as twelve consecutive CALENDAR MONTHS.

CHRONIC TOXICITY TEST: A test to determine an adverse effect (sub-lethal or lethal) on a group of test organisms during an exposure of duration long enough to assess sub-lethal effects.

CONTINUOUS DISCHARGERS: Facilities that discharge without interruption throughout its operating hours, except for infrequent shutdowns for maintenance, process changes, or other similar activities, and that discharge throughout the CALENDAR YEAR.

DILUTION CREDIT: The amount of dilution granted to a discharge in the calculation of a water quality-based effluent limitation, based on the allowance of a specified MIXING ZONE. It is calculated from the DILUTION RATIO or determined through conducting a MIXING ZONE study or modeling of the discharge and the receiving water.

DILUTION RATIO: The critical low flow of the upstream receiving water divided by the flow of the effluent discharged.

ENCLOSED BAYS: Indentations along the coast that enclose an area of oceanic water within distinct headlands or harbor works. ENCLOSED BAYS include all bays where the narrowest distance between headlands or outermost harbor works is less than 75 percent of the greatest dimension of the enclosed portion of the bay. This definition includes, but is not limited to: Humboldt Bay, Bodega Harbor, Tomales Bay, Drakes Estero, San Francisco Bay, Morro Bay, Los Angeles Harbor, Upper and Lower Newport Bay, Mission Bay, and San Diego Bay.

BIOLOGICAL ENDPOINT: Reproduction, growth, or survival.

TEST ENDPOINT: A measured RESPONSE of a receptor to a stressor. A ~~test~~ endpoint can be measured in a toxicity test or field survey. Promulgated endpoints include NOEC/LOEC and IC/EC25 for chronic toxicity, and LC50 for acute toxicity.

ESTUARIES and COASTAL LAGOONS: Waters at the mouths of streams where fresh and OCEAN WATERS mix during a portion of the year. Mouths of streams that are temporarily separated from the ocean by sandbars shall be considered as estuaries. Estuarine waters will generally be considered to extend from a bay or the open ocean to the upstream limit of tidal action, but it may be considered to extend seaward if significant mixing of fresh and salt water occurs in the open coastal waters. The waters described by this definition include, but are not limited to, the Sacramento-San Joaquin Delta as defined by Water Code section 12220, Suisun Bay, Carquinez Strait downstream to Carquinez Bridge, and appropriate areas of the Smith, Klamath, Mad, Eel, Noyo, and Russian Rivers.

FLOW-THROUGH ACUTE TOXICITY TESTING SYSTEMS: A toxicity testing system where an effluent sample is either pumped continuously from the sampling point directly to a dilutor system, or collected and placed in a tank adjacent to the test laboratory and pumped continuously from the tank to a dilutor system.

INLAND SURFACE WATERS: All surface waters of the state (including waters of the United States) that do not include the ocean, ENCLOSED BAYS, or ESTUARIES AND COASTAL LAGOONS.

INSIGNIFICANT DISCHARGES: NPDES discharges, ~~including water reclamation plants, that are~~ determined to be a very low threat to water quality by the PERMITTING AUTHORITY.

INSTREAM WASTE CONCENTRATION (IWC): The concentration of effluent in the receiving water after mixing as determined by the PERMITTING AUTHORITY. For purposes of aquatic toxicity, when a MIXING ZONE and DILUTION CREDIT are granted for a NON-STORMWATER NPDES DISCHARGER, the IWC shall be determined as indicated in Section IV.B.2.d. For a NON-STORMWATER NPDES DISCHARGER, if no MIXING ZONE is allocated, then the undiluted effluent (100 percent) shall be used as the IWC. For assessing whether receiving waters meet the numeric water quality objectives, the undiluted ambient water shall be used as the IWC ~~in the TEST OF SIGNIFICANT TOXICITY (TST)~~ as indicated in Section IV.B.1.c.

~~MAXIMUM DAILY EFFLUENT LIMITATION (MDEL): For the purposes of chronic and acute aquatic toxicity, an MDEL is an effluent limitation based on the outcome of the TEST OF SIGNIFICANT TOXICITY (TST) approach and the resulting PERCENT EFFECT at the IWC, as described in Section IV.B.2.e.~~

~~MEDIAN MONTHLY EFFLUENT LIMITATION (MMEL): For the purposes of chronic and acute aquatic toxicity, an MMEL is an effluent limitation based on a maximum of three independent toxicity tests, analyzed using the TST, as described in Section IV.B.2.e.~~

~~MMEL COMPLIANCE TESTS: For the purposes of chronic and acute aquatic toxicity, MMEL COMPLIANCE TESTS are a maximum of two tests that are used in addition to the ROUTINE MONITORING test to determine compliance with the chronic and acute toxicity MMEL triggers to determine if a TRE is required to address the toxicity discovered.~~

MIXING ZONE: A limited zone within a receiving water ~~that is~~ allocated for mixing with a wastewater discharge where a water quality objective can be exceeded without causing adverse effects to the overall water body.

MOST SENSITIVE SPECIES: The single species selected from an array of test species to be used in a single species laboratory test series to determine toxic effects of effluent or ambient water.

NON-CONTINUOUS DISCHARGERS: Facilities that do not discharge in a continuous manner or do not discharge throughout the CALENDAR YEAR (e.g. intermittent and seasonal dischargers).

NON-STORM WATER NPDES DISCHARGERS: Dischargers that are regulated pursuant to one or more NPDES permit(s), but excluding any discharges subject to the United States Code title 33 section 1342(p). This includes dischargers that discharge a combination of treated municipal or industrial waste water and storm water.

NONPOINT SOURCES: Sources that do not meet the definition of a POINT SOURCE, as defined below.

~~NULL HYPOTHESIS: A statement used in statistical testing that has been put forward either because it is believed to be true or because it is to be used as a basis for argument, but has not been proved.~~

OCEAN WATERS: The territorial marine waters of the state, as defined by California law, to the extent these waters are outside of ENCLOSED BAYS, ESTUARIES, and COASTAL LAGOONS. Discharges to OCEAN WATERS are regulated in accordance with the State Water Board's California Ocean Plan.

PERCENT EFFECT: The value that denotes the difference in RESPONSE between the test concentration and the control, divided by the mean control RESPONSE, and multiplied by 100.

PERMITTING AUTHORITY: The State Water Board or a regional water board that issues a permit, waste discharge requirements, water quality certification, or other authorization for the discharge or proposed discharge of waste. To the extent that the action is delegable, the term "Permitting Authority" can include the Executive Officer or Executive Director.

POINT SOURCE: Any discernible, confined and discrete conveyance including, but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which POLLUTANTS are or may be discharged. This term does not include agricultural storm water discharges and return flows from irrigated agriculture.

POLLUTANT: Defined in section 502(6) of the CWA as "dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water."

PUBLICLY OWNED TREATMENT WORKS (POTW): Facilities owned by a state or municipality that store, treat, recycle, and reclaim municipal sewage or industrial wastes of a liquid nature. Similar facilities that are privately, instead of publicly owned, are included in this definition for purposes of Section IV.B.

REASONABLE POTENTIAL: A designation used for a waste discharge ~~that is~~ projected or calculated to cause or contribute to an instream excursion above a water quality standard.

REGULATORY MANAGEMENT DECISION (RMD): The decision that represents the maximum allowable error rates and thresholds for toxicity and non-toxicity that would result in an acceptable risk to AQUATIC LIFE.

Commented [A79]: Since 25% was selected as acceptable risk, there is no justification to use less for RP.

REPLICATES: Two or more independent organism exposures of the same treatment (i.e. effluent concentration) within a toxicity test. REPLICATES are typically conducted with separate test chambers and test organisms, each having the same effluent concentration.

RESPONSE (also BIOLOGICAL ENDPOINT): A measured biological effect (e.g., survival, reproduction, growth) as a result of exposure to a stimulus.

ROUTINE MONITORING: Required monitoring that occurs during a permit term. For purposes of Section IV.B.2, ROUTINE MONITORING refers to the required toxicity testing described in Section IV.B.2.c, and is used to determine violations of the MDEL, and is used with MMEL COMPLIANCE TESTS to determine violations of the MMEL.

SMALL DISADVANTAGED COMMUNITIES: Municipalities with populations of 20,000 persons or less, or a reasonably isolated and divisible segment of a larger municipality encompassing 20,000 persons or less, with an annual median household income ~~that is~~ less than 80 percent of the statewide annual median household income.

SPECIES SENSITIVITY SCREENING: An analysis to determine the single MOST SENSITIVE SPECIES from an array of test species to be used in a single species laboratory test series.

STORM WATER: Same meaning set forth in 40 Code of Federal Regulations section 122.26(b)(13) (Nov. 16, 1990).

Commented [A80]: Should just include the definition from this regulation so people don't have to go find the definition elsewhere.

TEST OF SIGNIFICANT TOXICITY (TST): An unpromulgated statistical approach that cannot be used to analyze aquatic toxicity test data, as described in Section IV.B.1.c, unless an Alternative Test Procedure (ATP) is issued to a discharger or laboratory allowing its use as a supplemental test method.

TOXICITY IDENTIFICATION EVALUATIONS (TIEs): Techniques used to identify the unexplained cause(s) of toxic event. TIE involves selectively removing classes of chemicals through a series of sample manipulations, effectively reducing complex mixtures of chemicals in natural waters to simple components for analysis. Following each manipulation, the toxicity sample is assessed to see whether the toxicant class removed was responsible for the toxicity.

Commented [A81]: There are no provisions of the policy that address TIEs even though this is an important step in determining the cause of toxicity. Instead of assessing violations, more guidance on TIEs should be included.

TOXICITY PROVISIONS: Refers to Section III.B and Section IV.B of the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California (Plan)

TOXICITY REDUCTION EVALUATION (TRE): A study conducted in a step-wise process designed to identify the causative agents of effluent or ambient toxicity, isolate the sources of toxicity, evaluate the effectiveness of toxicity control options, and then confirm the reduction in toxicity. A TIE may be required as part of the TRE, if appropriate.

Commented [A82]: This appears to be the only discussion of TIEs, which seems odd if the purpose of the policy is to reduce toxicity and not just assess violations.

APPENDIX B: Examples of Compliance Determination for Toxicity Effluent Limitations

Chronic *Ceriodaphnia dubia* test, example 1.

Step 1: Conduct the aquatic toxicity test according to the procedures in the appropriate test method manual, as described in Section IV. B.1.b of the Provisions. The corresponding results are reported below and used for the following example calculations.

Replicate/Statistic	Control Reproduction	Control Survival	IWC Reproduction	IWC Survival
1	29	1	31	1
2	38	1	28	1
3	31	1	25	1
4	34	1	28	1
5	36	1	22	1
6	35	1	21	1
7	30	1	27	1
8	31	1	26	1
9	36	1	29	1
10	34	1	30	1
Mean	33.4	1	26.7	1
Standard Deviation	2.989	0	3.268	0
# of REPLICATES (n)	10	10	10	10

Step 2: Determine if there is no variance in the ENDPOINT for each concentration. If there is no variance in both concentrations being compared, compute the PERCENT EFFECT as described in Section IV.B.1.d of the Provisions.

