# Summary of Comments and Responses

for

Staff Report Appendix J. Evaluating Laboratory Performance with the Chronic *Ceriodaphnia dubia* Reproduction Toxicity Test and

Staff Report Appendix K. Survey of Laboratory Toxicity Testing Logistical Capacities

and the differences between

the October 18, 2018 Draft and the July 7, 2020 Second Revised Draft Versions

of the Provisions and Staff Report

for the

Water Quality Control Plan for

Inland Surface Waters, Enclosed Bays, and Estuaries of California;

and the Toxicity Provisions

Release Date: November 9, 2020

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## List of Abbreviations and Short-Hand Names

| **Abbreviation** | **Definition** |
| --- | --- |
| APA | Administrative Procedures Act |
| ATP | Alternate Test Procedures |
| *C. dubia* | *Ceriodaphnia dubia* |
| CEQA | California Environmental Quality Act |
| CFR | Code of Federal Regulations |
| CV | Coefficient of Variation |
| CWA | Clean Water Act |
| ELAP | Environmental Laboratory Accreditation Program |
| IWC | Instream Waste Concentration |
| MDEL | Maximum Daily Effluent Limitation |
| MDET | Maximum Daily Effluent Target |
| MGD | Million Gallons per Day |
| MMEL | Median Monthly Effluent Limitation |
| MMET | Median Monthly Effluent Target |
| MMP | Mandatory Minimum Penalty |
| MS4 | Municipal Separate Storm Sewer System |
| MUR | Methods Update Rule |
| NOEC | No Observed Effect Concentration |
| NPDES | National Pollutant Discharge Elimination System |
| OAL | Office of Administrative Law |
| PMSD | Percent Minimum Significant Difference |
| POTW | Publicly Owned Treatment Works |
| Regional Water Board | Regional Water Quality Control Board |
| Response to 2018 Comments | July 22, 2020 Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report |
| RMD | Regulatory Management Decision |
| SED | Substitute Environmental Documentation |
| SIP | Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California (2005), also known as the State Implementation Policy |
| State Water Board | State Water Resources Control Board |
| SWAMP | Surface Water Ambient Monitoring Program |
| TAC | Test Acceptability Criteria |
| TIE | Toxicity Identification Evaluation |
| TMDL | Total Maximum Daily Load |
| TRE | Toxicity Reduction Evaluation |
| TST | Test of Significant Toxicity |
| U.S. EPA | United States Environmental Protection Agency |
| Water Boards | The State Water Resources Control Board and the Regional Water Quality Control Boards |
| WDR | Waste Discharge Requirements |
| WET | Whole Effluent Toxicity |
| WLA | Waste Load Allocation |
| WQBELs | Water Quality-based Effluent Limitations |
| WWTP | Wastewater Treatment Plant |

## Introduction

The State Water Resources Control Board (State Water Board) received public comments related to draft versions of the “Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California; and Toxicity Provisions” (Toxicity Provisions) and the “Staff Report, Including Substitute Environmental Documentation, for the Proposed Establishment of the Water Quality Control Plan for Inland Surface Wates, Enclosed Bays, and Estuaries of California; and Toxicity Provisions” (Staff Report) in accordance with the following two notices of opportunity for public comment:

* The December 24, 2019 notice of opportunity for public comment stated that the State Water Board will accept input and recommendations on the content of two draft appendices to the Staff Report through written comments and additional evidence directly related to the content of the appendices. The appendices are “Appendix J. Evaluating Laboratory Performance with the Chronic *Ceriodaphnia dubia* Reproduction Toxicity Test” and “Appendix K. Survey of Laboratory Toxicity Testing Logistical Capacities.” The comment period closed at 12:00 noon on February 10, 2020.
* The July 7, 2020 notice of opportunity for public comment stated that the State Water Board will receive written comments, input, recommendations, and additional evidence directly related to the differences between the October 18, 2018 Draft and the July 7, 2020 Second Revised Draft versions of the Toxicity Provisions and the Staff Report. The comment period closed at 12:00 noon on August 24, 2020.

This document includes individual comments received from the public in accordance with the two notices, a summary of the comments grouped by category, and responses to the comments.

The short-hand title of this document is the “Summary of Comments and Responses on Appendices J and K and the Differences Between the October 2018 and July 2020 Versions of the Toxicity Provisions and Staff Report.”

## Explanation of Categories, Comment Codes, Summary Comments, and Summary Responses

### Categories

Comments are sorted into one of several categories. Each category has a Category Code and Title. For example, “Category F – Effluent Limitations” contains comments related to the effluent limitations described in the Toxicity Provisions.

### Summary Comments

“SC” stands for Summary Comment. Similar comments are grouped and summarized in “Summary Comments.” For example, “SC B.002” refers to the second summary comment within Category B.

### Summary Responses

“SR” stands for Summary Response. A response to each Summary Comment is provided in the corresponding Summary Response. For example, “SR B.002” refers to the second summary response within Category B.

### Individual Comments

Numbers in the “Comment Code” column refer to individual comments within a comment letter. The digits to the left of the period correspond to the comment letter code (provided in the Index of Commenters). The last three digits provide a unique identifier to each comment within the letter. For example, “3.005” refers to the fifth comment in Comment Letter #3.

### Tracked Changes

Several commenters proposed edits to the 2020 Draft Toxicity Provisions and Staff Report. In the original comment letters, these changes are shown in various formats (e.g. strikeout deletions, underline additions, red text). For document accessibility purposes, these edits have been converted from the original format provided and are shown in this document using the Microsoft Word “Track Changes” feature.

### Figures and Tables

Several commenters provided figures and tables in their comment letters. In order to ensure this document is accessible for screen readers, these figures and tables are not included in this document. Instead, references to the object’s original location are provided in brackets. For example: [See Figure X on page Y of comment letter #123].

To obtain a copy of the comment letters, please refer to the instructions provided in the “Index of Commenters” section of this document.

## Index of Commenters

To request a copy of the comment letters, please send your request via email to [commentletters@waterboards.ca.gov](mailto:commentletters@waterboards.ca.gov). In your request, please indicate which comment letters you are interested in receiving.

| **Commenter Code:** | **Commenter(s):** | **Submitted by:** |
| --- | --- | --- |
| 1 | California Association of Sanitation Agencies | Adam Link |
| 2 | Robertson-Bryan, Inc. | Cameron Irvine  Paul Bedore |
| 3 | Central Valley Clean Water Association | Debbie Webster |
| 4 | Exponent | Joy McGrath  William Goodfellow  Susan Paulsen |
| 5 | California Coastkeeper Alliance  Heal the Bay | Kaitlyn Kalua  Annelisa Moe |
| 6 | Los Angeles Department of Water and Power | Katherine Rubin |
| 7 | Bay Area Clean Water Agencies | Lorien Fono |
| 8 | Sacramento Regional County Sanitation District | Terrie Mitchell |
| 9 | Risk Sciences | Timothy Moore |
| 10 | General Public | Robyn Stuber |
| 11 | California Association of Sanitation Agencies | Jared Voskuhl |
| 12 | Central Valley Clean Water Association | Debbie Webster |
| 13 | Association of California Water Agencies California Municipal Utilities Association | Nicholas Blair Danielle Blacet-Hyden |
| 14 | Bay Area Clean Water Agencies | Lorien Fono |
| 15 | California Stormwater Quality Association | Amanda Carr |
| 16 | Coachella Valley Water District | Steve Bigley |
| 17 | Los Angeles County Sanitation Districts | Ann Heil |
| 18 | Sacramento Regional County Sanitation District | Terrie Mitchell |
| 19 | California Coastkeeper Alliance  Heal the Bay | Kaitlyn Kalua  Annelisa Moe |
| 20 | Quartz Valley Indian Reservation | Crystal Robinson |
| 21 | Robertson-Bryan, Inc. | Cameron Irvine  Paul Bedore |
| 22 | Calleguas Creek Watershed Management Plan | Lucia McGovern |
| 23 | Los Angeles Department of Water and Power | Katherine Rubin |
| 24 | United States Environmental Protection Agency, Region IX | Ellen Blake |
| 25 | Downey Brand LLP | Melissa Thorme  David Aladjem |
| 26 | Western States Petroleum Association | Keven Buchan |

## Category A – Interactions of the Toxicity Provisions

| **Comment Code** | **Comment** |
| --- | --- |
| **SC A.001** | The Water Boards have the authority to issue National Pollutant Discharge Elimination System (NPDES) permits, which must incorporate water quality-based effluent limitations (WQBELs) for Total Maximum Daily Load (TMDL) constituents. The Toxicity Provisions must be clear that all monitoring and reporting done in accordance with a TMDL shall be done to demonstrate compliance with receiving water limitations imposed by the TMDL. |
| **SR A.001** | TMDL-related toxicity monitoring requirements could be included in an NPDES permit for purposes other than to determine compliance with effluent limitations or receiving water limitations. For example, there may be a source study or other monitoring effort required.  Additionally, Section III.B.3(D) of the Toxicity Provisions was revised to state that Section IV.B applies to all dischargers subject to TMDL requirements except to the extent the permitting authority determines that any specific aquatic toxicity TMDL provisions are more protective than any comparable requirements of Section IV.B of the Toxicity Provisions. In this case, those specific TMDL provisions will apply in lieu of the comparable requirements of Section IV.B.  Section 2.5 of the Staff Report was also revised to explain that the program of implementation in the Provisions applies to dischargers subject to TMDL requirements except to the extent the Regional Water Board determines that any specific provisions of the aquatic toxicity TMDL are more protective than any comparable requirements of the Provisions, in which case those specific provisions of the TMDL will apply in lieu of the comparable requirements of the Provisions. If TMDLs include targets or waste load allocations which are based on a statistical approach other than the Test of Significant Toxicity (TST), the Regional Water Board could include effluent limitations or receiving water limitations using Table 1 species and a statistical approach other than the TST only if the Regional Water Board makes a finding that the TMDL based requirement is more protective than the comparable requirement in the Provisions. |
| 19.020 | Additionally, pursuant to 40 CFR parts 122 and 123, the State and Regional Water Boards have the authority to issue general NPDES permits to regulate a category of point sources if the sources involve the same or substantially similar types of operations, discharge the same type of waste require the same type of effluent limitations, and require similar monitoring. These NPDES permits must then properly incorporate applicable WQBELs for TMDL constituents, such as toxic materials and toxicity. The inclusion of WQBELs and associated implementation requirements is non discretionary given that merely monitoring is not protective of human health or aquatic life. 12 Therefore, it must be clear in the final Toxicity Provisions that all monitoring and reporting done in accordance with a TMDL shall be done to demonstrate compliance with the receiving water limitations imposed by the TMDL. |
| 19.021 | Requested Language (Suggested language in the “Track Changes” feature): 1.1 Interactions with the Regional Water Board Basin Plans and the Statewide Implementation Policy (Staff Report, p. 12) The program of implementation in the Provisions apply to all dischargers subject to TMDL requirements except to the extent the Regional Water Board determines that the aquatic toxicity TMDL requirements are more protective than the Provisions. Existing TMDLs may include waste load allocations or targets that are assessed using approaches other than the TST, in limited circumstances. … In such cases the same aquatic toxicity tests can be used to meet both monitoring and reporting requirements, but the resulting data would need to be assessed using both statistical approaches and reported to the Water Boards to demonstrate compliance with the TMDL requirements. |
| **SC A.002** | Numeric aquatic toxicity water quality objectives are structured to be protective for 95% of all aquatic organisms. They are not meant to be protective of all aquatic organisms. Thus, whole effluent toxicity (WET) testing is a tool for the assessment of NPDES permit compliance, but it is not intended to be a predictor of overall impact to a water body. *Ceriodaphnia dubia* (*C. dubia*) may be found to be the most sensitive species among those listed in Table 1 of the Provisions, but it is not possible to determine if it is the most sensitive of all species in a specific water body. Therefore, the word “fully” should be removed from the relevant portions of the Provisions and Staff Report. |
| **SR A.002** | Section III.B.4 of the Provisions was revised to remove the word “fully.”  The Staff Report was revised to remove the term “fully” when used in this context. |
| 26.005b | The notion that WET testing fully protects all organisms in a water body |
| 26.013 | **While WET testing is intended to protect the majority of organisms in a water body, WET testing may not fully protect all organisms in a water body** |
| 26.014 | **Numeric aquatic toxicity water quality objectives are not intended to be protective of all species in the water body**    Issue: As presented in U.S. EPA’s National Guidelines for deriving numerical national water quality criteria, numeric aquatic toxicity water quality objectives are structured to be protective for 95% of all aquatic organisms (with additional provisions for lowering the criteria to be protective of commercially or recreationally important species) (USEPA 1985). They are not meant to be protective of all aquatic organisms. Furthermore, WET testing uses species that can be readily cultured and dependably tested in the laboratory. As a result, species used in WET testing are sensitive, but WET testing is not intended to be (and by definition cannot be) protective of all aquatic organisms in the water body. Thus, WET testing is a tool for the assessment of NPDES permit compliance, but it is not intended to be a predictor of overall impact to a water body (Grothe et al. 1995).    Toxicity Provisions, Section III.B.4, 6th paragraph on page 5 (and similar content in the Staff Report, Section 2.5, 6th paragraph on page 11).  “The PERMITTING AUTHORITY may rely solely on the numeric aquatic toxicity water quality objectives in Section III.B.2 to address non-chemical specific aquatic toxicity unless there is information to suggest that the numeric aquatic toxicity water quality objective would not fully protect all aquatic species in the relevant water body.”    Staff Report, Section 5.4.3, last paragraph on page 117.  “When *C. dubia* is identified as the most sensitive species, it is important that it be used for routine monitoring to be fully protective of aquatic life.”    Discussion: Numeric guidelines are derived for the protection of aquatic species from adverse effects when exposed to a chemical and are intended to protect 95% of species (USEPA 1985). *C. dubia* may be found to be the most sensitive species among the species listed in Table 1 of the Toxicity Provisions. However, it is not possible to determine if it is the most sensitive of all species in a specific water body.  Recommendations:  Edit the following sentence, from page 5 of the proposed Toxicity Provisions, as follows:    “The PERMITTING AUTHORITY may rely solely on the numeric aquatic toxicity water quality objectives in Section III.B.2 to address non-chemical specific aquatic toxicity unless there is information to suggest that the numeric aquatic toxicity water quality objective would not protect specific species in the relevant water body.”    Remove the word “fully” on pages 11, 108, and 117, of the Staff Report. |
| **SC A.003** | The Staff Report should clarify that in cases where the TMDL waste load allocations (WLAs) are different from the implementation requirements of the Toxicity Provisions for non-storm water dischargers, the permitting authority can solely utilize the Toxicity Provisions if they do not find that more stringent TMDL requirements are warranted. |
| **SR A.003** | Section III.B.3(D) of the Toxicity Provisions was revised to clarify that if individual requirements included in a TMDL are more protective than the implementation requirements in the Toxicity Provisions, those individual requirements in the TMDL need to continue to be applied. Additional clarity and examples were added to Section 2.5 of the Staff Report to clarify that although the Toxicity Provisions do not supersede TMDLs established prior to the effective date of the Toxicity Provisions, if any specific aquatic toxicity requirements in the Provisions is as protective or more protective than any specific aquatic toxicity TMDL requirement, then the comparable requirement of the Toxicity Provisions shall apply. Section 5.5.1 and 5.6.1 of the Staff Report also explain that some TMDLs include targets or WLAs which are based on a statistical approach other than the TST. For these TMDLs, the permitting authority could include effluent limitations or receiving water limitations using Table 1 species and a statistical approach other than the TST only if the permitting authority makes a finding that the TMDL based requirement is more protective than the comparable requirement in the Provisions. |
| 22.001 | **Comment #1 - Clarify the Added TMDL Discussion in the Staff Report**  The Stakeholders appreciate the clarifications to Sections III.B.3 and III.B.4 for watersheds like Calleguas Creek where a Total Maximum Daily Load (TMDL) for toxicity is in effect. We appreciate that the language in the Revised Draft Toxicity Provisions itself is now clear that the implementation provisions for non-stormwater dischargers apply unless there is a more stringent TMDL requirement. However, we request clarification of the discussion in the Staff Report to make sure it is clear that, in cases where the TMDL Wasteload Allocations (WLAs) are different, the RWQCB can solely utilize the Revised Draft Toxicity Provisions if they do not find that more stringent requirements are warranted.  **Requested Changes**  To clarify the staff report and align with the Revised Draft Toxicity Provisions, we request the following modifications to the staff report:  Page 12-Add the underlined language to the following paragraph:  "The program of implementation in the Provisions apply to dischargers subject to TMDL requirements except to the extent the Regional Water Board determines that the aquatic toxicity TMDL requirements are more protective than the Provisions. Existing TMDLs may include waste load allocations or targets that are assessed using approaches other than the TST. If the TMDL is not updated, NPDES permits that are subject to the requirements of both the TMDL and the Provisions may include permit requirements to report the results of toxicity test data assessed using the TST (per the Provisions) and another statistical approach (per the TMDL) or just the Provisions, if the TMDL approach is not determined to be more protective. If the TMDL is not updated, NPDES permits that are subject to the requirements of both the TMDL and the Provisions may include permit requirements to report the results of toxicity test data assessed using the TST (per the Provisions) and another statistical approach (per the TMDL). In such cases the same aquatic toxicity tests can be used to meet both monitoring and reporting requirements, but the resulting data would need to be assessed using both statistical approaches and reported to the Water Boards."  Page 158-Add the underlined language to the following paragraph:  "Discharges that are subject to permit requirements based on a TMDL that includes targets or waste load allocations which need to be assessed using a statistical approach other than the TST, may use the same aquatic toxicity tests to meet the monitoring and reporting requirements for both the TMDL based requirements and the Provisions. However, the resulting data may need to be assessed using both the statistical approach required by the TMDL based requirements and the TST, only if the Regional Water Board determines that it is necessary because the TMDL requirements are more protective. Typically, toxicity testing for storm water would consist of comparing a single concentration of 100 percent ambient water or storm water runoff at a particular location to a control, unless specified otherwise by the Regional Water Board or by law.  Page 164-Add the underlined language to the following paragraph:  "Likewise, if the Regional Water Board requires toxicity testing using test methods and species in Table 1 after the effective date of these provisions, then the discharger would be required to analyze the data using the TST. Discharges that are subject to permit requirements based on a TMDL that includes targets or waste load allocations which need to be assessed using a statistical approach other than the TST, may use the same aquatic toxicity tests to meet the monitoring and reporting requirements for both the TMDL-based requirements and the Provisions. However, the resulting data may need to be assessed using both the statistical approach required by the TMDL-based requirements and the TST, only if the Regional Water Board determines that it is necessary because the TMDL requirements are more protective." |

## Category B – Instream Waste Concentration / Dilution

| **Comment Code** | **Comment** |
| --- | --- |
| **SC B.001** | The Toxicity Provisions should provide clarification as to when the permitting authority may set dilution rates and require scientific documentation of the basis for such a determination.  The permitting authority may grant dilution credits for chemical constituents using scientifically based information to determine the amount of dilution that occurs. These credits usually are very conservative because they are determined under reasonable worst-case scenarios and determined by *static* initial dilution rates, despite the dynamic nature of the discharge and receiving waters (e.g., dilution from currents). Hence, dilution credits granted to chemical constituents protect against toxicity effects, except under rare and extenuating circumstances. As such, if the Permitting Authority decides to require a higher IWC than allowed by existing dilution credits, the determination should be scientifically based and justified in the NPDES permit Fact Sheet (or equivalent document). |
| **SR B.001** | Section IV.B.2.a of the Provisions was revised to state that the permitting authority shall document the basis for any decision to use a higher concentration of effluent as the IWC in the NPDES fact sheet (or equivalent document).  The discretion for permitting authorities to select a higher concentration of effluent as the IWC in order to protect beneficial uses, or because of site-specific conditions, or both, is consistent with the discretion given to permitting authorities in the State Implementation Policy (SIP) when determining dilution credits for dischargers. |
| 11.006 | **3. The Toxicity Provisions should provide clarification as to when the Permitting Authority may set dilution rates lower than for other parameters and require documentation of the basis for such a determination.**  A Permitting Authority may grant dilution credits for chemical constituents using scientifically based information to determine the amount of dilution that occurs. These credits usually are very conservative because they are determined under reasonable worst-case scenarios and determined by *static* initial dilution rates, despite the dynamic nature of the discharge and receiving waters (e.g., dilution from currents).  Hence, dilution credits granted to chemical constituents protect against toxicity effects, except under rare and extenuating circumstances. As such, if the Permitting Authority decides to require a higher IWC than allowed by existing dilution credits, the determination should be scientifically based and justified in the NPDES permit Fact Sheet (or equivalent document). Adding language to this effect to the Toxicity Provisions will ensure that dilution credits are not reduced without good cause.  We therefore request that the following language be added after the end of the provision reproduced above, which is the first sentence in the third paragraph of Section IV.B.2.a:  *“The PERMITTING AUTHORITY shall document the basis for any decision to use a higher concentration of effluent as the IWC, including an explanation of the scientific basis for the decision, in the NPDES Fact sheet (or equivalent document).”* |
| 17.005 | ***2. The State Water Board should provide clarification as to when the Permitting Authority can set lower dilution rates than for other parameters and require documentation of any such decision.***  Dilution credits are granted by the Permitting Authority for chemical constituents using scientifically based information such as modeling to determine the amount of dilution that occurs. These dilution credits are typically very conservative because they are commonly determined under reasonable worst-case scenarios and determine *static* initial dilution rates despite the dynamic nature of the discharge and receiving waters (e.g., dilution from currents). The dilution credits granted to chemical constituents should be adequate to protect against toxicity effects except under rare extenuating circumstances. Any decision made by the Permitting Authority to require a higher IWC than allowed by existing dilution credits needs to be scientifically based and justified in the NPDES permit Fact sheet (or equivalent document). Adding language to this effect to the Draft Plan will ensure that dilution credits are not reduced without good cause.  We therefore request that the following language be added after the end of the first sentence of the third paragraph of Section IV.B.2.a, “The PERMITTING AUTHORITY shall document the basis for any decision to use a higher concentration of effluent as the IWC, including an explanation of the scientific basis for the decision, in the NPDES Fact sheet (or equivalent document).” |
| **SC B.002** | Section IV.B.2.a of the Provisions should use the term “dilution credit” instead of “dilution ratio,” in order to be consistent with the SIP. |
| **SR B.002** | The “dilution credit” is not the same as the “dilution ratio.” Appendix 1 of the SIP provides these definitions for the two terms:  “DILUTION CREDIT is 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 receiving water.  DILUTION RATIO is the critical low flow of the upstream receiving water divided by the flow of the effluent discharged.”  These terms are also defined in the Glossary of the Toxicity Provisions.  Section IV.B.2.a of the Provisions states that the IWC is calculated as “the inverse of 1 plus the dilution credit multiplied by 100 percent (IWC = 100%×[1/(1+D)] where D = dilution credit) unless the permitting authority selects a higher concentration of effluent as the IWC in order to protect beneficial uses, or because of site-specific conditions, or both.”  In the sentence quoted by the commenter, the term “dilution ratio” was used in order to remain consistent with this sentence from Section 1.4.2 of the SIP: “In no case shall the RWQCB grant a dilution credit that is greater than the calculated *dilution ratio*” (emphasis added). This statement ensures that the dilution credit will not be set higher than the calculated dilution ratio, but may be set lower by the permitting authority. Similarly, the statement in the Toxicity Provisions ensures that the IWC will be, at the least, calculated from the critical flows (low receiving water flow and high effluent flow), but may be set higher in order to protect beneficial uses, or because of site-specific conditions, or both. |
| 12.006 | **In-stream Waste Concentration:** We request a simple wording change to ensure that the proposed Toxicity Provisions are consistent with Section 1.4.2 of the State Implementation Policy. |
| 12.017 | **The In-stream Waste Concentration Language Should Be Consistent with the SIP.**  Section IV.B.2.a, third paragraph, second sentence, states that “For the purpose of aquatic toxicity tests, in no case shall the PERMITTING AUTHORITY set the IWC at less than the inverse of 1 plus the DILUTION RATIO, multiplied by 100 percent.” To maintain consistency with the provisions of the SIP, and to avoid confusion, it is requested that either the subject sentence be eliminated, or the words “DILUTION RATIO” be changed to “DILUTION CREDIT.” |

