

Response to Comments

City of Simi Valley
 Simi Valley Water Quality Control Plant
 Tentative Amendment NPDES Permit

This Table describes all significant comments received from interested persons with regard to the above-mentioned tentative permit. Each comment has a corresponding response and action taken.

Commenter	#	Comment	Response	Action Taken
Comments received from City of Simi Valley on June 4, 2015				
City of Simi Valley	C-1	For the provisions of the Permits that were not amended, the Permittee's submitted comments and filed petitions for review on the previous permits.	<p>Comment noted, however, the instructions in the letter transmitting the Tentative Amendment Order clearly informed the public that "the Board will accept comments only with respect to the proposed changes to the tentative amended requirements in underline and strikeout format." As such, only those comments pertaining to language that appears in underline and strikeout format will be accepted in the context of this narrow NPDES permit amendment. The language below describing the purpose of the amendment was omitted on the tentative amendment dated May 6, 2015, for the Simi Valley WQCP. This language is consistent with the other tentative amendment for the Camarillo and Hill Canyon WRPs. The language below will be inserted on page F-4, section I.D of the Fact Sheet.</p> <p>On May 8, 2014, the Regional Water Board adopted Order No. R4-2014-0066 for the Simi Valley WQCP, which included chronic toxicity requirements using a two-concentration test design, based upon USEPA's Alternative Test Procedure (ATP) approval letter dated March 17, 2014. However, on February 11, 2015, USEPA withdrew its ATP approval. On April 9, 2015, the Regional Water Board adopted NPDES permits for the Joint Outfall System San Jose Creek WRP and other POTWs with revised chronic toxicity</p>	Revisions were made to the Fact Sheet.

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			requirements consistent with the USEPA ATP withdrawal letter. Order R4-2014-0066 is being amended to update the chronic toxicity requirements, consistent with those included in the San Jose Creek WRP permit, and to correct other reporting requirements. All other permit requirements will remain unchanged and in effect.” (Refer to Attachment C).	
City of Simi Valley	C-2	The comments and issues raised on appeal, including those challenging the numeric and maximum daily limits for chronic toxicity, remain valid and are incorporated by reference into this comment letter.	Please see response to Comment C-1.	None necessary.
City of Simi Valley	C-3	In addition, the arguments raised by the County Sanitation Districts of Los Angeles County in both their comments letters and petitions for review on the Pomona, Whittier Narrows, and San Jose Creek NPDES permits are also incorporated by reference herein.	Please see response to Comment C-1.	None necessary.
City of Simi Valley	C-4	<p><i>The Regional Board failed to adequately demonstrate reasonable potential.</i></p> <p>The proposed amendments include new language in footnote 15 for Thousand Oaks and Camarillo, and footnote 7 for Simi Valley, and in the Fact Sheets, which states: “a numeric WQBEL is established because the effluent data showed that there is reasonable potential for the effluent to cause or contribute to an exceedance of the water quality objective.” The proposed permit amendments contain no effluent data to support these findings and chronic toxicity is not included in the Tables contained in the Fact Sheets that provide the summary of the reasonable potential analyses. For this reason, the effluent limitations for chronic toxicity are not necessary or justified and must be removed.</p> <p>Reasonable potential also cannot just be presumed where there is a TMDL. The steps set out in 40 C.F.R. §122.44(d) must still be followed to determine if</p>	<p>Resolution No. R4-2005-009, <i>Amendment to the Water Quality Control Plan for the Los Angeles Region to Incorporate a Total Maximum Daily Load for Toxicity, Chlorpyrifos, and Diazinon in Calleguas Creek, its Tributaries, and Mugu Lagoon (Toxicity TMDL)</i>, assigns a chronic toxicity waste load allocation to the Simi Valley WQCP facility. Therefore, a water quality-based final effluent limitation for chronic toxicity is required in the NPDES permit for the Simi Valley WQCP.</p> <p>The TMDL imposes numeric WLAs for chronic toxicity on POTWs in the watershed. These numeric WLAs were approved by the State Water Board and USEPA under CWA section 303(d). Where a waste load allocation has been established for a particular discharger and pollutant pursuant to a TMDL, any effluent limitation in a permit for the discharge must be consistent with the assumptions and requirements of the available waste load allocation. (40 C.F.R. § 122.44(d)(1)).</p>	None necessary.