If there is variance in the ENDPOINT in both concentrations, then proceed with Steps 3-7.

For this example, the reproduction ENDPOINT would be used in the TST calculation. Both the Control and the IWC reproduction data have a standard deviation greater than 0 (i.e., both concentrations do have variance), so step 2 is not relevant and proceed to step 3.

Step 3: Calculate the mean RESPONSE for both concentrations and determine if an arcsine square root transformation is necessary.

Because reproduction data are not proportions of a binary response, this step is not necessary. Proceed to step 4.

Step 4: Conduct Welch's t-test, in this case for reproduction

Commented [A83]: Example 1 and Example 2 show the entire statistical analysis being based on only two test concentrations: the control and the IWC. However, the promulgated method requires all WET tests performed pursuant to an NPDES permit to analyze a control and FIVE effluent concentrations (one of which is the IWC). These examples prove conclusively that the TST procedure is a new method because it makes no use whatsoever of data that EPA says must be collected and evaluated in order to determine toxicity.

$$t = \frac{\bar{Y}_t - b \times \bar{Y}_c}{\sqrt{\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}}} = \frac{26.7 - (0.75 \times 33.4)}{\sqrt{\frac{10.68}{10} + \frac{(0.75)^2 (8.93)}{10}}} = 1.32$$

Step 5: Adjust the degrees of freedom.

$$v = \frac{\left(\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}\right)^2}{\frac{\left(\frac{S_t^2}{n_t}\right)^2}{n_t - 1} + \frac{\left(\frac{b^2 S_c^2}{n_c}\right)^2}{n_c - 1}} = \frac{\left(\frac{10.68}{10} + \frac{(0.75)^2 (8.93)}{10}\right)^2}{\frac{(10.68)^2}{10 - 1} + \frac{((0.75)^2 (8.93))^2}{10 - 1}} = 15$$

Step 6: Compare the calculated t-value with the critical t-value:

Given 15 degrees of freedom and an alpha level set at 0.20, the critical t-value = 0.87 (obtained from Table 2 in the Provisions). The calculated t-value from step 4 = 1.32, which is greater than the critical t-value of 0.87.

Step 7: 1.32 > 0.87 = pass

The calculated t-value (1.32) is greater than the critical t-value (0.87), so the NULL HYPOTHESIS is rejected, and the test result is a "pass".

Conclusion: The test in example 1 indicates compliance with both the MDEL and the MMEL.

Reporting: Calculate the PERCENT EFFECT for all endpoints and report as required by Section IV.B.1.d of the Provisions.

$$\text{Reproduction \% Effect at IWC} = \frac{33.4 - 26.7}{33.4} \cdot 100 = 20.1\%$$

$$\text{Survival \% Effect at IWC} = \frac{1 - 1}{1} \cdot 100 = 0\%$$

Commented [A84]: In this example, a 20.1% effect is deemed to be a pass. However, in a different test, the same result may be deemed a "fail" depending on the amount of statistical variability in the underlying data. This is a major change from what occurs when using EPA's preferred statistical procedure (IC25) where effects above 25% are always a fail and effects below 25% are always a pass regardless of the amount of variability in the underlying data.

Commented [A85]: EPA's preferred statistical procedure (IC25) would also have called example #1 a pass. Where is the benefit to using the TST?

Chronic *Ceriodaphnia dubia* test, example 2.

Step 1: Conduct the aquatic toxicity test according to the procedures in the appropriate test method manual, as described in Section IV. B.1.b of the Provisions. The corresponding results are reported below and used for the following example calculations.

Commented [A86]: The problem with the two *Ceriodaphnia dubia* examples is that they imply that when the percent effect is <25% the test will pass (Example 1) and when it is >25% the test will fail (Example 2). However, data from the Test Drive Study shows that about 9% of the *Ceriodaphnia dubia* reproduction tests failed the TST even though the percent effect was less than the 25% RMD threshold.

Replicate/Statistic	Control Reproduction	Control Survival	IWC Reproduction	IWC Survival
1	29	1	19	1
2	38	1	18	0
3	31	1	6	0
4	34	1	11	0
5	36	1	20	1
6	35	1	10	0
7	30	1	18	1
8	31	1	32	1
9	36	1	25	1
10	34	1	18	0
Mean	33.4	1	17.70	0.5
Standard Deviation	2.989	0	7.499	0.5
# of REPLICATES (n)	10	10	10	10

Step 2: Determine if there is no variance in the ENDPOINT for each concentration. If there is no variance in both concentrations being compared, compute the PRECENT EFFECT as described in Section IV.B.1.d of the Provisions.

If there is variance in the ENDPOINT in both concentrations, then proceed with Steps 3-7.

For this example, the reproduction ENDPOINT would be used in the TST calculation. Both the Control and the IWC reproduction data have a standard deviation greater than 0 (i.e., both concentrations do have variance), so step 2 is not relevant and proceed to step 3.

Step 3: Calculate the mean RESPONSE for both concentrations and determine if an arcsine square root transformation is necessary.

Because reproduction data are not proportions of a binary response, this step is not necessary. Proceed to step 4.

Step 4: Conduct Welch's t-test.

$$t = \frac{\bar{Y}_t - b \times \bar{Y}_c}{\sqrt{\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}}} = \frac{17.70 - (0.75 \times 7.499)}{\sqrt{\frac{56.24}{10} + \frac{(0.75)^2 (8.93)}{10}}} = -2.9696$$

Step 5: Adjust the degrees of freedom.

$$v = \frac{\left(\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}\right)^2}{\frac{\left(\frac{S_t^2}{n_t}\right)^2}{n_t - 1} + \frac{\left(\frac{b^2 S_c^2}{n_c}\right)^2}{n_c - 1}} = \frac{\left(\frac{56.24}{10} + \frac{(0.75)^2(8.93)^2}{10}\right)^2}{\frac{\left(\frac{56.24}{10}\right)^2}{10 - 1} + \frac{\left(\frac{(0.75)^2(8.93)^2}{10}\right)^2}{10 - 1}} = 10$$

Step 6: Compare the calculated t-value with the critical t-value:

Given 10 degrees of freedom and an alpha level set at 0.20, the critical t-value = 0.8791 (obtained from Table 2 in these Provisions). The calculated t-value from step 4 = -2.9696, which is less than the critical t-value of 0.8791.

Step 7: -2.9696 < 0.8791 = fail

The calculated t-value (-2.9696) is less than the critical t-value (0.8791), so the NULL HYPOTHESIS is not rejected, and the test result is a “fail”.

Conclusion: Because the test in example 2 resulted in a “fail”, up to 2 more MMEL compliance tests would need to be conducted to determine compliance with the MMEL. In addition, because the *Ceriodaphnia dubia* test does include a survival ENDPOINT, the percent effect for the survival ENDPOINT must be calculated to determine compliance with the MDEL (see Reporting section below).

Reporting: Calculate the PERCENT EFFECT for all endpoints and report as required by Section IV.B.1.d of the Provisions.

Commented [A87]: The promulgated method would have also called Example 2 a fail. Where is the benefit to using TST?

$$\text{Reproduction \% Effect at IWC} = \frac{33.4 - 17.70}{33.4} \cdot 100 = 47.0\%$$

$$\text{Survival \% Effect at IWC} = \frac{1 - 0.5}{1} \cdot 100 = 50\%$$

Conclusion: Because the percent effect at the IWC for the survival ENDPOINT is greater than 50% and the test result was a “fail”, the test in example 2 indicates a violation of the MDEL.

Acute fish survival test

Step 1: Conduct the aquatic toxicity test according to the procedures in the appropriate test method manual, as described in Section IV. B.1.b of the Provisions. The corresponding results are reported below, and used for the following example calculations.

Replicate/Statistic	Control	IWC
1	10	7
2	10	8
3	10	8
4	10	9
Mean	10	8
Standard Deviation	0.000	0.816
# of REPLICATES (n)	4	4

Step 2: Determine if there is no variance in the ENDPOINT for each concentration. If there is no variance in both concentrations being compared, compute the PRECENT EFFECT as described in Section IV.B.1.d of the Provisions.

If there is variance in the ENDPOINT in both concentrations, then proceed with Steps 3-7.

In this example, the survival ENDPOINT would be used in the TST calculation. The IWC data has variance (i.e., standard deviation greater than zero), so step 2 is not relevant and proceed to step 3.

Step 3: Calculate the mean RESPONSE for both concentrations and determine if an arcsine square root transformation is necessary.

For this example, survival data are a proportion of a binary response variable, so the data must be transformed using the arcsine square root transformation before calculating the mean RESPONSE for the control and the IWC.

Arcsine square root transformed data

Replicate/Statistic	Control	Treatment
1	1.412	0.991
2	1.412	1.107
3	1.412	1.107
4	1.412	1.249
Mean	1.412	1.11
Standard Deviation	0.000	0.106
# of REPLICATES (n)	4	4

Use the transformed data in the table above for the calculations in steps 4-7.

Step 4: Conduct Welch's t-test.

$$t = \frac{\bar{Y}_t - b \times \bar{Y}_c}{\sqrt{\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}}} = \frac{1.111 - (0.80 \times 1.412)}{\sqrt{\frac{0.027}{4} + \frac{(0.80)^2 (0.00)}{4}}} = -0.03$$

Step 5: Adjust the degrees of freedom.

$$v = \frac{\left(\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}\right)^2}{\frac{\left(\frac{S_t^2}{n_t}\right)^2}{n_t - 1} + \frac{\left(\frac{b^2 S_c^2}{n_c}\right)^2}{n_c - 1}} = \frac{\left(\frac{0.027}{4} + \frac{(0.80)^2 (0.00)}{4}\right)^2}{\frac{\left(\frac{0.027}{4}\right)^2}{4 - 1} + \frac{\left(\frac{(0.80)^2 (0.00)}{4}\right)^2}{4 - 1}} = 3$$

Step 6: Compare the calculated t-value with the critical t-value:

Given 3 degrees of freedom and an alpha level set at 0.10, the critical t-value = 1.64 (obtained from Table 2 in these Provisions). The calculated t-value from step 4 = -0.03, which is less than the critical t-value of 1.64.

Step 7: -0.03 < 1.64 = fail.

The calculated t-value (-0.03) is less than the critical t-value (1.64), so the NULL HYPOTHESIS is not rejected, and the test result is a "fail".

Conclusion: Because the test in example 3 resulted in a "fail", up to 2 more MMEL compliance tests would need to be conducted to determine compliance with the MMEL. In addition, because the acute fish survival test does include a survival ENDPOINT, the percent effect for the survival ENDPOINT must be calculated to determine compliance with the MDEL (see Reporting section below).