## Category C – Species Sensitivity Screening

| **Comment Code** | **Comment** |
| --- | --- |
| **SC C.001** | Species sensitivity screening for chronic toxicity should not be a requirement for a report of waste discharge. Instead, the permitting authority should require discharges to submit the most recent species sensitivity screening results as part of the report of waste discharge. |
| **SR C.001** | Section IV.B.2.b.i of the Provisions states that "[t]he [permitting authority] shall require [non-storm water NPDES dischargers] to conduct a [species sensitivity screening] for chronic aquatic toxicity as part of a report of waste discharge (ROWD), or as a permit condition, or both.” However, this does not mean that a species sensitivity screening must be conducted whenever a ROWD is required. Sections IV.B.2.b.i(A) and IV.B.2.b.i(B) of the Provisions state the requirements for how often a species sensitivity screening for chronic aquatic toxicity must be conducted.  Section 5.4.1 of the Staff Report explains that, “[s]pecifying the procedures, types of species, and the frequency for species sensitivity screening contributes to the goal of creating a consistent, yet flexible framework for monitory toxicity and laboratory analysis.” This aligns with Project Goal #3, which is described in Section 2.2 of the Staff Report. |
| 16.003 | 1. IV. B. 2. b. i. Species Sensitivity Screening (page 14): CVWD does not agree with conducting a species sensitivity screening for chronic aquatic toxicity, as a requirement for a report of waste discharge (ROWD). CVWD recommends revising this section to state, “The permitting authority shall require non-storm water NPDES dischargers to submit the most recent species sensitivity screening results for chronic aquatic toxicity as part of a Report of Waste Discharge (ROWD).” |
| **SC C.002** | Species sensitivity screenings should be conducted at every permit reissuance or renewal, or more frequently, to detect unanticipated changes in the character of a discharge.  The aquatic toxicity profile of toxicants can range depending on the chemical composition or interaction between compounds. The species sensitivity screening is a key tool to determine the most sensitive and thereby the most appropriate test species for toxicity monitoring and compliance, and even reduces costs by only requiring monitoring and testing against a single species.  It is also important to consider the presence of sensitive species in the receiving waters that are foundational to the ecological health of that receiving water and the wildlife and communities dependent on that ecosystem. Species sensitivity screening generally occurs every five years with a new permit cycle to capture any changes in the character or volume of the effluent, with limited exception for permits that require more frequent species sensitivity screening to detect potential effects of bioaccumulation that are specific to that receiving water. Extending species sensitivity screening beyond this five year period is unnecessary and runs contrary to the purpose of toxicity testing to prevent the potential of toxicants from affecting the survival, reproduction, and overall health of aquatic species, given contaminants of emerging concern and other unknown chemical compounds and interactions that may arise in effluent over a five-year period.  Further, all permits with existing, more frequent species sensitivity screening, such as those imposed by the Los Angeles Regional Water Board, should be explicitly upheld, and not superseded by the Provisions in order to prevent backsliding of existing permit requirements. Regional Water Boards should retain the authority to require more frequent species sensitivity screenings on a case-by-case basis, such as anticipated or frequent changes to the character of the effluent. |
| **SR C.002** | Section 5.4.1 of the Staff Report, under the “Option 1” heading, explains that the permitting authority would have the discretion to require a species sensitivity screening every permit cycle, but may forgo a species sensitivity screening if a screening has been conducted within 15 years of permit issuance, renewal, or reopening for that permit, and the nature of the effluent has not changed since the last screening was conducted.  The species sensitivity screening requirements in the Toxicity Provisions would not result in less stringent effluent limitations than those in existing permits and the use of the species sensitivity screening requirements in the Provisions would not constitute backsliding. Although species sensitivity screenings may be required more frequently in some current permits issued by the Los Angeles Regional Water Quality Control Board, these requirements are not inherently more or less protective than the requirements in the Provisions. A review of representative non-storm water NPDES permits issued by the Los Angeles Regional Water Quality Control Board indicates that, while screenings are sometimes required more frequently than would be required by the Provisions, these screenings typically involve only one set of tests. Section IV.B.2.b.iii of the Provisions describes the number of sets of tests that must be conducted as part of a species sensitivity screening for chronic aquatic toxicity, and states that for continuous dischargers, a species sensitivity screening includes four sets of tests, with a set of testing conducted in each quarter of a year. In addition, the permitting authority would conduct a permit-specific anti-backsliding analysis at the time of permit reissuance or reopening. See Section 9.3 of the Staff Report for additional discussion on anti-backsliding analyses.  Please see “SR23.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) regarding the comment that species sensitivity screenings should be conducted at every permit reissuance or renewal. |
| 19.010 | *Species sensitivity screenings must be conducted at every permit reissuance or renewal, or a more frequent intervals, to detect unanticipated changes in the character of a discharge.* |
| 19.056 | **V. SPECIES SENSITIVITY SCREENING MUST BE CONDUCTED AT EVERY PERMIT REISSUANCE OR RENEWAL, OR AT MORE FREQUENT INTERVALS, TO DETECT UNANTICIPATED CHANGES IN THE CHARACTER OF A DISCHARGE.** |
| 19.057 | 1. Species sensitivity screenings should occur every five years to capture any known or unknown changes of toxicity within a discharge. The aquatic toxicity profile of toxicants can range depending on the chemical composition or interaction between compounds. The species sensitivity screening is a key tool to determine the most sensitive and thereby the most appropriate test species for toxicity monitoring and compliance, and even reduces costs for the discharger by only requiring monitoring and testing against a single species, rather than a panel of test species for routine acute and chronic toxicity tests. As reflected in the Basin Plan for the San Francisco Regional Water Board, “[t]hus far, no one test species has consistently been the most sensitive to all discharges. This strongly supports the current approach of requiring screening using several test species.”37 As reflected in the Staff Report, “selection of the most sensitive species is an important component in detecting toxicants in effluent or a receiving water body. For example, if an effluent tends to contain pollutants that strongly affect invertebrates, using an algae or fish species for routine aquatic toxicity testing would not be as protective as using an invertebrate test species.”38 It is also important to consider the presence of sensitive species in the receiving waters that are foundational to the ecological health of that receiving water and the wildlife and communities dependent on that ecosystem. Species sensitivity screening generally occurs every five years with a new permit cycle to capture any changes in the character or volume of the effluent, with limited exception for permits that require more frequent species sensitivity screening to detect potential effects of bioaccumulation that are specific to that receiving water. Extending species sensitivity screening beyond this five year period is unnecessary and runs contrary to the purpose of toxicity testing to prevent the potential of toxicants from affecting the survival, reproduction, and overall health of aquatic species, given contaminants of emerging concern and other unknown chemical compounds and interactions that may arise in effluent over a five-year period. The final Toxicity Provisions should uphold the requirement that species sensitivity screening be conducted every permit cycle, or at a minimum require species sensitivity screening to occur every five years when permit reissuances are delayed, to detect potential changes in the toxicity of a permitted discharge. |
| 19.058 | Requested Language (Suggested language in red): IV.B.2.b.i(B). Subsequent Species Sensitivity Screening (p. 15) Following the first issuance, reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the permit after the effective date of these TOXICITY PROVISIONS, the PERMITTING AUTHORITY shall require the discharger to conduct a SPECIES SENSITIVITY SCREENING prior to any subsequent issuance, reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the permit if (1) the discharger has not conducted a SPECIES SENSITIVITY SCREENING in accordance with Section IV.B.2.b.iii. within the previous 5 years or (2) if the effluent used in the last SPECIES SENSITIVITY SCREENING is no longer representative of the effluent. |
| 19.059 | Further, all permits with existing, more frequent species sensitivity screening, such as those imposed by the Los Angeles Regional Water Board, must be explicitly upheld and not superseded by these Provisions in order to prevent anti-backsliding of existing permit requirements. Regional Water Boards should retain the authority to require more frequent species sensitivity screenings on a case-by-case basis, such as anticipated or frequent changes to the character of the effluent. |
| 19.060 | Requested Language (Suggested language in red): IV.B.2.b.i(B). Subsequent Species Sensitivity Screening (p. 16) The PERMITTING AUTHORITY may require a SPECIES SENSITIVITY SCREENING for chronic aquatic toxicity prior to every issuance, reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the permit, or at more frequent intervals. |
| **SC C.003** | The commenter supports the removal of the exemption for species sensitivity screening for dischargers participating in a regional monitoring program. |
| **SR C.003** | Comment noted. |
| 19.063 | We further support the removal of the exemption for species sensitivity screening for chronic toxicity for those who participate in regional monitoring program, given the unique toxicity profile and response by individual organisms to various effluent discharges. |
| **SC C.004** | Species testing requirements should not be arbitrarily assigned for those that discharge less than 15 days per quarter. Waiving the screening requirement for non-continuous dischargers that may discharge less than 15 days in a given quarter has the potential to adversely impact aquatic species to a significant or lethal degree, depending on the season and whether specific species are spawning or if eggs, larvae, or otherwise significant ecological cycles are occurring in the waterway.  If a species sensitivity screening is not required for these dischargers, the Regional Water Board must not arbitrarily assign the most sensitive species, given that no one species is consistently the most sensitive to all discharges. Instead, where a species sensitivity screening is not required, a multi-species test should be required, or the most sensitive species should be determined by the Regional Water Board based on specific environmental factors (e.g., seasonal early life-stages of insects, invertebrates, or fish species) and the specific character of the discharge. |
| **SR C.004** | The Provisions provide the permitting authority the flexibility to specify how the species sensitivity screening must be conducted, or to specify the most sensitive species for dischargers that do not discharge in any quarter in which there is expected to be at least 15 days of discharge. Depending on the timing of the days of discharge, it may not be feasible to conduct even a single chronic aquatic toxicity test (e.g., if the timing is such that it is not possible to collect renewal water for the test). Permitting authorities are best suited to determine the approach to identify the most sensitive species for these non-continuous dischargers. The permitting authority is better able to consider specific environmental factors, such as the aquatic life present in the receiving water and the nature of the discharge, on a permit-by-permit basis than is possible in the statewide Toxicity Provisions. The Provisions provide consistency in how species sensitivity screenings would need to be conducted, yet allow flexibility to permitting authorities to determine the best approach to use for dischargers that discharge less than 15 days in any calendar quarter. |
| 19.061 | 2. Species testing requirements should not be arbitrarily assigned for those that discharge less than 15 days per quarter. As discussed above, the aquatic toxicity profile of toxicants can range depending on the chemical composition or interaction between compounds, and different types of discharges can impact aquatic species differently. Waiving the species sensitivity requirement for non-continuous dischargers that may discharge less than 15 days in a given quarter have the potential to adversely impact aquatic species to a significant or lethal degree, depending on the season and whether specific species are spawning or if eggs, larvae, or otherwise significant ecological cycles are occurring in the waterway. If a species sensitivity screening is not required for these dischargers, the Regional Water Board must not arbitrarily assign the most sensitive species, given that no one species is consistently the most sensitive to all discharges. Instead, where a species sensitivity screening is not required, toxicity monitoring requirements shall use a multi-species test or otherwise be determined by the Regional Water Board based on specific environmental factors (e.g., seasonal early life-stages of insects, invertebrates, or fish species) and specific character of the discharge. |
| 19.062 | Requested Language (Suggested language in red): IV.B.2.b.ii. Non-Storm Water NPDES Dischargers Required to Conduct Species Sensitivity Screening for Acute Aquatic Toxicity. (p. 17) For NON-CONTINUOUS DISCHARGERS that do not discharge in any quarter in which there is expected to be at least 15 days of discharge, the PERMITTING AUTHORITY shall indicate if a SPECIES SENSITIVITY SCREENING is required and the number of sets of testing to be conducted in that SPECIES SENSITIVITY SCREENING. If a SPECIES SENSITIVITY SCREENING is not required, a multi-species test shall be used or the PERMITTING AUTHORITY shall specify the MOST SENSITIVE SPECIES based on relevant environmental factors and character of the discharge. |
| **SC C.005** | Two sets of species sensitivity screening during a 5-year permit cycle is sufficient to determine the most sensitive species. The increase in frequency has no apparent benefit and in a 5-year permit cycle will increase cost to $106,000 if the species screening is performed quarterly throughout the 5-year permit term. |
| **SR C.005** | The Provisions do not state that the species sensitivity screening must be conducted quarterly throughout a five-year permit term. Rather, Section IV.B.2.b.iii of the Provisions states that “For [continuous dischargers], a [species sensitivity screening] includes four sets of testing, with a set of testing conducted in each quarter of a year.” In other words, once the discharger has completed the four sets of testing, more screening tests would not be required until the permitting authority requires another species sensitivity screening. This likely would not occur until the next permit term, or later. Section 5.1 of the January 2020 Economic Report estimates that the average cost for a three species freshwater tests, using multiple concentrations, is about $3,730. Based on this estimate, the cost for a three species test each quarter for a calendar year would be about $15,000. Therefore, the commenter’s estimate that the cost of species sensitivity screening during a 5-year permit cycle would increase to $106,000 overestimates the likely cost for species sensitivity screening. Section IV.B.2.b.i of the Provisions and Section 5.4.1 of the Staff Report explain the requirements for how frequently a species sensitivity screening would be required.  Please see response “SR23.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for further discussion of why four sets of tests are required for species sensitivity screening. For a discussion of costs, see Chapter 9 of the Staff Report. |
| 16.004 | 2. IV. B. 2. b. iii. Type and Number of Tests Required for a Species Sensitivity Screening (page 16): This section proposes continuous dischargers to perform four sets of species sensitivity screening testing, with a set of testing conducted in each quarter of a year. CVWD currently conducts chronic/ acute toxicity species screening during years 1 and 4 of a 5 year permit cycle for one of its waste discharge facilities. The cost for CVWD to perform this screening is around $5,300 for one round or $10,600 over a 5 year permit cycle. The increase in frequency has no apparent benefit and in a 5 year permit cycle will increase cost to $106,000, if the species screening is performed quarterly throughout the 5 year permit term. CVWD believes two sets during a 5 year permit cycle is sufficient to determine the most sensitive species. |
| **SC C.006** | The Toxicity Provisions should define or clarify the term “next applicable species.” During the July 29, 2020 public staff workshop, staff indicated the phrase could be intended to mean the next most sensitive species. However, instances occur when the next most sensitive species is not the most preferable or appropriate species to substitute, as in the event where the most sensitive species is not commercially available, and the next most sensitive is not sufficiently protective of fisheries.  One example where this could become an issue is for waters with topsmelt (*Atherinops affinis*) as the most sensitive species. Topsmelt are only available from a single supplier in the United States and are known to have decreased organism quality during the year. Currently, with a Permitting Authority approval, dischargers may substitute inland silversides (*Menidia beryllina*) for topsmelt in the event that topsmelt are unavailable. If “next applicable species” is intended to equate to the next most sensitive species, this current practice would not be allowed even though it is more protective than using the next most sensitive species. |
| **SR C.006** | The phrase “next applicable species” was used in Sections IV.B.2.b.iv and IV.B.2.e.i of the Toxicity Provisions. The term had different meanings in these two contexts. Therefore, these two sections of the Toxicity Provisions were revised to provide clarity.    Section IV.B.2.b.iv of the Toxicity Provisions was revised to replace the term “next applicable species” with “next appropriate species.” Additionally, this section was revised to clarify that the “next appropriate species” is a species in Table 1 in the same test method classification (e.g., chronic aquatic toxicity test methods, acute aquatic toxicity test method), in the same salinity classification (e.g., freshwater or marine), and in the same taxon as the most sensitive species. When there are no other species in Table 1 in the same taxon as the most sensitive species, the “next appropriate species” is the species exhibiting the highest percent effect at the IWC tested in the species sensitivity screening other than the most sensitive species. Section 5.4.1 of the Staff Report was revised to further explain this term and provide additional clarity.  Section IV.B.2.e.i of the Toxicity Provisions was revised to remove the term “next applicable species” and to specify that either *Pimephales promelas* (fathead minnow) or *Selenastrum capricornutum* (green alga)would be used as the most sensitive species. Sections 5.4.3 and 9.3 of the Staff Report were also similarly revised. |
| 11.008 | **5. The Toxicity Provisions should define or clarify “next applicable species.”**  The Toxicity Provisions currently provide a definition for “Most sensitive species” in the glossary of Appendix A, and we recommend adding a definition for “Next applicable species,” as it is undefined yet used in multiple locations throughout the Toxicity Provisions, and it otherwise may be construed to have different meanings.  For this concern, a question arose during the staff workshop, and Staff indicated the phrase could be intended to mean the next most sensitive species. However, instances occur when the next most sensitive species is not the most preferable or appropriate species to substitute, as in the event where the most sensitive species is not commercially available, and the next most sensitive is not sufficiently protective of fisheries.  One example where this could become an issue is for waters with topsmelt (*Atherinops affinis*) as the most sensitive species. Topsmelt are only available from a single supplier in the United States and are known to have decreased organism quality during the year. Currently, with a Permitting Authority approval, dischargers may substitute Inland Silversides (*Menidia beryllina*) for topsmelt in the event that topsmelt are unavailable. If “next applicable species” is intended to equate to the next most sensitive species, this current practice would not be allowed even though it is more protective than using the next most sensitive species. Accordingly, we recommend formally defining the term “next applicable species” given its prevalence in the Toxicity Provisions. |
| 17.008 | ***5. The term “next applicable species” should be defined.***  The term “next applicable species” is used in multiple locations throughout the Draft Plan (see Section IV.B.2.b.iv) but the Draft Plan does not define this term. As stated during the July 29, 2020 Public Staff Workshop, this phrase could be intended to mean the next most sensitive species. However, there are instances where the next most sensitive species is not the most appropriate species to substitute in the event that the most sensitive species is unavailable. Specifically, for waters with *Atherinops affinis* (topsmelt) as the most sensitive species, the next most sensitive may not be sufficiently protective of fisheries. Topsmelt are only available from a single supplier in the US and they are known to have seasonal and/or sporadic dips in organism quality. Currently, with Permitting Authority approval, dischargers can substitute *Menidia beryllina* (Inland Silversides) for topsmelt in the event that topsmelt are unavailable. If “next applicable species” is interpreted to mean the next or second most sensitive species, this practice would be disallowed. It is recommended that the term “next applicable species” be defined to mean an appropriate substitute for the most sensitive organism or the next most sensitive species. |
| **SC C.007** | The Toxicity Provisions allow the Executive Officer or Executive Director to allow the temporary use of the next applicable species as the most sensitive species when the discharger has encountered an “unresolvable interference” with a toxicity test. It is inappropriate for Regional Water Board staff – and thereby the Executive Director or Officer – to interpret what constitutes an “unresolvable interference.”  Interferences with toxicity testing and laboratory results should be reported to laboratory licensing programs (ELAP) and the State Water Resources Control Board’s Quality Assurance Officer, and noticed to the public, at a minimum. |
| **SR C.007** | The term “next applicable species” has been replaced with “next appropriate species.” For further discussion on this change please see SR C.006.  Use of the next appropriate species as the most sensitive species should be on a temporary basis. Once a test interference has been resolved or a reliable supply of the original most sensitive species test organisms can be secured, the discharger would be required to return to using the original most sensitive species. If a discharger cannot obtain a reliable supply of test organisms, it may not be possible for them to conduct their required aquatic toxicity monitoring unless they use the next appropriate species on a temporary basis. Monitoring using a different species as the most sensitive species on a temporary basis would be more protective of aquatic life beneficial uses than not monitoring at all. Therefore, Section IV.B.2.b.iv of the Provisions would allow the permitting authority to specify in the NPDES permit that the Executive Officer or Executive Director may allow the temporary use of the next appropriate species, provided that the discharger submits documentation and the Executive Officer or Executive Director makes the appropriate determination. In making the determination to allow the use of the next appropriate species, the Executive Officer or Executive Director would be able to consult as needed with the Water Board’s Quality Assurance Officer, ELAP, or other trained toxicologists.  Section IV.B.2.b.iv of the Provisions would require the discharger to submit documentation of the need to temporarily monitor with the next appropriate species. Therefore, there is already a mechanism in place for these situations to be reported to the Water Boards. Additionally, any testing using the next appropriate species would be performed using an approved method and species listed in Table 1 of the Provisions, which provides additional confidence in the use of the next appropriate species. |
| 19.064 | 3. Unresolvable test interferences, and the use of the next applicable species, should be reported to laboratory licensing programs, the State Water Resources Control Board’s Quality Assurance Officer, and noticed to the public. The Toxicity Provisions additionally allow the Executive Officer or Executive Director to allow the temporary use of the next applicable species as the most sensitive species when the discharger submits, and the Executive Officer or Executive Director determines, that the discharger has encountered an “unresolvable interference” with a toxicity test. However, given the Regional Water Boards are not toxicologists by training, it is inappropriate for Regional Water Board staff – and thereby the Executive Director or Officer – to interpret what constitutes an “unresolvable interference.” We request interferences with toxicity testing and laboratory results be reported to laboratory licensing programs and the State Water Resources Control Board’s Quality Assurance Officer, and noticed to the public, at a minimum. |
| 19.065 | Requested Language (Suggested language in red): IV.B.2.b.iv. Determination of the Most Sensitive Species (p. 19) In the NPDES permit, the PERMITTING AUTHORITY may also delegate to the Executive Officer or Executive Director, as applicable, the authority to allow the temporary use of the next applicable species as the MOST SENSITIVE SPECIES when the discharger submits documentation and the Executive Officer or Executive Director, as applicable, determines that the discharger has encountered unresolvable test interference or cannot secure a reliable supply of test organisms. All such test interferences shall be reported to the ELAP and State Water Resources Control Board Quality Assurance Officer and noticed to the public. |
| **SC C.008** | Non-storm water NPDES dischargers required to conduct species sensitivity screening for acute toxicity should be allowed to use additional information, such as available literature data.  The seven species for acute freshwater toxicity testing listed in Table 1 of the Toxicity Provisions are well known, commonly used species for acute toxicity testing (e.g., fathead minnows, *Daphnia magna*, rainbow trout). There is acute toxicity information available from the U.S. EPA ECOTOX database that can be used to determine the species sensitivity distribution for these species in lieu of conducting additional testing. Unless there is a specific toxicant in the effluent that is of concern, available information should be used before additional testing is deemed necessary.  NPDES discharges are often evolving based on changes or modifications of the treatment process. The Provisions should caution against the use of the extended time period data when it is not characteristic of the current discharge. An evaluation of the data (from a 5 to 10 year period against the latest 5 years of data) may be necessary to determine if species sensitivity has changed based on changes to the discharge or treatment process over time. |
| **SR C.008** | Section IV.B.2.b.ii of the Toxicity Provisions states that the permitting authority has discretion to require non-storm water NPDES dischargers to conduct a species sensitivity screening for acute aquatic toxicity. The basis for requiring a species sensitivity screening for acute toxicity must be documented in the NPDES Fact Sheet or equivalent document.  For example, Section 5.4.4 of the Staff Report states that if significant changes to the facility or the discharge have occurred since the last species sensitivity screening, then a species sensitivity screening should be conducted prior to the next permit reissuance. Additionally, a species sensitivity screening may be required if the use of existing literature data would not accurately depict actual sensitivities, given the real-world conditions. If a species sensitivity screening is not required, nothing in the Provisions would limit the permitting authority’s ability to consider relevant information (e.g., acute toxicity information available from the U.S. EPA ECOTOX database) when selecting the most sensitive species for acute toxicity. The Toxicity Provisions require the permitting authority to specify the most sensitive species in the permit and to identify the basis for selecting a different approach (i.e. not selecting the species exhibiting the highest percent effect at the IWC) in the NPDES fact sheet, or equivalent document. Therefore, the Provisions were not revised as suggested.  Regarding the statement that the Provisions should caution against the use of extended time period data, Section 5.4.4 of the Staff Report explains that the permitting authority “would have the discretion to require non-storm water NPDES dischargers to conduct a species sensitivity screening for acute toxicity prior to every issuance, reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the permit. If there have been any significant changes to the facility or the discharge since the last species sensitivity screening was conducted, a species sensitivity screening should be required prior to the next permit reissuance. In making this determination, the [permitting authority] would need to document the justification in an NPDES fact sheet or an equivalent document.” Therefore, the permitting authority would have the discretion to consider the specific situation of each facility, and determine whether the use of extended time period data is warranted on a case-by-case basis. |
| 26.015 | **Non-stormwater NPDES dischargers required to conduct species sensitivity screening for acute toxicity should be allowed to use additional information**  Issue: The SWRCB has extended the period of considered data to 10 years. However, it is important to acknowledge that NPDES discharges are often evolving due to adaptive management of the facility and installation or upgrading of technologies to improve treatment efficiencies. In addition to using facility data, dischargers should be allowed to use available literature data in determining species sensitivity for acute toxicity.  Staff Report, Section 2.6.6 I. A., 1st paragraph, page 18  “Non-storm water NPDES dischargers will be required to conduct a species sensitivity screening for chronic toxicity to determine the most sensitive species to use in chronic aquatic toxicity monitoring. The Water Boards will also have the discretion to require non-storm water NPDES dischargers to conduct a species sensitivity screening for acute toxicity.”  Toxicity Provisions Section IV B.2.b.ii, page 16.  “The PERMITTING AUTHORITY may require NON-STORM WATER NPDES DISCHARGERS to conduct a SPECIES SENSITIVITY SCREENING for acute aquatic toxicity.”  Discussion: The Water Boards have discretion to require species sensitivity screening for non-stormwater NPDES dischargers for acute toxicity, which, as stated, should include a minimum of two species, including one invertebrate and one vertebrate. The seven species for acute freshwater toxicity testing listed in Table 1 of the Toxicity Provisions are well known, commonly used species for acute toxicity testing (e.g., fathead minnows, Daphnia magna, rainbow trout). There is a wealth of acute toxicity information available from the U.S. EPA ECOTOX database that can be used to determine the species sensitivity distribution for these species in lieu of conducting additional testing. Unless there is a specific toxicant in the effluent that is of concern, available information should be used before additional testing is deemed necessary.  We support the 10-year time period extension of available data to be considered in the species sensitivity assessment. However as stated above, it is important to acknowledge that NPDES discharges are often evolving based on changes or modifications of the treatment process. We believe that it is important that the SWRCB incorporate a statement that cautions the use of the extended time period data when it is not characteristic of the current discharge. An evaluation of the data (from 5-10 year period against the latest 5 years of data) may be necessary to determine if species sensitivity has changed based on changes to the discharge or treatment process over time.  Recommendation: Add text that allows use of available acute toxicity data relevant to the effluent contaminant for assessing the most sensitive species before requiring new acute toxicity testing. Example text as follows could be added at the two citations noted above:  “Unless otherwise determined for a specific site or discharge by the PERMITTING AUTHORITY, existing acute toxicity data may be used to assess the most sensitive species.”  “Toxicity data used to evaluate the most sensitive should be representative of current discharge conditions.” |

## Category D – Reasonable Potential

| **Comment Code** | **Comment** |
| --- | --- |
| **SC D.001** | Revise the Provisions to delete using any threshold (5 million gallons per day (MGD), pretreatment program, etc.) to determine a subset of non-storm water NPDES-permitted dischargers that automatically require effluent limitations for chronic toxicity. Rather, the reasonable potential analysis should be conducted for all non-stormwater NPDES-permitted dischargers.  According to state regulations (CCR § 2233(a)), all publicly owned treatment works (POTWs) in California designed to treat an average dry weather flow of 5 MGD or greater are required to have an approved pretreatment program. For this reason, the changes to Section IV.B.2.c.i. of the Second Revised Draft Toxicity Provisions would not exclude POTWs authorized to discharge at greater than 5 MGD and without significant industrial users (SIUs) from automatic effluent limitations, as appeared to be the intent.  Having a pretreatment program or industrial users within a POTW’s service area is not a reliable indication of effluent risk.  Data for nine POTWs from the Central Valley indicates that all facilities have Regional Board-approved pretreatment programs, yet the actual proportion of industrial inputs from SIUs to the facilities ranges from 0 percent to 50 percent. Therefore, the requirement to have a pretreatment program, the presence of significant industrial users in the service area, and being authorized to discharge at 5 MGD or greater are poor indicators of the potential for voluminous influent from industrial discharges, influent being less fully understood, the presence of pollutants that influence operations, pollutant pass through, or general risk of effluent toxicity.  The fact that some POTWs implement NPDES-permit required pretreatment programs makes them more capable of identifying complex inputs to their treatment plant from industrial sources and controlling them.  Additionally, CVCWA (2018) found that industrial inputs were the suspected cause of toxicity in only 3 of 35 toxicity reduction evaluations (TREs) they reviewed for Central Valley POTWs.  Any attempt to generalize characteristics of problematic POTW discharges based on course regulatory requirements, such as the authorized flow threshold or pretreatment program requirement, is inequitable to many dischargers. Any attempt to continue to hone in on a particular threshold will only require more work on behalf of the Regional Water Boards to determine whether that particular qualification applies to a POTW. This time is better spent on reviewing actual toxicity data as part of conducting the reasonable potential analysis. To be equitable to all parties, it is not appropriate to select a threshold/qualification that automatically triggers effluent limitations.  The 5 MGD authorized flow threshold is also not reliable for determining POTWs that should monitor monthly. Provide the Regional Water Boards discretion to deviate from the prescribed routine monitoring requirements to appropriately account for POTW-specific conditions and risk. |
| **SR D.001** | The Toxicity Provisions were revised to specify that POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD and are required to have a pretreatment program by the terms of 40 CFR § 403.8(a) (effective January 1, 2020) are not required to perform a reasonable potential analysis, because the permitting authority must include an effluent limitation for these dischargers pursuant to Section IV.B.2.e. POTW discharges that have a pretreatment program, but are not required to per 40 CFR § 403.8(a) would conduct a reasonable potential analysis to determine if they are required to have effluent limitations.  Section 5.4.2 of the Staff Report explains that “[t]he Provisions do not include a determination or an assumption that POTW dischargers that are authorized to discharge at a rate equal to or greater than five MGD and are required to have a pretreatment program per federal regulations have reasonable potential. Instead, a reasonable potential analysis would not be required for these dischargers before a Water Board included effluent limitations for toxicity in a permit.”  Please see response “SR21.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for further discussion of reasonable potential and the 5.0 MGD threshold. Also see response “SR07.015” for a discussion on monitoring frequencies.  Comments regarding chronic toxicity monitoring requirements based on actual flows are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, see Section 5.4.4.2.1 of the Staff Report for a discussion on the term “authorized rate of discharge” and how the Regional Water Board determines it. |
| 13.001 | **1. ACWA and CMUA suggest that the State Water Board amend the 5 Million Gallon per Day (MGD) permitted discharge rate for municipal wastewater treatment plants to enable the regional water boards to have greater discretion in determining reasonable potential, setting effluent limits, and establishing monitoring frequency.**  ACWA and CMUA suggest that the State Water Board grant Regional Water Boards greater flexibility to set the chronic toxicity monitoring requirements based on actual flows for wastewater treatment agencies. This request is in agreement with Robertson Bryan Inc.’s comments on the July 2020 revised draft Toxicity Provisions. This consideration would allow wastewater treatment plants (WWTP) and their ratepayers to avoid penalization for having a publicly owned treatment works (POTW) capacity that exceeds the 5 MGD design capacity threshold prescribed while actual flows do not attain this level. In this situation, it is appropriate to consider actual flows and grant sufficient flexibility so that permit and monitoring requirements can consider seasonally variable flows, and incentivize recycled water usage during summer irrigation periods. The 5 MGD permitted discharge rate being used automatically requires effluent limits for toxicity (no exception) and monthly monitoring. Many WWTPs permitted at or above 5 MGD do not actually discharge 5 MGD, and often are much less. The 5 MGD threshold should be reconsidered consistent with feedback from State Water Board members at the October 2019 workshop. If not, perhaps an annual average discharge above 5 MGD should be considered instead. The addition of having a pretreatment program is not helpful, since where pretreatment programs exist, the POTW has greater control over the industrial discharges into the plant, so this is another instance of penalizing the POTW because they are doing the right thing. Thus, more flexibility should be integrated into the final Toxicity Provisions to require the most stringent regulation on the POTWs demonstrated to have reasonable potential, not just those of a certain size or with a pretreatment program. |
| 21.018 | **Comment 5. Reasonable Potential Analysis – Revised Draft Toxicity Provisions Section IV.B.2.c.i**  Reasonable Potential Analysis (RPA) is not required for POTWs authorized to discharge at a rate of 5 million gallons per day (MGD) or greater because monthly monitoring and numeric effluent limits for chronic toxicity (i.e., MDEL and MMELs) will be required for these dischargers. Changes were made in the second revised draft Toxicity Provisions to apply these automatic effluent limitations to POTWs that are required to have a pretreatment program:  “Except for POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 million gallons per day (MGD) and are required to have a pretreatment program, all NON-STORM WATER NPDES DISCHARGERS shall conduct a REASONABLE POTENTIAL analysis for chronic aquatic toxicity, pursuant to the procedures specified in Section IV.B.2.bc.iii, for review and approval by the PERMITTING AUTHORITY. A REASONABLE POTENTIAL analysis for chronic aquatic toxicity is not required for POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD and are required to have a pretreatment program, because the PERMITTING AUTHORITY shall include an effluent limitation for these dischargers pursuant to Section IV.B.2.e.” (Section IV.B.2.c.i., underline and strikethrough from the original)  The revised staff report cites federal law in its rationale for this qualification.  “Federal regulations require POTW dischargers that have a total design flow greater than 5 MGD and that receive pollutants from industrial users that may pass through or interfere with the operations of the POTW to establish a pretreatment program. This federal regulation also allows Regional Water Boards to require POTW dischargers with a design flow of less than 5 MGD to develop a pretreatment program if circumstances warrant a pretreatment program to prevent interference with the POTW or pass through (40 CFR § 403.8(a)).” (Revised Staff Report, Section 5.4.2)  However, the new “qualification” that a POTW must be required to have a pretreatment program does not change the Toxicity Provisions. State law is more stringent than the federal code and all POTWs in California designed to treat an average dry weather flow of 5 MGD or greater are required to have an approved pretreatment program.  “A condition shall be included for a publicly owned treatment works, treating or designed to treat, an average dry weather flow of 5 mgd or more of community wastewater that the operating entity shall have and enforce an adequate pretreatment program approved by the appropriate regional board. A condition requiring a local pretreatment program may be included for a publicly owned treatment works treating or designed to treat an average dry weather flow of less than 5 mgd of community wastewater where deemed appropriate by the state board or regional board.” (CCR § 2233(a), emphasis added)  This is reiterated in the State Water Board’s 2019 Standard Operating Procedure for Approval of New Program Submittals and Program Modification Submittals (prepared by PG Environmental). |
| 21.019 | Since all POTWs in California that are designed to treat 5 MGD or more are required by state law to have an approved pretreatment program, the changes to Section IV.B.2.c.i. of the revised draft Toxicity Provisions is effectively not a change that would exclude POTWs authorized to discharge at >5 MGD and without SIUs from automatic effluent limits, as it would seem was intended. Moreover, State Water Board members recognized at the October 3, 2019, State Water Board workshop that discharge volume alone is not a sufficient justification for automatic issuance of effluent limitations and issuance of a monthly monitoring frequency. |
| 21.020 | Having a pretreatment program or industrial users within a POTW’s service area is not a reliable indication of effluent risk. Although changes in the revised Provisions attempt to identify to a greater degree those POTWs that exhibit the greatest risk to receiving waters (those with pretreatment programs), the threshold used is not reliable and over-generalizes POTW characteristics. According to the revised Staff Report (Section 5.4.2), POTWs authorized to discharge at 5 MGD and having a pretreatment program are of greater concern because:   * “…such dischargers generally receive voluminous influent from a variety of sources that may include municipal and/or industrial discharges … and … are less likely to be fully understood.” * “…influent may contain pollutants that interact with plant operations affecting the quality of the effluent…” * “…pollutants may also pass through a POTW’s removal and filtration process into the effluent.” * “…differing pollutants, from more than one source, may interact creating a higher risk of toxicity that can affect plant operations and effluent quality.” * “This threshold is consistent with the threshold used by U.S. EPA in requiring POTWs to have pretreatment programs for similar reasons as mentioned above.” |
| 21.021 | Technical information provided by RBI at the October 3, 2019, State Water Board workshop indicates these generalizations do not apply equally across such facilities. State Water Board members agreed. Data for nine POTWs from the Central Valley (Table 1 [See Table 1 on page 12 of Comment Letter #21]) indicates that all facilities, even two permitted at less than 5 MGD, have Regional Board-approved pretreatment programs, yet the actual proportion of industrial inputs from significant industrial users (SIUs) to the facilities varies 0–50%. The industrial contribution to five of nine facilities ranges 0–1%. Therefore, the requirement to have a pretreatment program, the presence of SIUs in the service area, and being authorized to discharge at 5 MGD or greater are poor indicators of the potential for voluminous influent from industrial discharges, influent being less fully understood, the presence of pollutants that influence operations, pollutant pass through, or general risk of effluent toxicity. |
| 21.022 | The fact that POTWs listed in Table 1 implement NPDES-permit required pretreatment programs makes them more capable of identifying complex inputs to their treatment plant from industrial sources and controlling them. CVCWA (2018) also found that industrial inputs were the suspected cause of toxicity in only 3 of 35 TREs they reviewed for Central Valley POTWs—two being related to SIUs and one being related to a non-SIU (state university). Were industrial inputs to POTWs to create on-going and substantial risk in terms of effluent quality, there would be a high proportion of TREs that have identified industrial inputs as the cause, but this is not the case. Data for California POTWs clarifies, in contrast to the revised draft Staff Report rationale, that having a pretreatment program, SIUs in the service area, or being authorized to discharge at 5 MGD or greater are not appropriate characteristics of the potential for toxicity, or potential risks to beneficial uses in receiving waters, from POTW discharges.  Table 1. Flow, pretreatment program, and testing frequency for select POTWs from the Central Valley.  [See Table 1 on page 12 of Comment Letter #21] |
| 21.023 | The Provisions should require RPA of all discharges. Any attempt to generalize characteristics of problematic WWTP discharges based on course regulatory requirements, such as the authorized flow threshold or pretreatment program requirement, is inequitable to many dischargers, as demonstrated above. Any attempt to continue to hone in on a particular threshold will only require more work on behalf of the Regional Water Boards to determine whether that particular qualification applies to a POTW. This time is better spent on reviewing actual toxicity data as part of conducting the RPA. To be equitable to all parties, it is not appropriate to select a threshold/qualification that automatically triggers effluent limitations. State Water Board members were in agreement at the October 3, 2019, Board workshop.  **Requested Change to Address Comment 5:**  We request the State Water Board revise the Provisions to delete using any threshold (5 MGD, pretreatment program, etc.) to determine a subset of non-stormwater NPDES-permitted dischargers that automatically require effluent limitations for chronic toxicity. Rather, RPA should be conducted for all non-stormwater NPDES-permitted dischargers. |
| 21.024 | **Comment 6. Routine Monitoring Frequency for Chronic Aquatic Toxicity – Revised Draft Toxicity Provisions Section IV.B.2.d.ii.(A)(1).**  At the October 2019, State Water Board workshop, members of the State Water Board recognized that less frequent monitoring for smaller POTWs was justified, and this resulted in changes to the revised draft Toxicity Provisions. Further, members of the State Water Board expressed concern that the 5 MGD authorized flow threshold was not reliable for determining POTWs that should monitor monthly and POTWs that should automatically be issued effluent limitations (as described in Comment 6, above). Despite this, the revised draft Toxicity Provisions continue to require all POTWs in California that are authorized to discharge at 5 MGD or greater to monitor monthly if they are issued effluent limitations. As described below, changes to the routine monitoring frequencies specified in the revised draft Toxicity Provisions should be extended to the category of POTWs authorized to discharge at 5 MGD or greater.  Relying upon the 5 MGD threshold generalizes all such POTWs into an overly broad, single category. This category groups POTWs such as the City of Brentwood Wastewater Treatment Plant (WWTP), which discharges tertiary-treated, Title 22-equivalent wastewater, with the City of Los Angeles Hyperion WWTP, which discharges secondary-treated wastewater. Brentwood WWTP is authorized to discharge 5 MGD (Table 1), while Hyperion WWTP is authorized to discharge 450 MGD, nearly a 100-fold difference. The differences in treatment level, discharge rate, flows from SIUs, rate payer base, and agency resources across this category are stark. This is also demonstrated by the information in Table 1.  [See Table 1 on page 12 of Comment Letter #21]  Lastly, the revised draft Toxicity Provisions deviate from current approaches within the State for establishing monitoring requirements for chemical constituents that demonstrate reasonable potential. For such constituents, Regional Water Boards have been granted full discretion to set the appropriate monitoring frequency in NPDES permits for effluent limitation compliance monitoring.  Requested Change to Address Comment 6:  We request that the revised draft Toxicity Provisions provide Regional Water Board discretion to deviate from the prescribed routine monitoring requirements to appropriately account for POTW-specific conditions and risk. This would keep the expectation of monthly testing, but allow Regional Water Boards to prescribe less frequent or seasonal monitoring based on individual discharger-specific factors and risk that cannot be addressed in detail in the Toxicity Provisions. The following text is recommended to be added to Section IV.B.2.d.ii.(A)(1):  “The PERMITTING AUTHORITY has the authority to deviate from the routine monitoring frequencies prescribed herein to account for discharger-specific factors and risk level.”  Alternatively, granting the bimonthly testing frequency proposed by CVCWA is an acceptable approach to address this issue. |
| **SC D.002** | The Toxicity Provisions should clarify if POTWs authorized to discharge 5 MGD or greater and are required to have a pretreatment program, but do not have an approved pretreatment program due to the absence of significant industrial users present in their service area, would be required to complete a reasonable potential analysis. |
| **SR D.002** | The Toxicity Provisions were revised to specify that POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD and are required to have a pretreatment program by the terms of 40 CFR § 403.8(a) (effective January 1, 2020) are not required to perform a reasonable potential analysis, because the permitting authority must include an effluent limitation for these dischargers pursuant to Section IV.B.2.e. Those POTW dischargers that are not authorized to discharge at a rate equal to or greater than 5.0 MGD and POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD but are not required to have a pretreatment program by the terms of 40 CFR § 403.8(a) would conduct a reasonable potential analysis to determine if they are required to have effluent limitations.  Please see Section 5.4.2 of the Staff Report and response “SR21.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for an explanation of why POTWs authorized to discharge at a rate equal to or greater than 5 MGD and are required to have an industrial pretreatment program are required to have effluent limitations. |
| 16.005 | 3. IV. B. 2. c. i. Non-Storm Water NPDES Dischargers Required to Conduct Reasonable Potential Analysis for Chronic Aquatic Toxicity (page 19): This section states POTWs that are authorized to discharge at a rate equal to or greater than 5.0 million gallons per day (MGD) and are required to have a pretreatment are exempt from completing a reasonable potential analysis. CVWD requests the state board to clarify if POTWs who are authorized to discharge 5.0 MGD or greater and are required to have a pretreatment program, but do not have an approved pretreatment program due to the absence of significant industrial users present in their service area are required to complete a reasonable potential analysis. |
| **SC D.003** | The Toxicity Provisions now include an additional, and unnecessary, caveat that reasonable potential will only be automatically assigned to facilities that discharge greater than 5 MGD *and* are required to have a pretreatment program. This would increase the number of facilities that will not automatically be assigned reasonable potential.  Due to the sheer volume of the discharge, any facility that discharges greater than 5 MGD should automatically be assigned reasonable potential with the requirement to comply with monitoring requirements and toxicity effluent limits outlined in the Provisions.  If the final Provisions include this additional greater than 5 MGD and pretreatment requirement in order for a facility to automatically be assigned reasonable potential, then it is critical that the reasonable potential analysis be applied to all dischargers – including stormwater and agricultural discharges – to ensure that the Toxicity Provisions are protective of ecological health. |
| **SR D.003** | The Toxicity Provisions were revised to specify that POTW dischargers that are authorized to discharge at a rate equal to or greater than 5.0 MGD and are required to have a pretreatment program by the terms of 40 CFR § 403.8(a) (effective January 1, 2020) are not required to perform a reasonable potential analysis, because the permitting authority must include an effluent limitation for these dischargers pursuant to Section IV.B.2.e.  Please see Section 5.4.2 of the Staff Report and response “SR21.008” and “SR21.009” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for an explanation of why a reasonable potential analysis is required for non-storm water NPDES dischargers (except POTWs authorized to discharge at a rate equal to or greater than 5 MGD and are required to have an industrial pretreatment program). Section 5.4.2 of the Staff Report explains that “[t]he Provisions do not include a determination or an assumption that POTW dischargers that are authorized to discharge at a rate equal to or greater than five MGD and are required to have a pretreatment program per federal regulations have reasonable potential. Instead, a reasonable potential analysis would not be required for these dischargers before a Water Board included effluent limitations for toxicity in a permit.”  Neither the 2018 Draft Provisions nor the 2020 Second Revised Draft Provisions propose a statewide mandate that agricultural and storm water dischargers conduct a reasonable potential analysis. Therefore, this portion of comment number 19.027 is outside the scope of the comments the State Water Board will receive for its consideration on the differences between the 2018 and 2020 versions of the Toxicity Provisions. Please see Section 5.5 and 5.6 of the Staff Report for a discussion of the options considered for storm water and non-point source dischargers and the reasons for recommending the preferred options. |
| 19.006 | *Ensure the reasonable potential analysis threshold is upheld and remove the pretreatment requirement of facilities greater than 5 MGD.* |
| 19.024 | **II. THE STATE WATER BOARD SHOULD UPHOLD THE REASONABLE POTENTIAL ANALYSIS THRESHOLD AND REMOVE THE PRETREATMENT REQUIREMENT FOR FACILITIES GREATER THAN 5 MGD.** |
| 19.027 | Despite our support of the reasonable potential analysis threshold imposed by these Provisions, new changes to the discharge volume threshold of greater than 5 million gallons per day (MGD) are unnecessary and will needlessly prevent some major POTWs from automatically falling under the requirements of these Provisions. The Provisions as drafted in 2018 required a reasonable potential analysis for all applicable discharges before applying toxicity limits and monitoring requirements, and only automatically applied the requirements of the Provisions to major POTW facilities discharging greater than 5 MGD. The Toxicity Provisions as now drafted include an additional, and unnecessary, caveat that reasonable potential will only be automatically assigned to facilities that discharge greater than 5 MGD *and* are required to have a pretreatment program, increasing the number of facilities that will not automatically be assigned reasonable potential. Due to the sheer volume of the discharge, any facility that discharges greater than 5 MGD should automatically be assigned reasonable potential with the requirement to comply with monitoring requirements and toxicity effluent limits outlined in the Provisions. If the final Provisions will include this additional greater than 5 MGD and pretreatment requirement in order for a facility to automatically be assigned reasonable potential, then it is critical that the reasonable potential analysis be applied to all dischargers – including stormwater and agricultural discharges – to ensure the final Toxicity Provisions are protective of ecological health. |