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		<p>reasonable potential exists before a Waste Load Allocation must be applied consistently in an effluent limitation. 40 C.F.R. §122.44(d)(1)(vii) (“When developing water quality based effluent limits under this paragraph the permitting authority shall ensure that: (B) effluent limits developed to protect a narrative water quality criterion, a numeric water quality criterion, or both, are consistent with the assumptions and requirements of any available wasteload allocation for the discharge prepared by the State and approved by EPA pursuant to 40 CFR 130.7.”) “The requirements of paragraphs (iii), (iv), (v) or (vi) apply <i>after</i> the permitting authority has determined that water quality based effluent limits are necessary under paragraph (ii).” 54 Fed. Reg. 23868, at 23873 and 23878 (emphasis added). “If the permitting authority, after applying the principles in paragraph (ii), determines that a pollutant or pollutant parameter is exceeding or is expected to exceed a water quality criterion, then the permitting authority uses one or more of paragraphs (iii), (iv), (v) or (vi) to determine the appropriate controls for the pollutant or pollutant parameter.” <i>Id.</i> “[T]he permitting authority must satisfy the procedures in paragraph (ii) before establishing limits under paragraph (d)(1) (iii), (iv), (v) or (vi).” <i>Id.</i></p>		
City of Simi Valley	C-5	<p><i>The Regional Board cannot rely on the Toxicity TMDL to demonstrate reasonable potential or justify limits.</i></p> <p>The Simi Valley permit contains the following footnote 7:</p> <p>The <i>Calleguas Creek Watershed Toxicity TMDL</i> includes a WLA of 1.0 TUC for toxicity, which is required to be implemented in accordance with USEPA, State Water Board, and Regional Water Board resolutions, guidance and policy at the time of permit issuance or renewal. In addition, a numeric WQBEL is established because effluent data showed that there is reasonable potential for the effluent to cause or contribute to an exceedance of the chronic toxicity water quality</p>	<p>Footnote 7 on page 7 of the Order is the same footnote that appeared on footnote 15, page F-42 of the Fact Sheet, before this tentative amendment was proposed, with the underline/strikeout changes below:</p> <p>The <i>Calleguas Creek Watershed Toxicity TMDL</i> includes a WLA of 1.0 TUC for toxicity, which is required to be implemented in accordance with USEPA, State Water Board, and Regional Water Board resolutions, guidance and policy at the time of permit issuance or renewal. <u>In addition, a numeric WQBEL is established because effluent data showed that there is reasonable potential for the effluent to cause or contribute to an exceedance of the chronic toxicity water quality objective.</u> The numeric WLA is protective of</p>	None necessary.

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		<p>objective. The numeric WLA is protective of both the numeric acute toxicity and the narrative toxicity Basin Plan water quality objectives. Consistent with the <i>Toxicity TMDL Implementation Plan</i>, these chronic toxicity WLA-based final effluent limitations will be implemented using the <i>Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms</i> (U.S. EPA 2002, EPA-821-R-02-013), and current USEPA guidance in <i>National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, June /2010)</i> and <i>EPA Regions 8, 9 and 10 Toxicity Training Tool (January 2010)</i>, http://www2.epa.gov/region8/epa-regions-8-9-and-10-toxicity-training-tool-january-2010.</p> <p>The two USEPA guidance documents referenced do not mandate the inclusion of a numeric effluent limitation for chronic toxicity:</p> <ul style="list-style-type: none"> • <i>National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, June 2010)</i> (2010 TST Guidance), and • <i>EPA Regions 8, 9 and 10 Toxicity Training Tool (January 2010)</i> (Training Tool), http://cfpub.epa.gov/npdes/wqbasedpermitting/wet.cfm. <p>Reasonable potential also cannot just be presumed where there is a TMDL.</p> <p>The Regional Board also cannot rely upon the terms of the State Water Board's Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California (SIP) to justify inclusion of effluent limitations for chronic toxicity because that policy only applies to "each priority pollutant with an applicable criterion or objective." SIP at Section 1.3.</p>	<p>both the numeric acute toxicity and the narrative <u>toxicity</u> Basin Plan <u>water quality</u> objective. Consistent with the <i>Toxicity TMDL Implementation Plan</i>, these <u>chronic</u> toxicity WLA-based final effluent limitations will be implemented using the Short Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms (USEPA 2002, EPA-821-R-02-013), and current USEPA guidance in <i>National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, June /2010)</i> and <i>EPA Regions 8, 9 and 10 Toxicity Training Tool (January 2010)</i>, http://www2.epa.gov/region8/epa-regions-8-9-and-10-toxicity-training-tool-january-2010.</p> <p>Footnote 7 was duplicated from the Fact Sheet to make all POTW permits being revised at this time consistent. Since footnote 7 is not new amended language, except for the underline/strikeout that appeared above, the comment is addressing language that was already present in the adopted permit and will not be accepted in the context of this narrow NPDES permit amendment.</p> <p>Also, please see response to Comment 4.</p>	