Reporting: Calculate the PERCENT EFFECT for all endpoints and report as required by Section IV.B.1.d of the Provisions

$$\% \text{ Effect at IWC} = \frac{10 - 8}{10} \cdot 100 = 20\%$$

Conclusion: Because the percent effect at the IWC for the survival ENDPOINT is less than 50%, the test in example 3 indicates compliance with the MDEL.

Commented [A88]: The TST called this test a "fail" despite the fact that the measured 20% effect was LESS than the 25% RMD threshold. The test failed only because the effluent was initially presumed to be toxic not because the data showed there was actually an unacceptable level of adverse effect.

Commented [A89]: EPA's preferred statistical technique (IC25) would have deemed this test to "pass." Moreover, 80% survival is within the normal range deemed acceptable for valid control performance. It is unreasonable to subsequently construe that same level of performance as an indication of effluent toxicity when it is something that can and does happen due solely to natural biological variability in the standard test organisms.

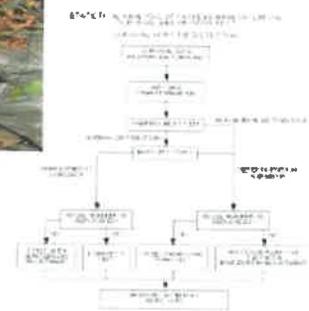
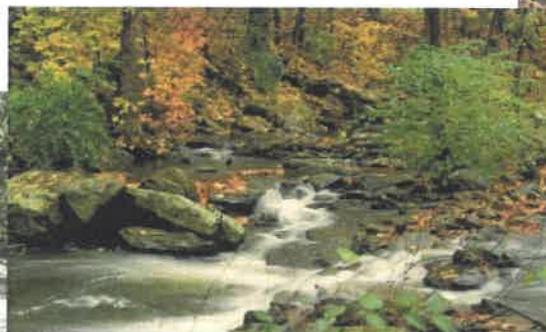
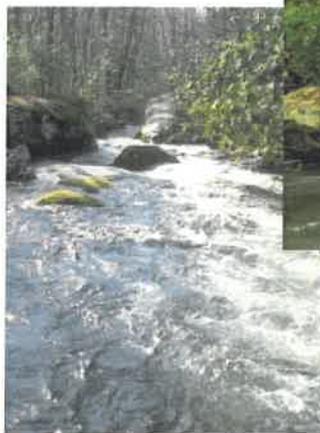
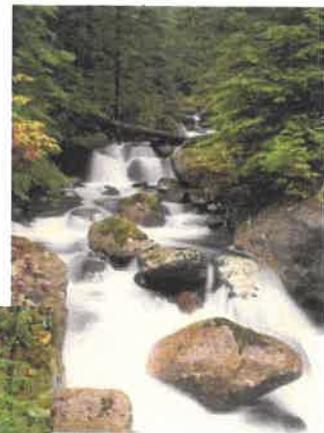
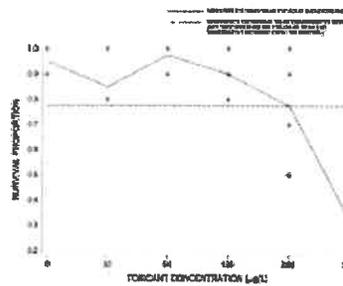
ATTACHMENT 2.



Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms

Fourth Edition

October 2002



2.1.16 The use of short-term toxicity tests including subchronic and chronic tests in the NPDES Program is especially attractive because they provide a more direct estimate of the safe concentrations of effluents in receiving waters than was provided by acute toxicity tests, at an only slightly increased level of effort, compared to the fish full life-cycle chronic and 28-day ELS tests and the 21-day daphnid, *Daphnia magna*, life-cycle test.

2.2 TYPES OF TESTS

2.2.1 The selection of the test type will depend on the NPDES permit requirements, the objectives of the test, the available resources, the requirements of the test organisms, and effluent characteristics such as fluctuations in effluent toxicity.

2.2.2 Effluent chronic toxicity is generally measured using a multi-concentration, or definitive test, consisting of a control and a minimum of five effluent concentrations. The tests are designed to provide dose-response information, expressed as the percent effluent concentration that affects the hatchability, gross morphological abnormalities, survival, growth, and/or reproduction within the prescribed period of time (four to seven days). The results of the tests are expressed in terms of the highest concentration that has no statistically significant observed effect on those responses when compared to the controls or the estimated concentration that causes a specified percent reduction in responses versus the controls.

2.2.3 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**. If the NPDES permit has a whole effluent toxicity limit for acute toxicity at the RWC, it is prudent to use that permit limit as the midpoint of a series of five effluent concentrations. This will ensure that there is sufficient information on the dose-response relationship. For example, the effluent concentrations utilized in a test may be: (1) 100% effluent, (2) $(RWC + 100)/2$, (3) RWC, (4) $RWC/2$, and (5) $RWC/4$. More specifically, if the RWC = 50%, appropriate effluent concentrations may be 100%, 75%, 50%, 25%, and 12.5%.

2.2.4 Receiving (ambient) water toxicity tests commonly employ two treatments, a control and the undiluted receiving water, but may also consist of a series of receiving water dilutions.

2.2.5 A negative result from a chronic toxicity test does not preclude the presence of toxicity. Also, because of the potential temporal variability in the toxicity of effluents, a negative test result with a particular sample does not preclude the possibility that samples collected at some other time might exhibit chronic toxicity.

2.2.6 The frequency with which chronic toxicity tests are conducted under a given NPDES permit is determined by the regulatory agency on the basis of factors such as the variability and degree of toxicity of the waste, production schedules, and process changes.

2.2.7 Tests recommended for use in this methods manual may be static non-renewal or static renewal. Individual methods specify which static type of test is to be conducted.

2.3 STATIC TESTS

2.3.1 Static non-renewal tests - The test organisms are exposed to the same test solution for the duration of the test.

2.3.2 Static-renewal tests - The test organisms are exposed to a fresh solution of the same concentration of sample every 24 h or other prescribed interval, either by transferring the test organisms from one test chamber to another, or by replacing all or a portion of solution in the test chambers.

100%, 10.0%, 1.00%, and 0.100%, and a control, for 8-24 h. **Caution:** if the sample must also be used for the full-scale definitive test, the 36-h limit on holding time (see Subsection 8.5.4) must not be exceeded before the definitive test is initiated.

8.9.3 It should be noted that the toxicity (LC50) of a sample observed in a range-finding test may be significantly different from the toxicity observed in the follow-up chronic definitive test because: (1) the definitive test is longer; and (2) the test may be performed with a sample collected at a different time, and possibly differing significantly in the level of toxicity.

8.10 MULTI-CONCENTRATION (DEFINITIVE) EFFLUENT TOXICITY TESTS

8.10.1 The tests recommended for use in determining discharge permit compliance in the NPDES program are multi-concentration, or definitive, tests which provide (1) a point estimate of effluent toxicity in terms of an IC25, IC50, or LC50, or (2) a no-observed-effect-concentration (NOEC) defined in terms of mortality, growth, reproduction, and/or teratogenicity and obtained by hypothesis testing. The tests may be static renewal or static non-renewal.

8.10.2 The tests consist of a control and a minimum of five effluent concentrations. USEPA recommends the use of a ≥ 0.5 dilution factor for selecting effluent test concentrations. Effluent test concentrations of 6.25%, 12.5%, 25%, 50%, and 100% are commonly used, however, test concentrations should be selected independently for each test based on the objective of the study, the expected range of toxicity, the receiving water concentration, and any available historical testing information on the effluent. USEPA (2000a) provides additional guidance on choosing appropriate test concentrations.

8.10.3 When these tests are used in determining compliance with permit limits, effluent test concentrations should be selected to bracket the receiving water concentration. This may be achieved by selecting effluent test concentrations in the following manner: (1) 100% effluent, (2) $[RWC + 100]/2$, (3) RWC, (4) $RWC/2$, and (5) $RWC/4$. For example, where the RWC = 50%, appropriate effluent concentrations may be 100%, 75%, 50%, 25%, and 12.5%.

8.10.4 If acute/chronic ratios are to be determined by simultaneous acute and short-term chronic tests with a single species, using the same sample, both types of tests must use the same test conditions, i.e., pH, temperature, water hardness, salinity, etc.

8.11 RECEIVING WATER TESTS

8.11.1 Receiving water toxicity tests generally consist of 100% receiving water and a control. The total hardness of the control should be comparable to the receiving water.

8.11.2 The data from the two treatments are analyzed by hypothesis testing to determine if test organism survival in the receiving water differs significantly from the control. Four replicates and 10 organisms per replicate are required for each treatment (see Summary of Test Conditions and Test Acceptability Criteria in the specific test method).

8.11.3 In cases where the objective of the test is to estimate the degree of toxicity of the receiving water, a multi-concentration test is performed by preparing dilutions of the receiving water, using a ≥ 0.5 dilution series, with a suitable control water.

9.4.1.2 The statistical methods recommended in this manual are not the only possible methods of statistical analysis. 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. Among alternative hypothesis tests some, like Williams' Test, require additional assumptions, while others, like the bootstrap methods, require computer-intensive computations. Alternative point estimation approaches most probably would require the services of a statistician to determine the appropriateness of the model (goodness of fit), higher order linear or nonlinear models, confidence intervals for estimates generated by inverse regression, etc. In addition, point estimation or regression approaches would require the specification by biologists or toxicologists of some low level of adverse effect that would be deemed acceptable or safe. 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.

9.4.2 PLOTTING THE DATA

9.4.2.1 The data should be plotted, both as a preliminary step to help detect problems and unsuspected trends or patterns in the responses, and as an aid in interpretation of the results. Further discussion and plotted sets of data are included in the methods and the Appendices.

9.4.3 DATA TRANSFORMATIONS

9.4.3.1 Transformations of the data, (e.g., arc sine square root and logs), are used where necessary to meet assumptions of the proposed analyses, such as the requirement for normally distributed data.

9.4.4 INDEPENDENCE, RANDOMIZATION, AND OUTLIERS

9.4.4.1 Statistical independence among observations is a critical assumption in all statistical analysis of toxicity data. One of the best ways to insure independence is to properly follow rigorous randomization procedures. Randomization techniques should be employed at the start of the test, including the randomization of the placement of test organisms in the test chambers and randomization of the test chamber location within the array of chambers. Discussions of statistical independence, outliers and randomization, and a sample randomization scheme, are included in Appendix A.

9.4.5 REPLICATION AND SENSITIVITY

9.4.5.1 The number of replicates employed for each toxicant concentration is an important factor in determining the sensitivity of chronic toxicity tests. Test sensitivity generally increases as the number of replicates is increased, but the point of diminishing returns in sensitivity may be reached rather quickly. The level of sensitivity required by a hypothesis test or the confidence interval for a point estimate will determine the number of replicates, and should be based on the objectives for obtaining the toxicity data.