## Category E – Aquatic Toxicity Monitoring

| **Comment Code** | **Comment** |
| --- | --- |
| **SC E.001** | Changes made in the second revised draft Toxicity Provisions to allow a replacement test (i.e., retest) when a required test is not completed are appreciated. |
| **SR E.001** | Comment noted. |
| 21.010 | Comment 3. Dual Purpose Tests – Revised Draft Toxicity Provisions Section IV.B.2.d.iv.  Changes made in the second revised draft Toxicity Provisions to allow a replacement test (i.e., retest) when a required test is not completed are appreciated.  “When a required toxicity test for ROUTINE MONITORING, MMET TESTS, or MMEL COMPLIANCE TESTS is not completed, a new toxicity test to replace the toxicity test that was not completed shall be initiated as soon as possible.” Section IV.B.2.d.iv. (underline/markup from the original) |
| **SC E.002** | Define test acceptability criteria (TAC) in the Glossary of the Toxicity Provisions. |
| **SR E.002** | TAC was not defined in the Glossary of the Toxicity Provisions because TAC is a requirement included in U.S. EPA methods manual and is defined in the U.S. EPA-approved methods manuals listed in Section IV.B.1.b of the Toxicity Provisions. |
| 21.009 | Comment 2. Define “TAC” – Revised Draft Toxicity Provisions Section IV.B.2.d. It would be helpful to define this acronym in the Glossary. Suggested text is provided below.  Suggested Language Change to Address Comment 2:  “Test Acceptability Criteria (TAC): These are minimum performance standards for control organisms in toxicity tests to determine a result is valid, as described by the USEPA approved method. Any test not meeting the minimum test acceptability criteria is invalid.” |
| **SC E.003** | The definition in the Toxicity Provisions affects the conditions under which the conduct of a “*replacement test*” (i.e., retest) would be performed, i.e. when a test is “*not completed.*” Revise the language on toxicity “test completion” as “when all test requirements have been met” to ensure that the full range of testing requirements in U.S. EPA standard methods and guidance is considered.  The statement in Second Revised Draft Toxicity Provisions that toxicity testing “…*shall follow methods identified in the Code of Federal Regulations, title 40, part 136, or other U.S. EPA-approved methods, or included in the following United States Environmental Protection Agency (U.S. EPA) method manuals*:…” reinforces the need to follow all test requirements to determine a valid/complete test, rather than only those listed in the tables of test conditions tables or as TAC.  TAC are the minimum required performance standards for control organisms. Additional test *requirements,* not listed in the tables of test conditions or TAC, must also be met for a valid result, according to USEPA (2002) test methods. For example, “[t]he concentration-response relationship generated for each multi-concentration test must be reviewed to ensure that calculated test results are interpreted appropriately” (Section 10.2.6.2). Not meeting any test *requirement* produces an invalid test and creates the need for a retest. U.S. EPA toxicity test methods clearly explain which parts of a test method are required, using words such as “must” or “shall,” and which are not, using words such as “may” or “should.” Therefore, following the full range of “test requirements” in U.S. EPA-approved methods is not optional.  A toxicity test that does not meet all test requirements can produce an invalid result and create the need for a retest according to U.S. EPA (2002); whereas, under the Toxicity Provisions, a retest would not be allowed when a requirement described only within the narrative of the test protocol is not met. Such a toxicity test would be considered invalid by U.S. EPA (2002) but would need to be reported and used for regulatory purposes according to the revised draft Toxicity Provisions. Reporting data that does not meet all test requirements compromises the intent of U.S. EPA approved test methods to produce reliable data of sufficient quality for regulatory decisions.  This conflict between U.S. EPA approved toxicity test methods and the revised draft Toxicity Provisions is problematic for laboratories that must meet accreditation standards. Specifying that toxicity tests may only be invalidated due to the failure of TAC may place laboratories in the untenable position where they must invalidate toxicity test results under their certification requirements but must also report these results as valid under the Plan. This is also problematic for the Regional Water Boards and for dischargers if results that do not meet all test method requirements must be submitted for compliance with an NPDES permit. It is not appropriate for regulatory decisions to be made with data generated by tests that do not meet all test requirements, making them invalid according to the U.S. EPA approved test method.  Additionally, the draft Toxicity Provisions are inconsistent with the TST Technical Document that indicates this statistical analysis applies to data from tests that have meet *all* method requirements. |
| **SR E.003** | For purposes of compliance with the Toxicity Provisions, toxicity tests must be completed according to Section IV.B.2.d of the Toxicity Provisions and must follow the U.S. EPA methods manuals according to Section IV.B.1.b of the Toxicity Provisions.  Section IV.B.2.d of the Toxicity Provisions has been changed to define test completion as follows: “For purposes of this section, completion of a test means when the test has been terminated at the prescribed time (e.g., 96 hours, 7 days) and test acceptability criteria have been met.”  The statement in the Toxicity Provisions that test completion means that “all required conditions have been met” was removed because laboratories have some flexibility regarding certain test conditions and can use their professional judgement to determine if the test results are still acceptable. For example, an individual test may be conditionally acceptable if temperature, dissolved oxygen, and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (U.S. EPA 1995, 2002a, 2002b, 2002c).  Test completion should not be confused with test data review. Test completion is a separate step from data analysis and test data review. For each test method in the U.S. EPA methods manuals, data review is in a separate section following test completion requirements for a test.  Although the current U.S. EPA methods manuals require multi-concentration tests to be conducted, review of the concentration-response curve is not a required test review step. Review of the concentration-response relationship generated for each multi-concentration test is only conducted to ensure that calculated test results are interpreted appropriately when the NOEC or point estimate statistical approach is used. When using the TST statistical approach to determine compliance with the Toxicity Provisions, conducting the full multi-concentration test is still required according to the U.S. EPA methods manuals, but the review of the concentration-response curve is not required by the U.S. EPA method prior to relying on results. Please see “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on why evaluation of the concentration-response curve is not valuable when using the TST statistical approach. Additionally, as discussed in Section 2.6.5 of the Staff Report, the State Water Board is currently drafting an application for a limited-use statewide Alternate Test Procedure (ATP) for the use of the one effluent concentration, in lieu of the five effluent concentrations, and a control when the TST is the required statistical approach in the NPDES permit. If approved, this ATP would provide an option for laboratory cost savings.  The Toxicity Provisions do not include changes or modifications to the U.S. EPA or the ELAP accreditation, or quality assurance process, including the implementation of recently adopted TNI 2016 Standards. The Toxicity Provisions specify that the TST statistical approach is required to be used to analyze toxicity test data. Other components of toxicity testing, such as reference toxicant tests and TRE/TIEs, may require other statistical approaches, such as the NOEC or point estimate, to determine a specific concentration at which there is a toxic effect.  The statements in the Toxicity Provisions and the TST Technical Document implying that all test/method requirements must be met to determine a complete test have been taken out of context. |
| 12.005  18.002 | • **Toxicity Test Completion:** We request that a simple wording change be made to ensure that the full range of testing requirements specified in USEPA standard methods and guidance be considered in the determination of test completion. |
| 12.016 | **The Language on Toxicity Test Completion Should Be Revised to Ensure That the Full Range of Testing Requirements Is Considered.**  This definition, which is also described in Section 5.4.4.1 of the staff report, affects the conditions under which the conduct of a “*replacement test*” (i.e., retest) would be performed, i.e. when a test is “*not completed*”. For the reasons below, we request that Section IV.B.2.d of the proposed Toxicity Provisions be modified to define the completion of a test as “*when all test requirements have been met.”* This simple change would expand “all required test conditions and Test Acceptability Criteria (TAC)” to the full range of “test requirements” specified in USEPA Standard Methods.  Under USEPA (2002) chronic toxicity test method guidance, “test conditions” describe the specific laboratory procedures for conducting a toxicity test (e.g., temperature, age of organisms, volume of sample, number of replicates, etc.) and are presented in tables of test conditions for each test species. Some of the “test conditions” described by USEPA are denominated as “required.”2 TAC are the minimum required performance standards for control organisms. Additional test *requirements,* not listed in the tables of test conditions or TAC, must also be met for a valid result, according to USEPA (2002) test methods. Not meeting any test *requirement* produces an invalid test and creates the need for a retest. Examples of chronic toxicity test requirements in USEPA (2002) test methods that are not TAC, or are not listed in the tables describing test conditions, are as follows.  • “In addition to these test acceptability criteria, if fewer than eight replicates in the control remain after excluding males and blocks with 50% or more surviving organisms identified as males, the test is invalid and must be repeated with a newly collected sample.” (Section 13.13.1)  • “The concentration-response relationship generated for each multi-concentration test must be reviewed to ensure that calculated test results are interpreted appropriately” (Section 10.2.6.2)  • “If the data from the samples are to be acceptable for use in the NPDES Program, the lapsed time (holding time) from sample collection to first use of each grab or composite sample must not exceed 36 h.” (Section 8.5.3)  USEPA toxicity test methods clearly explain which parts of a test method are required and which are not. “*Words of obligation, such as “must” or “shall” indicate a required procedure. When WET method manuals use discretionary terms such as “may” or “should,” the manuals provide flexibility so that the laboratory analyst may optimize successful test completion (USEPA, 1996a).*” (USEPA 2000). Therefore, following the full range of “test requirements” in USEPA-approved methods is not optional. |
| 17.007 | ***4. The State Water Board should include clarifying language that all required test conditions must be met for a toxicity test to be considered valid.***  The updated Section IV.B.2.d.iv details the use of “replacement tests.” A number of recent California NPDES permits specify that toxicity tests may only be invalidated due to the failure of “Test Acceptability Criteria (TAC).” However, in the EPA methods manuals, TAC represent a small subset of conditions and requirements which must be met in order for a test to be considered valid. For example, the methods manuals are equally clear that there are “required test conditions” which are not specified as TAC (e.g., temperature deviation restrictions). Specifying that tests shall be invalidated and repeated if any TAC or required test conditions are not met would both help dischargers ensure that only the highest quality data are used and reduce the burden on Permitting Authorities stemming from individual dischargers seeking clarification or a decision on validity for specific tests. Furthermore, the implementation of national certification standards (via The NELAC Institute, TNI) in California will expand the list of required conditions as many currently “recommended” conditions will become “required” under TNI. Specifying that toxicity tests may only be invalidated due to the failure of TAC may place laboratories in the untenable position where they must invalidate toxicity test results under their certification requirements but must also report these results as valid under the Plan. |
| 18.010  21.002 | **Toxicity Test Completion**  The completion of a toxicity test is now described in Section IV.B.2.d of the second revised draft Toxicity Provisions, as follows:  “For the purposes of this section, completion of a test means when the test has been terminated, and all required test conditions and TAC have been met.” Section IV.B.2.d. (underline/markup from the original)  This definition affects the possibility of conducting a “*replacement test*” (i.e., retest) when a test is “*not completed*”.  “When a required toxicity test for ROUTINE MONITORING, MMET TESTS, or MMEL COMPLIANCE TESTS is not completed, a new toxicity test to replace the toxicity test that was not completed shall be initiated as soon as possible.” Section IV.B.2.d.iv (underline/markup from the original)  The revised draft Staff Report (Section 5.4.4.1) adds only that these test conditions are indicated in the USEPA approved test method and “*If these conditions are not met, the test cannot be considered complete and the test cannot be used to meet monitoring requirements for conducting aquatic toxicity tests*.” References to “test conditions” and Test Acceptability Criteria (TAC), which are the minimum required performance standards for control organisms, would seem to be helpful, but both are specific terms in USEPA toxicity test guidance that refer to only some of the test requirements and, therefore, USEPA test requirements are excluded. This may, at times, create a conflict between the draft Toxicity Provisions and the test method. |
| 18.012  18.013  21.003 | USEPA2 (2002) chronic toxicity test method guidance “test conditions” describe the specific laboratory procedures for conducting a toxicity test (e.g., temperature, age of organisms, volume of sample, number of replicates, etc.) and are presented in tables of test conditions for each test species. Some of these “test conditions” described by USEPA are identified as “required” while others are “recommended.” This understanding that “test conditions” in the revised Provisions are referring to required procedures for conducting toxicity tests was confirmed by State Water Board Staff at the July 29, 2020, Toxicity Provisions staff workshop. However, there are additional test requirements not listed in the tables of test conditions or TAC, but delineated within the narrative of the test method protocols. These additional test requirements must also be met for a test to be valid according to USEPA (2002) test methods.  Examples of chronic toxicity test requirements in USEPA (2002) test methods that are not TAC or are not listed in the tables describing test conditions are as follows.   * “In addition to these test acceptability criteria, if fewer than eight replicates in the control remain after excluding males and blocks with 50% or more surviving organisms identified as males, the test is invalid and must be repeated with a newly collected sample.” (Section 13.13.1) * “The concentration-response relationship generated for each multi-concentration test must be reviewed to ensure that calculated test results are interpreted appropriately” (Section 10.2.6.2) |
| 18.014  18.015  21.004 | USEPA toxicity test methods clearly explain which parts of a test method are required and which are not. “*Words of obligation, such as “must” or “shall” indicate a required procedure. When WET method manuals use discretionary terms such as “may” or “should”, the manuals provide flexibility so that the laboratory analyst may optimize successful test completion (USEPA, 1996a).*” (USEPA 2000). Therefore, following all the test requirements in USEPA approved methods is not optional.  A toxicity test that does not meet all test requirements can produce an invalid result and create the need for a retest according to USEPA (2002). Whereas, under Section IV.B.2.d.iv of the revised Toxicity Provisions, a retest would not be allowed when a requirement described only within the narrative of the test protocol is not met. Such a test would be considered invalid by USEPA (2002) but would need to be reported and used for regulatory purposes according to the revised draft Toxicity Provisions. Reporting data that does not meet all test requirements compromises the intent of USEPA approved test methods to produce reliable data of sufficient quality for regulatory decisions. |
| 18.016  21.005 | This conflict between USEPA approved toxicity test methods and the revised draft Toxicity Provisions is problematic for laboratories that must meet accreditation standards (e.g., those certified by The National Environmental Laboratory Accreditation Program [NELAP], and those of the California Environmental Laboratory Accreditation Program [ELAP], which recently adopted TNI 2016 Standards; State Water Board Resolution 2020-0012). Accreditation agencies require labs to follow all of the test methodology and adhere to all test requirements. This is also problematic for the Regional Water Boards and for dischargers if results that do not meet all test method requirements must be submitted for compliance with an NPDES permit. It is not appropriate for regulatory decisions to be made with data generated by tests that do not meet all test requirements, making them invalid according to the USEPA approved test method. |
| 18.017  21.006 | The revised draft Toxicity Provisions also state in Section IV.B.1.b. that toxicity testing “…*shall follow methods identified in the Code of Federal Regulations, title 40, part 136, or other U.S. EPA-approved methods, or included in the following United States Environmental Protection Agency (U.S. EPA) method manuals*:…” USEPA (2002) chronic toxicity test methods are described throughout the document. The requirement in the revised draft Toxicity Provisions to follow these test methods reinforces the need to follow all test requirements to determine a valid/complete test, rather than only those listed in the tables of test conditions tables or as TAC. |
| 18.018  21.007 | The Test of Significant Toxicity (TST) Technical Document (USEPA 2010) states “*Once the WET test has been conducted (using multiple effluent concentrations and other requirements as specified in the WET test methods), the TST approach can be used to analyze valid WET test results to assess whether the effluent discharge is toxic*.” Therefore, the revised draft Toxicity Provisions are also inconsistent with the TST methodology that indicate this statistical analysis applies to data from tests that have meet *all* method requirements. |
| 18.019  21.008 | In summary, although changes in the second revised draft Toxicity Provisions have described what is meant by a “completed test” and when a “replacement test” (i.e., retest) may be performed, the specificity of this new terminology has made the revised Provisions inconsistent with USEPA test method requirements, internally inconsistent with other requirements in the Provisions, and contrary to the TST Technical Document.  A simple and straightforward change that will address this conflict is to define the completion of a test as “*when all test requirements have been met”*. We are asking that this change be made to the language in Section IV.B.2.d of the proposed Toxicity Provisions and Section 5.4.4.1 of the staff report. |
| **SC E.004** | Routine monitoring should be conducted quarterly at a minimum to detect unanticipated toxic events and account for seasonal variability in discharges. The 2018 Draft Provisions required POTW dischargers and other non-storm water NPDES dischargers that discharge greater than or equal to 5 MGD to conduct monthly routine chronic toxicity monitoring, but required POTW dischargers and other non-storm water NPDES dischargers that discharge less than 5 MGD to conduct quarterly routine chronic toxicity monitoring. The 2020 Second Revised Draft Provisions reduce monitoring requirements to at least two times per year for non-storm water NPDES dischargers without effluent limitations and all POTW dischargers authorized to discharge less than 1 MGD. This is a significant step back and leaves the Water Boards, the discharger, and the public with gaps in information regarding whether a discharge is contributing toxicity to nearby waterways. This is especially concerning in effluent-dominated waters. |
| **SR E.004** | The 2020 Second Revised Toxicity Provisions expanded routine monitoring requirements to all non-storm water NPDES dischargers, even those without effluent limitations, and require a minimum routine monitoring frequency of at least twice per year. The 2018 Draft Toxicity Provisions would have required toxicity monitoring only for non-storm water NPDES dischargers that have effluent limitations.  The biannual routine monitoring frequency was included in the Toxicity Provisions because POTW dischargers with a low volume of effluent (less than 1 MGD) and other dischargers without reasonable potential to exceed toxicity standards pose less of a threat to aquatic life than high volume dischargers. Additionally, the biannual frequency would provide some economic relief, compared to a quarterly or monthly routine monitoring frequency, while still increasing the monitoring frequency from the current chronic toxicity monitoring frequency for most of these discharges. As stated in Section 5.4.4 of the Staff Report, only about two percent of non-storm water NPDES dischargers are likely to have a reduction in their chronic toxicity routine monitoring frequency under the Provisions as compared to current permit requirements.  Furthermore, section IV.B.2.d.ii(A)(1) of the Toxicity Provisions, states that the permitting authority may require dischargers to conduct more frequent chronic aquatic toxicity routine monitoring. Reasons for the Regional Water Board to increase routine monitoring frequencies is included in Section 5.4.4.2.2.1 of the Staff Report.  For a discussion on the reduced monitoring frequency eligibility, see SR E.005. |
| 19.009 | *Require routine monitoring to be conducted quarterly, at a minimum, with reduced monitoring frequency eligibility limited only to discharges without a toxicity exceedance in the past five consecutive years.* |
| 19.047 | **IV. ROUTINE MONITORING SHOULD BE CONDUCTED QUARTERLY, AT A MINIMUM, WITH REDUCED MONITORING FREQUENCY ELIGIBILITY LIMITED ONLY TO DISCHARGES WITHOUT A TOXICITY EXCEEDANCE IN THE PAST FIVE CONSECUTIVE YEARS.** |
| 19.048 | 1. Routine monitoring must be conducted quarterly at a minimum to detect unanticipated toxic events and account for seasonal variability in discharges. As accurately discussed in the Staff Report, routine monitoring frequency for toxicity varies widely among the numerous dischargers located throughout the state. These inconsistencies harbor the potential to undermine the aquatic beneficial uses of receiving waters and may offer economic advantages to those dischargers that are seldom or never required to conduct toxicity tests. In addition to establishing a consistent regulatory framework, a routine schedule of toxicity tests will help maintain the biological integrity of receiving waters by acting as a backstop against the additive and synergistic effects of known and unknown pollutants. The 2018 Draft Provisions required that all POTW facilities and other NPDES permittees that discharge greater than or equal to 5 MGD must complete routine chronic toxicity monitoring monthly, but that POTW facilities and NPDES permittees that discharge less than 5 MGD must only complete routine chronic toxicity monitoring quarterly. Despite the benefits of routine toxicity tests and consistent monitoring requirements as acknowledged in the Staff Report, the Provisions now reduce monitoring requirements to at least two times per year for non-stormwater NPDES dischargers without effluent limitations and for all POTW facilities authorized to discharge less than 1 MGD. This is a significant step back from the proposed routine monitoring frequency in the 2012 Draft Toxicity Provisions, which required facilities that continuously discharge at a rate greater than or equal to one MGD – or POTWs with dry weather design capacity of one MGD – would be required to conduct monthly monitoring, and required facilities that continuously discharge at a lower rate to conduct quarterly monitoring. |
| 19.049 | Reducing this monitoring frequency leaves the Water Boards, the discharger, and the public with gaps in information regarding whether a discharge is contributing toxicity to nearby waterways. This is especially concerning in effluent-dominated rivers and streams, where discharges less than 5 MGD can be the dominant source of flow in the waterway35 and therefore have a large impact on the ecological health of that waterways if the effluent is or becomes toxic. If routine monitoring is not conducted monthly, as previously recommended by the NGO community to detect unanticipated toxic events that may occur abruptly, then routine monitoring should be required to take place quarterly, at a minimum, to capture seasonal variation in the effluent as a backstop against the additive and synergistic effects of known and unknown pollutants that may be present in effluent discharge at different times of the year. |
| **SC E.005** | Eligibility for a reduced routine monitoring frequency must be limited only to those dischargers who have not violated effluent limitations or have not had a toxicity test result in a TST “fail” at the IWC within the past five consecutive years. Dischargers without effluent limitations may only qualify for a potential reduction in routine monitoring if no chronic toxicity test has resulted in a “fail” at the IWC, whereas dischargers with effluent limitations may be subject to a reduction in routine monitoring only without a violation, meaning that these dischargers may be eligible for a reduction of routine monitoring even when an exceedance (i.e., a “fail) has occurred within the past five consecutive years.  The language of the 2018 Draft Provisions for dischargers with effluent limitations should be reinstated and no reduction in routine monitoring should be granted when an exceedance (a TST “fail”) has occurred in the past five years. |
| **SR E.005** | The criteria for a reduced routine monitoring frequency was revised in the Provisions (Section IV.B.2.ii(A)(2) of the Second Revised Draft Toxicity Provisions) from no exceedances of effluent limitations to no violations of effluent limitations for clarity as dischargers with an existing effluent limitation may have a fail, so long as that fail does not lead to a violation. When a discharger has a violation, there is a high probability that a toxic event has occurred.  The change in the term also provided clarity because the Toxicity Provisions were revised to allow dischargers without an existing effluent limitation to be eligible for a reduced monitoring frequency. Because dischargers without effluent limitations are not subject to violations, eligibility is based on pass/fail results using the TST approach. This set of requirements is more stringent than for dischargers with effluent limitations in their permit. Please see “SR07.013” ” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion of why the Toxicity Provisions were revised to allow dischargers without effluent limitations to be eligible for a reduced monitoring frequency |
| 19.050 | 2. Reduced monitoring frequency eligibility must be limited only to those who have not exceeded MDEL, MMEL, or otherwise have not demonstrated a “fail” at the IWC within the past five consecutive years. The Provisions, as currently drafted, now provide Regional Water Boards with the explicit discretion to reduce chronic toxicity routine monitoring frequency for dischargers, under specific conditions. The threshold of these conditions, however, vary between those dischargers that have MDEL and MMEL requirements in an NPDES permit. Essentially, those without MDEL and MMEL requirements may only qualify for a potential reduction in routine monitoring if no chronic toxicity test has resulted in a “fail” at the IWC, whereas those with MDEL and MMEL requirements may be subject to a reduction in routine monitoring only without a violation of an MDEL or MMEL, meaning that these dischargers may be eligible for a reduction of routine monitoring even when an exceedance (i.e., a “fail) has occurred within the past five consecutive years. We respectfully request that if reductions for routine monitoring are allowed, that the original language for dischargers with MDEL and MMEL requirements be reinstated and that no reduction in routine monitoring be granted when an exceedance has occurred in the past five years. |
| 19.051 | **Requested Language** *(Suggested language in red):*  **B.2.d.ii(A)(2) (p. 26)**  If an NPDES permit includes the MDEL and MMEL as specified in Section IV.B.2.e, the PERMITTING AUTHORITY may approve a reduction in the frequency of the ROUTINE MONITORING specified in Section IV.B.2.d.ii(A)(1) upon reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the NPDES permit when during the prior five consecutive years the following conditions have been met: 1) The MDEL and MMEL as specified in Section IV.B.2.e have not been exceeded; 2) The toxicity requirements in the applicable NPDES permit(s) have been followed. |
| **SC E.006** | Reduced routine monitoring is not encouraged due to new contaminants of emerging concern that may enter comingled systems through stormwater that pose new and unknown challenges to effluent treatment.  Monthly monitoring is one practical safeguard against emerging contaminants and is needed to provide an accurate depiction of a discharger’s current potential for toxicity. At a minimum, any monitoring frequency reduction should only apply during dry weather months for any comingled system or stormwater discharger that is required to conduct toxicity testing by a Regional Water Board, given the increase and range of contaminants that arise through stormwater runoff during wet weather months. Routine monitoring should also be done during a singular storm event or “first-flush” event following dry periods.  The conditions provided under Section IV.B.2.ii(A)(2) provide reasonable criteria that should not be redacted or weakened for a discharger to qualify for a potential reduction in routine monitoring; however, under no circumstance should routine monitoring be conducted less than once per quarter in order to detect potential seasonal variation and introduction of new and unknown contaminants that may cause toxicity. |
| **SR E.006** | For non-storm water NPDES dischargers, as stated in Section 5.4.4 of the Staff Report, the permitting authority would have the option of reducing the monitoring frequency for dischargers that comply with effluent limitations and permit terms. The permitting authority could also increase the routine monitoring frequency for any discharges that represent a higher threat to aquatic life or the environment, or increase the frequency for other reasons. The option to increase or decrease the monitoring frequency is up to the permitting authority and the rationale must be documented in the NPDES fact sheet (or equivalent), Water Code section 13383 Order, or both.  For storm water dischargers, complying with the aquatic toxicity monitoring in the Toxicity Provisions is only required for stormwater dischargers with existing toxicity monitoring requirements or at the discretion of the Water Board. If the Water Board requires chronic and/or acute toxicity testing using test methods as described in Section IV.B.1.b of the Toxicity Provisions, then the TST statistical approach would be required for analyzing the resulting data generated from the acute or chronic toxicity tests.  For a discussion of the minimum routine monitoring frequency, see SR E.004. |
| 19.052 | We do not encourage the reduction of routine monitoring due to new contaminants of emerging concern – such as pharmaceuticals, household chemicals, urban pesticides, per- and poly- fluoroalkyl substances (PFAS), and other contaminants that may enter comingled systems through stormwater – that pose new and unknown challenges to effluent treatment. Maintaining monthly routine monitoring is one practical safeguard against emerging contaminants in order to detect new and unknown toxicity that may arise as new compounds interact. Monthly monitoring is needed to provide an accurate depiction of a discharger’s current potential for toxicity. At a minimum, any monitoring frequency reduction should only apply during dry weather months for any comingled system or stormwater discharger that is required to conduct toxicity testing by a Regional Water Board, given the increase and range of contaminants that arise through stormwater runoff during wet weather months. Routine monitoring should also be done during a singular storm event or “first-flush” event following dry periods.  The conditions provided under Section IV.B.2.ii(A)(2) provide reasonable criteria that should not be redacted or weakened for a discharger to qualify for a potential reduction in routine monitoring; however, under no circumstance should routine monitoring be conducted less than once per quarter in order to detect potential seasonal variation and introduction of new and unknown contaminants that may cause toxicity. |
| 19.053 | **Requested Language** *(Suggested language in red)*:  **B.2.d.ii(A)(2) (p. 27)** |
| **SC E.007** | During a reduction in monitoring during a TRE, any samples taken as part of any TRE or TIE must be used to determine compliance with toxicity requirements pursuant to 40 CFR section 122.41(1)(4)(ii) as a general condition that is applicable to all permits: “If the permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 CFR Part 136, or another method required for an industry-specific waste stream under 40 CFR subchapters N or O, the results of such monitoring shall be included in the calculation and reporting of the data submitted in the [Discharge Monitoring Report] or sludge reporting form specified by the Director.”  This data must additionally be uploaded to the State Water Board’s central California Integrated Water Quality System (CIWQS) database to ensure public transparency and accountability of this data. |
| **SR E.007** | Section IV.B.2.d.ii(A)(2) of the Toxicity Provisions states that the routine monitoring frequency may be reduced to a minimum of two toxicity tests per year when the discharger is conducting aquatic toxicity testing as part of the TRE during that year. This does not mean that the discharger is not subject to possible violations. Any toxicity test conducted at the IWC using the most sensitive species is subject to a potential MDEL and MMEL violation, even if the toxicity test is not part of required routine monitoring.  As required in NPDES permits, dischargers must electronically submit their monitoring data and other specified data as Self-Monitoring Reports to the State Water Board’s CIWQS database in compliance with adopted orders. These data are readily available to the public. |
| 19.054 | Finally, even during a reduction in routine monitoring during a TRE, all samples taken as part of any Toxicity Identification Evaluation (TIE) or TRE must be used to determine compliance with toxicity requirements pursuant to 40 C.F.R. section 122.41 (1)(4)(ii) as a general condition that is applicable to all permits: “If the permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 CFR Part 136, or another method required for an industry-specific waste stream under 40 CFR subchapters N or O, the results of such monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Director.”36 |
| 19.055 | Further, any sample taken under the permit must be submitted on a Discharge Monitoring Report (DMR) and all data collected – even data collected that is done more frequently than specified in the permit -- must be reported and may be used to determine compliance with the permit. This data must additionally be uploaded to the State Water Board’s central CIWQS database to ensure public transparency and accountability of this data. We respectfully request these requirements be made explicit under section IV.B.2.d.ii(A)(2) when a Regional Water Board allows a temporary reduction of routine monitoring during a TRE. |
| **SC E.008** | Remove the provision allowing the permitting authority to specify the "exact dates or time periods" of routine monitoring tests or specify that these are “target” dates and not firm requirements, in recognition that flexibility may be required in the implementation of toxicity monitoring programs.  Placing a time restriction or limitation on when chronic aquatic toxicity testing shall be initiated reduces discharger’s flexibility in factors such as scheduling analysis with specialized toxicity labs, staffing, system upsets, laboratory issues (e.g., the availability of test organisms, laboratory workflow or scheduling issues), or other conditions that cannot be foreseen at the current time. Also, there is not sufficient laboratory capacity to have all dischargers perform this monitoring almost simultaneously. |
| **SR E.008** | The permitting authority would have the discretion to specify in the permit the exact dates or time periods in which the samples for routine monitoring tests for chronic toxicity must be collected, though it is not required that it be specified. The reason that the permitting authority may wish to specify the exact dates or time periods that routine monitoring samples must be collected would be to make sure that samples are collected early in the calendar month or calendar quarter. For dischargers with a monthly routine monitoring schedule, initiating the routine monitoring test early within the calendar month would allow sufficient time for two MMEL compliance tests if the routine monitoring test results in a fail. For dischargers with a quarterly routine monitoring frequency, the calendar month would start when the routine monitoring test is initiated. Initiating routine monitoring early in the calendar quarter would ensure that the calendar month does not extend into the following calendar quarter. However, it may not be practical for intermittent dischargers to always initiate routine monitoring tests early within the calendar month or quarter. The permitting authority may make the determination as to specify exact dates or time periods based on the individual circumstances of the discharger.  The Toxicity Provisions state that, in setting the start of the calendar month, calendar quarter, and calendar year the permitting authority shall consider relevant scheduling constraints identified by the discharger and applicable laboratories. The Toxicity Provisions allow flexibility for dischargers and laboratories to work with their permitting authority to define the start of the calendar month, as long as there are 12 distinct calendar months within a calendar year. In doing so, a permitting authority may prefer to stagger the start of the calendar months between different permits in order for laboratories to maximize their staff and laboratory resources. This way, laboratories should not be overwhelmed at the beginning of each month.  See SR K-4.003 for a discussion on the logistical challenges faced by the dischargers such as scheduling, staffing, and system updates.  See SR K-4.001 for a discussion on circumstances outside of the discharger’s control that include laboratory constraints and availability of test organisms. |
| 16.006 | 4. IV. B. 2. d. i. Defining the Start of the Calendar Month, Calendar Quarter, and Calendar Year (page 21): Placing a time period restriction or limitation on when chronic aquatic toxicity testing shall be initiated (e.g., a requirement to initiate a test within five days of the calendar quarter, a requirement to initiate a test between the 10th and the 15th of each calendar month), creates challenges in scheduling analysis with specialized toxicity labs, and POTWs will lose the flexibility of deciding when to initiate toxicity testing. Additionally, we do not believe sufficient laboratory capacity exists to have all dischargers perform this monitoring almost simultaneously. |
| 23.008  23.025 | LADWP recommends that monitoring requirements for non-stormwater National Pollutant Discharge Elimination System (NPDES) dischargers be modified to allow greater flexibility. |
| 23.026 | The revised Toxicity Provisions and Staff Report specify that the Regional Water Boards “would also have the discretion to specify in the permit the exact dates or time periods in which the samples for routine monitoring tests must be collected.” This modification to the Toxicity Provisions has the potential to eliminate flexibility that would be needed to account for relevant factors such as staffing, system upsets, laboratory issues (e.g., the availability of test organisms, laboratory workflow or scheduling issues), or other conditions that cannot be foreseen at the current time. |
| 23.028 | Recommendation 1: LADWP recommends that the provision allowing the Regional Boards to specify the "exact dates or time periods" of routine monitoring tests be eliminated, in recognition that flexibility may be required in the implementation of toxicity monitoring programs. |
| 26.025 | **Monitoring requirements for non-stormwater NPDES dischargers are restrictive and logistically difficult to meet**  **Specifying the exact date for routine monitoring sample collection is overly restrictive**  Issue: The Regional Water Boards have discretion to specify the exact date a routine monitoring sample is to be collected in the permit.  Staff Report, Section 5.4.4.1.1, 2nd paragraph on page 129 and similar text in Staff Report, Section 5.4.4.1.3, 4th paragraph on page 130, Section 5.4.4.2.2, 1st paragraph on page 135, and Toxicity Provisions, Section IV.B.2.d.i, 4th paragraph on page 24.  “The Regional Water Boards would also have the discretion to specify in the permit the exact dates or time periods in which the samples for the routine monitoring tests for chronic toxicity must be collected. For example, a Regional Water Board may require samples to be taken by the 10th day of each calendar month, or between the 15th and the 20th of each month.”    Discussion: The Regional Water Boards should not have the discretion to specify the exact date for the sample to be collected because this approach eliminates flexibility dischargers may need to account for manpower issues, plant upsets, equipment issues, etc. Flexibility may also be needed at the laboratory to account for test organism availability. The Toxicity Provisions should only suggest a time period that the routine monitoring test be conducted and allow the discharger some flexibility in scheduling sampling dates and coordinating with the laboratory.    Recommendation: Omit the phrase “exact dates of” from the referenced sections of the Staff Report and Toxicity Provisions, or specify that these are targets, not firm requirements:  “The Regional Water Boards would also have the discretion to specify in the permit the target dates or time periods in which the samples for the routine monitoring tests for chronic toxicity must be collected.” |
| **SC E.009** | The Provisions should allow a single sample to be used for dual purposes. Concurrent testing with split samples might need to be conducted by a discharger who cannot conduct all their required tests sequentially within the available time, to avoid rescheduling retesting into the successive calendar months. This testing approach adds costs, may not always be possible due to sample volume requirements, and should not be necessary. It would be more economical, and technically justified, if a replacement test conducted in the next calendar month can also be used as the routine monitoring test result for the month in which the samples are collected.  State Water Board staff explained at the July 29, 2020, Toxicity Provisions staff workshop that the intent of the revised draft Toxicity Provisions was to avoid multiple violations for a single sample. However, this outcome may be unavoidable. A discharger conducting either concurrent testing with effluent split samples, or a single test to meet two required tests (e.g., for a replacement test and a routine test), would face the same consequence if the sample(s) result is a TST “fail”. A single test that meets the requirement for a replacement test and routine monitoring would also cause less confusion than testing split samples in two concurrent tests if one produces a “pass” and the other a “fail.” |
| **SR E.009** | As stated in Section IV.B.2.d.iv of the Toxicity Provisions, a replacement test cannot be used to substitute for any other required toxicity tests. This is to ensure that each toxicity test is independent and prevents one “fail” from determining compliance with the MMEL in two different calendar months. See SR K-2.003 for further discussion. Please see SR E.010 for further discussion on logistical challenges that replacement tests may present. Please see SR L.019 regarding the use of split samples. |
| 12.002 | • **Dual Purpose Tests:** We request that the Provisions be revised to allow the same sample to be used for dual purposes—as a routine test and as a replacement test. |
| 12.012 | **The Provisions Should Allow a Single Sample to be Used for Dual Purposes.**  CVCWA appreciates the changes to the second revised draft Toxicity Provisions to allow a replacement test (i.e., retest) when a required test is not completed. A replacement test is also allowed when a required test cannot be initiated in the required period due to circumstances outside of the discharger’s control. This flexibility is necessary to accommodate logistical constraints associated with toxicity testing (e.g., multiple composites samples per test, sampling coordination with facility maintenance and operations). However, a discharger may have to conduct up to four or more tests in the next calendar month (i.e., the replacement test from the previous month, a routine monthly monitoring test for the current month, and two median monthly effluent limit [MMEL] or median monthly effluent target [MMET] compliance tests). As currently drafted, a replacement test, if conducted in the calendar month following the month when it was originally required, cannot be used to demonstrate effluent quality for a routine test in the month in which samples are collected. This would require more testing in a calendar month than is physically or logistically possible when replacement tests and MMEL or MMET compliance tests are required. Concurrent testing with splits of the same samples might need to be conducted by a discharger that cannot conduct all of its required tests sequentially within the available time, to avoid pushing retesting into the successive calendar months. This testing approach adds costs, may not always be possible due to sample volume requirements, and should not be necessary. It is a waste of resources to conduct multiple tests on the same sample(s) when a reliable and reproducible test method should produce the same result. Instead, it would be more economical, and technically justified, if a replacement test conducted in the next calendar month could also be used as the routine monitoring test result for the month in which the samples were collected. |
| 12.013 | State Water Board staff explained at the July 29, 2020 staff workshop that one reason for this limitation was to avoid multiple violations for a single sample. However, this outcome may be unavoidable. A discharger conducting either concurrent testing with effluent split samples, or a single test to meet two required tests (e.g., for a replacement test and a routine test), would face the same consequence if the sample(s) result is a TST “fail.” The consequence of a TST “pass” in this situation is also the same. A single test that meets the requirement for a replacement test and routine monitoring would also cause less confusion than testing split samples in two concurrent tests if one produces a “pass” and the other a “fail.” To allow the same sample to be used for dual purposes—as a routine test and as a replacement test—we suggest modifying the proposed provisions to delete the following sentence: Section IV.B.2.d.iv. |
| 18.004 | **A Single Sample Should be Allowed For Dual Purposes:** We also request that, in the event of a replacement-test, that samples used to complete a testing regimen for a specified time period be allowed to be used as the first test in the next monitoring period. |
| 21.012 | Concurrent testing with splits of the same samples might need to be conducted by a discharger who cannot conduct all their required tests sequentially (i.e., one after the other) within the available time, to avoid rescheduling retesting into the successive calendar months. This testing approach adds costs, may not always be possible due to sample volume requirements, and should not be necessary. It is a waste of resources to conduct multiple tests on the same sample(s) when a reliable and reproducible test method should produce the same result. Instead, it would be more economical, and technically justified, if a replacement test conducted in the next calendar month can also be used as the routine monitoring test result for the month in which the samples are collected. |
| 21.013 | State Water Board staff explained at the July 29, 2020, Toxicity Provisions staff workshop that the intent of the revised draft Toxicity Provisions was to avoid multiple violations for a single sample. However, this outcome may be unavoidable. A discharger conducting either concurrent testing with effluent split samples, or a single test to meet two required tests (e.g., for a replacement test and a routine test), would face the same consequence if the sample(s) result is a TST “fail”. Likewise, the consequences resulting from a TST “pass” in this situation is also the same. A single test that meets the requirement for a replacement test and routine monitoring would also cause less confusion than testing split samples in two concurrent tests if one produces a “pass” and the other a “fail.” |
| 21.014 | Requested Change to Address Comment 3:  To allow the same sample to be used for dual purposes—as a routine test and as a replacement test—we suggest deleting the following sentence. This is recommended to avoid confusion, avoid unnecessary additional costs associated with conducting multiple tests with the same sample, and to improve the ability of dischargers to complete required testing.  “” Section IV.B.2.d.iv.  Alternatively, we find it acceptable for the Permitting Authority to be granted discretion on whether or not the same sample and test can be used for dual purposes. This could be accommodated by modifying the section as follows.  “The new toxicity test and any MMET TESTS or MMEL COMPLIANCE TESTS required to be conducted due to the results of the new toxicity test shall not be used to substitute for any other required toxicity tests unless otherwise authorized by the PERMITTING AUTHORITY.” Section IV.B.2.d.iv. |
| 23.027 | The revised Toxicity Provisions also specify that when a routine monitoring test results in a “fail” determination, two additional MMEL compliance tests must be initiated within the same month. Particularly for tests with longer turnaround times (e.g., *C. dubia* 7-day tests), logistical issues may make meeting this requirement highly challenging or infeasible. The SWRCB acknowledges that MMEL compliance testing may carry over into the following calendar month, such that it may be difficult for a discharger to know if there is an MMEL violation for the previous month and if further monitoring is required. This sampling requirement may result in MMEL compliance samples that are collected in close proximity to the subsequent routine monitoring sample. |
| 23.029 | Recommendation 2: LADWP requests that, for long-duration toxicity tests, the following month's routine monitoring sample may be used as the second MMEL compliance test to determine if a violation has occurred. |
| **SC E.010** | Commenters appreciate changes to the Provisions which allow a replacement test when a test is not completed or when a test cannot be initiated in the required time period due to circumstances outside of the discharger’s control. This replacement test, if conducted in the calendar month following the month when it was originally required, cannot be used to demonstrate effluent quality for a routine test the month in which samples are collected. Additionally, this flexibility may result in the need for the discharger to conduct four or more tests in the next calendar month. The State Water Board has not demonstrated that dischargers and laboratories will be able to do this. Logistical challenges will sometimes prevent them from collecting all the samples needed to perform these required toxicity tests within a calendar month. |
| **SR E.010** | Please see SR K-2.003 regarding the use of a single toxicity test for two different calendar month compliance periods and for a discussion on complying with the monitoring requirements using replacement tests. Four aquatic toxicity tests would only be required within a calendar month if a replacement test is initiated in a subsequent calendar month and the routine monitoring test in that subsequent calendar month results in a fail. Replacement tests are anticipated to rarely be needed, and often may be initiated within the calendar month in which the initial test is required. In addition, few routine monitoring tests that are currently being assessed using the TST result in a fail. Instances where both a replacement test is needed, and routine monitoring tests results in a fail within the same month are expected to be rare and limited to dischargers with a monthly routine monitoring frequency. Therefore, replacement tests are not anticipated to impact laboratory capacity. If there are any laboratory capacity issues, dischargers and laboratories can take actions to address these challenges, such as sub-contracting to other laboratories or increasing laboratory capacity. |
| 18.021 | Regional San appreciates changes to the revised draft Toxicity Provisions to allow a replacement test when a test is not completed or when a required test cannot be initiated in the required time period due to circumstances outside of the discharger’s control. This flexibility is necessary to accommodate logistical constraints associated with toxicity testing (e.g., multiple composites samples per test, sampling coordination with facility maintenance and operations), but will, at times, results in the need for a discharger to conduct up to four or more tests in the next calendar month (i.e., the replacement test from the previous month, a routine monthly monitoring test for the current month, and two median monthly effluent limit [MMEL] or median monthly effluent target [MMET] compliance tests). Appendix K of the revised Staff Report was intended to demonstrate that laboratories are capable of conducting up to three toxicity tests in a calendar month; however, the State Water Board has not demonstrated that dischargers and laboratories will be able to conduct up to four (or potentially more) toxicity tests in a calendar month. Logistical challenges faced by dischargers will, at times, prevent them from collecting all the samples needed to perform these required toxicity tests within a calendar month as shown in Table K-1 “Practicable Timeframe for Initiating MMEL Compliance Tests”, even if laboratories are capable of performing these tests (see Regional San’s written comments to the State Water Board on February 10, 2020: Comment Letter – Toxicity Appendices J and K). |
| 21.011 | A replacement test is also allowed when a required test cannot be initiated in the required time period due to circumstances outside of the dischargers’ control. This flexibility is necessary to accommodate logistical constraints associated with toxicity testing (e.g., multiple composites samples per test, sampling coordination with facility maintenance and operations), but may require a discharger to conduct up to four or more tests in the next calendar month (i.e., the replacement test from the previous month, a routine monthly monitoring test for the current month, and two median monthly effluent limit [MMEL] or median monthly effluent target [MMET] compliance tests). However, this replacement test, if conducted in the calendar month following the month when it was originally required, cannot be used to demonstrate effluent quality for a routine test the month in which samples are collected, as stated in the second revised draft Toxicity Provisions.  “The new toxicity test and any MMET TESTS or MMEL COMPLIANCE TESTS required to be conducted due to the results of the new toxicity test shall not be used to substitute for any other required toxicity tests.” Section IV.B.2.d.iv. (underline/markup from the original)  As written, the second revised draft Toxicity Provisions may require more testing in a calendar month than is physically or logistically possible when replacement tests and MMEL or MMET compliance tests are required (i.e., the replacement test from the previous month, a routine monthly monitoring test for the current month, and two MMEL or MMET compliance tests). The revised draft Toxicity Provisions (Appendix K) and State Water Board’s responses to comments on the 2018 draft Toxicity Provisions have asserted that dischargers and laboratories are capable of conducting up to three toxicity tests in a calendar month; although, multiple Publicly Owned Treatment Works (POTWs) have consistently expressed concerns to State Water Board staff and to Board members that this will not always be possible (see RBI written comments to the State Water Board on February 10, 2020; Comment Letter – Toxicity Appendices J and K). Most importantly, the State Water Board has not demonstrated that dischargers and laboratories will be able to conduct up to four (or potentially more) toxicity tests in a calendar month, which may be necessary as described above. |