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City of Simi Valley	C-6	<p><i>The proposed amendments are inconsistent with the Toxicity TMDL</i></p> <p>The amendments related to the Toxicity TMDL focus only on the ability to use “guidance” and ignore the language of the Basin Plan Amendment incorporating that TMDL, which expressly states that the “WLAs” would be <u>implemented as trigger</u> for initiation of the TRE/TIE process as outlined in EPA’s ‘Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the National Pollutant Discharge Elimination System Program’ (2000) and current NPDES permits held by dischargers to the CCW.” See Exhibit G, Resolution No. R4-2005-009 at pg. 7 (Implementation Plan), and Exhibit H, excerpts of the CCW Toxicity, Chlorpyrifos and Diazinon TMDL Technical Report (April 25, 2005) at pg. 122 (emphasis added). The adopted and applicable resolutions and precedential policies at the time of these proposed permit amendments all mandate narrative effluent limitations for chronic toxicity and a trigger for initiation of the TRE/TIE process. State Water Board Order Nos. WQO 2003-0012, WQO 2003-0013, WQO 2008-0008 at pp. 5-7 (concluding that numeric effluent limitations for chronic toxicity are not appropriate at this time), and WQO 2012-0001.</p>	<p>Consistent with the public notice that was distributed for this item, the issue about whether the chronic toxicity final effluent limit should be numeric or a trigger will not be considered at the July 9, 2015 Board hearing, since that is outside of the scope of the proposed NPDES permit amendment.</p> <p>Moreover, this issue was addressed on April 30, 2014 in response to Simi Valley WQCP’s comment letter dated April 15, 2014, Comment C-4 on page 9 of 54 in the Response to Comments Table prepared by Water Board staff and included in the Board agenda package for the adoption of NPDES Order No. R4-2014-0066 for the Simi Valley WQCP.</p>	None necessary.
	C-7	<p>In fact, the most recent guidance from EPA is <u>withdrawing</u> its approval of an Alternate Test Procedure (“ATP”) providing regulatory approval to use the TST. In EPA’s March 17, 2014 TST ATP, EPA had “determined that the State Water Board’s proposed use of the two-concentration toxicity test evaluated using the Test of Significant Toxicity (TST) is an acceptable equivalent under the ATP process to the five-concentration test evaluated using NOEC-LOEC hypothesis testing recommended in 40 CFR Part 136.5.” However, on February 11, 2015, EPA <u>withdrew the approval of this Limited Use ATP</u>, effective immediately. So the TST is no longer able to be used in a regulatory context and is</p>	<p>The Simi Valley WQCP Order is consistent with the letter dated February 11, 2015, from USEPA to the State Water Resources Control Board (State Water Board) withdrawing approval of the alternate test procedure using a two-concentration test design. The Order requires the test methods described in <i>Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms</i> (October 2002) (EPA-821-R-02-013), including review of the concentration-response pattern. USEPA withdrew its ATP approval for use of a two-concentration test design in lieu of the five concentration plus a control specified in the WET Test method, due to the currently pending proposed rulemaking to revise the ATP</p>	

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		not consistent with the TUC/NOEC approach used in the Toxicity TMDL, and the promulgated Part 136 methods.	<p>regulations at 40 CFR Part 136.</p> <p>The State permitting authority, here, the Regional Water Board, has the discretion to select the statistical approach for analyzing WET test data that is most appropriate for use in a particular permit. (See Section 9.4.1.2 of <i>Short-term Methods</i>, October 2002, EPA-821-R-02-013 (“[T]he statistical methods recommended in the manual are not the only possible methods of statistical analysis.”)) The Regional Water Board has selected the TST statistical approach for use in this Order. Use of an alternate statistical calculation is contemplated in USEPA’s 2002 the WET Test Method, which predates the 2010 TST document.</p>	
City of Simi Valley	C-8	<i>The Regional Board has no authority to ignore SWRCB precedent.</i>	Please see response to Comment C-1.	None necessary.
City of Simi Valley	C-9	<p><i>No approved alternative method For WET exists or is allowed.</i></p> <p>The EPA’s Part 136 methods are the only methods that may be used for determining compliance in NPDES permits. EPA regulation clearly state that “<u>Monitoring must be conducted according to test procedures approved under 40 CFR Part 136.</u>” 40 C.F.R. §122.41(J)(4).</p> <p>EPA’s promulgated Part 136 methods include a null hypothesis that water is presumed non-toxic until proven differently, has specified allowable statistical methods, and has two allowable endpoints (NOEC/LOEC, or EC25/IC25). The Part 136 methods do not authorize a null hypothesis presuming water to be “toxic,” allowing a t-test based on the TST, or endpoints based on the TST.</p> <p>The approved 2002 Methods contain just four (4) approved specified statistical methods to be used with hypothesis tests: 1) Dunnett’s Procedure; 2) T-test with the Bonferroni Adjustment; 3) Steel’s Many-One Rank Test; and 4) Wilcoxon Rank Sum Test with the</p>	<p>Please see response to Comment C-7 and C-10.</p> <p>The commenter notes that USEPA’s 2010 publication regarding the TST statistical analysis is guidance and not regulation. Similarly, USEPA’s published materials on the point-estimate technique and NOEC-LOEC hypothesis testing methods are guidance and not required statistical approaches. The 2002 Chronic Toxicity Testing Method clarifies that the “statistical methods recommended in this manual are not the only possible methods of statistical analysis ... there are other reasonable and defensible methods of statistical analysis for this kind of toxicity data.” (Chronic WET Testing, October 2002, 9.4.1.2.) Contrary to the commenter’s allegation, the Regional Water Board does not consider itself bound by USEPA’s 2010 publication. The permitting authority has the discretion in this circumstance to select the means of statistical analysis that is most appropriate for the particular permit to be required for compliance and reporting purposes. (See 40 CFR §§ 122.44(d) and 122.43.).</p>	None necessary.