9.4.5.2 In a statistical analysis of toxicity data, the choice of a particular analysis and the ability to detect departures from the assumptions of the analysis, such as the normal distribution of the data and homogeneity of variance, is also dependent on the number of replicates. More than the minimum number of replicates may be required in situations where it is imperative to obtain optimal statistical results, such as with tests used in enforcement cases or when it is not possible to repeat the tests. For example, when the data are analyzed by hypothesis testing, the nonparametric alternatives cannot be used unless there are at least four replicates at each toxicant concentration.

9.4.6 RECOMMENDED ALPHA LEVELS

9.4.6.1 The data analysis examples included in the manual specify an alpha level of 0.01 for testing the assumptions of hypothesis tests and an alpha level of 0.05 for the hypothesis tests themselves. These levels are

common and well accepted levels for this type of analysis and are presented as a recommended minimum significance level for toxicity test data analysis.

9.5 CHOICE OF ANALYSIS

9.5.1 The recommended statistical analysis of most data from chronic toxicity tests with aquatic organisms follows a decision process illustrated in the flowchart in Figure 2. An initial decision is made to use point estimation techniques (the Probit Analysis, the Spearman-Karber Method, the Trimmed Spearman-Karber Method, the Graphical Method, or Linear Interpolation Method) and/or to use hypothesis testing (Dunnett's Test, the t test with the Bonferroni adjustment, Steel's Many-one Rank Test, or the Wilcoxon Rank Sum Test with the Bonferroni adjustment). **NOTE: For the NPDES Permit Program, the point estimation techniques are the preferred statistical methods in calculating end points for effluent toxicity tests.** If hypothesis testing is chosen, subsequent decisions are made on the appropriate procedure for a given set of data, depending on the results of the tests of assumptions, as illustrated in the flowchart. A specific flow chart is included in the analysis section for each test.

9.5.2 Since a single chronic toxicity test might yield information on more than one parameter (such as survival, growth, and reproduction), the lowest estimate of a "no-observed-effect concentration" for any of the responses would be used as the "no-observed-effect concentration" for each test. It follows logically that in the statistical analysis of the data, concentrations that had a significant toxic effect on one of the observed responses would not be subsequently tested for an effect on some other response. This is one reason for excluding concentrations that have shown a statistically significant reduction in survival from a subsequent hypothesis test for effects on another parameter such as reproduction. A second reason is that the exclusion of such concentrations usually results in a more powerful and appropriate statistical analysis. In performing the point estimation techniques recommended in this manual, an all-data approach is used. For example, data from concentrations above the NOEC for survival are included in determining ICp estimates using the Linear Interpolation Method.

9.5.3 ANALYSIS OF GROWTH AND REPRODUCTION DATA

9.5.3.1 Growth data from the fathead minnow, *Pimephales promelas*, larval survival and growth test are analyzed using hypothesis testing or point estimation techniques according to the flowchart in Figure 2. The above mentioned growth data may also be analyzed by generating a point estimate with the Linear Interpolation Method. Data from effluent concentrations that have tested significantly different from the control for survival are excluded from further hypothesis tests concerning growth effects. Growth is defined as the dry weight per original number of test organisms when group weights are obtained. When analyzing the data using point estimation techniques, data from all concentrations are included in the analysis.

9.5.3.2 Reproduction data from the daphnid, *Ceriodaphnia dubia*, survival and reproduction test are analyzed using hypothesis testing or point estimation techniques according to the flowchart in Figure 2. In hypothesis testing, data from effluent concentrations that have significantly lower survival than the control, as determined by Fisher's Exact test, are not included in the hypothesis tests for reproductive effects. Data from all concentrations are included when using point estimation techniques.

9.5.4 ANALYSIS OF ALGAL GROWTH RESPONSE DATA

9.5.4.1 The growth response data from the green alga, *Selenastrum capricornutum*, toxicity test, after an appropriate transformation, if necessary, to meet the assumptions of normality and homogeneity of variance, may be analyzed by hypothesis testing according to the flowchart in Figure 2. Point estimates, such as the IC25 and IC50, would also be appropriate in analyzing algal growth data.

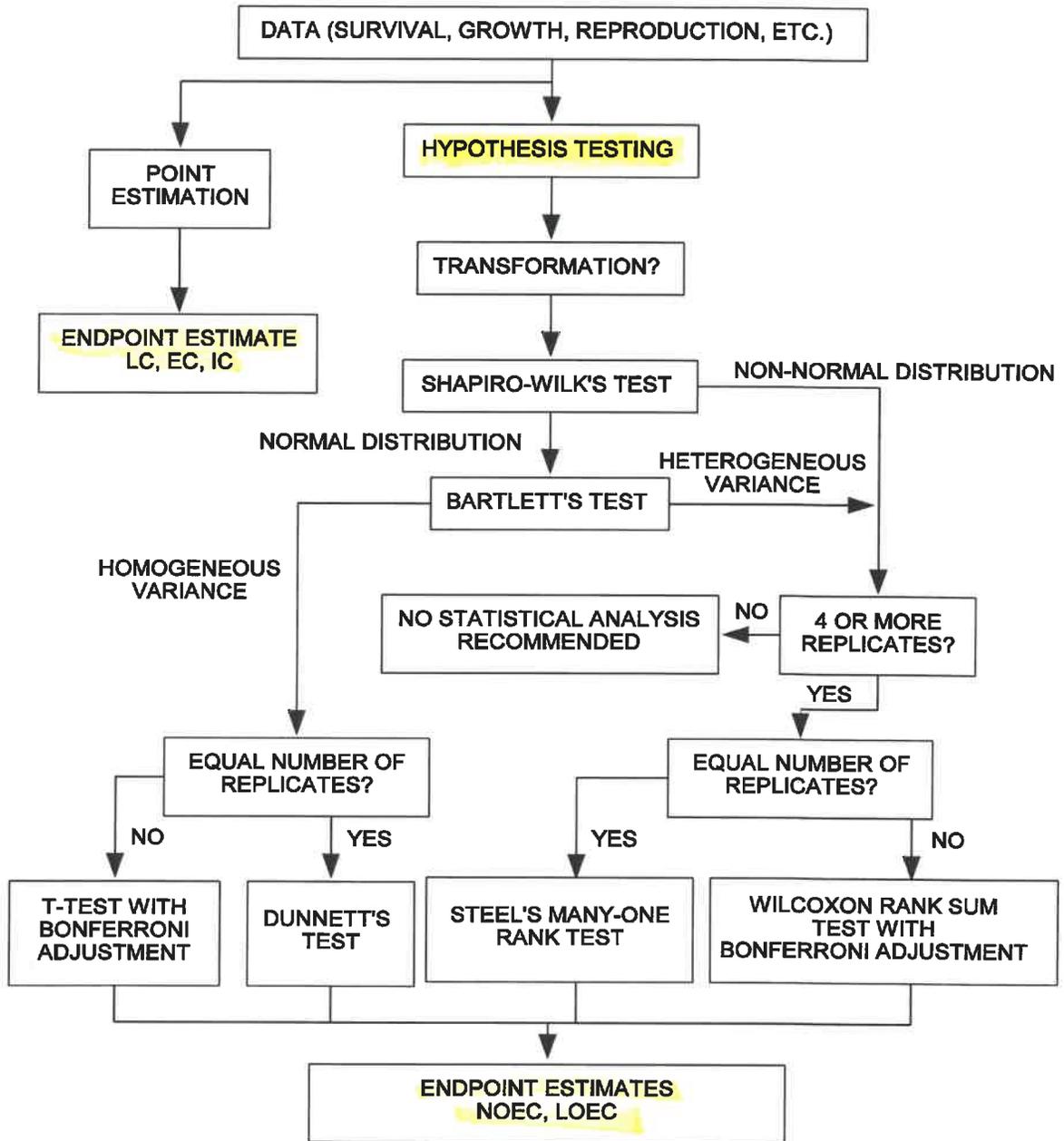


Figure 2. Flowchart for statistical analysis of test data

9.6 HYPOTHESIS TESTS

9.6.1 DUNNETT'S PROCEDURE

9.6.1.1 Dunnett's Procedure is used to determine the NOEC. The procedure consists of an analysis of variance (ANOVA) to determine the error term, which is then used in a multiple comparison procedure for comparing each of the treatment means with the control mean, in a series of paired tests (see Appendix C). Use of Dunnett's Procedure requires at least three replicates per treatment to check the assumptions of the test. In cases where the numbers of data points (replicates) for each concentration are not equal, a t test may be performed with Bonferroni's adjustment for multiple comparisons (see Appendix D), instead of using Dunnett's Procedure.

9.6.1.2 The assumptions upon which the use of Dunnett's Procedure is contingent are that the observations within treatments are normally distributed, with homogeneity of variance. Before analyzing the data, these assumptions must be tested using the procedures provided in Appendix B.

9.6.1.3 If, after suitable transformations have been carried out, the normality assumptions have not been met, Steel's Many-one Rank Test should be used if there are four or more data points (replicates) per toxicant concentration. If the numbers of data points for each toxicant concentration are not equal, the Wilcoxon Rank Sum Test with Bonferroni's adjustment should be used (see Appendix F).

9.6.1.4 Some indication of the sensitivity of the analysis should be provided by calculating (1) the minimum difference between means that can be detected as statistically significant, and (2) the percent change from the control mean that this minimum difference represents for a given test.

9.6.1.5 A step-by-step example of the use of Dunnett's Procedure is provided in Appendix C.

9.6.2 T TEST WITH THE BONFERRONI ADJUSTMENT

9.6.2.1 A t test with Bonferroni's adjustment is used as an alternative to Dunnett's Procedure when the number of replicates is not the same for all concentrations. This test sets an upper bound of alpha on the overall error rate, in contrast to Dunnett's Procedure, for which the overall error rate is fixed at alpha. Thus Dunnett's Procedure is a more powerful test.

9.6.2.2 The assumptions upon which the use of the t test with Bonferroni's adjustment is contingent are that the observations within treatments are normally distributed, with homogeneity of variance. These assumptions must be tested using the procedures provided in Appendix B.

9.6.2.3 The estimate of the safe concentration derived from this test is reported in terms of the NOEC. A step-by-step example of the use of the t test with Bonferroni's adjustment is provided in Appendix D.

9.6.3 STEEL'S MANY-ONE RANK TEST

9.6.3.1 Steel's Many-one Rank Test is a multiple comparison procedure for comparing several treatments with a control. This method is similar to Dunnett's Procedure, except that it is not necessary to meet the assumption of normality. The data are ranked, and the analysis is performed on the ranks rather than on the data themselves. If the data are normally or nearly normally distributed, Dunnett's Procedure would be more sensitive (would detect smaller differences between the treatments and control). For data that are not normally distributed, Steel's Many-one Rank Test can be much more efficient (Hodges and Lehmann, 1956).

9.6.3.2 It is necessary to have at least four replicates per toxicant concentration to use Steel's test. Unlike Dunnett's procedure, the sensitivity of this test cannot be stated in terms of the minimum difference between treatment means and the control mean that can be detected as statistically significant.