## Category F – Effluent Limitations

| **Comment Code** | **Comment** |
| --- | --- |
| **SC F.001** | Use of the chronic *C. dubia* median monthly effluent limitation (MMEL) should not be delayed during the timeframe of the laboratory performance study. The study should be limited to providing laboratory best practices for chronic toxicity testing using *C. dubia*.  As demonstrated in numerous studies and Appendix J of the Staff Report, the chronic *C. dubia* reproduction test is a reliable test and is already being used as the most sensitive species in a number of exiting California NPDES permits. The Toxicity Provisions' chronic toxicity objective relies on *C. dubia* reproduction as its sole component protecting invertebrates from chronic toxicity in California's fresh surface waters. This component of the objective and its full implementation in permits is essential for the freshwater objective to immediately protect California surface waters from chronic toxicity. Failing to use *C. dubia* to determine compliance inappropriately shields dischargers from potential violations and can have cascading consequences, especially when the Provisions as drafted allow reduced monitoring frequency and species sensitivity screenings for certain dischargers based on whether a violation has occurred within the past five consecutive years.  Further, using *C. dubia* when it is identified as the most sensitive species as a simple trigger for further testing and investigation as proposed under the current Provisions does not comply with the requirements of the federal Clean Water Act, anti-backsliding, and anti-degradation requirements. In addition, it fails to address the chronic presence of toxicity in California’s waterways. |
| **SR F.001** | While the chronic *C. dubia* reproduction toxicity test is a reliable test and is essential in protecting California’s surface waters from toxicity as mentioned in Section 5.4.3 of the Staff Report, public concerns remain regarding laboratory performance while conducting the test and the possible effect on the statistical results when using the data for compliance purposes. Appendix J of the Staff Report indicates that most California laboratories in the analysis had low within-test variability and can attain the acceptable false positive probability of 5 percent or less when using 10 replicates. However, not all of the laboratories were able to achieve the acceptable false positive probability of 5 percent due to higher within-test variability. Therefore, the *C. dubia* study is a quality assurance study to describe specific test procedures and quality assurance recommendations to improve toxicity data quality and comparability when conducting *C. dubia* toxicity testing.  Section 5.4.3 of the Staff Report was revised to add further explanation on the delayed statewide implementation of the MMEL using *C. dubia* to January 1, 2024, the scenarios that apply in the interim, and how no adverse changes to water quality are expected. Due to the need to build stakeholder and public confidence in the ability of laboratories to perform well when conducting the chronic *C. dubia* test method for MMEL compliance purposes, it is appropriate, and in the maximum benefit of the people of the state to include a short-term delay in the statewide implementation of the *C. dubia* MMEL, as long as it is consistent with federal law for each NPDES permit. Revisions to the Toxicity Provisions were made to clarify that the permitting authority would be required to include the MMEL using *C. dubia* whenever necessary to comply with federal law. In the long-term, when *C. dubia* is identified as the most sensitive species, mandating a statewide MDEL and MMEL using *C. dubia* is essential to restrict pollutants, to protect beneficial uses, to improve water quality, to investigate and reduce the sources of toxicity, and to provide the appropriate incentive for dischargers to address the causes of toxicity. Please see section 5.4.3 for further discussion.  Section 5.4.3 of the Staff Report was revised to add information that the permitting authority may consider in “scenario 3” when choosing between option A and option B. To make this determination, the permitting authority may review recent control data (e.g., long-run median control CV) from the laboratory used by the discharger to evaluate ongoing laboratory performance. For example, the permitting authority may compare laboratory control performance data to data from laboratories currently meeting the acceptable false positive rate (see Table J-7 in Appendix J for this information for California laboratories).  For a reduced monitoring frequency, the conditions in Section IV.B.2.d.ii.(A)(2) of the Toxicity Provisions must be met and the Regional Water Board must approve the reduction. The Regional Water Board should consider possible indications of toxicity (e.g., failing to meet the MMET, required to conduct a TRE, etc.) for specific dischargers that may have delayed *C. dubia* numeric effluent limitations before approving a reduction in monitoring frequency. The discretion provided by the Toxicity Provisions to permitting authorities in determining when a species sensitivity screening is required is not dependent on the discharger having any violations within the previous five years. Please see Section 5.4.1 of the Staff Report for more information on the frequency of species sensitivity screenings.  See SR F.002, SR F.003, and SR F.004 for a discussion on how the Toxicity Provisions comply with the requirements of the federal Clean Water Act, anti-backsliding, and anti-degradation requirements. |
| 10.002 | My critical comments are limited to *Ceriodaphia dubia* reproduction implementation provisions applicable to nonstormwater NPDES permits. The provisions' chronic toxicity objective relies on *C. dubia* reproduction as its sole component protecting invertebrates from chronic toxicity in California's fresh surface waters. This component of the objective and its full implementation in permits is essential for your freshwater objective to immediately protect California surface waters from chronic toxicity. |
| 19.007 | *Apply numeric toxicity limits for Ceriodaphnia dubia (C. dubia) to determine compliance with toxicity testing when C. dubia is identified as the most sensitive species to comply with the Clean Water Act, Antibacksliding, and Antidegredation requirements.* |
| 19.008 | *Any forthcoming study should be limited to providing laboratory best practices for chronic toxicity testing using C. dubia, but should not delay the use of C. dubia to demonstrate compliance with chronic toxicity requirements due to the demonstrated test reliability of C. dubia.* |
| 19.028 | **III. THE STATE WATER BOARD MUST APPLY NUMERIC TOXICITY LIMITS FOR C DUBIA TO DETERMINE COMPLIANCE WITH TOXICITY TESTING WHEN C DUBIA IS IDENTIFIED AS THE MOST SENSITIVE SPECIES PURSUANT TO FEDERAL AND STATE REQUIREMENTS** |
| 19.031 | Further, as acknowledged in the Staff Report itself, the chronic *C. dubia* test is a reliable test as evidenced by numerous studies outlined in Appendix J: “ During public comment periods and workshops, stakeholders expressed concerns about the reliability of the *Ceriodaphnia dubia* *C. dubia* chronic reproduction toxicity test in compliance monitoring programs. However, the chronic *C. dubia* test is a reliable test and is already being used as the most sensitive species in a number of existing California NPDES permits.23 Failing to use *C. dubia* to determine compliance inappropriately shields dischargers from potential violations and can have cascading consequences, especially when the Provisions as drafted allow reduced monitoring frequency and species sensitivity screenings for certain dischargers based on whether a violation has occurred within the past five consecutive years. Further, using *C. dubia* when it is identified as the most sensitive species as a simple trigger for further testing and investigation as proposed under the current Provisions does not comply with the requirements of the federal Clean Water Act and fails to address the chronic presence of toxicity in California’s waterways. We strongly recommend *C. dubia* continue to be used to determine MMEL compliance for all dischargers that have identified *C. dubia* as the most sensitive species to uphold the integrity of toxicity requirements and to ensure the implementation of these Provisions is fully protective of aquatic life, given the demonstrated reliability of *C. dubia* in toxicity testing. |
| 19.043 | **Requested Language** *(Suggested language in red)*:  **IV.B.2.e. Chronic Aquatic Toxicity Effluent Limitations (p. 33)**  For NON-STORMWATER NPDES DISCHARGERS with numeric effluent limitations in their current permit and when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include the MDEL indicated in Section IV.B.2.e.iii and MMEL indicated in Section IV.B.2.e.iv using *Ceriodaphnia dubia* as the MOST SENSITIVE SPECIES. |
| SC F.002 | Numeric toxicity limits for *C. dubia* when *C. dubia* is identified as the most sensitive species must be used and upheld in permits under the federal Clean Water Act. The Clean Water Act requires WQBELs for chronic WET to be “as stringent as necessary” to meet water quality standards. Numeric median monthly and maximum daily effluent limits are a necessary regulatory structure under the final Toxicity Provisions to provide clear, numeric restrictions of highly toxic daily discharges, ensure long term compliance with toxicity water quality standards to improve aquatic health and protect beneficial uses of California waterways, and provide clear permit requirements that can be understood by the regulators, the regulated community, and the public. The State Water Board must clearly require actual effluent limitations for chronic toxicity where there is a demonstration of reasonable potential.  However, in Scenario 1, the Toxicity Provisions replace the MMEL with a trigger for follow up tests. This is not sufficient to meet the regulatory requirement that permits contain effluent limitations when a discharge has the reasonable potential to cause or contribute to an exceedance of toxicity. If *C. dubia* is determined to be the most sensitive species, but is not applied to the MMEL, California’s waterways and ecosystems will not be protected from the detrimental effects of chronic toxicity, which would otherwise be detected during MMEL compliance tests. |
| SR F.002 | The Toxicity Provisions include a program of implementation for non-storm water NPDES discharges that includes effluent limitations to meet the numeric aquatic toxicity water quality objectives. After the effective date of the Toxicity Provisions and before January 1, 2024, the Toxicity Provisions allow the application of a *C. dubia* MMET instead of an MMEL in certain scenarios, except where required by federal law. Revisions to the Toxicity Provisions were made to clarify that the permitting authority would be required to include the MMEL using *C. dubia* whenever necessary to comply with federal law. Please see Section 5.4.3 of the Staff Report for an explanation on how in totality, no adverse changes in water quality are expected as a result from the delayed implementation of the *C. dubia* MMEL. If there are any adverse changes, those changes would be minor and limited in duration. As a result, delaying the application of the MMEL using *C. dubia* to January 1, 2024, is appropriate and adequately protective of receiving water and beneficial uses.  As further explained the Section 5.4.3 of the Staff Report, in the short-term only, the statewide inclusion of MMELs using *C. dubia* in non-storm water NPDES permits is not feasible (i.e., “not appropriate”) in certain circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions between the effective date of the Toxicity Provisions and January 1, 2024. See *Communities for a Better Environment v. State Water Resources Control Board* (2003) 109 Cal. App.4th 1089 affirming the Board’s interpretation of “infeasible” as used in 40 Code of Federal Regulations, section 122.44(k)(3) to mean “not appropriate.” It is feasible and appropriate that on and after January 1, 2024, all accredited laboratories conduct the reliable and promulgated *C. dubia* chronic reproduction toxicity test. It is also feasible to include the *C. dubia* MDEL without delay, because laboratory performance is less of a concern for stakeholders due to the higher effect level required for a violation of the MDEL. However, for certain laboratories, the application of an MMET using *C. dubia* instead of an MMEL using *C. dubia* prior to January 1, 2024, will provide an opportunity for improvements in laboratory performance, as needed. It would also provide an opportunity for stakeholders to engage in the *C. dubia* study so as to improve stakeholder and public confidence.  Nothing in the Toxicity Provisions indicates that the permitting authority is not required to comply with federal law. After the effective date and before January 1, 2024, the permitting authority would determine on a permit by permit basis, whether an MMEL using *C. dubia* is required to comply with federal law.  Given the variety of permits and fact scenarios, it is appropriate for the permitting authority to determine on a case by case basis, the necessary requirement to comply with federal law. This may mean that the permitting authority includes the MMEL using *C. dubia* to comply with federal law. But there may be instances in which the permitting authority concludes that a receiving water limitation based on the numeric water quality objective is sufficient to comply with federal law and include scenario 1 or scenario 3, option b. There also may be instances in which a MDEL and an MMET (scenario 1) without an MMEL is adequate to comply with federal law. The permitting authority would make this determination in consultation with U.S. EPA on a permit-by-permit basis, as recommended by U.S. EPA in their comment letter on the differences between the October 19, 2018 Toxicity Provisions and the July 7, 2020 Toxicity Provisions, dated August 24, 2020 (see comment 24.009). The permitting authority must document the basis for its conclusion that federal law does not require the inclusion of the *C. dubia* MMEL in scenario 1 or scenario 3, option B in the NPDES permit fact sheet. |
| 19.029 | 1. Numeric toxicity limits for C dubia when C dubia is identified as the most sensitive species must be used and upheld in permits under the federal Clean Water Act. The federal Clean Water Act is a “comprehensive water quality statute designed to ‘restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.’”14 Pursuant to the Clean Water Act section 303, California must adopt and implement water quality standards to protect navigable waters within its borders, subject to oversight and approval by the U.S. EPA.15 According to the U.S. EPA: “A water quality standard defines the water quality goals of a water body, or portion thereof, by designating the use or uses to be made of the water, by setting criteria necessary to protect the uses, and by preventing degradation of water quality through antidegradation provisions. States adopt water quality standards to protect public health or welfare, enhance the quality of water, and serve the purposes of the Clean Water Act.”16 |
| 19.030 | The Clean Water Act also requires that water quality standards be “established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.”17 The Clean Water Act requires WQBELs for chronic WET to be “as stringent as necessary” to meet water quality standards.18 Federal regulations are also clear that a narrative effluent limit is only appropriate when a numeric effluent limit is infeasible to calculate.19 Numeric median monthly and maximum daily effluent limits are a necessary regulatory structure under the final Toxicity Provisions to (i) provide clear, numeric restrictions of highly toxic daily discharges, (ii) ensure long term compliance with toxicity water quality standards to improve aquatic health and protect beneficial uses of California waterways, and (iii) provide clear permit requirements that can be understood by the regulators, the regulated community, and the public. To meet the requirements of the Clean Water Act and associated federal regulations,20 the State Water Board must clearly require actual effluent limits for chronic toxicity where there is a demonstration of reasonable potential. As drafted, however, the current Provisions replaces the Monthly Median Effluent Limitation (MMEL) for those dischargers that have *C. dubia* identified as the most sensitive species that did not previous have effluent limits in their permit (i.e., “Scenario 1”), and instead imposes a trigger for follow-up tests. The use of *C. dubia* as a trigger for toxicity testing that simply requires further investigation is not appropriate and is inconsistent with the use of effluent limits.21 For those dischargers that fall under Scenario 1, the Provisions would require only further toxicity testing and investigation without an effluent limitation for chronic toxicity. This is not sufficient to meet the regulatory requirement that permits contain effluent limitations when a discharge has the reasonable potential to cause or contribute to an exceedance of toxicity.22 As proposed under the current draft Provisions, individual days when lethal levels of toxicity are present would be identified by using *C. dubia* to determine compliance with a Maximum Daily Effluent Limit MDEL if it is determined to be the most sensitive species. However, if *C. dubia* is determined to be the most sensitive species, but is not applied to the MMEL, California’s waterways and aquatic ecosystems will not be protected from the detrimental effects of chronic toxicity, which would otherwise be detected during MMEL compliance tests. |
| SC F.003 | Section IV.B.2.e.i of the Toxicity Provisions invites all facilities, not just those which cannot immediately comply, to receive a delayed *C. dubia* reproduction MMEL in their reissued permit. No other toxicity effluent limit is in effect to actually protect the *C. dubia* reproduction component of the applicable objective. First, a temporary MMEL for the freshwater fish or alga biologically under protects the chronic toxicity objective for *C. dubia* reproduction. Second, the *C. dubia* MDEL biologically and statistically under protects the chronic toxicity objective because its statistical properties are heavily weighted on exceeding a high threshold for mortality (50%), rather than the unacceptable RMD for chronic toxicity (25%). Third, the unexplained delay of the *C. dubia* MMEL is not supported by the Clean Water Act and its implementing regulations. Together, these three choices result in the absence of the immediate chronic toxicity WQBEL required by 40 CFR 122.44(d)(1).  The proposed permit provision requiring an investigation (aka the trigger “limit” approach) of *C. dubia* reproduction toxicity in effluents also does not suffice as a chronic toxicity WQBEL. The trigger “limit” approach remains for another three years, with no absolute assurance that its end date will remain December 31, 2023. The improper concession to permittees in two 2003 State Water Board orders for Long Beach and Los Coyotes POTWs and the resulting spectacular policy failure of California's non-ocean permits to not actually limit chronic toxicity to freshwater invertebrates are maintained. |
| SR F.003 | Section IV.B.2.e.i of the Toxicity Provisions is limited only to dischargers with NPDES permits that are renewed, reissued, or reopened after the effective date of the Toxicity Provisions and through December 31, 2023.  Due to the need to build stakeholder and public confidence in the ability of laboratories to perform well when conducting the chronic *C. dubia* test method for MMEL compliance purposes, it is appropriate, and in the maximum benefit of the people of the state to include a short-term delay in the statewide implementation of the *C. dubia* MMEL, as long as it is consistent with federal law for each permit. Revisions to the Toxicity Provisions were made to clarify that the permitting authority would be required to include the MMEL using *C. dubia* whenever necessary to comply with federal law.  See Section 5.4.3 of the Staff Report for an explanation on how in totality, no adverse changes in water quality are expected as a result from the delayed implementation of the *C. dubia* MMEL. If there are any adverse changes, those changes would be minor and limited in duration. As a result, delaying the application of the MMEL using *C. dubia* to January 1, 2024, is appropriate and adequately protective of receiving water and beneficial uses.  Section IV.B.2.e.i of the Toxicity Provisions also states that the MMET using *C. dubia* and effluent limitation requirements are in effect only through December 31, 2023. This section was revised to clarify that starting January 1, 2024, not December 31, 2023, the MMEL indicated in Section IV.B.2.e.iv of the Toxicity Provisions must be applied in all permits that have been issued, reissued, renewed, or reopened (if the permit reopening is to address toxicity requirements) after the effective date of the Toxicity Provisions, even if the most sensitive species is *C. dubia*.  The scenarios in Section IV.B.2.e.i of the Toxicity Provisions do not result in the absence of effluent limitations required by 40 CFR 122.44(d)(1). Each scenario includes a maximum daily effluent limitation. As further responded to in SR F.002, the permitting authority would determine on a permit by permit basis, whether an MMEL using *C. dubia* is required to comply with federal law. There may be instances in which the permitting authority concludes that a receiving water limitation based on the numeric water quality objective is sufficient to comply with federal law. There may also be instances in which a MDEL and an MMET (scenario 1) without an MMEL is adequate to comply with federal law. Given the variety of permits and fact scenarios, it is appropriate for the permitting authority to determine on a case by case basis, whether an MMEL using *C. dubia* is required to comply with federal law.  See SR F.002 and SR F.004 for a discussion on how the Toxicity Provisions comply with the requirements of the federal Clean Water Act, anti-backsliding, and anti-degradation requirements. Please see SR F.005 for a discussion on how the circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions are not compliance schedules. |
| 10.003 | My comment is that one section of the provisions incorporates unexplained flaws that will impede immediate implementation of the chronic toxicity objective for *C. dubia* reproduction by wrongly delaying or removing *C. dubia* reproduction WQBELs in permits. These implementation flaws in section IV.B.2.e.i of the provisions-will result in permits issued contrary to the Clean Water Act, NPDES regulations, and policies governing antidegradation and NPDES permit compliance schedules.  *The toxicity provisions improperly delay the required chronic toxicity WQBEL for C. dubia reproduction.*  As an experienced permit writer comfortable with effluent limits and their statistical attributes, as well as water quality standard variance and NPDES permit compliance schedule authorizing provisions, I'm concerned section IV.B.2.e.i (paragraphs 1, 2, 4, 6, 7, pp. 27-28) improperly invites all facilities-not just those which cannot immediately comply-to receive a delayed *C. dubia* reproduction MMEL in their reissued permit. During this period of delay, I note no other toxicity effluent limit is in effect to actually protect the *C. dubia* reproduction component of the applicable objective. When reasonable potential and the most sensitive species are affirmed as *C. dubia* reproduction, a temporary MMEL for the freshwater fish or alga does not protect the *C. dubia* reproduction component of the applicable objective. Neither does the proposed *C. dubia* MDEL because it's statistical properties are heavily weighted on exceeding a high threshold for mortality (relative mean percent effect, 50). This unfortunate weighting makes it virtually impossible for the *C. dubia* MDEL on its own to restrict the discharge of unacceptable chronic toxicity with the high level of confidence (80%) specified at the chronic toxicity objective's RMD (relative mean percent effect, 25). In plain language: (1) As the alternative to using *C. dubia* reproduction, the temporary MMEL for the freshwater fish or alga biologically underprotects the chronic toxicity objective; (2) The *C. dubia* MDEL biologically and statistically under-protects the chronic toxicity objective; and (3) The unexplained delay of the *C. dubia* reproduction MMEL is not supported by the Clean Water Act and its implementing regulations. Taken together, these three policy choices for the toxicity provisions result in an absence of the immediate chronic toxicity WQBEL required by 40 CFR 122.44(d)(l). |
| 10.004 | During this period of delay, the proposed permit provision requiring an investigation of *C. dubia* reproduction toxicity in effluents also does not suffice as a chronic toxicity WQBEL. See October 9, 2014 letter from J. Diamond, U.S. EPA Region 9, to S. Unger, Los Angeles RWQCB, on NPDES permits for Pomona and Whittier Narrows POTWs discharging to the San Gabriel River: https://www.waterboards.ca.gov/losangeles/board decisions/tentative orders/individual/npdes/Whittier Narrows Water Reclamation Plant/U.S.EPA%20comment%20letter%20- %20Whittier%20Narrows%20and%20Pomona%20WRPs.pdf. |
| 10.005 | However, most alarming is this provision's lasting effect as the capitulation so long sought by many California permittees: |
| 10.006 | Finally codifying into your State water quality control plan the permit authorization to discharge a toxic effluent (here, toxic to freshwater invertebrates) without limitation, as long as the chronic toxicity is investigated (a.k.a. the trigger "limit" approach). This provision sustains the trigger "limit" approach for yet another three years, with no absolute assurance that its end date will remain December 31, 2023. As such, the improper concession to permittees in two 2003 State Water Board orders for Long Beach and Los Coyotes POTWs and the resulting spectacular policy failure of California's non-ocean permits to not actually limit chronic toxicity to freshwater invertebrates are maintained. |
| SC F.004 | Allowing permits that already include numeric chronic effluent limitations for *C. dubia* to not use *C. dubia* for toxicity testing and compliance during the study period violates anti-backsliding and anti-degradation requirements. The Toxicity Provisions authorize illegal removals of achieved WQBELs for *C. dubia* reproduction where they have been set and met from 2012 to the present. This is particularly alarming for permitting discharges to low and no dilution waters, as many of California’s fresh surface waters are effluent dominated. A legitimate decision to backslide from an existing WQBEL, including one for toxicity, can only be made in the context of a permit-specific record, which is not considered in the Toxicity Provisions. Also, when reasonable potential and the most sensitive species are affirmed for *C. dubia* reproduction, removal of existing *C. dubia* reproduction WQBELs would contradict State and federal antidegradation policies guarding against the reissuance of a relaxed NPDES discharge authorization that allows a worsening of *C. dubia* reproduction toxicity in the surface water.  The State Water Board must uphold existing permits’ ability to use *C. dubia* in order to demonstrate compliance with those permit requirements, unless a species sensitivity screening no longer indicates *C. dubia* as the most sensitive species. The end of the permit term or re-opening of a permit cannot end the use of *C. dubia* to test for compliance and must be based on the results of a species sensitivity screening. The option for an existing permit to use a lesser standard for compliance is unacceptable, is in contrast to state and federal clean water requirements, and would place a burden on the Regional Water Boards, who are already facing resource and personal constraints caused by the COVID-19 pandemic. |
| SR F.004 | The State Board is adopting uniform requirements for establishing effluent limitations for non-storm water NPDES permits in the Toxicity Provisions. The State Water Board has determined that it is appropriate to phase in the MMEL using *C. dubia* as the most sensitive species until January 1, 2024. As further explained in SR F.002, the State Board does not deem the statewide application of that effluent limitation appropriate for this limited period of time for every permit that is renewed, reissued, or reopened to address the Toxicity Provisions. However, while the State Water Board is not applying a statewide requirement for an MMEL using *C. dubia* as the most sensitive species for this limited time period, the Toxicity Provisions do require the application of the MMEL effluent limitation by the permitting authority on a case-by-case basis, as required to be consistent with federal law (including anti-backsliding and antidegradation).  Revisions to Section 5.4.3 of the Staff Report and Chapter 9 were made to clarify that the permitting authority at the time of NPDES permit issuance would need to ensure that the NPDES permit is consistent with federal law, and follow the appropriate notice and public comment process. In all cases, the permitting authority will be required to conduct a permit-specific anti-backsliding analysis at the time of permit reissuance or reopening. As discussed in Chapter 9.3 of the Staff Report, it is possible that a relaxation of existing effluent limitations could occur when a current permit includes a MMEL using *C. dubia* as the most sensitive species and the reissuance includes a MMEL using *Pimephales promelas* (fathead minnow) or *Selenastrum capricornutum* (green alga) as the most sensitive species through December 31, 2023. If the permitting authority determines that there is a relaxation of existing effluent limitations, an exception to the anti-backsliding prohibition may apply. If an exception does not apply, then to comply with federal law, the permitting authority would include the MMEL using *C. dubia*.  In addition, revisions to Section 5.4.3 and Chapter 9.3 of the Staff Report were made to explain how in totality, no adverse changes in water quality are expected as a result from the delayed implementation of the *C. dubia* MMEL. If there are any adverse changes, those changes would be minor and limited in duration. As discussed in Section 5.4.3 of the Staff Report, if there are any adverse changes, they are expected to be minor because (1) monitoring using *C. dubia* would still be required and the sensitivity of the species would still be used to determine chronic toxicity of the effluent and whether a TRE should be conducted, and (2) lower treatment performance, lower effluent quality, or higher effluent volumes for individual treatment plants as a result of a delay in imposing the *C. dubia* MMEL is also not reasonably expected. If there is a change in water quality due to the Toxicity Provisions, that change is consistent with federal and state antidegradation policies. Revisions were made to Section 9.3 of the Staff Report explaining how it is appropriate, and in the maximum benefit of the people of the state to include a short-term delay in the statewide implementation of the *C. dubia* MMEL, as long as it is consistent with federal law for each permit, due to the need to build stakeholder and public confidence in the ability of laboratories to perform well when conducting the chronic *C. dubia* test method for MMEL compliance purposes. Incentives described in Section 5.4.3 will ensure that the change in water quality does not unreasonably affect present and anticipated beneficial uses of such water, and not result in water quality less than that prescribed in applicable water quality control policies or plans. Please see Section 9.3 of the Staff Report for the antidegradation analysis. In addition, the Toxicity Provisions specify that the permitting authority must confirm that delaying the use of the chronic *C. dubia* test for MMEL compliance purposes is consistent with federal law (including antidegradation requirements) on a permit-by-permit basis for any permit that is issued, reissued, renewed, or reopened (if the permit reopening is to address toxicity requirements) prior to January 1, 2024.  These requirements are not expected to impose a significant burden on NPDES permit writers as these scenarios are only incorporated into NPDES permits as permits are issued, reissued, renewed, or reopened after the effective date of the Toxicity Provisions and through December 31, 2023. |
| 10.009 | *The toxicity provisions' blanket authorization to backslide fails to protect applicable water quality standards, including the antidegradation standard.*  Turning to my second concern, section IV.B.2.e.i (paragraph 4) creates a new framework that authorizes illegal removals of achieved WQBELs for *C. dubia* reproduction where they have been set and met, beginning in 2012 to the present. More to the point, when reasonable potential and the most sensitive species are affirmed for *C. dubia* reproduction, why are existing *C. dubia* reproduction MMELs fully consistent with the applicable chronic toxicity objective ( e.g., Los Angeles Regional Water Board POTW permits) even being considered removable WQBELs by paragraph 4? The proposed inexplicable unraveling of existing *C. dubia* MDELs and MMELs offered under paragraph 4 is particularly alarming for permitted discharges to low and no dilution waters (e.g., San Gabriel, Los Angeles, and Santa Clara Rivers, Calleguas Creek, etc.). Many of California's fresh surface waters receive NPDES discharges where the pollutant composition of the discharge dominates the receiving water's quality. When reasonable potential and the most sensitive species are affirmed for *C. dubia* reproduction, the removal of existing *C. dubia* reproduction WQBELs--even if that number turns out to be small-would generally contradict State and federal antidegradation policies guarding against the reissuance of a relaxed NPDES discharge authorization that allows a worsening of *C. dubia* reproduction toxicity in the surface water receiving the discharge. A blanket 3-year relaxation is not a temporary lowering of water quality in the context of your antidegradation requirements. For these reasons, the blanket authorization to backslide under paragraph 4 should simply be dropped from your final provisions. A legitimate decision to backslide from an existing WQBEL, including one for toxicity, can only be made in the context of a permit-specific record, which paragraph 4 does not consider. |
| 19.041 | 5. Allowing permits that already include numeric chronic effluent limitations for *C. dubia* to not use *C. dubia* for toxicity testing and compliance during the study period violates Antibacksliding and Antidegradation requirements. The Clean Water Act contains “anti-backsliding” provisions that prohibit relaxation of permit terms upon renewal. The Clean Water Act requires that, for effluent limitations based on a state water quality standard, “a permit may not be renewed, reissued, or modified to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit,” unless certain exceptions apply.31 It also states that “[i]n no event may such a permit to discharge into waters be renewed, reissued, or modified to contain a less stringent effluent limitation if the implementation of such limitation would result in a violation of [water quality standards].”32 As proposed by the draft Provisions, dischargers operating under permits that already include numeric chronic effluent limitations for *C. dubia* shall continue using *C. dubia* to determine compliance. When the permits are reissued, however, they are required to be consistent with the Toxicity Provisions in its entirety – including the provision that dischargers with *C. dubia* identified as the most sensitive species may no longer use *C. dubia* toxicity testing to determine compliance until the completion of the forthcoming study. Because dischargers would no longer be using the most sensitive species identified in the species sensitivity screening, this will result in the unlawful relaxing of permit requirements to determine compliance with toxicity effluent limitations. |
| 19.042 | Further, the State Antidegradation Policy requires that, in high-quality waters, baseline water quality must be maintained unless it is demonstrated that any change in quality will (1) be consistent with the maximum benefit to the people of the state; (2) not unreasonably affect present or probable future beneficial uses; and (3) not result in water quality less than that prescribed by state policies. Furthermore, any activity that produces or may produce waste, and that discharges into high-quality waters,33 must result in best practicable treatment control (BPTC) to ensure that (a) pollution or nuisance will not occur, and (b) the highest water quality consistent with maximum benefit will be maintained. By allowing the permit standards for existing permits that already include chronic effluent limitations for *C. dubia* to be relaxed, and only subject the second most sensitive species to determine compliance, the current Provisions violate antidegradation requirements by allowing discharge that is more toxic and will result in lower water quality that may not support aquatic beneficial uses because the permit requirements will no longer protect those organisms that are most sensitive and less resilient to the discharge. To prevent the ongoing degradation of our waterways and the health of aquatic ecosystems, and to comply with the federal Clean Water Act and the State Antidegradation Policy, the State Water Board must uphold existing permits’ ability to use *C. dubia* in order to demonstrate compliance with those permits’ requirements, unless a species sensitivity screening no longer indicates *C. dubia* as the most sensitive species. Ultimately, the end of the permit term, or re-opening of a permit, cannot end the use of *C. dubia* to test for compliance and must instead be based on the results of a species sensitivity screening. The option for an existing permit to use a lesser standard for compliance is unacceptable and stands in contrast to state and federal clean water requirements. Further, the option for existing permittees to re-open a permit and relax the compliance requirements for toxicity testing prior to the study end-date places an undue burden on the Regional Water Boards, who are already facing resource and personnel constraints caused by the COVID-19 pandemic. For this reason, coupled with the demonstrated confidence in *C. dubia* toxicity testing as outlined in *Fox et. al* and as stated in the Staff Report,34 the option for permits with existing effluent limitations using *C. dubia* to use an alternate species for compliance during the study period must be struck. |
| SC F.005 | Delaying the use of *C. dubia* may constitute an unlawful compliance schedule. Under Section 301(b)(1)(C) of the Clean Water Act, permits must require immediate compliance with an effluent limitation. Compliance schedules that are longer than one year must include interim requirements and dates for their achievement. In order to grant a compliance schedule, the permitting authority must make a reasonable finding that the compliance schedule will lead to compliance with an effluent limitation to meet water quality standards by the end of the compliance schedule. Additionally, the *C. dubia* study is schedule to be completed in three years, not one, and permittees are not able to use *C. dubia* when identified as most sensitive species to achieve compliance with the numeric aquatic toxicity effluent limitation to protect the waterways and associated beneficial uses. |
| SR F.005 | Section IV.B.2.e.i. of the Toxicity Provisions would not establish a compliance schedule. Rather, in the short-term only, the statewide inclusion of MMELs using *C. dubia* in non-storm water NPDES permits is on a delayed implementation and is not feasible (i.e., “not appropriate”) in certain circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions between the effective date of the Provisions and January 1, 2024. It is feasible and appropriate that on and after January 1, 2024, all accredited laboratories conduct the reliable and promulgated *C. dubia* chronic reproduction toxicity test.  Compliance schedules are a discretionary regulatory tool for bringing NPDES dischargers into compliance with new, revised, or newly interpreted water quality objectives, without being in violation of their permits. The purpose is to give dischargers time to make necessary changes in facilities or operations to comply with new, or more stringent, water quality-based permit limitations without subjecting the discharger to enforcement proceedings. Compliance schedules are included in the discharger’s permit and lay out the enforceable sequence of actions or operations the discharger will take to comply as rapidly as possible. Regional Water Boards would have the discretion to include a compliance schedule in non-storm water NPDES permits after the effective date of the Toxicity Provisions. Such a compliance schedule may be necessary to allow discharges to come into compliance with the Toxicity Provisions. However, the delayed implementation of the *C. dubia* MMEL to January 1, 2024, is not in of itself, a compliance schedule as it is not designed to give dischargers time to make changes to their facilities or operations. |
| 19.039 | 3. Delaying the use of *C. dubia* until the completion of a forthcoming study may constitute an unlawful compliance schedule. Under section 301(b)(1)(C) of the Clean Water Act, permits must require immediate compliance with an effluent limitation. Specifically, any compliance schedule contained in an NPDES permit must be an “enforceable sequence of actions or operations leading to compliance with an effluent limitation” as required by the definition of “schedule of compliance.”26 Compliance schedules that are longer than one year in duration must include interim requirements and dates for their achievement.27 Importantly, in order to grant a compliance schedule in an NPDES permit, the permitting authority must make a reasonable finding, adequately supported by the administrative record, that the compliance schedule “will lead to compliance with an effluent limitation to meet water quality standards” by the end of the compliance schedule. 28 Without using the species identified to be the most sensitive for toxicity testing, it is not possible for a discharger to achieve compliance with a numeric aquatic toxicity effluent limitation specified in a permit. Further, any forthcoming study is not scheduled to be completed within a year rather three years. For these reasons, the Provisions as drafted may lead to an unlawful compliance schedule and prevent dischargers from achieving compliance with the necessary numeric aquatic toxicity effluent limitation to protect our waterways and associated beneficial uses. |
| SC F.006 | Delaying the use of *C. dubia* may constitute an unlawful variance. The Water Quality Standards Handbook states that variances will only be allowed if the State demonstrates that meeting the standard is unattainable based on one or more of the grounds outlined in 40 C.F.R. 131.10(g) for removing a designated use. Under Scenario 3 in the Toxicity Provisions, the State Water Board is downgrading the water quality standard for toxicity by not using the most sensitive species to demonstrate compliance. Also, while laboratory procedures may be improved to increase the accuracy of *C. dubia* testing, it is not infeasible or unattainable to demonstrate compliance with numeric aquatic toxicity effluent limitations, as demonstrated by the successful use of *C. dubia* under NPDES permits issued and implemented by the Los Angeles Regional Water Board. |
| SR F.006 | Section IV.B.2.e.i. of the Toxicity Provisions would not establish a variance from the numeric aquatic toxicity water quality objectives. Rather, in the short-term only, the statewide inclusion of MMELs using *C. dubia* in non-stormwater NPDES permits is not feasible (i.e., “not appropriate”) in certain circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions between the effective date of the Provisions and January 1, 2024. It is feasible and appropriate that on and after January 1, 2024, all accredited laboratories conduct the reliable and promulgated *C. dubia* chronic reproduction toxicity test. The State Water Board is not authorizing the exceedance of the numeric aquatic toxicity water quality objectives. As further discussed in revisions to Section 5.4.3 of the Staff Report, no adverse changes in water quality are expected from the delayed implementation of the *C. dubia* MMEL. If there are any adverse changes, those changes would be minor and limited in duration. The permitting authority would be required to include the MMEL using *C. dubia* whenever necessary to comply with federal law. Similarly, there may be instances in which the permitting authority concludes that a receiving water limitation based on the numeric water quality objective is required by federal law.  See SR F.002 for further discussion on the implementation of Section IV.B.2.e.i.  See SR F.004 for a discussion on anti-backsliding and anti-degradation.  See response “SR25.013” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on why “accuracy” is not applicable in WET testing.  See SR F.001 for an explanation as to why there is an option for the Regional Water Board to delay *C. dubia* numeric effluent limitations for certain dischargers. |