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		<p>Bonferroni Adjustment. See accord USEPA, Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms (Fourth Ed., Oct. 2002) (“2002 Methods”) at pp. 44-45. Each of these statistical methods is used for hypothesis tests resulting in the endpoint estimates of NOEC or LOEC (No or Lowest Observable Effect Concentration). Id. at p. 43 (Figure 2 - Flowchart for statistical analysis of test data). However, the 2002 Methods express a promulgated preference for the alternative endpoint to the NOEC/LOEC, which is the point estimate approach (EC/IC25). The TST’s “Pass/Fail” or “Greater than 50% Effect” are not approved endpoints and the TST is not an approved statistical method</p> <p>While the 2002 Methods and the proposed additions to the Permits’ Fact Sheets recognize that “[t]he statistical methods recommended in this manual are not the only possible methods of statistical analysis,” the Permits’ amendments take this one statement out of context and ignore the remaining explanatory language stating that “[m]any other methods have been proposed and considered.” EPA chose the specific statistical methods and hypothesis tests in that manual, which were incorporated by reference into Part 136, “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. 2002 Methods at p. 40, Section 9.4.1.2.</p> <p>The only way that TST could have been used was through a new rulemaking, or through an ATP, which was tried and has been withdrawn. EPA has acknowledged these limitations:</p> <p>“[A]s 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</p>		

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		<p><u>control plus five effluent concentrations under the methods' test acceptability criteria</u>. As such, <u>the promulgated methods do not allow for only two concentrations for use in NPDES permits</u>. 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."</p> <p>Memo from Robert Wood, EPA HQ, to Alexis Strauss, EPA Region IX, SUBJECT: Response to "Approval to use 'two concentrations only' experimental design with EPA's Test of Significant Toxicity (TST) hypothesis testing approach (Oct. 22, 2013); see also email from Ross Brennan, EPA HQ, to David Smith, EPA Region IX (March 18, 2013)(stating that Region 9 mischaracterized the TST Guidance document and was seeking to endorse "a whole effluent toxicity (WET) test method approach that is <u>not approved in EPA's promulgated WET test methods</u> (40 CFR Part 136)." The email goes on to say that "A WET test method that uses only two concentrations does not meet the minimum mandatory [test acceptability criteria] TAC.").</p>		
City of Simi Valley	C-10	EPA Region IX and the Los Angeles Regional Water Board may prefer the TST, but the TST is not an approved Part 136 test method, endpoint, or statistical procedure. In fact, although EPA recently proposed amendments to the Part 136 methods a few months ago, including specific changes to the promulgated 2002 Methods and the ATP approval regulations, the TST was not included in this proposed rulemaking. See Federal Register Notice, http://www.gpo.gov/fdsys/pkg/FR-2015-	Not just USEPA Region IX, but USEPA Headquarters in Washington D.C., endorsed the use of the TST in a memo dated, June 18, 2010 (Refer to Attachment A). The purpose of the memo was to transmit a copy of the final guidance document "National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA833-R-10-003)." The introduction refers to the TST as "an additional recommended statistical approach for analyzing WET test data used for whole effluent toxicity (WET)	None necessary.

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		<p>02-19/pdf/2015-02841.pdf (February 19, 2015).</p> <p>If the TST was a truly superior method, the TST would have been included in these revised methods either in 2015 or in the last revisions in 2012. Yet, it was not, and the TST is not a valid Part 136 method and cannot be utilized as such.</p> <p>The TST cannot be used in NPDES permits based solely on outdated and unapproved 2010 EPA guidance documents that have never been adopted as rules. To do otherwise constitutes underground rulemaking, violating the Administrative Procedures Act and important public participation requirements.</p>	<p>reasonable potential determinations and NPDES permit compliance.” The memo goes on to state that the document was peer reviewed according to EPA’s requirements and that the TST may be used for NPDES permit compliance.</p> <p>While it is true that in February of this year USEPA initiated the process to update 40 CFR part 136, the rulemaking process is still underway, and is by no means over. Comments on USEPA’s proposed changes were due on May 20, 2015. USEPA has yet to respond to comments received or to issue a revised proposed rule based on the comments received. It is premature for the Permittee to judge what additional changes may or may not take place. However, we do know that the State Water Resources Control Board submitted a comment letter dated May 14, 2015 (Refer to Attachment B), requesting that USEPA modify a few sections of the WET Test Method to incorporate the TST statistical analysis.</p> <p>The use of the TST in the Simi Valley WQCP NPDES permit is allowed under the <i>Toxicity TMDL</i> implementation section which grants the Regional Water Board flexibility to determine the appropriate method to implement the WLAs based on USEPA, State Board, and Regional Board resolutions, “guidance, and policy at the time of permit issuance (emphasis added).” While the Regional Water Board agrees that one step to achieving compliance with a water quality-based WET requirement can be a toxicity reduction evaluation to identify the constituents of concern, on its own, it is not enough to serve as the required NPDES WQBEL. The NPDES permit Orders adopted on May 8, 2014, require numeric chronic toxicity WQBELS and the TIE/TRE process if the numeric effluent limit is exceeded.</p>	
City of Simi Valley	C-11	<p><i>The proposed amendments ignore the 2002 methods requirements to use and analyze multi-concentration tests and consider the PMSD.</i></p> <p>The 2002 Methods intended for the use of a multi-concentration test design for chronic toxicity, with</p>	<p>USEPA’s position is that applying its 2000 concentration-response pattern review guidance and/or inapplicable NOEC/LOEC variability criteria (i.e., PMSDs) to the TST – an unrelated statistical approach – prior to reporting compliance will undercut the transparency of the reported toxicity result, shroud a potentially non-compliant result prior to reporting,</p>	None necessary.