9.6.3.3 The estimate of the safe concentration is reported as the NOEC. A step-by-step example of the use of Steel's Many-one Rank Test is provided in Appendix E.

9.6.4 WILCOXON RANK SUM TEST WITH THE BONFERRONI ADJUSTMENT

9.6.4.1 The Wilcoxon Rank Sum Test with the Bonferroni Adjustment is a nonparametric test for comparing treatments with a control. The data are ranked and the analysis proceeds exactly as in Steel's Test except that Bonferroni's adjustment for multiple comparisons is used instead of Steel's tables. When Steel's test can be used (i.e., when there are equal numbers of data points per toxicant concentration), it will be more powerful (able to detect smaller differences as statistically significant) than the Wilcoxon Rank Sum Test with Bonferroni's adjustment.

9.6.4.2 The estimate of the safe concentration is reported as the NOEC. A step-by-step example of the use of the Wilcoxon Rank Sum Test with Bonferroni Adjustment is provided in Appendix F.

9.6.5 A CAUTION IN THE USE OF HYPOTHESIS TESTING

9.6.5.1 If in the calculation of an NOEC by hypothesis testing, two tested concentrations cause statistically significant adverse effects, but an intermediate concentration did not cause statistically significant effects, the results should be used with extreme caution.

9.7 POINT ESTIMATION TECHNIQUES

9.7.1 PROBIT ANALYSIS

9.7.1.1 Probit Analysis is used to estimate the LC₁, LC₅₀, EC₁, or EC₅₀ and the associated 95% confidence interval. The analysis consists of adjusting the data for mortality in the control, and then using a maximum likelihood technique to estimate the parameters of the underlying log tolerance distribution, which is assumed to have a particular shape.

9.7.1.2 The assumption upon which the use of Probit Analysis is contingent is a normal distribution of log tolerances. If the normality assumption is not met, and at least two partial mortalities are not obtained, Probit Analysis should not be used. It is important to check the results of Probit Analysis to determine if use of the analysis is appropriate. The chi-square test for heterogeneity provides one good test of appropriateness of the analysis. The computer program (see Appendix I) checks the chi-square statistic calculated for the data set against the tabular value, and provides an error message if the calculated value exceeds the tabular value.

9.7.1.3 A discussion of Probit Analysis, and examples of computer program input and output, are found in Appendix I.

9.7.1.4 In cases where Probit Analysis is not appropriate, the LC₅₀ and associated confidence interval may be estimated by the Spearman-Kärber Method (Appendix J) or the Trimmed Spearman-Kärber Method (Appendix K). If the test results in 100% survival and 100% mortality in adjacent treatments (all or nothing effect), the LC₅₀ may be estimated using the Graphical Method (Appendix L).

9.7.2 LINEAR INTERPOLATION METHOD

9.7.2.1 The Linear Interpolation Method (see Appendix M) is a procedure to calculate a point estimate of the effluent or other toxicant concentration [Inhibition Concentration, (IC)] that causes a given percent reduction (e.g., 25%, 50%, etc.) in the reproduction or growth of the test organisms. The procedure was designed for general applicability in the analysis of data from short-term chronic toxicity tests.

9.7.2.2 Use of the Linear Interpolation Method is based on the assumptions that the responses (1) are monotonically non-increasing (the mean response for each higher concentration is less than or equal to the mean response for the previous concentration), (2) follow a piecewise linear response function, and (3) are from a random, independent, and representative sample of test data. The assumption for piecewise linear response cannot be tested statistically, and no defined statistical procedure is provided to test the assumption for monotonicity. Where the observed means are not strictly monotonic by examination, they are adjusted by smoothing. In cases where the responses at the low toxicant concentrations are much higher than in the controls, the smoothing process may result in a large upward adjustment in the control mean.

9.7.2.3 The inability to test the monotonicity and piecewise linear response assumptions for this method makes it difficult to assess when the method is, or is not, producing reliable results. Therefore, the method should be used with caution when the results of a toxicity test approach an "all or nothing" response from one concentration to the next in the concentration series, and when it appears that there is a large deviation from monotonicity. See Appendix M for a more detailed discussion of the use of this method and a computer program available for performing calculations.

methods or alternate methods), reviewers should verify that the necessary assumptions are met for the statistical method used.

10.2.6 CONCENTRATION-RESPONSE RELATIONSHIPS

10.2.6.1 The concept of a concentration-response, or more classically, a dose-response relationship is “the most fundamental and pervasive one in toxicology” (Casarett and Doull, 1975). This concept assumes that there is a causal relationship between the dose of a toxicant (or concentration for toxicants in solution) and a measured response. A response may be any measurable biochemical or biological parameter that is correlated with exposure to the toxicant. The classical concentration-response relationship is depicted as a sigmoidal shaped curve, however, the particular shape of the concentration-response curve may differ for each coupled toxicant and response pair. In general, more severe responses (such as acute effects) occur at higher concentrations of the toxicant, and less severe responses (such as chronic effects) occur at lower concentrations. A single toxicant also may produce multiple responses, each characterized by a concentration-response relationship. A corollary of the concentration-response concept is that every toxicant should exhibit a concentration-response relationship, given that the appropriate response is measured and given that the concentration range evaluated is appropriate. Use of this concept can be helpful in determining whether an effluent possesses toxicity and in identifying anomalous test results.

10.2.6.2 The concentration-response relationship generated for each multi-concentration test must be reviewed to ensure that calculated test results are interpreted appropriately. USEPA (2000a) provides guidance on evaluating concentration-response relationships to assist in determining the validity of WET test results. 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 (USEPA, 2000a). This guidance provides review steps for 10 different concentration-response patterns that may be encountered in WET test data. Based on the review, the guidance provides one of three determinations: that calculated effect concentrations are reliable and should be reported, that calculated effect concentrations are anomalous and should be explained, or that the test was inconclusive and the test should be repeated with a newly collected sample. It should be noted that the determination of a valid concentration-response relationship is not always clear cut. Data from some tests may suggest consultation with professional toxicologists and/or regulatory officials. Tests that exhibit unexpected concentration-response relationships also may indicate a need for further investigation and possible retesting.

10.2.7 REFERENCE TOXICANT TESTING

10.2.7.1 Test review of a given effluent or receiving water test should include review of the associated reference toxicant test and current control chart. Reference toxicant testing and control charting is required for documenting the quality of test organisms (Subsection 4.7) and ongoing laboratory performance (Subsection 4.16). The reviewer should verify that a quality control reference toxicant test was conducted according to the specified frequency required by the permitting authority or recommended by the method (e.g., monthly). The test acceptability criteria, test conditions, concentration-response relationship, and test sensitivity of the reference toxicant test are reviewed to verify that the reference toxicant test conducted was a valid test. The results of the reference toxicant test are then plotted on a control chart (see Subsection 4.16) and compared to the current control chart limits (± 2 standard deviations).

10.2.7.2 Reference toxicant tests that fall outside of recommended control chart limits are evaluated to determine the validity of associated effluent and receiving water tests (see Subsection 4.16). An out of control reference toxicant test result does not necessarily invalidate associated test results. The reviewer should consider the degree to which the reference toxicant test result fell outside of control chart limits, the width of the limits, the direction of the deviation (toward increasing test organism sensitivity or toward decreasing test organism sensitivity), the test conditions of both the effluent test and the reference toxicant test, and the objective of the test. More frequent and/or concurrent reference toxicant testing may be advantageous if recent problems (e.g., invalid tests, reference toxicant test results outside of control chart limits, reduced health of organism cultures, or increased within-test variability) have been identified in testing.

ATTACHMENT 3

Stuber, Robyn

From: McNaughton, Eugenia
Sent: Friday, October 25, 2013 11:19 AM
To: Smith, DavidW
Subject: RE: Response to Region 9 Request concerning Test of Significant Toxicity Approach

OK – I'll get something back to you in two weeks.

From: Smith, DavidW
Sent: Friday, October 25, 2013 11:09 AM
To: McNaughton, Eugenia
Subject: RE: Response to Region 9 Request concerning Test of Significant Toxicity Approach

Would be great to do statewide ATPs for CA and HI. CA would be great to get done within a month, HI by the end of the year perhaps?

David Smith
Manager
NPDES Permits Office (WTR-5)
U.S. EPA Region 9
75 Hawthorne Street
San Francisco, CA 94602
(415) 972-3464 (office)
(415) 972-947-3545 (fax)

From: McNaughton, Eugenia
Sent: Friday, October 25, 2013 9:53 AM
To: Smith, DavidW
Subject: RE: Response to Region 9 Request concerning Test of Significant Toxicity Approach

Right...this will be a bit of change, as you know ATPs are usually granted for a specific discharger or lab doing work for specific discharger(s). I'll work with my staff on how to develop what I'm reading in Rob Wood's memo as an ATP for the State of California and get back to you. You and Robyn have indicated that Hawai'i is also using the TST approach. If that is so, we'll do the same for Hawai'i. Let me know if I've got my facts straight and what you believe should be the deadline for a Region 9 letter to go out to the States.

From: Smith, DavidW
Sent: Wednesday, October 23, 2013 11:27 AM
To: Denton, Debra; Stuber, Robyn; McNaughton, Eugenia
Subject: FW: Response to Region 9 Request concerning Test of Significant Toxicity Approach

I guess we handle this as a regional ATP. We should talk to determine how to carry this out.

David Smith
Manager
NPDES Permits Office (WTR-5)
U.S. EPA Region 9
75 Hawthorne Street
San Francisco, CA 94602
(415) 972-3464 (office)
(415) 972-947-3545 (fax)

From: Wood, Robert

Sent: Wednesday, October 23, 2013 9:59 AM

To: Strauss, Alexis

Cc: Smith, DavidW; McNaughton, Eugenia; Brennan, Ross; Lavery, Tom; Nagle, Deborah; Matuszko, Jan; Goodwin, Janet; Southerland, Elizabeth; Phillips, Laura; Oshiro, Robin

Subject: Response to Region 9 Request concerning Test of Significant Toxicity Approach

Hi Alexis,

Attached is a memo from me responding to your request for OST approval to use a “two concentrations only” experimental design with EPA’s Test of Significant Toxicity (TST) hypothesis testing approach. Thanks to everyone in Headquarters and in Region 9 who helped to reach a constructive way forward on this matter and thanks for everyone’s patience as we worked through the issues. The attached memo explains that the Region can move forward under its authority to approve the method as a limited use alternative test procedure. Please let me know if you have any questions.