| 19.040 | *4. Delaying the use of C. dubia until the completion of the study for those dischargers that already have numeric effluent limits using C. dubia may constitute an unlawful variance.*  Sound interpretation and implementation of the Clean Water Act is essential to restoring and maintaining the chemical, physical and biological integrity of our waters. Water quality standards are the core regulations under the Clean Water Act that the public depends on to ensure our nation’s waters are swimmable, drinkable and fishable. Any modification to water quality standards must be undertaken with extreme care to ensure that there will be no weakening of Clean Water Act protections for human health and the environment. Since 1977, EPA has allowed variances so long as they are “adopted consistent with the substantive and procedural requirements for permanently downgrading a designated use.”29 EPA defined a variance as “the practice of temporarily downgrading the WQS as it applies to a specific discharger rather than permanently downgrading an entire water body or waterbody segment(s).”30 This interpretation is repeated in the Water Quality Standards Handbook which states that variances will only be allowed if “the State demonstrates that meeting the standard is unattainable based on one or more of the grounds outlined in 40 C.F.R. 131.10(g) for removing a designated use.” Under Scenario 3, in which a discharger with existing toxicity effluent limits using *C. dubia* may instead use the next applicable species to demonstrate compliance, the State Water Board is downgrading the water quality standard for toxicity by not using the most sensitive species to demonstrate compliance. Further, while laboratory procedures may be improved to increase the accuracy of *C. dubia* testing, it is not infeasible or unattainable to demonstrate compliance with numeric aquatic toxicity effluent limitations, as demonstrated by the successful use of *C. dubia* under NPDES permits already issued and implemented by the Los Angeles Regional Water Quality Control Board. By delaying the use of *C. dubia* as an indicator species to demonstrate compliance – after a species sensitivity screening has indicated *C. dubia* as the most sensitive species – until after the completion of the study, the Provisions risk weakening existing numeric aquatic toxicity water quality objectives. And without demonstrating that the standard is unattainable based on one or more grounds outlined in 40 C.F.R. 131.10(g), the Provisions give rise to an illegal variance under Scenario 3 that could risk the approval of these final provisions by the U.S. EPA, further delaying statewide standards for toxicity that are already long overdue. |
| SC F.007 | The State Water Board should continue building public confidence in the reliability of the *C. dubia* reproduction testing by conducting a time-limited study, but the delay in the implementation of effluent limitations is not necessary and the delay will increase the burden on NPDES permit writers.  Fox et al. (2019) evaluated statistical error rates for California toxicity laboratories using the *C. dubia* reproduction test method and confirmed that a pattern of high within-test variability (i.e., lower laboratory performance) can predictably result in a toxicity laboratory false positive rate greater than 5 percent. Many California laboratories have already taken the steps necessary to reduce their operational causes of high within-test variability by investigating and improving operational practices and/or increasing the number of replicates tested. The State Water Board should consider limiting these options to dischargers utilizing laboratories who are experiencing data quality issues.  Scenario 3, Option 2 could place a heavy burden on NPDES permit writers since the Clean Water Act prohibits backsliding from previous permit limits, yet this option would allow removal of a previously enforceable limitation in favor of an effluent target. In order to comply with anti-backsliding requirements, permit writers must ensure that the revised permit limits meet an exception to backsliding and must justify the exception in the fact sheet on a permit by permit bases. If the State Board proceeds with this option, the delay should be time-limited with deadlines that do not extend past 2023.  The State Board should also provide further instructions and training to permit writers to ensure implementation of these provisions meets all applicable NPDES permitting requirements, including anti-backsliding, effluent toxicity limits, anti-degradation, and compliance schedules. U.S. EPA is available to assist with the development of training materials and guidance. As per the 1989 NPDES Memorandum of Agreement between U.S. EPA and California, U.S. EPA will continue to review and comment on NPDES permits in our oversight capacity. |
| SR F.007 | Please see Section 5.4.3 of the Staff Report and SR F.001 explaining the delayed effect of the statewide mandate to include an MMEL using *C. dubia* to January 1, 2024and the permitting authority’s determination on a permit-by-permit basis as to whether an MMEL for *C. dubia* should be included to comply with federal law.  See SR F.004 and Section 9.3 of the Staff Report for further discussion on anti-backsliding and antidegradation and the workload burden on NPDES permit writers.  See SR F.005 for a discussion on how the circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions are not compliance schedules  The State Water Board is planning to provide training to permit writers in the future to ensure implementation of these provisions meets all applicable NPDES permitting requirements. |
| 24.005 | We understand that the State Board is considering allowing delayed implementation of certain effluent limits based on the numeric chronic toxicity objective in order to increase public confidence in the reliability of *C. dubia* reproduction testing by conducting a time-limited study. We support the State Board in building public confidence, yet do not believe this delay is necessary and are concerned that the delay will increase the burden on NPDES permit writers. |
| 24.007 | A recent peer-reviewed study, Fox et al. (2019), evaluated statistical error rates for California toxicity laboratories using the *C. dubia* reproduction test method and confirmed that a pattern of high within-test variability (i.e., lower laboratory performance) can predictably result in a toxicity laboratory false positive rate greater than 5 percent. Many California laboratories have already taken the steps necessary to reduce their operational causes of high within-test variability by investigating and improving operational practices and/or increasing the number of replicates tested. As such, if the State Board moves forward with the options in Table 5-3 of the Staff Report, we recommend that the State Board considering limiting these options to dischargers utilizing laboratories who are experiencing data quality issues. |
| 24.009 | EPA is concerned about the additional work implementing the proposed Scenario 3, Option 2 could place on California’s already overburdened NPDES permit writers. The Clean Water Act prohibits backsliding from previous permit limits, however, Scenario 3, Option 2 would allow removal of a previously enforceable effluent limitation in favor an effluent “target.” In order to comply with CWA anti-backsliding requirements, permit writers must ensure that the revised permit limits meet an exception to backsliding and must justify the exception in the fact sheet on a permit by permit basis. CWA sections 303(d)(4) and 402(o)(2). If the State Board proceeds with this option, we strongly support the proposal that the delay be time-limited with deadlines that do not extend past 2023. |
| 24.010 | We also recommend that the State Board provide further instructions and training to permit writers to ensure implementation of these provisions meets all applicable NPDES permitting requirements, including anti-backsliding, effluent toxicity limits, anti-degradation, and compliance schedules. EPA is available to assist with the development of training materials and guidance. |
| 24.011 | Finally, as per the 1989 NPDES Memorandum of Agreement between EPA and California, EPA will continue to review and comment on NPDES permits in our oversight capacity. |
| SC F.008 | Commenters appreciate the use of the MMET instead of the MMEL for qualifying dischargers and support the study to improve the accuracy and reliability of results for the *C. dubia* reproduction test as there is concern regarding *C. dubia* variability, subsequent incorrect determinations of toxicity, and ultimately increased violations based on inaccurate measures of real toxicity. A previously submitted analysis with referenced studies indicated that the proportion of tests falsely identifying non-toxic blank samples as toxic (15-43%) results in up to a 29% probability that the MMEL will be violated by dischargers due to non-toxic samples incorrectly identified as toxic with this test. Additionally, another study showed that 41% of chronic *C. dubia* toxicity testing results with 17 split effluent samples did not agree if samples were toxic or not. Reducing within-test variability with recommendations from the *C. dubia* special study may help alleviate these uncertain results and provide confidence that is needed for effluent limits based on *C. dubia* chronic toxicity results.  However, the hard end date of December 31, 2023, when all permits would be required to include monthly median numeric limits for *C. dubia* when *C. dubia* is identified as the most sensitive species, is problematic. These MMELs would have regulatory effect and could be modified only by undertaking a separate regulatory process to amend the Toxicity Provisions. Doing so would be an unnecessary drain on resources, time, and effort. Also, the hard end date assumes that the study will yield an outcome supporting the use of *C. dubia* for compliance assessments, but the entire purpose of conducting the study is to determine if this is appropriate.  Additionally, the concept of a “Board Check-In” was discussed at a workshop to ensure the results from this study would inform use of this test method/endpoint in a numeric effluent limitations scenario. However, the Toxicity Provisions indicate that on December 31, 2023, the *C. dubia* numeric limitations will be in effect for all dischargers, regardless of the study outcome. Not only does this preempt the concept of a “Board Check-In” but it presupposes the results of the aforementioned study.  Only after the completion of the study may the State Water Board decide that the monthly median numeric limits for *C. dubia* reproduction are appropriate and the December 31, 2023 implementation date should stand. The State Water Board should be informed by what the study shows after its completion and should have more flexibility to exercise its authority and discretion over a full range of options, rather than being bound to a decision before the study had been initiated. The results of the study should also be subject to public and peer review and the Toxicity Provisions should be revised through a public comment and hearing process, all while the compliance options (including the MMET) are retained in the permit. Also, the schedule for completing this study is no longer realistic due to the COVID-19 pandemic and laboratories are currently facing equipment shortages due to supply chain interruptions.  Modify the language of the Toxicity Provisions to eliminate the December 31, 2023 “trigger date” or include reopener language common to TMDLs and other regulatory actions that will be informed by developing science. |
| SR F.008 | The chronic *C. dubia* reproduction toxicity test is a reliable test and is essential in protecting California’s surface waters from toxicity as mentioned in Section 5.4.3 of the Staff Report. U.S. EPA conducted a robust method variability study prior to promulgating the *C. dubia* chronic test method. Please refer to the U.S. EPA publication “Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods, Vol. 1” ([EPA 821-B-01-004](https://nepis.epa.gov/Exe/ZyPDF.cgi/P100IK48.PDF?Dockey=P100IK48.PDF)) for more information. Please also see response “SR25.029” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion of the test method and its promulgation.  Appendix J of the Staff Report indicates that most California laboratories in the analysis had low within-test variability and can attain the acceptable false positive probability of 5 percent or less when using 10 replicates. However, not all of the laboratories were able to achieve the acceptable false positive probability of 5 percent due to higher within-test variability. Therefore, the *C. dubia* study is a quality assurance study to determine whether more specific guidelines for test method execution and/or laboratory best practices might be developed and recommended to reduce within-test variability and improve between-laboratory comparability for the *C. dubia* chronic toxicity test.  The *C. dubia* study is not:  1. A method validation study. It is not a “blank” study to determine whether *C. dubia* should be used in California regulatory programs or to determine whether *C. dubia* is a reliable and valid WET test species. A study of that magnitude would need to follow a design similar to the 2000 U.S. EPA Method Variability Study.  2. A study to estimate false positive or false negative rates using the Test of Significant Toxicity (TST).  Task 12.3 of the [*C. dubia* study contract](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) explains that the Study Work Plan will be developed by SCCWRP, in consultation with the Stakeholder Advisory Committee and the Expert Panel. Please see SR L.010 for more information about the Stakeholder Advisory Committee, and how to provide input on the study plan by communicating with Committee members.  The schedule and commitment from laboratories for completing the *C. dubia* study is not affected by the COVID-19 pandemic and is still expected to be completed with a report generated prior to December 31, 2022.  Due to the need to build stakeholder and public confidence in the ability of laboratories to perform well when conducting the chronic *C. dubia* test method for MMEL compliance purposes, it is appropriate, to include a short-term delay in the statewide implementation of the *C. dubia* MMEL, as long as it is consistent with federal law for each NPDES permit. However, in the long-term, mandating a statewide MDEL and MMEL using *C. dubia* is essential to restrict pollutants, to protect beneficial uses, to improve water quality, to investigate and reduce the sources of toxicity, and to provide the appropriate incentive for dischargers to address the causes of toxicity, when *C. dubia* is identified as the most sensitive species. It is feasible and appropriate that on and after January 1, 2024, all accredited laboratories conduct the reliable and promulgated *C. dubia* chronic reproduction toxicity test. Please see section 5.4.3 of the Staff Report for further discussion.  In addition, Section IV.B.2.e.i. of the Toxicity Provisions has been revised to clarify that starting January 1, 2024, not December 31, 2023, the MMEL indicated in Section IV.B.2.e.iv of the Toxicity Provisions must be applied in all permits that have been issued, reissued, renewed, or reopened (if the permit reopening is to address toxicity requirements) after the effective date of the Toxicity Provisions, even if the most sensitive species is *C. dubia*.  See response “SR25.013” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on why “accuracy” is not applicable in WET testing. See SR J-1.001 regarding the “incorrect determinations of toxicity,” see SR J-1.010 regarding the “proportion of tests falsely identifying non-toxic blank samples as toxic,” and see SR L.019 for a discussion on split samples. |
| 11.003 | Finally, at the core of our concerns with the Toxicity Provisions has been the required use of *Ceriodaphnia dubia (C. dubia)* due to its test variability, subsequent incorrect determinations of toxicity, and ultimately increased violations based on inaccurate measures of real toxicity… However, as discussed, the timetables for use of this species should await final results from the research study and a subsequent regulatory action by the State Water Board members. |
| 11.004 | **1. The Toxicity Provisions related to permit requirements using *C. dubia* should be modified to provide for meaningful consideration of the laboratory study.**  CASA appreciates the State Water Board’s funding and initiation of a study to examine the *C. dubia* reproduction toxicity test method. Given the well documented issues regarding this test, CASA fully endorses the need for the study to improve the accuracy and reliability of results for the *C. dubia* reproduction test. We look forward to working with State Water Board Staff and other stakeholders on the proposed study. CASA also supports the inclusion of the alternative permitting approaches, which specify how permit limits and triggers will be structured while the study is underway.  However, we have a very real concern with including the proposed hard end date of December 31, 2023 as the time that all permits would be required to include monthly median numeric limits for *C. dubia* reproduction. If included in these Toxicity Provisions, this date would have a regulatory effect and could be modified only by undertaking a separate regulatory process to amend the Toxicity Provisions. Not only would this be an unnecessary drain on resources, but given the time and effort it has taken to get to this point, and the State Water Board’s workload, we do not have a sense that the resources for such an undertaking would be available.  Moreover, the State Water Board and stakeholders are undertaking the study of *C. dubia* in order to gain important information relevant to the regulation of toxicity under the plan. Following completion of the study, the State Water Board may decide that monthly median numeric limits for *C. dubia* reproduction are appropriate and the December 31, 2023 implementation date should stand. However, that is not the only potential outcome of the study, and based on the study findings or other developments over the next three years, the State Water Board could very well conclude that the interim provisions should be extended, either to allow additional time or as a long-term permitting approach.  Thus, we recommend that the text of the Toxicity Provisions allow the State Water Board flexibility at the time the study is completed to exercise its authority and discretion over the full range of options available. The State Water Board at that time should be informed by what this study shows after its completion and should not be bound to a decision from the State Water Board in 2020 before the study had even been initiated.  Accordingly, we suggest adding provisions including a specific decision point for the State Water Board, similar to reopener language common to TMDLs and other regulatory actions that will be informed by developing science. We recommend the following language for section IV.B.2.e.i:  *On or before [date], the State Water Board will reopen this Section, based on new information, to specify one of the following:*  *• Require that permits renewed, reissued or reopened on or after December 31, 2023 shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv.*  • Revise Section IV.B.2.e.i. to extend the time period that Section IV.B.2.e.i is operative.  • *Revise Section IV.B.2.e.i to specify that where C. dubia is the most sensitive species, permits may include either (1) monthly median trigger (MMET) and a maximum daily effluent limit (MDEL) using C. dubia or (2) a monthly median effluent limit (MMEL) and an MDEL using the next most sensitive species.1* [footnote 1: The revised provision Revised Section IV.B.2.e.i would read as follows:  For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is not *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv using the MOST SENSITIVE SPECIES.  For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include either (1) the MDEL indicated in Section IV.B.2.e.iii and the MMET indicated in Section IV.B.2.g.ii using *Ceriodaphnia dubia* as the MOST SENSITIVE SPECIES or (2) the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iV using the next applicable species as the MOST SENSITIVE SPECIES.] |
| 12.003  18.001 | • **Permit requirements for use of *Ceriodaphnia dubia* reproduction test:** CVCWA supports the use of an interim approach during the pendency of the study regarding the *Ceriodaphnia dubia* reproduction test method. However, we believe that the proposed hard end date for these provisions presupposes the outcome and would not provide a meaningful opportunity to incorporate results of the study. We recommend alternative language providing for a specific decision informed by the study findings. |
| 12.014  18.005  18.007  18.008  18.009  18.011 | **The Provisions Related to Permit Requirements Using *Ceriodaphnia dubia* Reproduction Tests Should Be Modified to Provide for Meaningful Consideration of the Laboratory Study.**  CVCWA appreciates the Board’s funding and initiation of a study to examine the *C. dubia* reproduction toxicity test method. Our special study of toxicity results in the Central Valley clearly indicated that the *C. dubia* reproduction test is the most prevalent indicator of toxicity for Central Valley POTWs, and the most common reason for the initiation of Toxicity Reduction Evaluations (TREs). Given the well-documented and recognized issues regarding this test, CVCWA fully endorses the need for the study to improve the reliability and accuracy of results for the *C. dubia* reproduction test. We look forward to working with State Board staff and other stakeholders on the design and implementation of the proposed study. CVCWA also supports the inclusion of the alternative permitting approach during the conduct of the study and analysis of the findings, which specifies how permit limits and targets will be structured while the study is underway.  We have a very real concern, however, about including the proposed hard end date of December 31, 2023, at which time all permits would be required to include monthly median numeric limits for *C. dubia* reproduction. This date would have immediate regulatory effect, and could be modified only by undertaking a separate regulatory process to amend the statewide water quality plan. Not only would this would be an unnecessary drain on resources, but given the time and effort it has taken to get to this point, and the Board’s workload, we are skeptical that such a process would be undertaken.  The Board and stakeholders are undertaking the study of *C. dubia* in order to gain important information relevant to the regulation of toxicity under the plan. Following completion of the study, the Board may well decide that the December 31, 2023 deadline should stand. But that is not the only potential outcome of the study. The Board could very well conclude that the interim provisions should be extended, either to allow additional time or as a long-term permitting approach. The Toxicity Provisions should allow the Board to exercise its authority and discretion over the full range of options available, informed by the study. As currently drafted, the provisions favor one potential policy choice and would set up any alternative, other than the proposed default, for an uphill (perhaps futile) battle.  Instead, the provisions should include a specific decision point for the Board, similar to reopener language common to TMDLs and other regulatory actions that will be informed by the developing science under the proposed study. We recommend the following language be inserted into section IV.B.2.e.i:  On or before [date], the State Water Board will reopen this Section, based on new information, to specify one of the following:  • Require that permits renewed, reissued, or reopened on or after December 31, 2023 shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv.  • Revise Section IV.B.2.e.i. to extend the time period that Section IV.B.2.e.i is operative.  • Revise Section IV.B.2.e.i to specify that where *C. dubia* is the most sensitive species, permits may include either (1) monthly median trigger (MMET) and a maximum daily effluent limit (MDEL) using *C. dubia*, or (2) a monthly median effluent limit (MMEL) and an MDEL using the next most sensitive species.1 [footnote 1: The revised provision Revised Section IV.B.2.e.i would read as follows: For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is not *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv using the MOST SENSITIVE SPECIES. For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include either (1) the MDEL indicated in Section IV.B.2.e.iii and the MMET indicated in Section IV.B.2.g.ii using *Ceriodaphnia dubia* as the MOST SENSITIVE] |
| 13.005 | Additionally, we recommend that the Toxicity Provisions be revised so that the monthly median effluent limitation (MMEL) for *C. dubia* does not become effective without members of the State Water Board first evaluating findings from the study. Adverse public perception of recycled water as “toxic” is such a hurdle to widespread recycled water use and integrated regional water planning efforts that it is in the utmost interest of the state and public that we have confidence that violations of effluent limitations for *C .dubia* are due to chemical constituents and not test-related issues. |
| 17.001 | 1. ***Specific language should be included in the Draft Plan requiring action by the State Water Board after conclusion of the variability and comparability study before the provisions take effect regarding Ceriodaphnia dubia* *numeric effluent limitations.*** |
| 17.004 | Additionally, one of the only components discussed at the workshop was the concept of a “Board Check-In” to ensure that results from this study would inform use of this test method/endpoint in a numeric effluent limitations scenario. Unfortunately, the Draft Plan specifies that after December 31, 2023, *Ceriodaphnia* numeric limits will be in effect for all dischargers, regardless of the study outcome. Not only does this preempt the concept of a “Board Check-In” but it presupposes the results of the aforementioned study. The following language is recommended for inclusion in Section IV.B.2.e to resolve this issue:  On or before [date], the State Water Board will reopen this Section, based on new information, to specify one of the following:  • Require that permits renewed, reissued or reopened on or after December 31, 2023 shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv.  • Revise Section IV.B.2.e.i. to extend the time period that Section IV.B.2.e.i is operative.  • Revise Section IV.B.2.e.i to specify that where *C. dubia* is the most sensitive species, permits may include either (1) a monthly median effluent trigger (MMET) and a maximum daily effluent limit (MDEL) using *C. dubia* or (2) a monthly median effluent limit (MMEL) and an MDEL using the next most sensitive species.2 [footnote 2: The revised provision Revise Section IV.B.2.e.i would read as follows:  For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is not *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv using the MOST SENSITIVE SPECIES.  For NON-STORMWATER NPDES DISCHARGERS when the MOST SENSITIVE SPECIES identified by the PERMITTING AUTHORITY is *Ceriodaphnia dubia*, the PERMITTING AUTHORITY shall include either (1) the MDEL indicated in Section IV.B.2.e.iii and the MMET indicated in Section IV.B.2.g.ii using *Ceriodaphnia dubia* as the MOST SENSITIVE SPECIES or (2) the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iV using the next applicable species as the MOST SENSITIVE SPECIES.] |
| 18.006 21.015 | **Comment 4. Expiration of Monthly Median Effluent Targets (MMETs) – Revised Draft Staff Report Section 2.6.6.e.**  We appreciate and support revisions to the Toxicity Provisions which allow “targets” (i.e., MMETs) rather than “limits” (MMELs) for qualifying dischargers while a special study is performed to improve the application of C.dubia chronic toxicity test method. This study is described in the revised staff report “…to investigate factors that can be controlled to reduce within-test variability in the *C. dubia* chronic reproduction toxicity test. The study is to be completed with an end-certain date of December 31, 2023.” Completing this study is the rationale provided by the State Water Board for delaying the implementation of MMELs for *C. dubia* chronic toxicity testing and the use of MMETs for qualifying dischargers, as explained in Section 5.4.3 of the staff report. However, the schedule proposed for completing the special study, which was developed prior to the COVID-19 pandemic, is not realistic. Laboratories are currently facing equipment shortages due to supply chain interruptions. This and other unforeseen effects of the ongoing pandemic on the *C. dubia* study schedule is unknown.  Failing to meet the study deadline, or a failure of the study to identify solutions that can be implemented to reduce *C. dubia* variability, would leave testing laboratories and the discharger community without options for addressing the problematic within-test variability, as well as the propensity to identify non-toxic samples as toxic (as shown in tests with laboratory blank samples) in the *C. dubia* test (Schiff and Greenstein {Footnote 2: Schiff, K.C. and Greenstein, D. 2016. Stormwater Monitoring Coalition Toxicity Testing Laboratory Guidance Document. Southern California Coastal Water Research Project (SCCWRP), Technical Report 956.} 2016). Using data for blank samples from the study conducted by Schiff and Greenstein (2016), as well as other studies, we provided analysis in comments submitted to the State Water Board on Appendices J and K (RBI 2020) that demonstrate the probability that MMEL violations will occur due to the chronic *C. dubia* test incorrectly identifying non-toxic samples as being toxic (we incorporate by reference the technical discussion of Comment 2 from RBI 2020). The proportion of tests falsely identifying non-toxic blank samples as toxic in the referenced studies (15–43%) results in up to a 29% probability that the MMEL will be violated by dischargers due to non-toxic samples incorrectly being identified as toxic with this test. |
| 21.016 | Figure 1 illustrates one of the concerns with *C. dubia* testing shared with State Water Board staff by RBI on September 19, 2019. These data, from the CVCWA (2018) low-level toxicity study, show that 41% of chronic *C. dubia* toxicity testing results with 17 split effluent samples did not agree if samples were toxic or not toxic when tested at different laboratories. Reducing within-test variability with recommendations from the *C. dubia* special study may help alleviate these uncertain results and provide confidence that is needed for effluent limits based on *C. dubia* chronic toxicity results.  Figure 1. *C. dubia* chronic toxicity test results with split effluent samples at different laboratories  [See Figure 1 on page 9 of Comment Letter #21] |
| 21.017 | Requested Change to Address Comment 4:  We request that the State Water Board include a specific decision point, similar to reopener language common to Total Maximum Daily Loads (TMDLs) and other regulatory actions, which will be informed by data developed by the *C. dubia* special study. This request is to add the following language into Section IV.B.2.e.i:  “On or before [date], the State Water Board will reopen this Section, based on new information, to specify one of the following:   * Require that permits renewed, reissued or reopened on or after December 31, 2023 shall include the MDEL indicated in Section IV.B.2.e.iii and the MMEL indicated in Section IV.B.2.e.iv. * Revise Section IV.B.2.e.i. to extend the time period that Section IV.B.2.e.i is operative. * Revise Section IV.B.2.e.i to specify that where *C. dubia* is the most sensitive species, permits may include either (1) monthly median trigger (MMET) and a maximum daily effluent limit (MDEL) using *C. dubia* or (2) a monthly median effluent limit (MMEL) and an MDEL using the next most sensitive species.” |
| 23.005 | LADWP appreciates the addition of the median monthly effluent target (MMET) for the *C. dubia* chronic test. Alternatives to the use of the median monthly effluent limitation (MMEL) should be continued until results of the SWRCB’s study are available and the Toxicity Provisions are modified in accordance with the results of the study. |
| 23.017 | LADWP requests that alternatives to the use of the MMEL for *C. dubia* chronic tests should be continued until results of the SWRCB’s study are available and the Toxicity Provisions are modified in accordance with the results of the study. |
| 23.020 | In recognition of the need for additional study of chronic tests using *C. dubia*, the SWRCB has introduced four compliance options, which include a MMET as an alternative to a median monthly effluent limitation (MMEL) for *C. dubia* chronic tests. We support the use of the MMET instead of the MMEL, as exceedances of the MMET would not result in an effluent limit violation but could trigger requirements for a toxicity reduction evaluation (TRE). However, the Toxicity Provisions specify that an MMEL (not MMET) for *C. dubia* chronic tests must be used in permits issued after December 31, 2023, which is the final date for the *C. dubia* study to be completed. Just as it is unsuitable to pre-determine the outcome of the *C. dubia* study, it is also unsuitable to pre-determine the regulatory pathway that depends on the study results. |
| 23.022 | Recommendation 2: LADWP requests that the four compliance options (including the MMET) should be retained in the permit, until such time as the *C. dubia* study results are available, have been subject to public and peer review, and the Toxicity Provisions revised through a public comment and hearing process. |
| 26.019 | **Use of a median monthly effluent target (MMET) for *C. dubia* is appropriate, but should not be discontinued at the end of 2023 unless and until the SWRCB study demonstrates that *C. dubia* can be reliably used for compliance assessments.**  Issue: As noted above, the chronic test with *C. dubia* is currently being investigated to identify factors that would reduce within-test variability. In recognition of the need for additional study of chronic tests using *C. dubia*, the SWRCB has developed the concept of a “median monthly effluent target” (MMET). An exceedance of an MMET would not result in an effluent limit violation but could result in the requirement to conduct a TRE; we support this change. |
| 26.020 | We understand that the option to issue a permit using an MMET for *C. dubia* is only available before December 31, 2023, and that permits issued after that date would be required to use the median monthly effluent limitation (MMEL) for *C. dubia* if that is the most sensitive species. It appears that this approach is based on the assumption that the study will yield an outcome supporting the use of *C. dubia* for compliance assessments – but the entire purpose of conducting the study is to determine if this is appropriate. The 2023 date should be deleted from the permit, and the four compliance options should continue to be used until such time as the study results are available and the SWRCB amends the Toxicity Provisions, after public comment, to approve the use of *C. dubia* in chronic tests for compliance assessments.  Recommendation: Modify the language of the Toxicity Provisions to eliminate the December 31, 2023 “trigger date,” as follows (redlines indicate suggested deletions):  Toxicity Provisions, Section IV.B.2.e.i, page 34.  “IV.B.2.e.i. Recommendation: Revise the language regarding the MMET in the Staff Report to make conforming changes to eliminate the December 31, 2023 date. Changes in Staff Report would be needed at p. 28 and beginning at p. 116. |
| SC F.009 | Stakeholders appreciate the recognition of concerns with the *C. dubia* test and timeframe allowed for completion of a study before *C. dubia* can be utilized as a species for determining compliance.  However, it is unclear why dischargers that already have numeric effluent limitations in their permit are treated differently during the *C. dubia* study. The rationale for the study remains the same for all types of dischargers and therefore the effluent limitation setting procedure should be the same. Section IV.B.2.e of the Toxicity Provisions should be modified to remove different requirements for dischargers that already have a numeric effluent limitation and clarify that the remaining paragraphs apply to both discharges with and without existing numeric effluent limitations. |
| SR F.009 | See SR F.008 and Section 5.4.3 of the Staff Report for a discussion on the reliability of the chronic *C. dubia* reproduction test, the objective of the *C. dubia* study, and the numeric effluent limitation implementation requirements for *C. dubia* through December 31, 2020.  Revisions to Section 5.4.3 of the Staff Report were made to describe how in determining what testing and compliance should be conducted in the interim (between the effective date and January 1, 2024), two scenarios were developed when the most sensitive species is identified as *C. dubia.* These are identified as Scenario 1 and Scenario 3. The difference between these two scenarios is based on whether numeric effluent limitations are already included in the current permit. In Scenario 1, the baseline water quality protection is a permit with no numeric effluent limitation. While a delay in application of the MMEL using *C. dubia* would not improve water quality, it is not anticipated that the delay would lessen existing protection of aquatic life beneficial uses within Scenario 1. However, for Scenario 3, both options A and B include an MMEL to avoid the relaxation of existing effluent limitations.  For a discussion on anti-backsliding requirements, see SR F.004 and Section 9.3 of the Staff Report.  In addition, revisions to the Toxicity Provisions were made to clarify that the permitting authority would be required to include the MMEL using *C. dubia* whenever necessary to comply with federal law. |
| 22.002 | Comment #2-Clarify the Effluent Limitation Requirements Related to the *Ceriodaphnia dubia* Study  The Stakeholders also appreciate the recognition of concerns with the *Ceriodaphnia dubia* test and the timeframe allowed for completion of a study before *Ceriodaphnia dubia* can be utilized as a species for determining compliance. We hope this will help address some of the identified concerns provided in our previous letters. However, we have concerns that for dischargers that already have numeric effluent limitations in their permit the method for determining the effluent limitations for *Ceriodaphnia dubia* are different and have the potential to cause challenges to the Stakeholders while the study is being completed. Additionally, the rationale provided in the staff report does not explain why dischargers with an existing numeric effluent limitation for toxicity should be treated differently than other dischargers. The rationale for the study remains the same for all types of dischargers and therefore the effluent limitation setting procedure should be the same. We request that section IV.B.2.e on page 34 be modified to remove the different requirements for dischargers that already have a numeric effluent limitation  Requested Changes  Delete the following paragraph from section IV.B.2.e on page 34 and clarify that the remaining paragraphs apply to both discharges with and without existing numeric effluent limitations. |

## Category G – Targets for a Toxicity Reduction Evaluation

| **Comment Code** | **Comment** |
| --- | --- |
| **SC G-1.001** | The toxicity target requirements for small POTWs with no reasonable potential should be removed, in particular the chronic aquatic toxicity MMET, which can be triggered by low-level chronic toxicity results for small discharges that are unlikely to impact receiving waters. These requirements will impose an additional cost burden on the very communities on which the State Water Board members previously directed staff to focus for cost reductions. Communities with no history of effluent toxicity will be the ones found to have no reasonable potential. Such communities should be granted leniency in both monitoring requirements and requirements to prepare costly TREs. The proposed toxicity target requirements eliminate such leniency and will result in unwarranted costs to those small communities. |
| **SR G-1.001** | Non-storm water NPDES dischargers would be required to conduct a minimum of two chronic aquatic toxicity tests per year if there is at least one calendar quarter in which there is expected to discharge at least 15 days of discharge. For dischargers that discharge less than 15 days in all calendar quarters, the permitting authority could choose to not require routine monitoring or could set a routine monitoring frequency.  As discussed in Chapter 9 of the Staff Report, the monitoring and TRE requirements for dischargers without effluent limitations may increase costs for some dischargers. The benefit of the requirements is the establishment of a uniform quantity of routinely scheduled toxicity tests that would help maintain the biological integrity of receiving waters by acting as a backstop against the additive and synergistic effects of known and unknown pollutants and protect aquatic life beneficial uses.  Requiring a minimum of two routine chronic aquatic toxic monitoring tests per year would provide sufficient toxicity tests to perform a reasonable potential analysis when permits are reissued, renewed, or reopened and provides additional assurance that non-storm water NPDES permitted dischargers do not have an unacceptable level of toxicity in their effluent. If there is an indication of toxicity, then a TRE is valuable to assess the sources of toxicity and to confirm a reduction. If the effluent does not have an unacceptable level of toxicity, dischargers would not be required to conduct a TRE. See Appendix J for a discussion of the probability of dischargers being required to conduct a TRE when toxicity is not present in the effluent.  In addition, insignificant dischargers, that could possibly include a small POTW discharger, that have no reasonable potential to cause or contribute to aquatic toxicity may qualify for an exemption from the monitoring requirements as an insignificant discharger per Section IV.B.2.k.i of the Toxicity Provisions. |
| 12.004 | • **Toxicity Target Requirements for Small Communities with No Reasonable Potential:** We request that the proposed targets for initiation of Toxicity Reduction Evaluations in small communities with no Reasonable Potential be removed from the proposed Toxicity Provisions. |
| 12.015 | **The Toxicity Target Requirements for Small POTWs With No Reasonable Potential Should Be Removed.**  Sections IV.B.2.g and IV.B.2.d.iii of the proposed Toxicity Provisions include new requirements which would impose toxicity targets (Maximum Daily and Median Monthly Effluent Targets [MDETs and MMETs]) that would require small communities with no Reasonable Potential (RP) to initiate Toxicity Reduction Evaluations based on two exceedances of the proposed targets. These requirements will impose an additional cost burden on the very communities on which the State Board members previously directed staff to focus for cost reductions. Communities with no history of effluent toxicity will be the ones found to have no RP. Such communities should be granted leniency in both monitoring requirements and requirements to prepare costly TREs. The proposed toxicity target requirements eliminate such leniency and will result in unwarranted costs to those small communities. CVCWA requests that the proposed toxicity target provisions be removed to avoid these unnecessary costs to small communities, in particular the chronic aquatic toxicity MMET, which can be triggered by low-level chronic toxicity results for small discharges that are unlikely to impact receiving waters. |