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		<p>consideration of the resulting concentration-response pattern in assessing the validity of the test, along with a review of Percent Mean Significance Difference (“PMSD”). The amendments proposed to the Permits by the Regional Board do not allow these important validation steps and safeguards to be fully utilized. Thus, these Permit modifications conflict with the promulgated freshwater chronic toxicity test procedures in the 2002 Methods.</p> <p>The Part 136 approved methods for freshwater chronic toxicity in 40 C.F.R. section 136.3(a), Table 1A include Footnote 27, which mandates the use of <i>Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA-821-R-02-012</i>, Third Edition, October 2002 (EPA’s “2002 Methods”). The 2002 Methods clearly require a multi-concentration test design with dose-response evaluation. Several examples are as follows (underlining added):</p> <p>“The tests recommended for use in determining discharge permit compliance in the NPDES program are <u>multi-concentration</u>, or definitive, tests <u>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</u>” (2002 Methods, Section 8.10.1)</p> <p>“The <u>concentration-response relationship generated for each multi-concentration test must be reviewed</u> to ensure that calculated test results are interpreted appropriately” (2002 Methods, Section 10.2.6.2)</p> <p>“Tables 1, 3, and 4 (labeled as 3) - SUMMARY OF TEST CONDITIONS AND TEST ACCEPTABILITY CRITERIA WITH EFFLUENTS AND RECEIVING WATERS (TEST METHODS 1000.0, 1002.0, AND 1003.0): Test concentrations: Effluents: <u>5 and a control</u></p>	<p>and diminish the reliability and enforceability of the permit and its toxicity limits. Page F-46 of the Fact Sheet references audit correspondence from the State Water Board and USEPA.</p> <p>The preamble to the WET Test Method (Federal Register/ Vol. 67, No. 223, p. 69952 (November 19, 2002)) provides valuable insight into what USEPA intended when it was updating its WET Test Method. From the underlined language below, it is clear that the PMSD was only intended for permits that had limits in terms of NOEC or LOEC.</p> <p>“Variability Criteria</p> <p>Today’s action incorporates mandatory variability criteria for five chronic test methods. USEPA recommends the use of point estimation techniques over hypothesis testing approaches for calculating endpoints for effluent toxicity tests under the NPDES Permitting Program. However, to reduce the within-test variability and to increase statistical sensitivity when test endpoints are expressed using hypothesis testing rather than the preferred point estimation techniques, variability criteria must be applied as a test review step when NPDES permits require sublethal hypothesis testing endpoints (i.e., no observed effect concentration (NOEC) or lowest observed effect concentration (LOEC) and the effluent has been determined to have no toxicity at the permitted receiving water concentration. These variability criteria must be applied for the following methods: Fathead minnow Larval Survival and Growth Test; Selenastrum capricornutum Growth Test; Mysidopsis bahia Survival, Growth and Fecundity Test; and Inland Silverside Larval Survival and Growth Test. Within test variability, measured as the percent minimum significant difference (PMSD), must be calculated and compared to upper bounds established for test PMSDs...” (p. 69957)</p> <p>It is reasonable and appropriate for the Regional Board to conclude that the PMSD tool for evaluating test variability is not applicable to this permit because it does not include chronic toxicity limits expressed as TUC or NOEC.</p>	