Rob

Robert Wood

Director,

Engineering and Analysis Division

Office of Water

202-566-1822



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460

OCT 22 2013

OFFICE OF WATER

MEMORANDUM

SUBJECT: Response to "Approval to use 'two concentrations only' experimental design with EPA's Test of Significant Toxicity (TST) hypothesis testing approach"

FROM: 
Robert Wood, Director, Engineering and Analysis Division
Office of Science and Technology (OST)

TO: Alexis Strauss, Deputy Regional Administrator
U.S. EPA Region 9

Thank you for your letter to Betsy Southerland requesting OST's "Approval to use 'two concentrations only' experimental design with EPA's Test of Significant Toxicity (TST) hypothesis testing approach." Betsy asked me to respond on her behalf. We understand you are requesting approval for NPDES permits issued in Region 9 to require only two concentrations (a control plus one effluent concentration) only when evaluating whole effluent toxicity (WET) results using the EPA's 2010 Test of Significant Toxicity (TST) statistical approach. We have reviewed your memo and the TST documentation and, as we have indicated to your staff, we are not challenging the technical or programmatic merits of the TST statistical approach to analyze valid WET test data or the appropriateness of only two concentrations in this specific application. Rather, as stated in the promulgated CWA WET methods and re-iterated in the "EPA's National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document," these methods require a control plus five effluent concentrations under the methods' test acceptability criteria. As such, the promulgated methods do not allow for only two concentrations for use in NPDES permits. Recognizing that modifications to promulgated methods that are outside the scope of the method's flexibility may be appropriate, 40 CFR Part 136 defines a process that allows for such modifications. Therefore, the appropriate venue to consider the modification you are requesting is the Alternate Test Procedure (ATP) program, as described in 40 CFR 136.4 and 40 CFR 136.5 which allows for both limited use ATPs and nationwide ATPs.

As we have indicated to your staff, we do not yet have guidance for requesting or evaluating WET ATP requests as described in 40 CFR Part 136.4 and 136.5. We are developing that guidance for both limited use and nationwide WET ATPs and plan to issue it in December, 2013. That guidance will include information on the data, analysis, and documentation that should be submitted and evaluated for any WET ATPs evaluations. As such, it would be appropriate to consider an ATP to address your request after we have established clear guidance. Moreover, as specified in 40 CFR Part 136.4 and 136.5, limited use ATP requests are evaluated and approval is determined by the Regional Administrator (or their designee) and nationwide ATP requests are evaluated by the ATP Program Coordinator in my office. Because the exception you are describing would apply only for specific applications in NPDES permits in your Region rather than nationwide, as specified in 40

CFR Part 136.4 and 136.5, it is appropriate for consideration as a limited use ATP. Such ATP requests are evaluated and approval is determined by the Regional Administrator (or their designee) rather than the ATP Program Coordinator in my office. Therefore, even in absence of specific guidance for WET ATPs, Region 9 already has the authority to accept, review, and approve a limited use ATP for the specific application described in your memo. We suggest the State of California apply for a WET ATP for this specific application and that Region 9 review and, as appropriate, approve that application.

If you or your staff has additional questions about the ATP program, please call me at (202) 566-1822.

cc: David Smith, Region 9
Eugenia McNaughton, Region 9
Ross Brennan, OWM
Tom Lavery, OWM
Deborah Nagle, OWM
Jan Matuszko, OST
Janet Goodwin, OST
Elizabeth Southerland, OST

ATTACHMENT 4

January 21, 2011

VIA ELECTRONIC MAIL: commentletters@waterboards.ca.gov

State Water Resources Control Board Members
and Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
1001 I Street, Sacramento, CA 95814

Re: Comment Letter – Policy for Toxicity Assessment and Control

Dear State Water Resources Control Board Members:

Our firm represents numerous water districts and industrial and municipal wastewater dischargers throughout California. We also represent agricultural water districts, urban water districts, agricultural dischargers subject to the agricultural waste discharge requirements (“WDR”) waiver, urban POTWs with extensive histories of successful compliance with permit terms, and a number of municipal, construction, and industrial stormwater dischargers. Our clients from both southern and northern California have been statewide leaders in the capture and use of stormwater and in the development and use of recycled water, for both urban and agricultural purposes. If there is one thread that unites our clients, it is their desire to find reasonable and cost-effective ways to serve the needs of California’s growing population for municipal drinking water, for water to grow crops, and for the treatment and reuse of wastewater.

We have actively followed the discussion that the State Water Resources Control Board (“SWRCB”) began by issuing the draft Policy for Toxicity Assessment and Control (“WET Draft Policy”) on October 20, 2010.¹ Our clients believe that the SWRCB is serving the public interest in attempting to ensure that California has a uniform statewide policy for the control of toxicity in surface waters. Our clients also fully support the SWRCB’s goal of basing that policy on the best available scientific information. As was demonstrated in the context of the SWRCB’s Recycled Water Policy, it is important to use science – not unfounded and generalized “public concern” – to ensure that California’s waters are protected from heretofore unknown threats. Using the best available science allows the SWRCB to focus on real problems and to

¹ These comments incorporate by reference and build upon the comments submitted to the SWRCB by the California Association of Sanitation Agencies (“CASA”) and the California Storm Water Quality Association (“CASQA”). Neither organization, however, has endorsed these comments.

find the most cost-effective solutions to those problems. Particularly in this dire fiscal climate, California does not have the resources to chase imaginary problems; particularly when we have more than enough real water quality issues to address.

1. *Summary of the Problem*

In the discussions and comments that have followed the SWRCB's release of the WET Draft Policy, there seem to be several key concerns that have been expressed by the various parties (including the SWRCB). In no particular order, those concerns are:

- Toxicity in California's surface waters in amounts that cause either significant acute or chronic effects is not acceptable. Given the variability of California's waters, though, any definition of toxicity must recognize and respect the differences in water quality, temperature, and other constituents.
- There needs to be a way for the SWRCB to be reasonably assured that California's surface waters are not being subjected to unaddressed instream toxicity as a result of "false negatives" from the existing monitoring regime.
- Any regulatory regime should be focused on remediating continuing toxicity problems rather than trying to identify and resolve fleeting toxicity "hits" without clear impacts (either acute or chronic) on the instream aquatic ecosystem.
- Dischargers must be reasonably assured that they will not be subjected to criminal fines or civil penalties for "false positive" toxicity test results.
- The Policy should not require activities that currently do not require a National Pollutant Discharge Elimination System ("NPDES") permit or WDR to obtain such a permit and the Policy should not seek to expand the scope of present water quality regulations.
- Small communities (and others) should not be subject to the very high costs associated with toxicity testing and remediation unless there is a clear and documented problem in the applicable receiving water. To the extent that the Policy requires such agencies to incur substantial costs, the SWRCB should assist small and disadvantaged communities and others in securing funding for such efforts, recognizing the limits of Proposition 13, Proposition 218, Proposition 26, and other similar provisions of law.
- Remediation of identified problems will require reasonable compliance schedules to allow dischargers to undertake source control/pretreatment activities and/or to plan, design, conduct environmental review, construct and finance any new infrastructure needed to control toxicity.

- Any program adopted by the SWRCB should be able to be implemented by all dischargers at a reasonable cost.

We believe that it is the responsibility of the SWRCB to craft a revised policy that reasonably addresses all of these concerns, even if it does not fully satisfy all stakeholders. The purpose of the remainder of these comments is to provide the SWRCB with a “roadmap” for such a revised policy.

2. *Summary of a Revised Policy for Toxicity Assessment and Control*

We believe that a revised policy for toxicity assessment and control should have five key elements.

First, a revised policy should be able to address the SWRCB’s concerns about the potential effects of “false negatives” without creating a large number of “false positives.” We believe that the best way to achieve this balance is to require dischargers to engage in regular testing of effluent (to be prescribed based on the size, frequency and type of discharge), to base test results on regular testing intervals rather than on single tests, and to allow for several statistical methods to be used (both the promulgated EC/IC25 and NOEC methods as well as the Test of Significant Toxicity (“TST”) method proposed by the United States Environmental Protection Agency (“USEPA”)). Further, if it appears that there may be toxicity present that could cause adverse effects in the receiving water, the discharger should be required to begin a program of accelerated monitoring to determine whether the apparent presence of toxicity is a statistical fluke or evidence of actual toxicity. We have prepared proposed narrative objectives for acute and chronic toxicity that reflect these concepts; these draft objectives, along with an implementation construct for each, are attached to these comments as Exhibit A and are incorporated herein by reference. It is important to note that these proposed objectives and the accompanying implementation construct would, if adopted by the SWRCB, establish a uniform statewide standard of no acute or chronic toxicity for California’s surface waters.

Second, a revised policy should include an enforceable program for monitoring and the identification of the potential cause and source(s) of toxicity, for the evaluation of how a discharger must remediate that toxicity, and for the implementation of that remediation program. An important portion of that program will be the inclusion of compliance schedules that provide a discharger that must undertake the tasks needed to remediate actual toxicity in receiving waters with adequate time to do so. The parameters for a compliance schedule, as required by Water Code section 13242 for any new objectives, are also included in Exhibit A.

Third, a revised policy should recognize that the costs of monitoring for and remediating aquatic toxicity can be quite substantial. Particularly for small or disadvantaged communities, these costs can be prohibitive and these communities can be forced to choose between providing essential local services and monitoring for and remediating aquatic toxicity. A revised policy

should include regulatory relief for small communities as well as a recognition that the State Revolving Fund or other mechanisms are available to assist these communities in implementing a revised policy.

Fourth, as the SWRCB is aware, a large number of technical details must be considered in developing a revised policy. Those technical details, while important, should be included within the framework described in the preceding paragraphs. Because it is not possible in a short comment letter to fully develop a comprehensive revised policy that addresses all nuances of the issue, we urge the SWRCB to direct one or two of its Members and staff to convene a small group of stakeholders (i.e. not more than 8-10) that will attempt to more fully develop the concepts described in this letter and its attachment with the goal of providing the SWRCB members with a construct for a completely revised policy. The model for those discussions would be those that were facilitated by Vice-Chair Spivy-Weber and former Vice-Chair Wolff in the context of the SWRCB's Recycled Water Policy, with the difference that, in this context, the SWRCB would provide the stakeholders with the framework of a proposed policy.

Fifth, and last, the WET Draft Policy could be read to extend the State of California's permitting authority, either under the federal Clean Water Act or under the Porter-Cologne Water Quality Control Act, to virtually all surface waters in California and virtually all diversions, impoundments, discharges, and releases of water to or from surface waters. We do not believe that this was the intent of the SWRCB and believe that such an expansion of the current regulatory regime would be subject to successful legal challenge. A revised policy should respect the limits of the federal Clean Water Act and/or the Porter-Cologne Water Quality Control Act and expressly not subject water diversions or releases or activities subject to the agricultural discharge waiver to new or additional regulatory requirements.

3. *Problems with the SWRCB's Current WET Draft Policy*

(a) *The Potential Scope of the WET Draft Policy*

The WET Draft Policy purports to establish "water quality objectives for toxicity that apply to all inland surface waters, enclosed bays, and estuaries of the state, including both waters of the United States and surface waters of the state." (Policy, p. 1). Thus, the Policy – by its own terms – creates new water quality objectives that water diverters and dischargers must consider whenever an entity wishes to divert water, discharge a pollutant/waste, or convey water from one water body to another. Thus, the WET Draft Policy could be interpreted to apply to waterways such as the Sacramento and Feather Rivers and to potential changes in water quality due to releases from Lake Shasta, Lake Oroville, or other "rim reservoirs" in the Central Valley, provided that those releases had a detrimental effect as measured through the USEPA's unapproved, non-peer-reviewed TST methodology.