## Category H – Toxicity Reduction Evaluations

| **Comment Code** | **Comment** |
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| **SC H.001** | A TRE should not be required when there is no effluent available to complete a routine monitoring test, MMET test, or MMEL compliance test. A TRE can be long lasting, can easily become high in cost without any corresponding increase in beneficial use protection, and can be unsuccessful in identifying a definitive pollutant(s) or source(s). When effluent is not being discharged, there is no impact on the receiving water or beneficial uses. Additionally, there is no evidence that toxicity exists in the effluent that would warrant a TRE. A TRE should only be completed when there is evidence of toxicity. |
| **SR H.001** | As discussed in Section 5.4.6 of the Staff Report, a TRE “is a step-wise process that is used to identify the cause of effluent or ambient toxicity in a water body.” According to the U.S. EPA Toxicity Reduction Evaluation Guidance for Municipal Guidance for Municipal Wastewater Treatment Plants (EPA 833-B-99-002), components of a municipal TRE include: 1) Information and Data Acquisition, 2) Facility Performance Evaluation, 3) Toxicity Identification Evaluation, 4) Toxicity Source Evaluation, 5) Toxicity Control Evaluation, and 6) Toxicity Control Implementation. Only some of these components require toxicity testing of an effluent whereas other components can be conducted without effluent available. For more information, see the U.S. EPA TRE Guidance. Additionally, refer to the TRE Work Plan specified in each NPDES permit.  The Toxicity Provisions require a TRE whenever a discharger has any combination of two or more MDEL or MMEL violations in a single calendar month or within two successive calendar months. A TRE is also required whenever a discharger does not meet any combination of two or more MDET or MMET within a single calendar month or within two successive calendar months.  If other information indicates toxicity (e.g., results of additional monitoring, results of monitoring at a higher concentration than the IWC, fish kills, intermittent recurring toxicity), then the permitting authority may require a TRE. However, for intermittent dischargers, toxicity may exist but there may not be enough effluent available to conduct the follow-up MMEL compliance tests or MMET tests. This is because MMEL compliance tests and MMET tests are only required when there is sufficient effluent to complete these tests, even when a routine monitoring test results in a fail. A discharger may also lack sufficient effluent to conduct a routine monitoring test in the calendar month subsequent to a month in which a single violation or failure to meet a target has occurred. As a result, dischargers may have ongoing fails, indicating that there is persistent toxicity in the effluent, but not have effluent to determine whether there would be any combination of two or more MDET or MMET within a single calendar month or within two successive calendar months, which would typically result in a TRE.  The permitting authority has the discretion to require a TRE when there is no effluent available to complete a toxicity test because, although dischargers are not subject to a violation, there may be other information that indicates toxicity in the effluent. Such information may include, for example, multiple fails over a number of aquatic toxicity tests (indicating persistent toxicity) or when the magnitude of the effect is high. This option provides relief from violations to the dischargers that do not have sufficient effluent to comply with the monitoring requirements while also allowing the permitting authority to require a TRE if there is other information indicating toxicity. |
| 16.007 | 5. IV.B.2. h. Toxicity Reduction Evaluation (page 38): CVWD does agree with having a toxicity reduction evaluation (TRE) required when a non-storm water NPDES discharger does not meet MDET or MMET within two successive calendar months. CVWD does not agree with requiring a TRE when there is no effluent available to complete a routine monitoring test, MMET test, or MMEL compliance test. A TRE can be long lasting and can easily become high in cost. Recently, CVWD spent over $31,000 on a TRE/ TIE that was unsuccessful in identifying a definitive pollutant(s) or source(s). A TRE should only be completed when there is evidence of toxicity. Performing a TRE when there is no effluent to perform a routine toxicity test provides no apparent benefit and is not sensible or practical. |
| 22.003 | **Comment #3-Remove language allowing TREs to be required if no effluent is available**  On page 38 of the Revised Draft Toxicity Provisions, language was added that implies that if effluent discharge is not occurring, a TRE may still be required. When effluent is not being discharged, there is no impact on the receiving water or beneficial uses. Additionally there is no evidence that toxicity exists in the effluent that would warrant a TRE. The rationale and need for this language was not explained in the staff report. If the permitting authority chose to exercise this discretion, it would likely be a potentially significant cost burden without any corresponding increase in beneficial use protection, we request that the language be deleted.  **Requested Changes**  Delete the following sentence from section IV.B.2.h on page 38 of the Revised Draft Toxicity Provisions: |

## Category I – Exemptions

| **Comment Code** | **Comment** |
| --- | --- |
| **SC I.001** | Exemptions provided in the final Toxicity Provisions should be limited, given dischargers without the potential to cause or contribute toxicity are not required to comply with the Toxicity Provisions. |
| **SR I.001** | The exemptions are limited, as described in Section IV.B.2.k of the Toxicity Provisions. Except for biological pesticide and residual pesticide discharges, the permitting authority would need to make a finding that the discharges will have no reasonable potential to cause or contribute to an exceedance of the toxicity water quality objectives, or that reasonable potential exists only due to discharges of chlorine and chlorine effluent limitations are included in the NPDES permit. For the biological pesticide and residual pesticide discharges, the permitting authority would need to make a finding that it is infeasible to establish numeric effluent limitations. For all exempt discharges, the permitting authority would need to include the water quality objectives of the Toxicity Provisions as receiving water limitations in the NPDES permit. |
| 19.011 | *Limit any exemptions granted, given dischargers without the potential to cause or contribute toxicity are not required to comply with the Provisions.* |
| 19.066 | IV. EXEMPTIONS PROVIDED IN THE FINAL PROVISIONS SHOULD BE LIMITED, GIVEN DISCHARGERS WITHOUT THE POTENTIAL TO CAUSE OR CONTRIBUTE TOXICITY ARE NOT REQUIRED TO COMPLY WITH THE PROVISIONS. |
| **SC I.002** | The State Water Board should commit to providing financial assistance to small disadvantaged communities to comply with the requirements of the Toxicity Provisions. Rather than be exempt from the Toxicity Provisions, the communities that fall under the small disadvantaged communities should have access to additional support from the State Water Board to achieve compliance. The State Water Board, upon adopting these Toxicity Provisions, should include explicit resolution language outlining the resources available under the Department of Financial Assistance and explicitly commit to providing communities in need with direct financial assistance to comply with the requirements of the Toxicity Provisions. |
| **SR I.002** | The exemption for small disadvantaged communities was removed from Section IV.B.2.k of the Toxicity Provisions as all communities should be entitled to an equally non-toxic environment. The State Water Board’s Division of Financial Assistance provides resources and funding for improving treatment to wastewater treatment facilities serving small disadvantaged communities. Section 9.1.4.1.6 was added to the Staff Report. This section includes a list of existing financial resources offered by the Division of Financial Assistance to assist facilities serving small disadvantaged communities in complying with the requirements of the Toxicity Provisions. |
| 19.067 | 1. The State Water Board should commit to providing financial assistance to small disadvantaged communities to comply with the requirements of the Provisions. As originally drafted, the 2012 Draft Toxicity Provisions provided an exemption for “Small Disadvantaged Communities,” defined as populations of 20,000 or less. The State Water Board appropriately removed this exemption following the Board Workshop held in November of 2018, given all communities – regardless of their socio-economic status – should be entitled to an equally non-toxic environment. Rather than be exempt from the Provisions, the communities that fall under this definition should have access to additional support from the State Water Board to achieve compliance. We respectfully request that the State Water Board, upon adopting these Provisions, include explicit resolution language outlining the resources available under the Department of Financial Assistance and explicitly commit to providing communities in need with direct financial assistance to comply with the requirements of the Toxicity Provisions. |
| **SC I.003** | The biological and residual pesticides exemption should be removed to ensure effluent limitations apply whenever feasible because the potential toxic effect of pesticide use, biological pesticide and residual pesticide discharges must be regulated and to ensure statewide consistency, they must be regulated according to the Toxicity Provisions. At a minimum, the Toxicity Provisions must ensure that effluent limitations apply whenever feasible. To ensure that this exemption is used only when necessary, add language to Section IV.B.2.k.ii of the Toxicity Provisions to ensure this determination is “documented and sufficiently explained in the NPDES fact sheet (or equivalent document), Water Code section 13267 or 13383 Order(s), or both.” |
| **SR I.003** | Section 5.7.5 of the Staff Report explains that “[w]hen it is infeasible to establish numeric effluent limitations for the biological pesticide or residual pesticide discharges, the Water Board may exempt that discharge from some or all of the requirements contained in Section IV.B.2 of the Toxicity Provisions, including the inclusion of numeric effluent limitations. Aquatic pesticide discharges used for vector control, algae and aquatic weed control, spray applications, and aquatic animal invasive species control have specific requirements listed in the NPDES permits to prevent harm or adverse impacts on non-target organisms and beneficial uses. If residues from aquatic pesticides cause toxicity or add to an existing toxicity, best management practices or alternatives to the pesticide causing toxicity are required. If exempted from some or all of the Toxicity Provisions, the Water Board would still include the water quality objectives in Section III.B.2 of the Toxicity Provisions as receiving water limitations in the NPDES permit.”  Language was added to Section IV.B.2.k.ii of the Toxicity Provisions that requires the determination that it is infeasible to establish numeric effluent limitations for the biological pesticide or residual pesticide discharges be documented in the NPDES fact sheet (or equivalent document). |
| 19.069 | 3. The newly added exemption for biological and residual pesticides should be removed or revised to ensure effluent limitations apply whenever feasible. Under section IV.B.2.k.ii of the Draft Provisions, the permitting authority is authorized to exempt biological pesticide or residual pesticide discharges if it is infeasible to establish numeric effluent limitations for the discharges. We support the inclusion of the statement “If exempt, the PERMITTING AUTHORITY shall include the water quality objectives in Section III.B.2 as receiving water limitations in the NPDES permit.” However, given the potential toxic effect of pesticide use, biological pesticide and residual pesticide discharges must be regulated; and to ensure statewide consistency, they must be regulated according to the Draft Provisions. We request that section IV.B.2.k.ii be removed from the Draft Provisions. At a minimum, the Draft Provisions must ensure that effluent limitations apply whenever feasible. To ensure that this exemption is used only when necessary, we recommend the following addition to the Draft Provisions. |
| 19.070 | Requested Language (Suggested language in red):  IV.B.2.k.ii. Biological Pesticide and Residual Pesticide Discharges (p. 40) The PERMITTING AUTHORITY is authorized to exempt biological pesticide or residual pesticide discharges1 regulated by an NPDES permit from some or all of the provisions of Section IV.B.2 if the PERMITTING AUTHORITY makes a finding pursuant to the Code of Federal Regulations, title 40, part 122.44(k)(3) that it is infeasible to establish numeric effluent limitations for the biological pesticide or residual pesticide discharges. This determination must be documented and sufficiently explained in the NPDES fact sheet (or equivalent document), Water Code section 13267 or 13383 Order(s), or both. If exempt, the PERMITTING AUTHORITY shall include the water quality objectives in Section III.B.2 as receiving water limitations in the NPDES permit. |
| **SC I.004** | The drinking water exemption and the natural gas facilities exemption should be removed for the sake of statewide consistency and protection of aquatic health. The Toxicity Provisions already provide the permitting authority discretion to reduce routine monitoring under specific circumstances. Therefore, if there is no reasonable potential or reasonable potential exists only due to discharges of chlorine and chlorine effluent and chlorine effluent limitations are included in the NPDES permit, the burden on permittees to ensure and demonstrate that their discharge is not toxic is minimal under the current Toxicity Provisions, but is necessary to ensure the protection of aquatic health. |
| **SR I.004** | Sections 5.7.6 and 5.7.7 of the Staff Report explain that the contaminant of concern, chlorine, has specific monitoring requirements included in the NPDES permit that controls for such toxicity. In addition, to allow potable drinking water dischargers and discharges from hydrostatic testing of natural gas facilities to be exempt from some or all of the implementation requirements in Section IV.B of the Toxicity Provisions, the permitting authority must first make a finding that the discharger will have no reasonable potential to cause or contribute to an exceedance of the toxicity water quality objectives, or that reasonable potential exists only due to discharges of chlorine and chlorine effluent limitations are included in the NPDES permit. If exempted, the Water Board would still include the water quality objectives in Section III.B.2 of the Toxicity Provisions as receiving water limitations in the NPDES permit and the Water Board could require the discharger to conduct routine monitoring as necessary. |
| 19.071 | 4. The newly added exemption for drinking water should be removed. Under section IV.B.2.k.iii of the Draft Provisions, the permitting authority is authorized to exempt drinking water system discharges from some or all of the provisions if the discharges will have no reasonable potential to cause or contribute to an exceedance of the toxicity water quality objectives, or that reasonable potential exists only due to discharges of chlorine and chlorine effluent limitations are included in the NPDES permit. However, the draft provisions also state that this determination need not be based on the reasonable potential analysis methods set forth in Section IV.B.2.c. For the sake of statewide consistency and protection of aquatic health, this exemption cannot be allowed. The Draft Provisions already provide the permitting authority discretion to reduce routine monitoring under specific circumstances. Therefore, if there is no reasonable potential, as determined by the reasonable potential analysis methods set forth in Section IV.B.2.c, the burden on permittees to ensure and demonstrate that their discharge is not toxic is minimal under the current Draft Provisions, but is necessary to ensure the protection of aquatic health. We request that section IV.B.2.k.iii be removed from the Draft Provisions. |
| 19.072 | 5. The newly added exemption for natural gas facilities should be removed. Under Section IV.B.2.k.iv of the Draft Provisions, the permitting authority is authorized to exempt discharges from hydrostatic testing of natural gas facilities if the discharges will have no reasonable potential to cause or contribute to an exceedance of the toxicity water quality objectives, or that reasonable potential exists only due to discharges of chlorine and chlorine effluent limitations are included in the NPDES permit. However, the draft provisions also state that this determination need not be based on the RPA methods set forth in Section IV.B.2.c. For the sake of statewide consistency and protection of aquatic health, this exemption cannot be allowed. The Draft Provisions already provide the permitting authority discretion to reduce routine monitoring under specific circumstances. Therefore, if there is no reasonable potential, as determined by the RPA methods set forth in Section IV.B.2.c, the burden on permittees to ensure that their discharge is not toxic is minimal under the current Draft Provisions, but is necessary to ensure the protection of aquatic health. We request that section IV.B.2.k.iv be removed from the Draft Provisions. |
| **SC I.005** | Facilities enrolled in the statewide NPDES permit for drinking water discharges (Order WQ 2014-0194-DWQ) should be exempt from all of the implementation requirements stated in the Toxicity Provisions. |
| **SR I.005** | As stated in Section 5.7.6 of the Staff Report, discharges likely to be eligible for this exemption include those currently covered by the *Statewide NPDES Permit for Drinking Water System Discharges to Waters of the United States* (Order WQ 2014-0194-DWQ, General Order No. CAG140001). However, eligibility would be determined by the permitting authority (in this case, the State Water Board) at the time of the renewal of the general permit. To allow such an exemption the permitting authority must first make a finding that the discharger will have no reasonable potential to cause or contribute to an exceedance of the numeric aquatic toxicity water quality objectives, or that reasonable potential exists only due to discharges of chlorine and chlorine effluent limitations are included in the NPDES permit. The permitting authority has not yet made such a finding as the numeric toxicity water quality objectives included in the Toxicity Provisions were not in effect when the statewide drinking water NPDES permit was adopted. |
| 16.008 | 1. I. M. Drinking Water System Discharges (page 31): CVWD does not believe this analysis should be required for facilities enrolled in the statewide NPDES permit for drinking water discharges (Order WQ 2014-0194- DWQ). CVWD believes facilities enrolled in the statewide NPDES permit should be exempt from all of the implementation requirements stated in the Provisions. |