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		<p><u>(required minimum)</u></p> <p>In addition, the 2002 Methods also make it clear that consideration of PMSD is a required element of the procedure by specifically stating:</p> <p>“When NPDES permits require sublethal hypothesis testing endpoints from Methods 1000.0, 1002.0, or 1003.0 (e.g., growth or reproduction NOECs and LOECs), <u>within-test variability must be reviewed and variability criteria must be applied as described in this section.</u>” (2002 Methods, Section 10.2.8.2)(emphasis added).</p> <p>For the purposes of evaluating within-test variability, the 2002 Methods consistently rely on use of the PMSD as a tool. A higher PMSD is equivalent to greater within-test variability while a lower PMSD indicates lower within-test variability. The 2002 Methods describe <u>mandatory criteria</u> using the PMSD for interpreting and validating sublethal hypothesis test results using the PMSD metric. See 2002 Methods at p. 51 (Section 10.2.8.2)(“To measure test variability, calculate the percent minimum significant difference (PMSD) achieved in the test”). As quoted above, the 2002 Methods require review of the PMSD for any NPDES chronic toxicity hypothesis tests. The TST is a hypothesis test conducted on a chronic/ sublethal endpoint (albeit one unauthorized by the 2002 Methods), and if used, the TST must also be subjected to application of the PMSD criteria described in the 2002 Methods.</p> <p>The proposed amendments to the Permits specifically prohibit the use of the PMSD criteria and ignores the 2002 Method’s mandated steps for quality assurance. See proposed changes to the Permit at Section III. J. (“The Percent Minimum Significant Difference (PMSD) criteria only apply to compliance reporting for the NOEC and the sublethal statistical endpoints of the NOEC, and therefore are not used to interpret TST results.”). The</p>	<p>While section 10.2.8.2 of the WET Test Method specifies that “When NPDES permits require sublethal hypothesis testing endpoints from Methods 1000.0, 1002.0, or 1003.0 (e.g., growth or reproduction NOECs and LOECs), within-test variability must be reviewed and variability criteria must be applied as described in this section (10.2.8.2)” (emphasis added), the WET Test Method section does not require the use of the PMSD. Subsection 10.2.8.2.1 describes how to calculate the PMSD and subsequent subsections describe how to compare the PMSD to see if the PMSD falls within an acceptable range; i.e. if PMSD is within the upper and lower bounds.</p> <p>Subsection 10.2.8.3 states:</p> <p>“To assist in reviewing within-test variability, EPA recommends maintaining control charts of PMSDs calculated for successive effluent tests (USEPA, 2000b). A control chart of PMSD values characterizes the range of variability observed within a given laboratory, and allows comparison of individual test PMSDs with the laboratory’s typical range of variability. Control charts of other variability and test performance measures, such as the MSD, standard deviation or CV of control responses, or average control response, also may be useful for reviewing tests and minimizing variability. The log of PMSD will provide an approximately normal variate useful for control charting.” (emphasis added)</p> <p>USEPA recommends use of PMSD when the hypothesis test has endpoints expressed in terms of growth or reproduction NOECs and LOECs. However, the Simi Valley WQCP permit does not have endpoints expressed as NOEC/LOEC, but in terms of Pass or Fail and Percent Effect. In addition, under this permit, within-test variability of the WET test data utilized for the TST statistics will be reviewed and variability criteria will be applied by using control charts and coefficient of variation, as allowed by Subsection 10.2.8.3 of the WET Test Method.</p>	

Commenter	#	Comment	Response	Action Taken
		<p>proposed amendments to the Permits also propose to exclude evaluation of within-test variability (only reviewing “concentration-response patterns as appropriate.”) These proposals are inconsistent and contradictory to specific requirements contained in the promulgated 2002 Methods.</p> <p>EPA could have proposed the limited use of concentration response and non-application of PMSD review in conjunction with the TST in its recent proposed rulemaking. EPA failed to do so. See <i>U.S. v. Riverside Bayview Homes</i>, 474 U.S. 121, 137 (U.S.S.C. 1985)(An action not to include modifications of which the entity was aware can be read as a presumption that the modifications were not intended to be included). Thus, the Regional Board has no authority to go beyond the requirements of the Part 136 methods to limit the evaluation of concentration-response relationship or ignore PMSDs, which are part of the approved 2002 Methods.</p>	<p>Therefore, the permit disallows the PMSD approach to evaluate variability of the WET test data because that approach is applicable to the NOEC/LOEC statistical analysis and not the TST statistics required by the permit.</p>	
City of Simi Valley	C-12	<p><i>The modified test method procedures make certification of “Valid” results impossible.</i></p> <p>Because of the inherent uncertainties in chronic toxicity tests generally and the additional problems with the procedures as described in this letter, the Permittees will be unable to certify the validity or accuracy of TST results in their monthly Discharge Monitoring Reports (DMRs) despite new proposed language in the Permits’ amendments discussing “valid” results. In March of 2000, U.S. EPA published guidance regarding the certification of WET test results on the DMR wherein EPA stated:</p> <p style="padding-left: 40px;">“When a person certifies that the submission of WET testing information is accurate to the best of their knowledge and belief, the person certifies that the results obtained using the WET testing procedures are faithfully and truthfully transcribed on the information submission, and that the results were, in fact results that were obtained using the</p>	<p>A valid test result refers to having the test results meet the Test Acceptability Requirements (TAC) specified in the WET Test Method and Test Acceptability Criteria and summarized in Table E-6 of the MRP, on page E-15. The revised language in section V.A.9 of the Monitoring and Reporting Program (MRP), page E-17, requires that the Permittee submit a full laboratory report including a “valid” toxicity result. This standardized language was adopted into the San Jose Creek WRP NPDES permit during the April 2015 Board meeting and is included in the tentative Amended Order for Simi Valley WQCP. It aims to prevent future reporting deficiency problems that have been encountered in the past with other facilities, so that complete reports are submitted to the Regional Water Board.</p>	None necessary.