Similarly, the WET Draft Policy could be interpreted to apply to efforts to use natural channels to convey water (e.g., via a water transfer). Not only would the WET Draft Policy

apply in the Central Valley, but also elsewhere in California, such as to the introduction of water into terminal reservoirs (e.g., Castaic Lake, Lake Silverwood, or Diamond Valley Lake). Under the terms of the WET Draft Policy, such waters would be within the scope of the Policy if the SWRCB (or a regional board) considers these bodies of water to be “surface waters.” The Los Angeles Regional Board considers Castaic Lake and Lake Piru to be surface waters; the Santa Ana Regional Board considers Lake Mathews and Lake Elsinore to be surface waters. Thus, it seems likely that the WET Draft Policy would probably apply to most surface water reservoirs in California, either as a result of water being introduced into those reservoirs or as a result of water being released from those reservoirs into a surface stream. Thus, these drinking water reservoirs will likely be determined to be “toxic” enough given the inherent inaccuracy of the proposed TST test (i.e., 5-15% error rate) to be added to the state’s 303(d) list of “impaired waters.” The impacts of this designation to water purveyors attempting to sell this water has not been considered anywhere in this WET Draft Policy.

Perhaps as important as the potential application of the WET Draft Policy to all surface waters in California is the potential application of the WET Draft Policy to stormwater. Stormwater is likely to be needed as a major water resource to meet California’s future water needs. Southern California water agencies are already making strenuous efforts to use stormwater – which appears episodically and in large quantities – as part of their water supply portfolios. With the specter of climate change, Northern California water agencies are likely to adopt similar strategies to adapt to a smaller snowpack in the Sierras. The SWRCB has – rightly – encouraged water agencies to make such efforts in order to capitalize on a heretofore untapped resource. However, if the WET Draft Policy results in stormwater generally being labeled as “toxic” and so not usable (even for purposes of replenishing a groundwater basin) without additional treatment, California will – in all likelihood – forego the continued development of that resource. The costs and effects on the environment of this implication of the WET Draft Policy have also not been considered.

(b) *The Problems with the WET Draft Policy*

In addition to the comments submitted by others (e.g., CASA, CASQA), the WET Draft Policy suffers from two fundamental flaws. First, for the past half-century, efforts to improve water quality have relied on monitoring/testing by wastewater dischargers to identify potential water quality problems; the WET Policy now extends that burden to agencies discharging or diverting water. Particularly as California seeks to move towards policies that encourage long-term sustainability and water resource management, it is inappropriate for the SWRCB to assume – without evidence – that water-resource activities are somehow harmful to the environment. Indeed, Article X, Section 2 of the California Constitution strikes the right balance in charging the SWRCB to put California’s water resources to use for the public welfare while preventing waste or the unreasonable use of water. Second, the WET Draft Policy assumes that the currently used toxicity test methods contain high rate of “false negatives” that mask a host of water quality problems. Yet, rather than seeking to determine whether there may, in fact, be

water quality problems that have not yet been identified or addressed, the WET Draft Policy foregoes science and data in favor of an assumption where – by hypothesis – the data are lacking.

Proceeding to change long-standing regulatory policy without justified need or supporting data is bad enough. As noted above, however, the scope of the proposed WET Draft Policy would transform almost every discussion about water resources management in California into a discussion of the potential impacts of that activity on WET. For instance, if the U.S. Fish & Wildlife Service proposes to require the U.S. Bureau of Reclamation to increase releases from Shasta Reservoir in order to provide water for outmigrating salmonid smolts, the change in water temperature or quality may well lead to a change in the survival of the test species under the proposed WET protocol. If so, then it is entirely likely that all water project operations in California (including the Central Valley Project, the State Water Project and local water projects) will fall within the scope of the proposed Policy. Notwithstanding some unconfirmed reports in the media, there are no validated, peer-reviewed studies showing an unaddressed problem with chronic or acute toxicity in California's waters. Adopting the proposed WET Draft Policy with its potentially universal scope in the absence of real data showing harm to the aquatic ecosystem is arbitrary and capricious.

Moreover, there are substantial potential regulatory consequences of adopting the WET Draft Policy in its present form. Most notably, every federal permit/license requires the SWRCB to certify under section 401 of the federal Clean Water Act that the permit is consistent with state water quality objectives. Given the potentially wide scope of the WET Draft Policy and the fact that almost every change in water quality/temperature may be seen as evidence of toxicity, it may be difficult (if not impossible) for the SWRCB to provide section 401 certifications in the future. This is an unintended consequence of the proposed WET Draft Policy that would have profound impacts on a host of projects in California, which has not been explored at all in the staff report accompanying this WET Draft Policy or the SAIC economics analysis.

Similarly, virtually every applicant/permittee that comes before the SWRCB or any of the regional boards is required to comply with the provisions of the California Environmental Quality Act (CEQA). Under that statute, the applicant/permittee or the SWRCB/regional board must consider the potential impacts of a possible permit or project on the environment. An activity that would cause or contribute to the violation of a toxicity water quality objective would be deemed to be a "significant" impact on the environment that requires mitigation. However, given the transitory nature of toxicity events, it is unclear how an applicant/permittee might feasibly be able to mitigate for such an impact. The failure to do so, of course, would open the applicant/permittee – as well as the SWRCB/regional board – to CEQA litigation.

The SWRCB also failed to adequately support the conclusions of no significant or potentially significant effects in its CEQA checklist included with the WET Draft Policy. Because the SWRCB provided no evidence and documentation to show how these conclusions were reached, this action is contrary to law. (*See* 14 C.C.R. §15252(a)(2); *see also City of Arcadia v. State Water Resources Control Board*, 135 Cal.App.4th 1392, 1420 (2006)(The

Regional Board's environmental checklist for the Trash TMDL was held to be deficient and there was determined to be sufficient evidence of a fair argument that the project may have a significant effect on the environment, thus necessitating an EIR or its functional equivalent.) Further, the checklist did not address any of the potential effects on the environment resulting from the WET Draft Policy identified above. That failing violates CEQA. In this case, the SAIC's economic analysis demonstrates that additional treatment technologies may well be required to implement these new objectives, yet these foreseeable actions are not reflected in the CEQA checklist accompanying the new WET Draft Policy. This failure also violates CEQA.

Last, and perhaps most important, the adoption of the WET Draft Policy is likely to be found by the courts to be inconsistent with the California Constitution's mandate to put the water resources of the state to use for the general welfare. The provision of Article X, Section 2 is most often read for its prohibition on the waste or unreasonable use of water. However, the provision prefaces that prohibition on waste with the following language: "It is hereby declared that because of the conditions prevailing in this State the general welfare requires that the water resources of the State be put to beneficial use to the fullest extent of which they are capable." The plain meaning of this provision is that the waters of the state "be put to beneficial use." If the SWRCB were to adopt this WET Draft Policy, which would stymie most uses of water in California because of the perception that these waters are "toxic," the SWRCB would probably be in violation of this constitutional mandate.

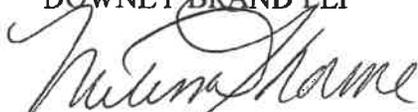
4. *Conclusion*

We believe that the SWRCB is facing a difficult task. The question of whether California's waters are "toxic" to aquatic life poses important issues, both for the regulation of discharges/wastes, but also for the beneficial uses of California's surface waters. We believe that the program that we have described in this comment letter strikes an appropriate balance that protects aquatic ecosystems without bankrupting wastewater, stormwater, agriculture, and water agencies that serve the basic needs of millions of Californians. We stand ready to assist the SWRCB in its efforts to achieve this balance because the alternative – years and years of litigation as occurred over the USEPA's previous attempts to regulate toxicity – will do nothing to improve the quality of California's surface waters.

Thank you for the opportunity to present these comments.

Very truly yours,

DOWNEY BRAND LLP


Melissa A. Thorne


David R.E. Aladjem

Draft Alternative

POLICY FOR TOXICITY ASSESSMENT AND CONTROL

Applicability of Policy

This Policy for Toxicity Assessment and Control (Policy) establishes, in Part I, definitions applicable to the Policy. Part II of this Policy establishes water quality objectives for acute and chronic aquatic toxicity that apply to all inland surface waters, enclosed bays, and estuaries of the state, including both waters of the United States and surface waters of the state. This Policy does not apply to ocean waters, including Monterey Bay and Santa Monica Bay. Part II of this Policy also establishes aquatic toxicity test (toxicity test) implementation procedures and assessment methodology for dischargers subject to this Policy. This Policy does not apply to sediment toxicity testing.

This Policy supersedes the toxicity control provisions in Section 4 of the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (SIP, 2005) and all Toxicity objectives and toxicity testing and implementation provisions established in Regional Water Quality Control Plans (Basin Plans). This Policy establishes minimum requirements to protect aquatic life beneficial uses including, but not limited to, warm freshwater habitat (WARM), cold freshwater habitat (COLD), wildlife habitat (WILD), estuarine habitat (EST), commercial and sport fishing (COMM), marine habitat (MAR), inland saline water habitat (SAL), and wetland habitat (WET).

Part I: Definitions

The following definitions apply to this Policy:

- A. **Acute toxicity tests** measure the adverse effect (usually mortality) of a waste discharge on a group of test organisms during a short-term exposure (e.g. 96 hours).
- B. **Applicable Water Board, or Water Boards** refers to the State Water Resources Control Board or Regional Water Quality Control Board that issues a National Pollutant Discharge Elimination System (NPDES) permit, Waste Discharge Requirements (WDR), or conditional waiver to a qualifying discharger.
- C. **Chronic toxicity tests** measure the sub-lethal effects of a discharge (e.g. reduced growth or reproduction). Certain chronic toxicity tests include an additional measurement of lethality.
- D. **Continuous dischargers** are NPDES permitted dischargers and point source WDR dischargers that discharge without interruption throughout the majority of the operating hours of the facility, except for infrequent shutdowns for maintenance, process changes, or other similar activities (including when water is being recycled instead of discharged).
- E. **Instream waste concentration (IWC)** is the concentration of a toxicant or effluent in the receiving water after mixing (the inverse of the dilution factor). A discharge of 100% effluent will be considered the IWC whenever mixing zones or dilution credits are not authorized by the applicable Water Board.

F. **Major POTW Facilities**, for the purposes of this Policy, are publicly owned treatment works that discharge at an average dry weather flow (ADWF) rate that is equal to or greater than five million gallons per day (MGD). All smaller POTW facilities (less than 5 MGD ADWF) are defined as **Minor POTW Facilities**.

G. **MS4 discharges** are NPDES permitted stormwater discharges from municipal separate storm sewer systems.

H. **Non-continuous dischargers** are NPDES permitted dischargers and point source WDR dischargers that do not discharge on a continuous basis (e.g, stormwater discharges), and include facilities that discharge on an intermittent and/or seasonal basis.