## Category J – Appendix J

| **Comment Code** | **Comment** |
| --- | --- |
| **SC J-1.001** | A test can be “truly non-toxic” and still result in a failure using the TST. A statistical “false positive” is not the same as a “false indication of toxicity.” Appendix J only addresses statistical false positives and does not address false indications of toxicity. Appendix J would be improved by clarifying that it does not report the probability of violating the MMEL or triggering a TRE based on incorrectly identifying samples as toxic. |
| **SR J-1.001** | The proposed distinction between "statistical false positives" and "false determinations of toxicity” is inaccurate. All determinations of toxicity based on WET testing are "statistical" because statistical analysis is necessary to determine whether a sample is toxic. Such analyses, including the No Observed Effect Concentration (NOEC) approach and the TST, build in a certain probability of errors (false positives and false negatives). Section J.2 of Appendix J states that “[a] false positive is when the IWC sample is declared toxic (fail) but the sample is in fact not toxic. In the TST statistical approach, the false positive probability is the probability of a fail occurring when the percent effect is at 10 percent or less.” This definition is consistent with the definition provided in the Glossary of the TST Technical Document. Therefore, no changes are being made to the definition.  The comment “false indications of toxicity” can only be used when referring to results of known non-toxic samples, not environmental samples. An environmental sample can never be found to be “truly non-toxic.” The Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule (U.S. EPA, 2002) explains that “[b]ecause toxicity is inherently defined by the measurement system (a ‘‘method-defined analyte’’), and toxicity cannot be independently measured apart from a toxicity test, accuracy as a performance characteristic is not completely applicable.”  Only blank samples that are prepared and tested using a rigorous scientific design can be assessed as truly non-toxic. U.S. EPA conducted a robust method variability study prior to promulgating the *C. dubia* chronic test method. This study included testing non-toxic “blank” samples. Please refer to the U.S. EPA publication “Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and Acute Whole Effluent Toxicity Test Methods, Vol. 1” (EPA 821-B-01-004) for more information.  The probability of declaring a sample toxic can be estimated using computational methods (e.g., computer simulations, mathematical “power” calculations), as described in Fox et al. 2019. These methods allow the user to input the desired values of percent effect, number of replicates used, and coefficient of variation (CV). Then, the probability of identifying a sample as toxic can be calculated. Some of these techniques may be used to estimate the probability of declaring toxicity using both the TST and the NOEC. If the percent effect is set to a value that is at or below the negligible effect level (10 percent effect), then these methods provide an estimate of the probability of “incorrectly identifying a sample as toxic.” This analysis was performed by Fox et al. (2019), and the results are presented in Appendix J.  Table J-5 and Figure J-2 give probabilities of declaring toxicity using the TST for various combinations of percent effect and CV. In this context, the percent effect and CV values refer to “true” values (i.e., parameters). The terms “parameter” and “parametric” refer to statistical values (e.g., mean, standard deviation) that apply to an entire population, rather than a sample. The “true mean” described in Section J.2 of Appendix J is also known as the parametric mean. Fox et al. 2019 (page 3) states that “[t]he term “percent effect” describes the percentage reduction in the biological measurement. This can refer either to the sample (observed) means or to the parameter values." Additionally, Fox et al. 2019 uses the term “true percent effect” to refer to the percent effect calculated from parametric means. To understand the information presented in Fox et al. 2019 and Appendix J, it is important to understand how these terms are used. In Fox et al. 2019 and Appendix J, when probabilities of declaring toxicity are presented, these probabilities were calculated based on parametric input values (please see SR J-3.002 for further discussion). For example, the MMEL violation probability analysis described in Section J.5 of Appendix J calculates the probability of violating the MMEL, for a given probability of declaring a sample toxic using the TST. The TST may result in a “fail" either because of high within-test variability or because of an actual effect on *C. dubia* reproduction (i.e. the test organisms exhibit reduced reproduction in the effluent, compared to the control).  Regarding the comment that the MMEL violation probability analysis described in Section J.5 of Appendix J addresses only “statistical false positives,” it is important to note that this analysis can be used to understand both within-test variability (by varying the median control CV) and effects on *C. dubia* reproduction (by varying the percent effect). Table J-5 provides probabilities of declaring toxicity (i.e. observing a TST “fail”) at various input values of control CV and percent effect. |
| 1.002 | CASA is also appreciative of the revisions made to improve the accuracy and clarity of the document, specifically the acknowledgement that a test can be “truly non-toxic” and still result in a failure using the Test of Significant Toxicity (TST) statistical approach. |
| 1.004 | A statistical “false positive” as described in the Appendix is not the same thing as a “false indication of toxicity.” The data in the Appendix only addresses the former and not the latter. This is an essential distinction. |
| 2.012 | Appendix J would be further improved by clarifying that the analysis does not report the probability of violating the MMEL or triggering a TRE based on the *C. dubia* test incorrectly identifying samples to be toxic (i.e., “fail”) that are known to be non-toxic. It would also be appropriate to describe the analysis currently in Appendix J as evaluating “statistical false positives.” This would avoid confusion with the similar concern that non-toxic samples are incorrectly identified as toxic. |
| 3.003 | 3. We support comments offered by CASA regarding the important difference between “false indications of toxicity” as opposed to “false positive” test results |
| 3.011 | **Comment No. 3 – We support comments offered by CASA regarding the important difference between “false indications of toxicity” as opposed to “false positive” test results**  In its comment letter, CASA has identified its primary and still unresolved concern: the frequency at which known non-toxic samples are identified as toxic.  CASA has highlighted the need to distinguish between “false positive” test results and “false determinations of toxicity”. In CASA’s words, a statistical “false positive” as described in Appendix J is not the same thing as a “false indication of toxicity” in non-toxic blank samples. CASA points out that the data in Appendix J only addresses the former, and not the latter. CVCWA supports the importance of this distinction and the need to address this issue in the upcoming *Ceriodaphnia dubia* study. |
| 8.013 | This Appendix would be further improved by clarifying that the analysis does not consider the potential for incorrectly determining a “fail” in samples that are known to be non-toxic. |
| **SC J-1.002** | CASA submitted a white paper highlighting concerns with false indications of toxicity in clearly non-toxic blank samples. |
| **SR J-1.002** | Please see SR J-1.001 for discussion of “statistical false positives” and “false indications of toxicity.” Only blank samples that are prepared and tested using rigorous scientific design can be assessed as truly non-toxic.  The State Water Board received comments from the public according to the State Water Board’s Notice of Opportunity to Comment (December 24, 2019). That notice stated that “[t]he State Water Board will accept input and recommendations on the content of the appendices through written comments. The State Water Board will also accept additional evidence directly related to the content of the appendices. Written comments and evidence unrelated to the content of the appendices, including comments on any of the actual language in the draft Toxicity Provisions, will not be accepted.” As a result, comments on the contents of the white paper submitted by CASA are outside the scope of the comments the State Water Board will accept for its consideration on Appendices J and K. However, the State Water Board provided a response to comments related to the CASA “white paper” in response “SR27.006” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 1.005 | CASA submitted a white paper to the Water Board and staff in 2019 entitled *Ceriodaphnia dubia Short-term Chronic Reproduction Test: Understanding the Probability of Incorrect Determinations of Toxicity in Non-toxic Samples*, which highlighted our concerns with false indications of toxicity in clearly non-toxic blank samples. |
| **SC J-1.003** | Appendix J is often vague as to whether statements apply to population versus sample level statistics or altogether non-statistical terms. The definition of a false positive in Appendix J is statistically based. There is a concern with false determinations of toxicity, where the observed effects in a known non-toxic sample are greater than the Regulatory Management Decision (RMD) of 25 percent. The commenter recommends clarification by using the term “statistical false positive” for the State Water Board’s “false positive.” |
| **SR J-1.003** | Section J-2 of Appendix J explains the difference between the terms “true mean” and “sample mean.”  See SR J-1.001 for a response to the proposed distinction between “statistical false positives” and “false determinations of toxicity.” |
| 1.010 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . .  Appendix J is often vague as to whether the statements being made apply to population versus sample level statistics or altogether non-statistical terms. The definition of a “false positive” in Appendix J is statistically based. However, CASA is more concerned with “false determinations of toxicity” where the observed effects in a known non-toxic sample are greater than the Regulatory Management Decision (RMD) of 25%. **We recommend clarification by using the term “statistical false positive” for the State Water Board’s “false positive” to distinguish between the two.** |
| **SC J-1.004** | Appendix J fails to recognize that the “true toxicity” of the samples used in the analysis was unknown. Consequently, these must be sample level statistics. However, this isn’t made clear, which could lead to the misinterpretation that these were truly non-toxic samples. |
| **SR J-1.004** | See SR J-1.001 for additional discussion of “true toxicity,” “false determinations of toxicity,” and statistics.  Appendix J did not evaluate method variability studies which assess truly non-toxic samples and if laboratory testing and use of the TST statistical approach lead to considering those samples to be toxic or non-toxic. As stated in SR J-1.001, the U.S. EPA conducted a robust method variability study prior to promulgating the *C. dubia* chronic test method. Please see “SR25.014” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for information on the low false positive rates (the percentage of test results that indicated toxicity in blank samples) from the U.S. EPA variability study.  Section J.4 of Appendix J states that “staff analyzed six data sets of actual test results using TST to evaluate how often a sample was declared toxic when the percent effect was 10 percent or less, and how often a sample was declared not toxic when the percent effect was 25 percent or greater.” Because the data sets consisted of *actual test results*, the term “true toxicity” is not applicable in the discussion and is not used. However, when referring to computer simulations and power calculations, like those described in the TST Technical Document and Fox et al. 2019, the term “true toxicity” is applicable because in these analyses, the “true” or parametric value of percent effect is known. |
| 1.011 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . .  Appendix J fails to recognize that the “true toxicity” of the samples used in this post-hoc analysis was unknown. Consequently, these must be sample level statistics. However, this isn’t made clear, which could lead to the misinterpretation that these were truly non-toxic samples. |
| **SC J-1.005** | The State Water Board’s work to establish the TST statistical approach statewide sets a consistent, actionable measure of toxicity. The TST statistical approach provides an unambiguous “pass” or “fail” measurement of a test concentration’s toxicity, and its low false positive and false negative rates provide increased statistical power to accurately identify a test concentration as either toxic or non-toxic which in turn, increases the confidence.  The commenter strongly supports the use of the TST statistical approach statewide to increase the precision of toxicity testing and to decrease the presence of false positives, which in turn will increase the overall confidence of toxicity testing throughout the state. |
| **SR J-1.005** | Comment noted. |
| 5.002 | **A. The use of the TST statistical approach increases test precision and decreases the likelihood of false positives.**  Toxicity testing in California has generally used the no-observed-effect concentration (NOEC) approach and TST statistical approach on an individual permit basis. Given that no statewide standard for the implementation of toxicity limitations has been clearly defined, Regional Water Boards have inconsistently established and monitored toxicity effluent limitations throughout the state. The State Water Board’s work to establish the TST statistical approach statewide sets a consistent, actionable measure of toxicity statewide. Importantly, the statistical approach provides an unambiguous “pass” or “fail” measurement of a test concentration’s toxicity, and its low false positive and false negative rates provide increased statistical power to accurately identify a test concentration as either toxic or non-toxic which in turn, increases the confidence of both those regulated by these provisions and the public in the results of toxicity testing.  Specifically, the NOEC is more likely to declare a sample toxic than the TST when within test variability and the percent effect is low. Meanwhile, when within test variability and the percent effect is high (i.e., greater than or equal to 25 percent), the NOEC is less likely to declare a sample toxic, while the TST will always declare the sample toxic, demonstrating the precision of the TST statistical approach. The TST further improves controls for false negatives and actually identifies occurrences of toxicity that may degrade California’s waterways. As described in the study of the City and County of Honolulu’s TST test drive:  “[T]oxic effects of effluents on *C. dubia* reproduction are difficult to detect with the NOEC approach because of the inherent within test variability of this chronic WET test. The alternative TST procedure controls false negatives and identifies toxicity that may have potential adverse environmental effects.”3  We strongly support the use of the TST statistical approach statewide to increase the precision of toxicity testing and to decrease the presence of false positives, which in turn will increase the overall confidence of toxicity testing throughout the state. |
| **SC J-1.006** | The Toxicity Provisions provide numerous safeguards against false positives, as seen by the low probability of an MMEL violation for tests at or below 10 percent effect. It is critical that all dischargers with an MMEL violation be required to conduct a TRE. |
| **SR J-1.006** | Comments regarding the support for the current TST statistical approach and the low probabilities of an exceedance of the MMEL based on false positive probabilities are noted.  Comments regarding a requirement that all dischargers with an MMEL violation conduct a TRE is outside the scope of the comments the State Water Board will accept for its consideration on Appendices J and K. However, please see Section 5.4.6 of the Staff Report for information on when a TRE is required. In addition, please see “SR10.002 from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a response to the comment that all dischargers with an MMEL violation should be required to conduct a TRE. |
| 5.004a | **The proposed Toxicity Provisions provide numerous safeguards against false positives, as seen by the low probability of an MMEL violation using the percent effect at or below 10.** |
| 5.005 | As is discussed and demonstrated by Dr. Fox, the probability of determining a single MMEL violation based on TST “fails” of *C. dubia* with a percent effect at or below 10 is very low. The probability of being required to conduct a TRE based on TST fails with a percent effect at or below 10 is even lower. Given the probability of receiving a MMEL violation using *C. dubia* and actually being required to conduct a TRE is extremely low, and that increasing replicates improves laboratory accuracy of chronic toxicity testing using *C. dubia* it is critical that all dischargers found with an MMEL violation actually be required to conduct a TRE even if a concurrent study is conducted alongside these Provisions to improve laboratory performance for chronic *C. dubia* toxicity testing in order to actually address discharges that are likely to be significant sources of toxicity.  Further, the proposed Toxicity Provisions provide a number of safeguards against poor samples and test interferences to protect dischargers from false positives. These include the use of Test Acceptability Criteria, which allow new tests to be conducted to determine compliance for those tests that do not meet the Test Acceptability Criteria, and discretion to use another test species when a discharger encounters unresolvable test interference or cannot secure a reliable supply of test organisms. Couple these safeguards with the inherent structure of the TST statistical approach and the MMEL compliance structure of the proposed Toxicity Provisions where a single fail does not constitute a violation, nor triggers a TRE the likelihood a discharger will be held responsible for an inaccurate test result is very low. |
| **SC J-1.007** | The use of *C. dubia* in the TST framework could result in false positive results. |
| **SR J-1.007** | Data presented in Appendix J demonstrate that California laboratories can execute the *C. dubia* reproduction WET test and achieve the precision that results in the TST statistical analysis achieving the acceptable false positive probability of 5 percent or less.  Please see SR J-1.001 for more information about non-toxic samples being declared toxic. |
| 6.003 | The second concern is regarding the use of *C. dubia* in the TST framework that could result in a false positive result (i.e., the effluent is categorized as toxic when it is not toxic). |
| **SC J-1.008** | Appendix J states that when the percent effect is 25 or greater, the TST always declares the sample to be toxic (fail). Therefore, the Appendix J should be revised to specify that when the percent effect is 10 percent or less, the TST should always declare the sample to be non-toxic (pass). |
| **SR J-1.008** | The development of the TST is described in the TST Technical Document.  The suggestion that all tests with a percent effect less than 10 be declared a “pass” is not consistent with how the TST was designed to assess the variability within the test results in determining toxicity. The percent effect is a simple mathematical calculation that does not incorporate within-test variability or number of replicates into the calculation and does not consider statistical probabilities.  As explained in Section 5.3.1 of the Staff Report and Section 1.3 the TST Technical Document, the TST statistical analysis incorporates established statistical principles to consider the probability that the true toxic effect exceeds the regulatory management decision (RMD), which is 20 percent for acute toxicity and 25 percent for chronic toxicity.  As shown in Fox et al. 2019 and discussed in Section J.3 of Appendix J, the probability of declaring toxicity is influenced by other factors besides just the percent effect observed in the test. Other factors include the number of replicates used and the within-test variability. Using solely a percent effect threshold to conclude whether a sample is toxic or non-toxic (e.g., declaring any sample with a percent effect less than 10 percent as non-toxic, as suggested by the commenter) would not provide the same level of confidence in the test result as the TST approach. Section 5.3.1 of the Staff Report explains that when using the TST, increasing the precision and test power (by increasing the number of replicates and/or decreasing the within-test variability) increases the chances of correctly rejecting the null hypothesis and declaring a sample non-toxic.  See Section 5.1.1 of the Staff Report for an explanation of RMDs and maximum allowable error rates. See Section 5.3.1 of the Staff Report for a discussion of the statistical approaches. |
| 6.029 | **7. Results from a Test of Significant Toxicity (TST) with a percent effect less than 10 percent should be explicitly considered a non-fail for compliance purposes**  LADWP has reviewed Draft Appendix J and has concerns regarding the language used to identify a sample as toxic.  Throughout Draft Appendix J, the SWRCB states that there was no result of a fail when the percent effect was 10 percent or less, and no result of a pass when the percent effect was 25 percent or greater. The SWRCB goes further by stating that when a sample's percent effect is greater than or equal to 25 percent, the TST will **always** declare the sample toxic. LADWP suggests that the converse should also be true, i.e., when a samples percent effect is 10 percent or less, the TST should **always** declare that the sample is not toxic. This is supported by the data provided by the SWRCB that "of the 984 California laboratory test results reviewed, there were no results of a fail when the effect was 10 percent or less ... "2 . By doing so, the SWRCB could provide a clearer understanding on what constitutes a fail under the TST, as well as reduce the possibility of a false positive occurring.  The LADWP requests that the SWRCB revise Draft Appendix J to make it clear that when the percent effect is 10 percent or less, the TST will always declare that the sample is not toxic. |
| **SC J-1.009** | The analysis presented in Appendix J underestimates “false positives” and underestimates the probability that false positives will result in MMEL violations or trigger a TRE. Appendix J incorporates invalid assumptions that result in the underestimations.  The Fox (2019) memo provides a list of assumptions and limitations of the analysis. The last qualifying statement by Fox (2019) identifies an additional approach for evaluating the potential for false positives using an upper percentile CV (like the 75th or 80th percentile) as “overly cautious.” On the contrary, such an approach would support the interpretation of these data by providing an upper bound on the probabilities. Doing so would make the analysis presented in Appendix J more robust instead of only presenting an overly optimistic analysis.  Data and equations in Fox (2019) can be used to calculate probabilities of MMEL violations and TREs due to false positives, based on CVs higher than those presented in the State Water Board’s Appendix J analysis. For example, testing with 10 replicates with a CV of 0.3 results in a 34 percent chance of a false positive in any single test and a 19 percent chance of an MMEL violation in a calendar month (Table 1a in Fox 2019). Likewise, the probability of triggering a TRE during a permit cycle is 48 percent when the chance of false positives causing an individual test “fail” is 25 percent (Table 2 in Fox 2019). These probabilities of an MMEL violation or triggering a TRE based on false positives are much higher than those indicated by State Water Board staff in Appendix J.  Figure J-2 of Appendix J shows that when the CV is 0.3 or greater, there is 45 percent probability that the NOEC will "fail" when effects less than 25 percent are observed. However, the TST is expected to fail in about 80 percent of all such tests. Therefore, the TST is far more likely to determine and mis-label an effect below the RMD as toxic.  The analysis also does not consider the potential for incorrectly determining a “fail” in samples that are known to be non-toxic. |
| **SR J-1.009** | In Appendix J, none of the California laboratories analyzed had a long-run median control CV as high as 0.3. This use of the “overly cautious” value for control CV would overestimate the probability of false positive results. For the eight laboratories listed in Table J-1, the highest median control CV value was 0.23. The median control CVs from the other seven laboratories ranged from 0.08 to 0.20. Therefore, based on the current performance of this sample of California laboratories, using a CV of 0.3 or greater is not expected to occur and would overestimate the probability of false positive results. High rates of MMEL violations or TREs based on false positive results are not expected to occur. Please see SR J-6.005 and SR J-3.002 for more information.  Additionally, as discussed in Appendix J, if a laboratory had a long-run median control CV of 0.3 or higher, they could either increase their replicates or improve laboratory practices to increase the statistical power of the analysis and achieve the acceptable false positive probability of 5 percent.  See SR J-1.001 for a response to the comment that Appendix J does not consider the potential for incorrectly determining a “fail” in samples that are known to be non-toxic. |
| 2.002 | Supporting documentation for Appendix J, including statistical assumptions and qualifiers for the use of median CVs in the analysis, is presented in Fox (2019). The author’s statements recognize the following limitations to the analyses:  …  4. “A cautious (perhaps overly cautious) approach would be to calculate an upper percentile (like the 75th or 80th percentile) of 10-20 values for the CVs of control and RWC, using the larger of the percentiles.”  This last qualifying statement by Fox (2019) identifies an approach for evaluating the potential for false positives using an upper percentile CV as “overly cautious.” On the contrary, such an approach would support the interpretation of these data by providing an upper bound to the probabilities. Presenting probabilities based on the range of observed CVs would make the analysis presented in Appendix J more robust. |
| 8.003 | This document describes how laboratory performance (i.e., within-lab test variability) with *Ceriodaphnia dubia* chronic bioassays affects toxicity determinations using the Test of Significant Toxicity (TST) and the No Observed Effect Concentrations (NOEC). It also estimates the probability of “false positives” (defined by the State Water Board as a “Fail” when the % effect is =10%) causing Median Monthly Effluent Limit (MMEL) violations or triggering a Toxicity Reduction Evaluation (TRE) according to the draft Provisions using the TST. The comments below support requests for Appendix J to be revised to clarify that the analysis presented underestimates “false positives”, as defined, and that it does not consider the potential for incorrectly determining a “fail” in samples that are known to be non-toxic. |
| 8.004 | Comment 1: The analysis in Appendix J underestimates the probability that false positives will result in MMEL violations or trigger a TRE. This appendix provides useful descriptions of the within-laboratory variability associated with chronic *C. dubia* whole effluent toxicity (WET) tests and differences between the NOEC and TST statistics. The extent to which additional replicates reduce the probability of a false positive is also presented in detail. However, the analysis incorporates invalid assumptions that result in an underestimation of the probability that false positives will cause MMEL violations or trigger a TRE. |
| 8.006 | Fox (2019), which provides supporting documentation for the analyses presented in Appendix J, states several assumptions and limitations for this analysis that include the following:  “…(e.g., the standard deviation of the sublethal endpoint was the same for IWC and Control) and should not be considered exact for actual WET tests.”  “…achieved probabilities of these events may differ from calculated estimates of probabilities when (a) probabilities are small, (b) replicate data are not well approximated by the normal distribution, (c) other assumptions do not match behavior of real data.”  “…CV values estimated from WET-test data will differ from the true, parametric value.”  “A cautious (perhaps overly cautious) approach would be to calculate an upper percentile (like the 75th or 80th percentile) of 10-20 values for the CVs of control and RWC, using the larger of the percentiles.”  This last qualifying statement by Fox (2019) identifies an additional approach for evaluating the potential for false positives using an upper percentile CV as “overly cautious”. On the contrary, such an approach would support the interpretation of these data by providing an upper bound on the probabilities. Doing so would make the analysis presented in Appendix J more robust instead of only presenting an overly optimistic analysis.  Data and equations in Fox (2019) can be used to calculate probabilities of MMEL violations and TREs due to false positives, based on CVs higher than those presented in the State Water Board’s Appendix J analysis. For example, testing with 10 replicates with a CV of 0.3 results in a 34 percent chance of a false positive in any single test and a 19 percent chance of an MMEL violation in a calendar month (Table 1a in Fox 2019). Likewise, the probability of triggering a TRE during a permit cycle is 48 percent when the chance of false positives causing an individual test “fail” is 25 percent (Table 2 in Fox 2019). These probabilities of an MMEL violation or triggering a TRE based on false positives are much higher than those indicated by State Water Board staff in Appendix J. |
| 9.005 | Figure J-2 on page 4 of Appendix J shows that, when the CV=0.2 there is a 10% chance that the TST procedure will declare effects greater than 10% to be toxic. The same figure reveals that, when the CV is 0.3, there is a 35% probability that the TST procedure would declare any effect larger than 10% as toxic regardless of whether the result was due to natural background variability or caused by the actual presence of toxic pollutants in the effluent sample. Given the level of natural background variability, the NOEC was expected to have a  [Note: The remaining portion of the comment was not provided in the comment letter.] |
| 9.006 | The proposed Toxicity Control Policy established the Regulatory Management Decision (RMD) threshold as a 25% inhibition effect. That is, effect greater than or equal to 25% is considered unacceptable toxicity. The data presented in Figure J-2 of Appendix J shows that, when the CV is 0.3 or greater, there is 45% probability that the NOEC "fail" when effects less than 25% are observed. However, the TST is expected to fail in about 80% of all such tests. Therefore, the TST is far more likely to determine and mis-label an effect BELOW the RMD as toxic. |
| **SC J-1.010** | Laboratories conducting toxicity tests on known non-toxic samples seem to identify large effects at an unacceptably high frequency. Experimental data collected by SCCWRP (2016), Moore and Moore (2013), and Moore et al. (2000) indicate that non-toxic samples are incorrectly identified as toxic at a higher frequency (i.e. 15 to 57 percent) than was determined by the analysis of “false positives” in Appendix J. These studies that convey *C. dubia* test data on laboratory dilution waters indicate a high proportion of instances falsely identifying non-toxic samples as toxic. The probabilities are thus high for triggering TREs or violating MMELs due to falsely identifying non-toxic samples as toxic using the chronic *C. dubia* test.  Based on the same calculations used in Appendix J, from the Fox (2019) memo, the probability of incorrectly determining chronic toxicity to *C. dubia* in a non-toxic sample (ranging from 29 to 57 percent in an individual test) indicates a 14 to 47 percent chance of an MMEL violation in a calendar month and a 100 percent chance of a TRE based on incorrect conclusions of toxicity over 60 months.  These results indicate that the *C. dubia* chronic WET tests can show effects in non-toxic samples. These data, therefore, identify the need for caution in using chronic *C. dubia* WET tests to evaluate numeric effluent limits for toxicity and they support the need for a study, as discussed at several of the State Water Board staff workshops in 2019 and the October 2019 Board Workshop. |
| **SR J-1.010** | State Water Board staff were unable to obtain the Moore and Moore (2013) document cited in comment 8.008. Commenters did not provide the information necessary in order to respond.  The other two cited documents (SCCWRP 2016 and Moore et al. 2000) describe studies that included known, non-toxic "blank" samples. The State Water Board provided a response to the concerns based on data from the SCCWRP (2016) study in response “SR27.006” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  The data in the Moore et al. 2000 study was collected from WET tests conducted in 1997 by laboratories conducting different WET test procedures than those used in the U.S. EPA Variability Study (2000) and the final promulgated WET test methods manuals (2002). Therefore, the results from the Moore et al. 2000 study do not contradict the findings presented in Appendix J.  Besides the different test procedures, the Moore et al. 2000 study had only 14 valid test results from 14 laboratories, while the U.S. EPA Variability Study had over 700 samples from 55 laboratories. Finally, the false positive rate of “non-toxic blank samples” in the Moore et al. 2000 study was much higher than the failure rate typically observed in actual effluent tests, which casts doubt on the validity of the study. Please see SR J-1.011 for more information about the U.S. EPA Variability Study.  The results presented in Moore et al. 2000 are not consistent with the results presented in more recent publications, such as Fox et al. 2019 and Appendix J, which examined laboratory performance approximately 20 years after the data presented in Moore et al. 2000 was collected.  For these reasons, calculations of probabilities of MMEL violations and TREs based on data presented in Moore et al. 2000 are likely not as representative or reliable as those presented in Fox et al. 2019 and Appendix J.  Regarding the statement that Appendix J does not address the primary and still unresolved concern (expressed in comment 1.003) about the frequency at which known non-toxic samples are identified as toxic, please see SR J-1.001 and SR J-1.011, which discuss the U.S. EPA Variability Study (which used known non-toxic samples) in further detail.  Additionally, Fox et al. 2019 provides an analysis of the probability that non-toxic samples may be identified as toxic based on the laboratory control CVs.  The chronic *C. dubia* reproduction toxicity test is a valid test method and has withstood legal challenges. For more information, please see responses “SR25.007” and “SR25.029” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). Regarding comments about the *C. dubia* study, please see SR L.005 through SR L.011. |
| 1.003 | Unfortunately, the Appendix does nothing to address or alleviate our primary and still unresolved concern: the frequency at which known non-toxic samples are identified as toxic. |
| 1.007 | Moreover, the occurrences of statistical false positives that can be ameliorated through careful laboratory controls on within test variability as described in Appendix J do not appear to be related to actual false indications of toxicity in non-toxic blank samples. Instead, a significant proportion of laboratories conducting toxicity tests on these known non-toxic samples seem to identify unacceptably large effects (>25%) at an unacceptably high frequency. |
| 2.005 | Comment 2. The analysis approach in Appendix J can be used to help consider a key stakeholder concern that heretofore has not been addressed by the Toxicity Provisions— the probability that MMEL violations will occur due to the chronic *C. dubia* test incorrectly identifying non-toxic samples as being toxic. The analysis in Appendix J presents a purely statistical approach to determine the probability of “false positive” toxicity results for *C. dubia*. This approach does not account for any incorrect determinations of toxicity in samples known to be non-toxic, such as demonstrated by inter-laboratory comparison studies where up to 60 percent effects to *C. dubia* reproduction were reported for dilution water (i.e., lab control waters; SCCWRP 2016). Experimental data collected by SCCWRP (2016), Moore and Moore (2013), and Moore et al. (2000) indicate that non-toxic lab water is incorrectly identified as toxic at a higher frequency (i.e. 15 to 57 percent) than the frequency/probability that a statistical “false positive” would occur according to the analysis in Appendix J.  Data describing the frequency of the TST determining a “Fail” in samples that are known to be non-toxic are presented in **Table 1** to provide a realistic probability that an MMEL violation or TRE would be triggered by non-toxic samples being incorrectly determined to be toxic using the chronic *C. dubia* test.  [See Table 1 on page 4 of Comment Letter #2] |
| 2.006 | SCCWRP (2016) conducted a blind inter-laboratory  study where non-toxic dilution water was sent to several toxicity laboratories in California for WET testing. These data were not evaluated with the TST. However, samples caused =25 percent reduction in *C. dubia* reproduction in four of seven tests (57 percent) in their first round of testing, and in two of seven tests (29 percent) in their second round of tests. All of the samples causing =25 percent effect would have resulted in a “fail” with the TST. Based on the same calculations used in Appendix J, as clarified in the Fox (2019) memo, the proportion of non-toxic blank samples from SCCWRP (2017) can be used to calculate the probability of an MMEL violation or triggering a TRE. Assuming an individual test failure rate of 29 to 57 percent for laboratory dilution waters, the probability of an MMEL violation is 14 to 47 percent for a given calendar month and the probability of triggering a TRE is 100 percent over a 60-month period. |
| 2.008 | A third analysis of *C. dubia* WET test data for samples known to be nontoxic considers valid results from 16 blank samples analyzed by multiple laboratories (Moore and Moore 2000).  These data were not evaluated with the TST. However, *C. dubia* reproduction was reduced by at least 25%, which the TST would determine to be a “Fail,” in five samples. Using the proportion of blank samples that failed the TST in this study (5 of 16; 31 percent), there is a 16 percent probability of *C. dubia* chronic WET testing causing an MMEL violation in any given month and a 100 percent probability of triggering a TRE over 60 months. |
| 2.009 | In summary, the three aforementioned studies that convey *C. dubia* test data on laboratory dilution waters indicates a high proportion of instances falsely identifying non-toxic samples as toxic. The probabilities are thus high for triggering TREs or violating MMELs due to falsely identifying non-toxic samples as toxic using the chronic *C. dubia* test. |
| 2.010 | Discussing these data was not intended to be critical of the TST because the known non-toxic samples were also found to show significant effects based on the NOEC. Rather, these results indicate that the *C. dubia* chronic WET test can show effects for non-toxic samples. Appendix J, provides a useful tool that helps identify the need for caution in using chronic *C. dubia* WET tests to evaluate numeric effluent limits for toxicity by quantifying the probability of MMEL violations or triggering a TRE based on incorrectly identifying a non-toxic samples as toxic. This supports the need for a *C. dubia* study, as discussed at several of the State Water Board staff workshops in 2019 and the October 2019 Board workshop. |
| 8.008 | Comment 2: The analysis does not account for incorrect identifications of non-toxic samples as toxic.  The analysis in Appendix J presents a purely statistical approach to determine the probability of “false positive” toxicity results (defined as a “Fail” according to the TST or NOEC when there is =10 percent effect) for *C. dubia*. This approach does not account for any incorrect determinations of toxicity in samples known to be non-toxic – such as demonstrated by interlaboratory comparison studies where up to 60 percent effects were reported for dilution water (SCCWRP 2016). Experimental data collected by SCCWRP (2016), Moore and Moore (2013), and Moore et al. (2000) indicate that non-toxic samples are incorrectly identified as toxic at a higher frequency (i.e. 15 to 57 percent) than was determined by the analysis of “false positives” in Appendix J.  Data describing the frequency of the TST determining a “Fail” in samples that are known to be non-toxic are presented below in Table 1 to provide a realistic probability that an MMEL violation or TRE would be triggered by such non-toxic samples. SCCWRP (2016) conducted a blind interlaboratory study where non-toxic dilution water was sent to several toxicity laboratories in California for WET testing. These data were not evaluated with the TST. However, samples caused =25 percent reduction in *C. dubia* reproduction relative to a laboratory control in 4 of 7 tests (57 percent) in round 1, and in 2 of 7 tests (29 percent) in round 2, which the TST would conclude to be a “Fail.” Based on the same calculations used in Appendix J, from the Fox (2019) memo, the probability of incorrectly determining chronic toxicity to *C. dubia* in a non-toxic sample (ranging from 29 to 57 percent in an individual test) indicates a 14 to 47 percent chance of an MMEL violation in a calendar month and a 100 percent chance of a TRE based on incorrect conclusions of toxicity over 60 months.  [Please see Table 1 on page 5 of comment letter #8] |
| 2.007  8.009 | Moore and Moore (2013) re-analyzed toxicity results from a blank study USEPA (2001) conducted to validate the use of the NOEC and 25 percent inhibition concentration (IC25) statistics for evaluating WET data. *C. dubia* reproduction data reevaluated by the authors using the TST which incorrectly concluded a “Fail” for 14.8 percent of these non-toxic blank samples. This probability of incorrect determinations of toxicity would result in a 4 percent chance of an MMEL violation in non-toxic samples and a 9 percent chance of incorrectly triggering a TRE over 60 months. |
| 8.010 | A third analysis of *C. dubia* WET test data for samples known to be non-toxic considers valid results from 16 blank samples analyzed by multiple laboratories (Moore and Moore 2000). These data were not evaluated with the TST. However, there were 5 samples where *C. dubia* reproduction was reduced by at least 25%, which the TST would determine to be a “Fail”. These data indicate a 21 percent chance of *C. dubia* chronic WET testing causing an MMEL violation in any given month and a 100 percent chance of triggering a TRE based on non-toxic samples over a 60 month permit term. |
| 8.011 | Recommendation:  These results indicate that the *C. dubia* chronic WET tests can show effects in non-toxic samples. These data, therefore, identify the need for caution in using chronic *C. dubia* WET tests to evaluate numeric effluent limits for toxicity and they support the need for a study, as discussed at several of the State Water Board staff workshops in 2019 and the October 2019 Board Workshop. Regional San supports the State Water Board’s commitment to developing such a study and looks forward to working with the State Water Board on this effort. |
| **SC J-1.011** | Appendix J continues to assume that only effects smaller than 10 percent should be considered potential false positives. The relevant regulatory question is not how often the TST will "fail" with less than a 10 percent effect but, rather, what is the probability that the TST will "fail" due to a random natural biological fluctuation of any magnitude. Since random biological fluctuations larger than plus or minus 10 percent are expected to occur naturally, there is a mathematically predictable chance that they can result in false positives using the TST procedure.  Under the TST approach, the risk of declaring a non-toxic sample to be toxic is 3-4 times higher than when using the NOEC (15-20 percent vs. 5 percent, respectively). |
| **SR J-1.011** | The *C. dubia* WET test method was evaluated in the U.S. EPA 2001 Variability Study. This study utilized known non-toxic “blank” samples to determine the inherent variability that would be found in execution of the method. The study concluded that known non-toxic blank samples were identified as toxic using the chronic *C. dubia* test at a rate of less than 5 percent (based on the recommended 0.05 alpha level for hypothesis testing). The variability observed could be due to the variability in organism population response to the blank sample, or due to the consistency of methods and procedures as executed by the specific laboratory and its staff. Please see response “SR25.029” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for additional information on within-test variability. Please see responses “SR25.014” and “SR27.006” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for further discussion of U.S. EPA’s Interlaboratory Variability Study.  As explained in the TST Technical Document and summarized in Table 5-1 in Section 5.3.1 of the Staff Report, when using the TST, a 10 percent effect level should be declared non-toxic at least 95 percent of the time.  Fox et al. 2019 performed thousands of simulated WET tests, and analyzed the data using both the TST and the NOEC. The results from these tests (presented in Figure J-2 of Appendix J) contradict the statement that the TST has a 3-4 times higher risk of declaring a non-toxic sample to be toxic, compared to the NOEC. Based on Figure J-2, this statement is only true when the laboratory has a long-run median control CV of approximately 0.4 or higher and is using only the method-required minimum number of replicates. As explained in SR J-1.009, none of the California laboratories analyzed in Appendix J had a long-run median control CV as high as 0.4. Therefore, no laboratories in California would be expected to identify toxicity in known non-toxic samples using TST at a rate 3-4 times higher than when using the NOEC to analyze the same test data. In addition, Figure J-2 shows that when the long-run median control CV is approximately 0.2 or less, the TST has a lower probability than the NOEC of declaring a non-toxic sample to be toxic, even with the minimum number of replicates.  Appendix J acknowledges that with higher long-run control CV values, the TST is more likely to declare toxicity at lower percent effect levels. However, Appendix J also presents actual test results where current laboratory performance, as measured by median control CV, is reflected in TST test results with no TST “fails” below the observed effect of 10 percent.  Section 5.3.1 of the Staff Report explains how the TST provides an incentive to produce high-quality data. Please see SR J-6.001 for further discussion.  For a response to the comment about TST "fails" due to random natural biological fluctuations of any magnitude, please see SR J-3.003.  Please see response “SR27.006” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for further discussion of TST error rates. |
| 9.003 | For stakeholders, the relevant regulatory question is not how often the TST will "fail" with less than a 10% effect but, rather, what is the probability that the TST will "fail" due to a random natural biological fluctuation of any magnitude. The fact that effects greater than 10% can occur by chance is now recognized by recent revisions to the definition of "false positive" on page 3 of Appendix J. Nevertheless, all of the other TST performance analysis presented in the text, tables and graphs of Appendix J continues to assume that only effects smaller than 10% should be considered potential false positives. |
| 9.004 | Since random biological fluctuations larger than plus or minus 10% are also expected to occur naturally, there is also a mathematically predictable chance that they can result in false positives using the TST procedure. This can also occur when using the NOEC; however the NOEC deliberately restricts the probability to only 5% of all tests. The risk is much greater for the TST because reversing the null hypothesis does not change the probability of a Type-II error (inaccurate failure to reject a reject the null). If the natural background variability results in a was a 15-20% probability of Type-II error using the NOEC, there will be the same risk of Type-II error using the TST. Thus, under the TST approach, the risk of declaring a non-toxic sample to be toxic is 3-4 times higher than when using the NOEC (15-20% vs. 5%, respectively). |
| **SC J-1.012** | The TST does not produce an unambiguous answer to the regulatory question of whether a sample is toxic or not. It merely alters the procedure for resolving such ambiguity when it occurs. By reversing the null hypothesis under the TST, increasing statistical uncertainty increases the probability that a sample will be declared toxic even when the actual percent effect observed during the test is less than the RMD.  Because U.S. EPA’s point-estimation method (i.e. IC25) does not rely on statistical hypothesis testing, it is not subject to the same ambiguity and uncertainty as the TST.  When all of these factors regarding natural background variability and statistical sensitivity are considered concurrently, overall the TST procedure is more than twice as likely to fail than is the NOEC method when both are used to evaluate the same set of data from known non-toxic samples. |
| **SR J-1.012** | Section 5.3.1 of the Staff Report explains that the TST approach uses two-concentration data analysis where the IWC is compared to a control concentration, to provide a clear and transparent pass/fail answer to the question, “Is the sample toxic?” This section also explains that the TST incorporates both false positive and false negative rates, which increases the confidence that correct determinations are made. Regarding statistical uncertainty and the “restated” null hypothesis, please see SR J-3.008.  Please see Section 5.3.1 of the Staff Report and SR J-1.013 for further discussion of the point estimate approach. Additionally, please see responses “SR25.003,” “SR25.012,” “SR25.015,” and “SR25.037” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  The statement that “the TST procedure is more than twice as likely to fail than the NOEC method when both are used to evaluate the same set of data from known non-toxic samples” is not supported by the data and analysis presented in Fox et al. 2019, the Fox 2019 Memorandum, and Appendix J. Figure J-2 shows that the TST is more likely than the NOEC to declare toxicity in known non-toxic samples *only* when the median control CV is relatively high (greater than approximately 0.3) and when the method-required minimum number of replicates are used. Recent data from a sample of California laboratories indicates that no laboratory has a long-run median control CV as high as 0.3. Therefore, California laboratories would be expected to declare toxicity in non-toxic samples using the TST at a rate less than or equal to the rate that would be observed using the NOEC. Evidence has not been presented to find otherwise. Please see SR J-1.009 and SR J-1.011 for further discussion. |
| 9.007 | Thus, contrary to the discussion in the proposed policy documents, the TST does not produce an unambiguous answer to the regulatory question of whether a sample is toxic or not. It merely alters the procedure for resolving such ambiguity when it occurs. When natural biological variability is relatively high, the lack of statistical certainty weighs against a finding of non-compliant toxicity in the effluent when using the NOEC approach. However, by reversing the null hypothesis under the TST, increasing statistical uncertainty increases the probability that a sample will be declared toxic even when the actual Percent Effect observed during the test is LESS than the 25% RMD threshold specified by the proposed policy. It should be noted that, because EPA’s point-estimation method (i.e. IC25) does not rely on statistical hypothesis testing, it is not subject to the same ambiguity and uncertainty. When the Percent Effect is >25%, the IC25 declares the sample toxic and when the Percent Effect is <25%, the IC25 declares the sample non-toxic. |
| 9.008 | When all of these factors regarding natural background variability and statistical sensitivity are considered concurrently, overall the TST procedure is more than twice as likely to fail than is the NOEC method when both are used to evaluate the same set of data from known non-toxic samples. This has been conclusively demonstrated by using the TST procedure to evaluate data produced from WET tests performed on non-toxic method blanks (an approach conceptually similar to that used to develop MDLs for chemical methods) and by Monte Carlo simulation studies using data gathered from non-toxic control groups to characterize and parameterize the natural biological variability intrinsic to *Ceriodaphnia dubia* reproduction. |
| **SC J-1.013** | Appendix J states that the TST will always declare a sample as toxic when the percent effect is 25 percent. The IC25, which is the preferred endpoint, by the WET test methods manual for assessing compliance with WET limits, will always do the same. The authors of Appendix J also state that none of the tests that exhibit less than a 10 percent effect failed the TST procedure. They omitted the fact that the IC25 will always declare a sample as toxic when the percent effect is greater than 25 percent and will always declare a sample as non-toxic when the percent effect is less than 25 percent. The IC25 will always perform better than the NOEC and TST. The Toxicity Provisions should substitute the IC25 for the TST. |
| **SR J-1.013** | Appendix J does not include a discussion of point estimate approaches, such as the IC25, for several reasons. First, the hypothesis test and point estimate (e.g. IC25) test answer different questions. The hypothesis test answers the question “is the sample toxic?” whereas the point estimate test answers the question “at what concentration is the sample toxic?” For purposes of compliance with the NPDES regulatory program, the hypothesis test, particularly the TST approach, is able to determine if the discharge impacts aquatic life uses and exceeds standards.  Second, the IC25 statistical approach results are not directly comparable to the hypothesis test-based statistical approaches. The IC25 approach is based strictly on a calculated percent effect. Section 5.3.1 of the Staff Report explains that because the U.S. EPA methods manuals do not require the inclusion of confidence intervals and state permits do not require the additional calculation of confidence intervals, there is no statistical confidence and reliability in the calculated point estimate value. While point estimate models could incorporate confidence intervals, it would be time consuming, costly, and require additional peer review.  Additionally, the IC25 approach provides no confidence in the test result since the within-test variability is not assessed. The TST incorporates the variability of the data into the calculations and is designed to control the false negative and false positive probabilities.  Please see SR J-6.007 for a discussion of the TST results when the percent effect is between 10 and 25. Please see Section 5.3.1 of the Staff Report for further discussion of the point estimate approach. Additionally, please see responses “SR25.003,” “SR25.012,” “SR25.015,” and “SR25.037” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 9.014 | The same first finding on page 1 also states that the TST will always declare a sample as toxic when the Percent Effect is greater than 25%. However, the discussion omits the fact that the IC25 will do the same. The WET test method manual promulgated by EPA pursuant to 40 CFR Part 136 explicitly recommends that point estimation techniques, like the IC25, are the preferred endpoint for use in assessing compliance with WET limits in NPDES permits. |
| 9.016 | The authors of Appendix J state that none of the tests that exhibited less than a 10% effect failed the TST procedure. They omitted the fact that all of these same  tests would have passed using EPA's preferred IC25 procedure as well. In fact, only the IC25 procedure produced a perfect record of always declaring a sample  toxic when the Percent Effect was greater than the 25% RMD and always declaring a sample as not toxic when the Percent Effect was less than the 25% RMD. For that reason, the IC25 performed better than both the NOEC and the TST. It is unclear why the IC25 is all but totally ignored in Appendix J (just as it previously was in Appendix A & Appendix B). The SWRCB should consider substituting the promulgated IC25 method in lieu of relying of the TST approach that has never been promulgated. Doing so would eliminate many of concerns and objections to the proposed Toxicity Provisions that have been raised by stakeholders throughout the state. |
| **SC J-1.014** | There is only one way to accurately estimate the true rate of false positives using the three different endpoints (i.e. NOEC, IC25 and TST). The methods must be evaluated using non-toxic blanks. This can be accomplished by submitting synthetic control waters for lab testing using a blind study design, or Monte Carlo simulation techniques can be used. |
| **SR J-1.014** | U.S. EPA conducted a robust method variability study prior to promulgating the *C. dubia* chronic test method. This study included testing non-toxic “blank” samples. Please see SR J-1.001 for further discussion.  In addition to performing a “blank” study, there are other methods available to estimate the false positive error rates of the statistical approaches when used to analyze data from the *C. dubia* chronic toxicity test. Fox et al. 2019 used three different methods to estimate the false positive rate of the TST.  The Monte Carlo simulation suggested by comment 9.019 has already been conducted and is described in Fox et al. 2019. Figure 1 of Fox et al. 2019 demonstrates that the results from this resampling approach align closely with other techniques that were used in the Fox et al. 2019 study to estimate false positive rates with the TST. |
| 9.019 | There is only one way to accurately estimate the true rate of false positives using the three different endpoints (i.e. NOEC, IC25 and TST). The methods must be evaluated using non-toxic method blanks. This can be accomplished by submitting synthetic control waters for lab testing using a blind study design. Or, Monte Carlo simulation techniques can be used to re-sample control data gathered from a large number of WET testing labs to characterize the natural background variability for *Ceriodaphnia dubia* reproduction under known non-toxic conditions. It is absolutely essential that State Board staff conduct such studies for themselves in order to thoroughly and objectively stress test the proposed methods on known non-toxic samples before relying on them in a regulatory context. |
| **SC J-2.001** | The simulations performed by Fox et al. assume that each test is independent. It is unclear whether this is accurate in practice. Downturns in culture are often not identified until tests are concluded and can take weeks to recover from. Poor culture health tends to be reflected in poor test performance and are often observed in clusters, as opposed to randomly distributed. If a false determination of toxicity is made in one test and it is caused or exacerbated by poor culture health, it would be expected to occur in multiple tests initiated concurrently and/or within several days of each other, and which may have no relation to “toxicity.” |