Commenter	#	Comment	Response	Action Taken
		<p>specified testing procedures.”</p> <p>Since the TST method has not been approved as part of a Part 136 method, the Permittees cannot legally certify the results derived from this method or assert that these results are “valid.” The fact that the TST procedure prescribed in the amendments relies on only two concentrations, rather than the minimum test concentrations mandated in the promulgated method 2002 Methods to adequately review the dose-response, also makes it impossible to verify or certify results. Finally, the Permittees cannot certify TST results as “true” or “accurate” where the conclusions are inconsistent with those reported using the IC25 or NOEC procedures and endpoints that EPA endorsed in the original rule promulgating the existing 2002 Methods. This is particularly true in light of the inability to confirm the validity of the dose response relationship. This position is also consistent with the U.S. Court of Appeals finding in the <i>Amoco</i> case. For all these reasons, the Regional Board should only prescribe permit requirements consistent with the 2002 Methods.</p>		
City of Simi Valley	C-13	<i>Request: Restore the chronic toxicity narrative effluent limitations and triggers from the last permit based on TUC to be consistent with the Toxicity TMDL and use the promulgated Part 136 methods (NOEC or IC25).</i>	Revision of the actual chronic toxicity limitation is outside the scope of this NPDES permit Amendment. Please see response to Comment C-1	None necessary.
Comments received from Heal the Bay June 8, 2015				
Heal the Bay	1	Numeric Chronic Toxicity Effluent Limits Must be Included.	Thank you for your comment in support of this permit.	None necessary.
Heal the Bay	2	Additional Self-Monitoring Report Requirements Will Help the Regional Board Track and Assess Permittees Chronic Toxicity Testing.	Thank you for your comment in support of the reporting requirements.	None necessary.

Commenter	#	Comment	Response	Action Taken
Heal the Bay	3	<p>Regional Board Should Approach Issuance of Time Schedule Orders for Chronic Toxicity Exceedances Cautiously.</p> <p>The Tentative Amendments would allow Permittees to submit a request for a time schedule order upon an exceedance of an effluent limitation for chronic toxicity. Although the Regional Board has included assessment criteria when determining if a time schedule order is appropriate (e.g. facility compliance with effluent limitations for chronic toxicity, magnitude and duration of exceedance, history of past TIE/TRE processes, efforts of Permittee to achieve compliance with effluent limitations for chronic toxicity), these criteria are extremely broad and lack clear guidance. The Tentative Amendments do not include information or guidance for determining the duration of time schedule orders. In addition, the Tentative Amendments do not address how chronic toxicity effluent limit exceedances occurring during time schedule orders, separate from the initial event, will be enforced; if these exceedances are included in time schedule orders, their inclusion would contradict previous Regional Board positions on chronic toxicity exceedance enforcement during TIE/TRE processes. The Regional Board has the discretion to enforce effluent limitation exceedances – it is unclear why the issuance of chronic toxicity time schedule orders are being considered at this time. We believe this is a slippery slope. Further, issuance of time schedule orders are resource intensive for Regional Board staff, time that may be better suited for other programs and projects. Because of these reasons, we believe the Regional Board should approach issuing time schedule orders for chronic toxicity effluent limitation exceedances cautiously as the criteria and requirements for crafting these enforcement actions are not clearly identified by the Regional Board at this time.</p>	<p>During the March 2015 Board meeting there was much discussion over a change sheet that offered language, proposed by the Discharger for the San Jose Creek WRP, that would have suspended enforcement action by the Board for chronic toxicity exceedances. The Board did not accept this proposal but instead directed staff to work with the Permittee and USEPA to consider alternative language and return to the Board in April 2015. The following language was considered by the Board during the April 2015 hearing and adopted into the San Jose Creek WRP NPDES permit. The same language is being incorporated into the NPDES permit for the Simi Valley WQCP facility, on page F-46 of the Fact Sheet, for consistency:</p> <p style="padding-left: 40px;">The Permittee may submit a request for a time schedule order upon an exceedance of the effluent limitations for chronic toxicity in this Order. In determining whether a time schedule order is appropriate, and the conditions and duration of such an order, the Regional Water Board or Executive Officer will consider the following factors among other relevant considerations: the facility's history of compliance with effluent limitations for chronic toxicity, including the magnitude and duration of any exceedances; history of and information acquired from past TIEs or TREs conducted for the facility; and the efforts of the Permittee to achieve compliance with effluent limitations for chronic toxicity.</p> <p>In addition to submitting a request for a TSO, the Permittee will need to provide adequate justification before the Executive Officer or the Regional Water Board would issue the TSO. Information submitted may include, but is not limited to, a proposed schedule with tasks for achieving compliance and milestone dates for completing such tasks. The duration of the TSO should be as short as practicable. However, if information is lacking, then the TSO would not be issued.</p>	None necessary.