I. **Point source WDR Dischargers** include point source discharges to inland surface waters, enclosed bays, and estuaries of the state that are subject to Waste Discharge Requirements other than an NPDES permit.

J. **Reasonable Potential or RP** is a designation used for a waste discharge that is calculated to cause or contribute to an excursion above a water quality standard. For the purposes of this Policy, Reasonable Potential for both acute and chronic toxicity is to be determined and demonstrated using the methods set forth in the USEPA Technical Support Document (1991) or the USEPA NPDES Permit Writers Manual (2010).

Part II. Narrative Aquatic Toxicity Objectives/Implementation

The following toxicity objectives apply to all inland surface waters, enclosed bays, and estuaries, including waters of the United States and surface waters of the state:

Acute Toxicity

There shall be no acute toxicity to aquatic organisms in ambient waters caused by non-natural or reasonably controllable water quality factors, outside any designated mixing zone. The median mortality in undiluted effluent for any three consecutive 96-hour static or continuous flow bioassay tests shall be no more than 10%, with no single test having more than 30% mortality.

Acute Toxicity Permit Requirements and Compliance Determination

1. **Effluent Limitation** - All Dischargers that exhibit a Reasonable Potential (RP) to exceed the Acute Aquatic Toxicity Objective, expressed as 1 TUa at the maximum permitted IWC, shall include a narrative acute toxicity effluent limitation, or for MS4 discharges a receiving water limitation, that requires the following:

“Acute Whole Effluent Toxicity. Mortality of aquatic organisms in 96-hour Bioassay tests shall be no more than:

- i. 30% of that shown by the control group, maximum for any one bioassay; and
- ii. 10%, median for any three consecutive bioassays.”

2. **Compliance Determination** - To determine compliance with this objective and effluent limitation, the Discharger shall conduct acute toxicity testing to determine whether the effluent is contributing acute toxicity to the receiving water. The Discharger shall meet the following acute toxicity testing requirements:

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a. **Monitoring Frequency** – For Major POTW Facilities and other continuous dischargers with an effluent limitation for acute toxicity that are not performing chronic toxicity testing shall perform quarterly or annual acute toxicity testing as prescribed by the Applicable Water Board. For continuous dischargers that do not exhibit RP, Minor POTW Facilities, and for non-continuous dischargers, the Discharger shall perform testing on a frequency specified for that discharge by the Applicable Water Board, but no less than once in a permit cycle.

b. **Sample Types** – For Static Non-renewal and Static Renewal testing of continuous discharges, the samples shall be 24-hour flow proportional composites and shall be representative of the volume and quality of the discharge. For non-continuous dischargers, samples shall be composite or grab samples representative of the effluent quality. The effluent samples shall be taken at the effluent monitoring location(s) as specified in the permit.

c. **Test Species** – Test species shall be fathead minnows (*Pimephales promelas*) or rainbow trout (*Oncorhynchus mykiss*), unless other species are justified or approved by the Applicable Water Board.

d. **Test Methods** – The acute toxicity testing samples shall be analyzed using EPA-821-R-02-012, Fifth Edition, or the most recent edition of this test method, and related guidance documents. Temperature, total residual chlorine, and pH shall be recorded at the time of sample collection. The Discharger may only make pH adjustments to reduce ammonia-related toxicity, otherwise no pH adjustments will be allowed unless approved by the Executive Officer.

e. **Test Failure** – If an acute toxicity test does not meet all test acceptance criteria, as specified in the test method, the Discharger must re-sample and re-test as soon as possible, not to exceed seven (7) days following notification of test failure.

f. **Reporting** - Acute toxicity test results shall be submitted with the routine discharger self-monitoring reports and reported as percent mortality. Percent mortality equal to or below the above specified percentages shall be deemed to be in compliance with the objective/limit.

Chronic Toxicity

There shall be no chronic toxicity to aquatic organisms in ambient waters caused by non-natural or reasonably controllable water quality factors, outside any designated mixing zone. Chronic toxicity is defined as a significant detrimental physiological effect on growth rate, reproduction, and fertilization success of a resident organism, population, or indicator species.

Chronic Toxicity Permit Requirements and Compliance Determination

1. **Effluent Limitation.** All Dischargers that exhibit a Reasonable Potential (RP) to exceed the Chronic Aquatic Toxicity Objective, expressed as 1 TUc as a monthly median at the maximum permitted IWC, shall include a narrative chronic toxicity effluent limitation, or for MS4 discharges a receiving water limitation, that requires the following:

“**Chronic Whole Effluent Toxicity.** The effluent shall not cause or contribute to chronic toxicity in the receiving water.”

2. **Monitoring Frequency** – For Major POTW Facilities and other continuous dischargers with an effluent limitation for chronic toxicity, the Discharger shall perform monthly chronic toxicity testing. For continuous dischargers that do not exhibit RP, Minor POTW Facilities, and

for non-continuous dischargers, chronic toxicity tests shall be performed no less than once per year, or on a frequency specified for that discharge by the Applicable Water Board.

3. **Compliance Determination** - To determine compliance with this objective and effluent limitation, critical life stage tests for at least three species with approved testing protocols shall be used to screen for the single most sensitive species. The test species used for initial screening shall include a vertebrate, an invertebrate, and an aquatic plant. The most sensitive species shall then be used for routine monitoring. Typical endpoints for chronic toxicity tests include survival, growth, and reproduction.

4. **Test Methods** - The Discharger shall conduct critical life stage chronic toxicity testing in accordance with "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms," Fourth Edition, Environmental Monitoring Systems Laboratory, USEPA (EPA 821-R-02-013, Oct. 2002), or the "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition, Environmental Monitoring Systems Laboratory, USEPA (EPA 821-R-02-014, Oct. 2002) or "Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms," First Edition, National Exposure Research Laboratory, USEPA (EPA 600-R-95-136, Aug. 1995), or the most recent editions of these test methods, depending on the salinity of the receiving water.

5. **Monitoring Results.** Results for the survival and reproduction endpoints shall be reported in TU_c , where $TU_c = 100/IC_{25}$ or EC_{25} (where the EC/IC_{25} is the percent effluent concentration estimated to cause a 25% effect) and/or $100/NOEC$. The Inhibition Concentration (IC) is a point estimate of the toxicant concentration that causes a given percent reduction in reproduction or growth, calculated from a continuous model (e.g., the USEPA Interpolation Method). The Effective Concentration (EC) is a point estimate of the concentration that would cause a given percent reduction in larval development or survival calculated from a continuous model (e.g., Probit). The No Observed Effect Concentration (NOEC) is the highest concentration of toxicant to which organisms from the most sensitive species are exposed in a chronic test that causes no observable adverse effect on the test organisms (e.g., the highest concentration to which the values for the observed responses are not statistically significant or different from the controls). Alternatively, at the Discharger's option, result for the survival and reproductive endpoints may be reported using the USEPA Test of Significant Toxicity (TST) method.

6. **Notice of Results.** The Discharger shall establish procedures to ensure that the toxicity testing laboratory notifies the Discharger of the results of the toxicity testing by the end of the next day following the completion of such tests.

7. **Accelerated Monitoring.** The Discharger shall implement accelerated monitoring when the results for monthly median chronic toxicity for continuous dischargers or the single sample test for intermittent dischargers exceeds the numeric trigger of 1 TU_c at the maximum permitted IWC or receives a fail result under the TST. Accelerated monitoring is required to confirm the chronic toxicity by running six more tests within ninety (90) days. If less than two of those six tests exhibits chronic toxicity, then the discharger returns to normal compliance monitoring frequency. If the source(s) of the toxicity is easily identified (i.e. temporary plant upset), the Discharger shall make necessary corrections to the facility and shall continue accelerated monitoring until four (4) consecutive accelerated tests do not exceed the monitoring trigger. Upon confirmation that the effluent toxicity has been removed, the Discharger may cease accelerated monitoring and resume normal chronic toxicity monitoring frequency.

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8. **TIE/TRE Workplan.** If two or more of those six tests exhibit chronic toxicity above the numeric trigger of 1 TUc at the maximum permitted IWC, then the Discharger shall submit a Toxicity Identification Evaluation (TIE)/Toxicity Reduction Evaluation (TRE) workplan. Once approved by the Applicable Water Board, the Discharger shall implement the workplan, which may include the initiation of a TIE and accelerated monitoring schedule, as approved by the Applicable Water Board Executive Officer. If during the course of the TIE/TRE process, the chronic toxicity is no longer evident in the effluent sampling results before the conclusion of the TIE/TRE process, the Discharger may terminate or suspend the TIE/TRE process and return to normal compliance monitoring frequency.

9. **Additional Requirements/Compliance Schedules.** If a toxicant is conclusively determined under a TIE/TRE and has not been resolved, effluent limits for that specific toxicant(s) can be imposed by the Applicable Water Board to control chronic toxicity. This permitting action and/or other source control or pretreatment actions may be taken as part of the TRE process to reduce the likelihood of future chronic toxicity excursions. The Applicable Water Board may provide a compliance schedule for new source control or pretreatment actions, or for actions necessary to comply with any new effluent limits needed to control toxicity, which shall be as short as possible, but no longer than ten (10) years from the date of the new requirements.

10. **Reporting.** Regular chronic toxicity monitoring results shall be reported to the Applicable Water Board and shall be submitted with the routine discharger self-monitoring reports following completion of the test, and shall contain, at a minimum:

- a. The results expressed in TUc at the maximum permitted IWC, measured as 100/NOEC, and/or as 100/LC50, 100/EC25, 100/IC25, or 100/IC50, as appropriate. Alternatively, the results may be reported using the USEPA TST method.
- b. The statistical methods used to calculate endpoints;
- c. The statistical output page, which includes the calculation of the Percent Minimum Significant Difference (PMSD);
- d. The dates of sample collection and initiation of each toxicity test;
- e. The results compared to the numeric toxicity monitoring trigger of 1 TUc at the maximum permitted IWC, unless the TST is used.
- f. Additionally, the discharge self-monitoring reports shall contain an updated chronology of chronic toxicity test results expressed in TUc at the maximum permitted IWC, and organized by test species, type of test (survival, growth or reproduction), and monitoring frequency, (i.e., either annually, quarterly, monthly, accelerated, or TRE).
- g. Reports for TREs shall be submitted in accordance with the schedule contained in the Discharger's approved TIE/TRE Work Plan.

11. **Quality Assurance (QA).** The Discharger must provide the following information for QA purposes for whole effluent toxicity testing:

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- a. Results of the applicable reference toxicant data with the statistical output page giving the species; NOEC, LOEC, and/or IC/EC; type of toxicant; dilution water used; concentrations used; PMSD; and dates tested.
- b. The reference toxicant control charts for each endpoint, which include summaries of reference toxicant tests performed by the contracting laboratory.
- c. Any information on deviations or problems encountered and how resolved.

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