Commenter	#	Comment	Response	Action Taken
Comments received from United States Environmental Protection Agency (USEPA) on June 4, 2015				
USEPA	1	<p>USEPA strongly support adoption of the chronic toxicity requirements in this permit.</p> <p>USEPA is pleased that the draft permits plainly require effluent limits on chronic whole effluent toxicity (WET), where there is reasonable potential.</p> <p>USEPA agrees with the Regional Water Board's decision to use numeric chronic WET WQBELs for these POTW permits, which are feasible to calculate for the discharges.</p> <p>USEPA supports the inclusion of both monthly and daily WQBELs for chronic toxicity, as the Regional Water Board has determined that such limits are necessary to protect against highly toxic short-term peaks of acute or chronic toxicity that exceed the applicable toxicity water quality standard.</p> <p>USEPA commented that the draft permits are consistent with the nine POTW permits this Board has adopted over the past 12 months, which express both monthly and daily chronic toxicity WQBELs numerically.</p> <p>USEPA commented that it is critical that permitting authorities explicitly choose and identify the statistical approach that will be used to protect their narrative toxicity water quality standard and interpret toxicity test results required by NPDES permits. The Los Angeles Regional Water Board has chosen to measure chronic toxicity for compliance reporting with the Test of Significant Toxicity (TST) bioequivalence statistical t-Test approach used to determine if two sets of observations - made for the effluent's instream concentration (IWC) and the control concentration - are different. The proposed modifications ensure that the subject permits, reissued over the past year, contain standardized transparent,</p>	Thank you for your comment in support of this permit.	None necessary.

Commenter	#	Comment	Response	Action Taken
		<p>clearly expressed, enforceable requirements for chronic WET.</p> <p>It is with that strong context that USEPA strongly supports the permit language updating Order section VII.J and associated fact sheet language, to result in consistency across all non-ocean POTW permits with chronic toxicity WQBELs expressed in terms of the TST. This provision specifies compliance evaluation and reporting requirements for chronic toxicity data expressed in terms of the TST and assures compliance with the multi-concentration test design requirement for NPDES effluents found in EPA's 2002 toxicity test methods. Also, it assures that - following EPA's 2002 toxicity test methods – the concentration-response pattern will be reviewed, as appropriate. On this point, USEPA notes that the National Organization of Clean Water Agencies (NACWA) has previously submitted comments critical of some of the POTW permits the Regional Water Board has recently issued. Bearing this in mind, we wish to draw your attention to a January 2006 white paper by NACWA, page 10, which states: "The [toxicity] methods do not specifically state that a permittee may invalidate a [toxicity] test purely on the basis of the concentration-response relationship. However, NACWA believes that, in context of a full Data Quality Objectives program, the testing laboratory and the clean water agency should consider a test invalid if an adequate relationship is not present." This position places NACWA and its member agencies holding this position squarely at odds with EPA's 2002 toxicity test methods rule and preamble regarding the proper role of concentration-response pattern reviews. After statistical analysis of the biological data, concentration-response pattern review specified by EPA plays a role limited to specific instructions for determining that particular endpoints - NOECs, LC50s, and IC25s - are interpreted appropriately.</p>		

Commenter	#	Comment	Response	Action Taken
		<p>It remains USEPA's position that the determination of toxicity is not based on achieving a specified concentration-response pattern. As a result, we concur with the proposed modifications to permit fact sheets, which correctly state that the appropriate interpretation of effluent (or receiving water) sample measurement results from the TST statistical approach is, by design, independent from the concentration-response patterns of the toxicity tests for those samples. When using the TST, we agree that the application of EPA's 2000 concentration-response pattern review guidance will not improve the appropriate interpretation of a TST result, as long as your permits require use of USEPA's toxicity test methods by which good QA/QC is demonstrated through ongoing evaluation and tracking of reference toxicant testing and measures (i.e., mean, standard deviation, and coefficient of variation) of control concentration performance.</p> <p>Also, USEPA commented that provision VII.J takes good steps to effectively address our concern that a laboratory's Standard Operating Procedures for chronic toxicity test data analysis and review can be used to improperly disqualify a test result. It is USEPA's position that applying EPA's 2000 concentration-response pattern review guidance and/or inapplicable NOEC/LOEC variability criteria (i.e., PMSDs) to the TST – an unrelated statistical approach – prior to reporting compliance will undercut the transparency of the reported toxicity result, shroud potentially non-compliance result prior to reporting, and diminish the reliability and enforceability of the permit and its toxicity limits. The three POTW permits adopted in April 2015 took a large step toward addressing EPA's ongoing observation that providing too much WET method flexibility on specific procedures has been a way for some NPDES permit holders to improperly disqualify test results. USEPA supports the inclusion of the proposed generic permit condition and fact sheet language that takes steps to ensure such</p>		

Commenter	#	Comment	Response	Action Taken
		practices will not be used for the proposed modified permits.		

Attachment A

USEPA Washington D.C. Memo dated June 18, 2010

Attachment B

**State Water Resources Control Board Letter
on 40 CFR 136 WET Method
dated May 14, 2015**

Attachment C

**USEPA Region IX
ATP Withdrawal Letter dated February 11, 2015**

Attachment D:

**TMDL for Toxicity, Chlorpyrifos, and Diazinon in Calleguas Creek,
its Tributaries, and Mugu Lagoon
(Toxicity TMDL)**