| **SR J-2.001** | Each WET test execution and subsequent statistical analysis is independent of each other, regardless of culture health.  The risk of false positives for the *C. dubia* test is influenced primarily by variance of reproduction among replicate containers (among-replicates variance). The TST incorporates the analysis of variability when determining if there is a significant difference in organism response between the control replicates and the IWC replicates. Culture health may influence this variability, but also other aspects of test execution can affect variability.  *C. dubia* culture health is an important aspect of meeting the test acceptability criteria (TAC) for each test and is the focus of stringent quality assurance (QA) procedures for each laboratory. The U.S. EPA methods manuals provide specific procedures for rearing and using *C. dubia* as a test species. Individuals from the same culture are used for both the control and IWC treatments. Therefore, the health condition of individuals in both treatments is the same, and the test is used to determine if there is a significant effect from exposure to the IWC.  If the test results met the TAC (e.g., number of broods, number of individuals surviving in the control treatment) for the method, then the results are valid and can be analyzed using the TST to determine if there is a significant difference between the control and the IWC treatments.  If a laboratory is unable to meet TAC for the WET test, then that test is invalid, and results cannot be used. In that case, the laboratory immediately assesses which component of test execution might have led to the rejection of the test, including the health of the test organisms. An assessment of the variability between replicates also provides additional information.  The commenter does not provide evidence regarding the frequency of poor culture health leading to increased variability and clustered poor test performance. If poor culture health is reflected in poor test performance, then this would be reflected in the laboratory’s control charts. Control charts are described in Section 4.16 of the document entitled “Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms; 4th Edition” (U.S. EPA 2002). If a laboratory identifies that a culture downturn is occurring and is the cause of increased variability, they could temporarily increase the number of replicates.  Regarding the long-run median control CVs presented in Fox et al. 2019 and in Appendix J, these were measured over a period of several years. Any culture downturns that may have occurred during this time period are included in the data set and were included in the calculation of the median CV values. An analysis of the few occurrences in facilities regulated by the Los Angeles Regional Water Quality Control Board of actual determinations of three sequential toxicity fails showed percent effects rarely below 20 percent, and therefore the probability of a false positive was extremely low.  Finally, the comment “false determination of toxicity” can only be used when referring to results of known non-toxic samples, not environmental samples. An environmental sample can never be found to be “truly non-toxic.” Please see SR J-1.001 for more information. |
| 1.015 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . .  The simulations performed by Fox *et al*. assume that each test is independent (i.e., the likelihood of misidentifying toxicity in one test has no impact on future tests). While this is true statistically, it is unclear whether this is accurate in practice. Downturns in culture happen to every lab. These dips are often not identified until tests are concluded and can take weeks to recover from. Poor culture health tends to be reflected in poor test performance (e.g., high CVs and lower than normal control reproduction) and are often observed in clusters, as opposed to randomly distributed. If a false determination of toxicity is made in one test and it is caused or exacerbated by poor culture health, it would be expected to occur in multiple tests initiated concurrently and/or within several days of each other, and which may have no relation to “toxicity.” |
| **SC J-3.001** | The statistical findings made by State Water Board staff in Appendix J appear to be accurate. |
| **SR J-3.001** | Comment noted. |
| 1.001 | CASA has reviewed Appendix J and the statistical findings made by State Water Board staff in Appendix J appear to be accurate. |
| **SC J-3.002** | The probabilities of MMEL violations and triggering a TRE based on false positives are much higher than those indicated in Appendix J. As a result of relying solely on the median coefficient of variation (CV) for these calculations, Appendix J likely underestimates the probability of MMEL violations and triggering TREs.  Appendix J relies upon long-term medians of within-test variability using the control treatments’ CV. However, the assumption that a CV, describing variability among control replicates within a test, will be the same for every test is unrealistic and underestimates the frequency of multiple false positives causing MMEL violations or triggering a TRE. Half of a laboratory’s tests had higher CVs than the median, and the corresponding number of additional replicates to achieve an acceptable statistical false positive rate will often be much higher. The end result of this underestimation of additional replicates may be significantly higher efforts and costs to achieve compliance.  CVs vary among WET tests due to many possible factors (e.g., organism health, food quality, etc.) and higher values will result in higher probabilities of MMEL violations and triggering TREs than those presented in Appendix J.  Laboratory data demonstrate that all laboratories can have high CVs for individual tests regardless of the median CV they achieve. The analysis would be less likely to underestimate the potential occurrences of false positives by analyzing a range of CVs that could occur in tests.  It would also improve transparency in the interpretation of these results to present the range of CVs reported by laboratories in each row of Tables J-1, J-2, and J-3.  Appendix J should be revised to:   1. Describe assumptions inherent in this statistical analysis in the main body of Appendix J, rather than in a referenced memo. 2. Clarify that the analysis underestimates the potential for “false positives” because CVs for many individual WET tests will be greater than the median CV used in the analysis; and 3. Consider an analysis that includes a range of CVs that could occur in tests (e.g., using a Monte Carlo simulation where CVs are generated from a frequency distribution for each test iteration in the analysis; or present false positive probabilities based on CVs that range up to 0.49). |
| **SR J-3.002** | The statistical analysis presented in Appendix J does not underestimate the potential for false positive results. The analysis does not assume that a CV, describing variability among control replicates within a test, will be the same for every test. Fox et al. 2019 explains that the control CV values used in the simulated WET tests are parameters, not observed values. Each simulated WET test had a specific, individual control CV for each test (calculated from the mean and standard deviation of the control replicates). This value was usually not exactly equal to the parameter value, because each test was simulated by randomly sampling values from a normal distribution representing the number of neonates likely to be produced in a single control replicate in a real WET test. This random drawing from the normal distribution explains why not all simulated tests have a test-specific control CV that is equal to the control CV parameter value. The parameter value is analogous to a laboratory’s long-run median control CV, while the CV for each individual simulated test is analogous to the test-specific CV that can be calculated for a real WET test. In this manner, the Monte Carlo simulations performed by Dr. Fox analyze a range of CVs that could occur in tests, not just a single value. It is not necessary to generate control CVs from a frequency distribution for each test iteration, because control CVs are calculated from samples that were randomly drawn from a normal distribution in each test iteration.  The long-run median control CV is an appropriate long-term measurement of a laboratory’s performance because it represents the level of precision that a laboratory is able to achieve on a long-term basis. Additionally, half of the individual observations in a dataset will fall above the median, and half will fall below the median. Therefore, the probabilities of false positive results, and MMEL violations and TREs required based on false positive results, are calculated based on the long-run median control CV for each laboratory that was studied in Appendix J. This also explains why only the median control CV for each laboratory (not a range, as suggested by commenters) is included in Tables J-1, J-2, and J-3.  The simulations described in Fox et al. 2019 account for the fact that half of a laboratory’s WET tests will have a test-specific control CV higher than the median for that laboratory. For a given set of simulations, approximately half of the simulated tests have a test-specific control CV that is higher than the control CV parameter value used in that set of simulations. This means that the probabilities of MMEL violations and TREs based on false positive results, calculated from long-run median control CVs as presented in Appendix J, provide the most valid estimate of these probabilities for an individual laboratory, based on its long-run median control CV.  The assumptions inherent in the statistical analysis used in the memorandum provided by Dr. Fox (Fox 2019 Memorandum) are not described in Appendix J because the memorandum provides a complete technical analysis and explanation of the information. The Fox 2019 Memorandum is publicly available on the State Water Board’s [Toxicity Provisions webpage](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/tx_ass_cntrl.html).  For concerns regarding the potential costs associated with using the TST, please see SR J-5.001. |
| 1.006 | Although CASA does not see any significant shortcomings in the statistical analysis as conducted in Appendix J, the analysis unfortunately failed to take into account several important factors that limit its applicability as a decision-making tool for development of statewide toxicity regulations. |
| 1.012 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . .  Appendix J relies upon long-term medians of within-test variability using the control treatments’ coefficient of variation (CV). This fails to acknowledge that half of a laboratory’s tests had higher CVs and that the corresponding number of additional replicates to achieve an acceptable statistical false positive rate will often be much higher. The end result of this underestimation of additional replicates may be significantly higher efforts and costs to achieve compliance. |
| 8.005 | Revised draft Appendix J reports the probabilities of determining an MMEL violation or triggering a TRE based on “false positives” (defined in Appendix J as a “Fail” according to the TST when there is =10 percent effect) for *C. dubia* chronic whole effluent toxicity (WET) tests. The analysis concludes that there is a 4.8 percent probability of any individual test resulting in a false positive and a 0.49 percent probability that these false positives would cause an MMEL violation (i.e., when 2 of 3 tests in a calendar month result in a “Fail”). The probability that a TRE will be triggered by false positive results was determined to be <1 percent over a permit cycle (i.e., 60 months). These statistics are true for chronic *C. dubia* WET tests when the coefficient of variation (CV) is 0.15 and there are 10 replicates. However, the assumption that a CV, describing variability among control replicates within a test, will be the same for every test is unrealistic and underestimates the frequency of multiple false positives causing MMEL violations or triggering a TRE. The median CV used in the analysis was based on laboratory data, but in practice the test-specific CV is used to analyze the individual test results, not a median CV from multiple tests. Half of the toxicity tests used to determine the median had CVs higher than the median by definition. Thus, the probabilities of an MMEL violation or triggering a TRE based on false positives are underestimated when using the median CV. CVs vary among WET tests due to many possible factors (e.g., organism health, food quality, etc.) and higher values will result in higher probabilities of MMEL violations and triggering TREs. CVs at a toxicity testing laboratory, as shown in Figure J-4, can be as high as 0.68 in a given year, even when the median CV that year is low (i.e., 0.113 in 2012 for the LACSD Municipal Laboratory) Fox et al. (2019), which is referenced in Appendix J as a source of laboratory data describing results for *C. dubia* WET tests, reports that the maximum CVs among laboratories after 2012 were similar (0.47 and 0.49) for the labs with highest mean CV and lowest mean CV. These data demonstrate that all laboratories can have high CVs for individual tests regardless of the median CV they achieve. |
| 8.012 | Regional San also recommends providing statistical summaries in Appendix J to show the probability of MMEL violations and triggering TREs for *C. dubia* for the range of CVs reported by laboratories. |
| 8.015 | It would also improve transparency in the interpretation of these results to present the range of CVs reported by laboratories in each row of Tables J-1, J-2, and J-3. These minimum and maximum CVs reflect the range of variability in test data whereas the median under-represents the CV that will be used in a given test to evaluate the results. Individual tests are not evaluated using the median CV and half of the tests used to calculate a median are more likely to result in a “Fail” due to a “false positive” when using the test-specific CV than when using the median CV. |
| 2.001 | **Comment 1. The analysis in Appendix J underestimates the probability that false positives will result in MMEL violations or trigger a TRE.**  …  These statistics correspond to chronic *C. dubia* WET tests when the coefficient of variation (CV) is 0.15 and there are 10 replicates. However, the assumption that a CV, describing variability among control replicates within a test, will be the same for every test is unrealistic, and because of this, the approach underestimates the frequency at which multiple false positives will cause MMEL violations or a TRE. The median CV used in the analysis was based on laboratory data, but in practice the test-specific CV is used to analyze the individual test results, not a median CV from numerous tests. By definition, half of toxicity tests used to determine the median CV had test-specific CVs higher than the median. Without using an approach that accounts for the range of CVs that actually occurred in the dataset, the probabilities of an MMEL violation or of triggering a TRE based on false positives presented in Appendix J are underestimated. CVs vary among WET tests due to many possible factors (e.g., organism health, food quality, etc.) and higher values will result in higher probabilities of MMEL violations and triggering TREs than those presented in Appendix J. CVs at a toxicity testing laboratory, as shown in Figure J-4, can be as high as 0.68 in a given year, even when the median CV that year is low (i.e., 0.113 in 2012 for the LACSD Municipal Laboratory). Fox et al. (2019), which is  referenced in Appendix J as a source of laboratory data describing results for *C. dubia* WET tests, reports that the maximum CVs among laboratories after 2012 were similar for the lab with highest mean CV and lowest mean CV (0.47 and 0.49, respectively). These data  demonstrate that all laboratories can have high CVs for individual tests regardless of the median CV they achieve. |
| 2.003 | Data and equations in Fox (2019) can be used to calculate probabilities of MMEL violations and TREs due to false positives based on CVs higher than the median value presented in Appendix J. For example, testing with a CV of 0.3, given 10 replicates, results in a 34 percent probability of a false positive in any single test and a 19 percent probability of an MMEL violation in a calendar month (Table 1a in Fox 2019). Likewise, the probability of triggering a TRE during a permit cycle is 48 percent when false positives causing an individual test “fail” have a probability of 25 percent (Table 2 in Fox 2019). These probabilities of MMEL violations and triggering a TRE based on false positives are much higher than those indicated in Appendix J. As a result of relying solely on the median CV for these calculations Appendix J likely underestimates the probability of MMEL violations and triggering TREs. |
| 2.004;  8.007 | We recommend that the State Water Board revise this appendix to:   1. describe assumptions inherent to this statistical analysis in the main body (rather than in a referenced memo), 2. clarify limitations of the analysis and identify that it underestimates the potential for “false positives” to cause MMEL violations or trigger a TRE because CVs for many individual WET tests will be greater than the median CV used in the analysis, and   consider an analysis that is less likely to underestimate these potential occurrences by analyzing a range of CVs that could occur in tests (e.g., using a Monte Carlo simulation where CVs are generated from a frequency distribution for each test iteration in the analysis; or present false positive probabilities based on CVs that range up to 0.49). |
| **SC J-3.003** | The data analysis presented in Appendix J improperly assumes that only tests that failed the TST with less than a 10 percent effect are considered potential "false positives." However, a very real possibility exists that effects much larger than 10 percent will occur due solely to random and natural biological fluctuations in *Ceriodaphnia dubia* reproduction even when there is no actual difference in the chemical composition of the sample waters. For example, when the CV of the control group is 0.15 (15 percent) differences greater than 10 percent will be observed in one-fourth of all tests. If the CV of the control group is 0.25 (25 percent), a 10 percent difference in mean reproduction will occur in one-third of all tests. The mean inter-replicate CV for *Ceriodaphnia dubia* reproduction in the TST Test Drive Study control groups was 0.25 (25 percent). Thus, the orange line in Fig. 4 [on page 5 of comment letter #9] provides the best estimate for real world performance when evaluating known non-toxic samples.  Data in Appendix J reveals that laboratories cannot attain a CV of 0.15 or less consistently and reliably across a large number of WET tests. Even though the median CV values is approximately 0.15, 25 percent of all *Ceriodaphnia dubia* tests had a CV greater than 0.24 and 10 percent of all tests had a CV greater than 0.35. By definition, the CV will be greater than the median value half the time. The mean inter-replicate CV for *Ceriodaphnia dubia* reproduction the TST Test Drive Study's control groups was much higher than the median (0.25 vs. 0.15, respectively). |
| **SR J-3.003** | Table 5-1 of the Staff Report states that a 10 percent effect level should be declared not toxic using the TST at least 95 percent of the time (i.e., the acceptable false positive probability is 5 percent or less at a 10 percent effect). Section 1.4 of the TST Technical Document explains the rationale for setting the false positive error probability at no higher than 5 percent at 10 percent effect. Additionally, the Fox 2019 Memorandum clarifies that “TST false positives can be defined as TST ‘fails’ that occur when the true (parametric) percent effect is not more than 10. A true percent effect of at least 25 can be used as a working threshold for a true positive. Toxicity occurs if the true percent effect is between 10 and 25, but for practical reasons, as a regulatory management decision, it was useful to select a value of 25 percent effect to use in the TST t-test."  Section J.2 of Appendix J states that “[a] false positive is when the IWC sample is declared toxic (fail) but the sample is in fact not toxic. In the TST statistical approach, the false positive probability is the probability of a fail occurring when the percent effect is at 10 percent or less.” This definition is consistent with the definitions provided above.  The possibility of there being “no actual difference in the chemical composition of the sample waters” is represented in the simulations performed by Dr. Fox, specifically when the parametric percent effect is set to zero. The “Percent Effect: “0%” column of Table J-5 provides the probability of TST “fails” at various values of parametric control CV and number of replicates. These values provide an estimate of the probability of declaring toxicity when the control water is chemically identical to the sample (IWC) water. Each of these probabilities is less than 0.05 (5%) unless the long-run median control CV is 0.30 or higher. Additionally, each of these probabilities is lower than the corresponding probability at a parametric percent effect of 10, which is the “negligible” level of toxicity according to the TST Technical Document. This shows that the possibility of failing the TST when there is no actual difference in the chemical composition of the sample waters is acceptably low for all of the California laboratories studied in Appendix J.  It is more instructive to consider the probability of failing the TST under various conditions, rather than simply examining the “natural background variability” of the *C. dubia* reproduction endpoint, because within-test variability is only one of several factors that determines the TST result.  The commenter raises concerns about the percentage of tests that exceed an observed percent effect of 10 percent, with tests with a higher test-specific CV showing a higher rate of exceeding 10 percent effect. However, merely exceeding 10 percent effect does not guarantee that the test will result in a fail, because the RMD for unacceptable chronic toxicity is set at 0.75, which corresponds to a parametric percent effect of 25. This means that tests with an observed percent effect between 10 and 25 may pass the TST. The TST result depends on the within-test variability and the number of replicates used in the test, as explained in Appendix J. Additionally, the CV values cited in the comment are test-specific CVs, not long-run median CVs. Please see SR J-3.002 for a discussion of why the long-run median CV was used in the analyses in Appendix J.  The data presented in comment 09.002 were obtained from the TST Test Drive. The TST Test Drive data were generated during the period when the NOEC and point estimate statistical approaches were used and reducing within-laboratory variability and increasing the number of replicates beyond the method-required minimum were not incentivized. This means that the within-test variability in the cited data is likely to be higher than that observed in the more recent data from laboratories that have started using the TST to evaluate WET data (for example, Figure J-4 demonstrates that the within-test variability for the LACSD Municipal Laboratory has decreased since the incorporation of the TST into their NPDES permits). Therefore, the commenter’s approach does not provide the most accurate and current examination of laboratory data.  As stated in Appendix J, most laboratories can achieve acceptable TST performance, as defined by their ability to achieve a false positive probability of less than or equal to 5 percent at a 10 percent effect. This is not an “assumption.” This conclusion is based on laboratory data presented in Fox et al. 2019 and shown in Table J-1 of Appendix J. Not all laboratories are assumed to “attain a CV of 0.15 or less.” Additionally, please see SR J-3.002, which explains that specifying a CV parameter value to use in a calculation does not imply that each test will have a CV exactly equal to the parameter value.  SR J-3.006 acknowledges that not all laboratories that were analyzed in Appendix J are able to meet the acceptable probability of false positive results, but provides several suggestions on how this problem may be remedied.  Using the mean (rather than the median) control CV as the parameter in the simulations would likely overestimate the false positive probability, because the mean is more sensitive to outliers than the median. For example, if a laboratory has a single test that has a very high test-specific control CV value, this value would cause the mean control CV value to rise, but would not affect the median control CV value.  Please see SR J-1.011 for further discussion of false positive results. |
| 9.002 | The data analysis presented in Appendix J improperly assumes that only tests that failed the TST with less than a 10% effect are considered potential "false positives." However, a very real possibility exists that effects much larger than 10% will occur due solely to random and natural biological fluctuations in *Ceriodaphnia dubia* reproduction even when there is no actual difference in the chemical composition of the sample waters. For example, when the CV of the control group is 0.15 (15%) differences greater than 10% will be observed in one-fourth of all tests. If the CV of the control group is 0.25 (25%), a 10% difference in mean reproduction will occur in one-third of all tests (see Fig. 6, above).4  [See comment letter #9]  This is extremely important because the text of Appendix J stating that most laboratories can achieve acceptable TST performance rests on the assumption that the labs can attain a CV of 0.15 (15%) or less. The authors of Appendix J cite the median CV of several labs to support this conclusion. However, this same data also reveals that the labs cannot do so consistently and reliably across a large number of WET tests. Table J-4 on page 9 of Appendix J reveals that, even though the median CV values is approximately 0.15, 25% of all *Ceriodaphnia dubia* tests had a CV greater than 0.24 and 10% of all tests had a CV greater than 0.35. By definition, the CV will be greater than the median value half the time. The mean inter-replicate CV for *Ceriodaphnia dubia* reproduction the TST Test Drive Study's control groups was much higher than the median (0.25 vs. 0.15, respectively).  4The mean inter-replicate CV for *Ceriodaphnia dubia* reproduction in the TST Test Drive Study control groups was 0.25 (25%). Thus, the orange line in Fig. 4 provides the best estimate for real world performance when evaluating known non-toxic samples. |
| **SC J-3.004** | Multiple states (e.g., South Carolina, North Carolina, Hawaii) have a test acceptability criterion that invalidates tests with a control CV exceeding 40 percent. This could have artificially underestimated the control CV percentiles in the U.S. EPA 2010 TST Technical Document. |
| **SR J-3.004** | The data used in the TST Technical Document were obtained from a national dataset. The TST Technical Document does not identify every data source used, but section 2.2 states that “[t]he sources included Washington State Department of Ecology, EPA’s Office of Science and Technology, North Carolina Department of the Environment and Natural Resources, California State Water Resources Control Board, and Virginia Department of Environmental Quality.”  Table J-4 of Appendix J demonstrates that the control CV percentiles obtained from a national sample of laboratories in the TST Technical Document are very similar to those obtained from a sample of California laboratories in Fox et al. 2019. Additionally, California’s WET program does not have a test acceptability criterion that invalidates tests with a control CV above a certain value. |
| 1.014 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . .  It is unknown which states and/or municipalities’ data were used to develop the control CV percentiles in the US EPA 2010 TST Technical Document. This could have the unintentional consequences of artificially underestimating variation and, ultimately, on the setting of appropriate alpha values. Multiple states’ (e.g., South Carolina, North Carolina and Hawaii) whole effluent toxicity programs have a test acceptability criterion that invalidates tests with a control CV exceeding 40%. If data from these states, and any others with upper CV test acceptability criteria, were included in the analysis and calculation of the CV percentiles, these national percentiles would be incorrectly identified as lower than they actually were. Figure J-4 demonstrates this phenomenon has a high likelihood of occurrence in a municipal monitoring program. Distribution of this data set would aid in addressing this underlying issue. |
| **SC J-3.005** | The reliability of laboratory data is critical to uphold the numeric toxicity limitations in the forthcoming Toxicity Provisions. Given the existing range in laboratory performance for chronic *C. dubia* toxicity testing, and need for accurate testing to uphold the integrity of the forthcoming Toxicity Provisions, we do not dispute that laboratories should strive to decrease test variability. Fortunately, multiple studies have concluded that increasing replicates will improve laboratory accuracy when using *C. dubia* for chronic toxicity testing. With this demonstrated ability to increase laboratory precision to the acceptable 10 percent effect by increasing replicates, dischargers and the public alike have confidence in chronic toxicity testing results using *C. dubia*. |
| **SR J-3.005** | The confidence in the chronic toxicity testing results using *C. dubia* is noted.  While increasing replicates will reduce the expected probability of false positive results, it is important to note that most laboratories are able to achieve the acceptable probability of false positive results (less than or equal to 5 percent at 10 percent effect) by using only 10 replicates, and do not need to increase replication. This is explained in the list of “Key Findings” in Section J-1 of Appendix J. |
| 5.003 | **B. Increasing replicates will improve laboratory accuracy of the use of *C. dubia* for chronic toxicity testing.**  The reliability of laboratory data is critical to uphold the numeric toxicity limitations in the forthcoming Toxicity Provisions. Given the existing range in laboratory performance for chronic *C. dubia* toxicity testing, and need for accurate testing to uphold the integrity of the forthcoming Toxicity Provisions, we do not dispute that laboratories should strive to decrease test variability. Fortunately, multiple studies have concluded that increasing replicates will improve laboratory accuracy when using *C. dubia* for chronic toxicity testing. For example, the City and County of Honolulu study found:  “The failures [in the 15 to 25 percent effect range] declared by TST in this study were very rare excursions caused by an episode of unusually poor *C. dubia* culture performance. While blocking by parentage minimizes within test variability, the effect of limited fecundity or mortality of even a single organism may be remarkable. For this reason, there must be an extremely thorough oversight of laboratory protocols to ensure consistent organism vigor. In addition, increased replication in the control and in the sample at the IWC may be adopted to decrease variance.”  Further, Fox et al. (examined data from a subset of California laboratories, and found that four of the six laboratories examined had low within test variability and could attain the acceptable false positive probability of five percent using 10 test replicates. Critically, Fox et al. found that if the number of replicates were increased to 20, then five of the six laboratories would meet the acceptable false positive probability. Meanwhile, as reported in Appendix J, State Water Board staff performed an independent review of recent data from four California laboratories, finding that three of four laboratories had low within test variability and could attain the acceptable probability of a fail at or below 10 percent effect of five percent using 10 replicates. If the number of replicates were increased to 20, then all four laboratories would meet the acceptable probability proposed in the draft Toxicity Provisions.  With this demonstrated ability to increase laboratory precision to the acceptable 10 percent effect by increasing replicates, dischargers and the public alike have confidence in chronic toxicity testing results using *C. dubia*. |
| **SC J-3.006** | *C. dubia* should not be used as the most sensitive species until the accuracy of the reproductive test can be verified or improvements can be made to the test method to reduce the variability through a comprehensive study.  Implementation of the TST statistical approach will require laboratories to reduce within-laboratory variability and increase the number of replicates for the *C. dubia* chronic test.  In three cases, the acceptable level of probability was met when the number of replicates was increased from 10 to 20. Data were also shown that if the within-test variability for control CVs ranged from 0.09-0.15, running 10 replicates would be sufficient to meet the acceptable probability rate for false positive. However, these CVs are representative of 10 percent to 50 percent of the control CVs from a national study conducted by the U.S. EPA (U.S. EPA 2010) and may not be achievable by a laboratory without some changes in laboratory practices. |
| **SR J-3.006** | Section 2.2 of the Staff Report explains that one project goal of the Provisions is to “provide an incentive for dischargers to generate valid, high quality test data.” The possibility that laboratories with high long-run median control CVs will need to increase replication and/or reduce within-test variability is consistent with this project goal.  Not all laboratories that were analyzed in Appendix J are able to meet the acceptable probability of false positive results. However, there are several ways to remedy this problem. Dischargers and laboratories may increase the number of replicates used in the test or find ways to decrease their long-run median control CV, which is expected to reduce the probability of false positive results. Additionally, the State Water Board is conducting a study that will be designed to answer key questions about the best practices for conducting the *C. dubia* reproduction chronic toxicity test method. This study may provide additional information and guidance to laboratories and dischargers on how to conduct the *C. dubia* chronic toxicity test with high precision, which may result in a decrease in their long-run median control CV. The *C. dubia* chronic toxicity test is a reliable test method, and the *C. dubia* study is not a required component of the Provisions. Please see SR L.005 through SR L.011 for more information.  The “Key Findings” section of Appendix J explains that most laboratories are able to achieve the acceptable false positive probability using only the required minimum number of replicates, and therefore do not need to increase replication. Please see SR J-3.005 for more information.  In the TST Technical Document (cited in comment 6.014), the control CV values from the national sample of laboratories were all grouped together and analyzed as one unit; they were not separated by individual laboratory. This means that the data from the TST Technical Document cannot be used to infer whether an individual laboratory is likely to be achieving the acceptable false positive probability. However, the analyses presented in Fox et al. 2019 and Appendix J consider the control CV values for each laboratory in the study, on a laboratory-by-laboratory basis. Appendix J indicates that if a laboratory has a long-run median control CV of approximately 0.15 or less, then that laboratory is expected to achieve the acceptable false positive probability of less than or equal to 5 percent at a 10 percent effect. This does not mean that every single test performed by that laboratory must achieve a test-specific control CV of 0.15 or less for the laboratory to achieve the acceptable false positive probability. Please see SR J-3.002 for more information.  Regarding the data from the LACSD Municipal Laboratory, Figure J-4 of Appendix J indicates that this laboratory’s performance has improved (i.e., median control CV has decreased) during the time period from 2010 to 2018. For this reason, the analysis in Appendix J focuses on the more recent data obtained from the LACSD Municipal Laboratory.  Regarding the request that *C. dubia* not be considered the most sensitive species until test methods improvements have been identified, please see SR F.008 and SR L.008. |
| 6.005 | The second issue is the variability of the *C. dubia* reproductive response when only a single effluent concentration is tested and the need for increased replicates to decrease the within laboratory variability. Stakeholders requested that *C. dubia* not be considered the most sensitive species until the accuracy of the reproductive test can be verified or improvements can be made to the test method to reduce the variability through a comprehensive study. |
| 6.013 | **3. Implementation of the TST statistical approach will require laboratories to lower within-laboratory variability and increase the number of replicates for the *C. dubia* chronic test.**  The SWRCB's analysis of chronic *C. dubia* reproduction control CV values for California laboratories demonstrated that for a laboratory to meet the acceptable probability level of 5% for a fail at or below 10 percent effect, the laboratory must consistently achieve low within-test variability and increase the number of replicates.  Data were presented for two laboratories that achieved low within-test variability but did not meet the acceptable false positive probability rate unless the number replicates were increased. From 2010 to 2012, the Los Angeles County Sanitation District's San Jose Creek Water Quality Laboratory (LACSD Municipal Laboratory) achieved a median control coefficient of variation (CV) of 0.17 and did not meet the required level of acceptable false positive with running 10 replicates. In 2018 and 2019, Commercial Laboratory #3, achieved median control CVs of 0.19 and 0.16, respectively and did not meet the acceptable level of false positive with 10 replicates. |
| 6.014 | In all three cases, the acceptable level of probability was met when the number of replicates was increased from 10 to 20. Data were also shown that if the within-test variability for control CVs ranged from 0.09-0.15, running 10 replicates would be sufficient to meet the acceptable probability rate for false positive. However, these CVs are representative of 10% to 50% of the control CVs from a national study conducted by the U.S. EPA (U.S. EPA 2010) and may not be achievable by a laboratory without some changes in laboratory practices.  For the foregoing reasons, LADWP requests that that *C. dubia* not be used as the most sensitive species until the accuracy of the reproductive test can be verified or improvements can be made to the test method to reduce the variability through a comprehensive study. |
| **SC J-3.007** | In order to fully appreciate stakeholder concerns regarding the *Ceriodaphnia dubia* reproduction test, it is essential to understand the level of natural background variability associated with this particular biological endpoint. There is substantial natural biological variability in the average number of offspring produced for a given group as seen by examining data generated when standard test organisms were exposed only to clean laboratory water during the TST Test Drive Study. There is also significant variability among the individual replicate organisms assigned to the same treatment group.  Data from the TST Test Drive Study shows that the natural background variability of the *C. dubia* reproduction is significantly higher than for fathead minnow growth and green algae cell density because the reproduction endpoint has much more natural variability.  The probability of observing a large reduction in average reproduction, due solely to random chance and not actual toxicity, is directly proportional to the level of natural background variability (CV) present in any given test. Using the data in the TST Test Drive, the magnitude of random effect, and the probability of its occurrence, can be computed as a function of CV. |
| **SR J-3.007** | Natural background variability in the *Ceriodaphnia*  reproduction endpoint, as measured by percentiles of control CV, was assessed in the TST Technical Document (for a national sample of laboratories) and Fox et al. 2019 (for a sample of laboratories in California). Table J-4 of Appendix J demonstrates that California laboratories’ performance is consistent with other laboratories across the nation and are able to successfully conduct chronic *C. dubia* reproduction toxicity tests with low within-in test variability.  Table J-4 also shows that there is natural background variability in the *Ceriodaphnia*  reproduction endpoint. However, the analyses presented in Fox et al. 2019 and Appendix J take this variability into account. The calculations presented in Fox et al. 2019 assume that there is variation in the average number of neonates produced by both the control and the IWC replicates.  Additionally, it is important to note that the U.S. EPA WET test methods have withstood legal challenges. In Edison Electric Institute et al. v. EPA, 391 F.3d 1267 (D.C. Cir. 2004), the Court of Appeals determined that U.S. EPA properly promulgated the test methods (including the *C. dubia* chronic toxicity test method). The Court found that U.S. EPA reasonably validated the standardized testing procedures, including their precision and bias, as well as their high rates of successful test completion; and that the methods did not produce unacceptably variable results. The Court acknowledged that every test, even chemical species instrumental tests, include some variation. Please see response “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for more information.  The TST Test Drive data were generated during the period when the NOEC and point estimate statistical approaches were used and reducing within-laboratory variability was not incentivized. This means that the within-test variability in the cited data is likely to be higher than that observed in the more recent data from laboratories that have started using the TST to evaluate WET data. Please see SR J-3.003 for more information.  Even with identical composition of effluent and control water, it is true that there will be variation in the number of neonates produced in the control and IWC treatments, and that the observed percent effect may be higher when the test-specific CV is higher. This situation was simulated by the analyses performed in Fox et al. 2019 and the Fox 2019 Memorandum, and presented in Appendix J. Specifically, this situation is simulated when the parametric percent effect is set to zero (i.e., the control and IWC replicates for each simulated test are randomly drawn from the exact same population). The “Percent Effect: 0%” column of Table J-5 provides the probability of failing TST at various values of parametric control CV and number of replicates. Additionally, each graph in Figure J-2 shows the probability of declaring toxicity (for both TST and NOEC) at various values of parametric control CV and number of replicates. It is more instructive to consider the probability of failing the TST under various conditions, rather than simply examining the “natural background variability” of the *C. dubia* reproduction endpoint, because within-test variability is only one of several factors that determines the TST result.  The commenter points out that *C. dubia* tends to have a higher CV than other freshwater test methods. The higher the CV, the less confidence there is that the sample mean effect represents the true mean effect. However, the U.S. EPA Method Manual requires a greater number of replicates for *C. dubia* than for other freshwater chronic toxicity tests. When additional replicates are included in a test, there is more confidence that the sample mean effect represents the true mean effect. The minimum number of replicates required for the *Pimephales promelas* and the *Selenastrum capricornutum* tests is four, while the minimum number of replicates required for *C. dubia* is ten. Therefore, the higher CV for the *C. dubia* chronic test is offset by the greater minimum number of replicates.  If the median control CVs are higher than the control CVs observed by U.S. EPA when designing the chronic *C. dubia* test, then additional replicates may be needed to maintain the same level of confidence. The test methods allow laboratories to include more than the minimum number of replicates. In this way they can maintain a low probability of a false positive, even with higher CVs.  Additionally, the method-required minimum number of replicates was taken into account in the analyses performed in the TST Technical Document and Fox et al. 2019. Fox et al. concluded that most California laboratories have a sufficiently low control CV and will not need to increase the number of replicates used in order to maintain a 5 percent or less probability of a fail when the true percent effect is 10 percent or less. |
| 9.001 | In order to fully appreciate stakeholder concerns regarding the *Ceriodaphnia dubia* reproduction test, it is essential to understand the level of natural background variability associated with this particular biological endpoint. This variability is easily seen by examining data generated when standard test organisms were exposed only to clean laboratory control water during the TST Test Drive Study.  The average number of neonates produced by the control groups in this study was 24.8 offspring per female. The standard deviation was 5.4 and the 95% confidence interval ranged from 14 to 36 offspring per female (see Fig. 1 below). [See Figure 1 on page 2 of comment letter #9] This is an accurate estimate of natural background variability because it represents the expected range of normal performance for *Ceriodaphnia dubia* under known non-toxic conditions.2  Given this level of natural variability, there no reason to expect that two randomly-selected groups of *Ceriodaphnia dubia* will produce exactly the same average number of offspring even if both are exposed only to identical samples of known non-toxic laboratory control water. And, for the same reason, it would not be surprising to see average reproduction for effluent- exposed organisms to differ slightly from control performance even if the chemical composition of both samples was absolutely identical.  The utility of WET testing as a tool for evaluating regulatory compliance depends on its ability to distinguish adverse effects induced by chemical toxicity from any other differences in average reproduction that may result from the natural background biological variability of the tested organisms. Appendix J acknowledges this fact and consistently emphasizes the important role that variability (measured as Coefficient-of-Variation) plays in determining the performance of this test method.  The statistical sensitivity of both the federally-promulgated NOEC procedure and the proposed TST guidance procedure rests largely on the level of variability observed between replicates assigned to the same treatment group during any given WET test. As noted in Appendix J, the Coefficient-of-Variation (CV) is commonly used to quantify such variability.  Not only is there substantial natural biological variability in the average number of offspring produced for a given group of, but there is also significant variability among the individual replicate organisms assigned to the same treatment group. During the TST Test Drive Study, the average inter-replicate CV for the control groups was 0.25 (25%) and the 95% confidence interval ranged from 0.07 to 0.52 (see Fig. 2, below). [See Figure 2 on page 3 of comment letter #9]  It is important to note that data from the TST Test Drive Study shows that the natural background variability of the *Ceriodaphnia dubia* reproduction is significantly higher than either of the other two sub-lethal biological measures used to characterize the potential for chronic toxicity in freshwater organisms: Fathead Minnow growth and Green Algae Cell Density. In more than 80% of all Fathead minnow and Green Algae tests, the natural background CV is less than 0.15; however, that is only true for half of all *Ceriodaphnia dubia* tests because the reproduction endpoint has much more natural variability (See Fig. 3, below).  [See Figure 3 on page 4 of comment letter #9]  The probability of observing a large reduction in average reproduction, due solely to random chance and not actual toxicity, is directly proportional to the level of natural background variability (CV) present in any given test. Using the data described above, the magnitude of random effect, and the probability of its occurrence, can be computed as a function of CV (see Fig. 4, below). [See Figure 4 on page 5 of comment letter #9]  2The TST Test Drive Data reported in Appendix J is a subset of the data originally reported in Appendix A & B. The mean, standard deviation and CV of this data was very similar to that shown in Fig. 1. |
| **SC J-3.008** | Appendix J omits the fact that when the percent effect is less than the proposed RMD, and the within-test variability is relatively high, the TST statistical approach is more likely to declare the sample as toxic. |
| **SR J-3.008** | High within-test variability indicates poor data quality. Rewarding poor data quality with a higher probability of a pass is not a desirable attribute for a statistical approach. Section 5.3.1 of the Staff Report discusses the inability of the NOEC to declare tests as toxic when there is poor data quality. This section of the Staff Report explains that, “[t]ests declared toxic using the TST approach had a significantly larger effect and higher within-test coefficient of variation in both the control and the test sample than those tests declared toxic using the NOEC approach. Thus, the TST approach is more likely to declare tests as toxic if the effect size is large and/or within-test variability is large (Diamond et al. 2013). The results were consistent with other previous observations. For the TST approach, a relatively high within-test variability resulted in the inability to reject the null hypotheses that the effluent is toxic. Thus, the TST approach provides an incentive for dischargers to provide high quality test data with low within-test variability. The direct benefit and incentive of using good laboratory practices to minimize within-test variability and improve laboratory performance when using the TST approach is that those tests with low within-test variability and a median effect below the RMD are generally declared non-toxic.” This incentive is provided by the “restated” null and alternative hypotheses, as further explained in Section 5.3.1 of the Staff Report. This aligns with the project goal in Section 2.2 of the Staff Report, to “provide an incentive for dischargers to generate valid, high quality test data.” Please see SR J-6.001 for additional information. |
| 9.013 | The first finding on page 1 describes only those conditions where the TST appears to perform better than the NOEC. The discussion omits the fact that, when the Percent Effect is LESS than the proposed RMD, and the within-test variability is relatively high, the TST procedure is MORE likely to declare the sample as toxic. |
| **SC J-3.009** | The Toxicity Provisions should be revised to consider the effects of effluent variability on the TST statistical approach by allowing dose-response information from the full dilution series to be considered when evaluating toxicity test results. Effluent variability is a concern in interpreting effluent responses, especially with *C. dubia* testing using the TST statistical approach, because variability cannot be adequately assessed with a dose-response relationship.  Inter-laboratory variability for the *C. dubia* survival and reproduction test has been evaluated since the development of the method. Earlier studies evaluating the inter-laboratory variability including ease of implementation concluded that the observed variability in the *C. dubia* chronic test was within the variability observed with other toxicity tests. Although laboratory performance for WET test methods as a whole has improved over the years, laboratory performance and personnel training were shown to be critical to the success of WET test assessments.  Fox et al. (2019) found laboratory performance to be the single most important influence leading to identification of an effluent as toxic and in using the TST, it is to the permittee's advantage to choose a laboratory that has smaller control variability, implying that conclusions reached using the TST method have less to do with identifying the "true toxicity" of the effluent and are more closely related to the fact that the TST method is set-up to address laboratory precision. |
| **SR J-3.009** | There is no need to consider the dose-response information from the full dilution series when using the TST to evaluate data from a WET test.  The TST is not intended to address laboratory precision. Rather, it is designed to make reliable inferences about toxicity.  A dose response curve is a fundamental component of answering the toxicological question, “at what concentration of a toxicant are detrimental effects to organisms observed?” The Toxicity Provisions use the TST statistical approach to address the NPDES permit compliance question, ''is the sample toxic at the IWC?'' The TST statistical approach provides a yes or no answer, which is determined using a hypothesis testing approach. Additionally, Section 5.3.1 of the Staff Report explains that with the TST approach, there is no need to review the concentration response curve, in contrast to using the NOEC statistical approach or point estimate statistical approaches.  Additionally, the dose-response information is not useful in reviewing within-test variability. The best indication of laboratory variability is the long-range control CVs. The control does not use a dilution series. Instead, it is always 100 percent control water, even when using the NOEC or point estimate approaches. Therefore, the dilution series does not provide any useful information on control variability. |
| 6.010 | **2. Effluent variability, especially with *C. dubia* testing using the TST, is a concern in the interpretation of effluent responses, because variability cannot be adequately assessed with dose-response relationships.**  The variability of the *C. dubia* 7-day survival and reproduction toxicity test has been evaluated since its development as a WET test method.  Earlier studies examining the intra-laboratory variability of the bioassay found many factors affecting the variability, including renewal frequency, photoperiod (Cooney et al. 1992a), food source (Cooney et al. 1992b), and temporal differences (DeGraeve et al. 1992). Earlier studies evaluating the inter-laboratory variability including ease of implementation concluded that the observed variability in the *C. dubia* chronic test was within the variability observed with other toxicity tests (Anderson and Norberg-King 1991; DeGraeve et al. 1992). |
| 6.011 | Although laboratory performance for WET test methods as a whole has improved over the years (as Fox et al. 2019 claim by citing other studies, including U.S. EPA 2010 and Denton et al. 2011), at recent 2018 and 2019 SETAC conferences, laboratory performance and personnel training were shown to be critical to the success of WET test assessments (Norberg-King et al. 2018; Naddy and Pillard 2018; Lozano 2019; Goodfellow 2019; Prosser et al. 2019). |
| 6.012 | It has been shown that the variability and reproducibility of the *C. dubia* chronic test has an influence on whether the TST Test or NOEC method declares the sample as toxic (Diamond et al. 2013; Fox et al. 2019). Fox et al. (2019) found laboratory performance to be the single most important influence leading to identification of an effluent as toxic.  They further stated that in using the TST, it is to the permittee's advantage to choose a laboratory that has smaller control variability, implying that conclusions reached using the TST method have less to do with identifying the "true toxicity" of the effluent and are more closely related to the fact that the TST method is set-up to address laboratory precision.  For the foregoing reasons, LADWP requests that the Toxicity Provisions be revised to consider the effects of effluent variability on the TST method by allowing dose-response information from the full dilution series to be considered when evaluating toxicity test results. |
| **SC J-4.001** | Require all dischargers that identify *C. dubia* as the most sensitive species, even where *C. dubia* was not previously used in discharge permits, to comply with chronic *C. dubia* toxicity testing in order to demonstrate compliance with the Toxicity Provisions and ensure California’s freshwater ecosystems are adequately protected.  The State Water Board should develop a study to provide best practices for chronic toxicity testing using *C. dubia*, but should not delay in using numeric limits for chronic toxicity using *C. dubia* as the most sensitive species. The State Water Board should build from the results of the recent study by Fox et. al as discussed in Appendix J to evaluate the error rates in WET tests for *C. dubia*, and limit the scope of a forthcoming study to identify laboratory practices that will improve the quality of the data, such as ensuring healthy cultures are used in toxicity testing and increasing replicates where necessary. |
| **SR J-4.001** | See SR L.005 through SR L.011 for a discussion of the *C. dubia* study and SR F.002 and Section 5.4.3 of the Staff Report for a discussion on the implementation of *C. dubia* numeric effluent limitations during the *C. dubia* study. |
| 5.006 | Critically, *C. dubia* is the only freshwater invertebrate species used to test toxicity. Without the use of *C. dubia* to determine compliance where *C. dubia* is identified as the most sensitive species, chronic toxicity testing will not be adequately protective of aquatic health. We urge the final Provisions to require all discharges that identify *C. dubia* as the most sensitive species, even where *C. dubia* was not previously used in discharge permits, to comply with chronic *C. dubia* toxicity testing in order to demonstrate compliance with the Toxicity Provisions and ensure California’s freshwater ecosystems are adequately protected. |
| 5.007 | D. The State Water Board should develop a study to provide best practices for chronic toxicity testing using *C. dubia* but should not delay in using *C. dubia* to demonstrate compliance with chronic toxicity requirements.  Finally, we support the development of a study to provide a best practices document to reduce laboratory variability of chronic *C. dubia* testing based on the findings of Fox et al. As discussed in Appendix J, Fox et al. evaluated the error rates of *C. dubia* in WET test methods using the TST and NOEC statistical approaches. We request the State Water Board build from the results of this recent study, and limit the scope of a forthcoming study to identify laboratory practices that will improve the quality of the data, such as ensuring healthy cultures are used in toxicity testing and increasing replicates where necessary.  While we support the development of new knowledge and improved laboratory practices to strengthen chronic toxicity testing, recent studies demonstrate that chronic toxicity testing using *C. dubia* can achieve the desired 10 percent effect, and we urge that the development of a best practices document coincide with the use of *C. dubia* in chronic toxicity testing. |
| 5.008 | Toxicity water quality testing identifies discharges with toxic effluent that have cumulative negative impacts on aquatic life, even though these discharges may meet the requirements of the limited list of California Toxic Rule (CTR) priority pollutants. Toxicity limits are, therefore, an important safety net in discharge permits to integrate the actual biological impacts of the numerous pollutants that plague California’s waterways. The State Water Board must adopt statewide numeric toxicity limits that are widely applicable and readily enforceable using scientifically sound and statistically significant test methods to complement the chemical approach for individual CTR priority pollutants. Given the demonstrated confidence and accuracy that can be achieved by California laboratories to conduct chronic *C. dubia* toxicity tests, we strongly urge the State Water Board not delay its use of numeric limits for chronic toxicity using *C. dubia* as the most sensitive species. |
| **SC J-4.002** | Commenters support the chronic *C. dubia* study that could identify sources of variability and improve the *C. dubia* chronic test. Additionally, commenters support Option 4 to address *C. dubia* numeric effluent limitations while a study occurs (Issue 3), as discussed at the November 15, 2019 State Water Board staff workshop.  A clear understanding of the variability and limitations of the *C. dubia* chronic bioassay test method as well as adequate training of laboratory personnel and permit writers are required and should be performed before this test (as well as other WET tests) is used to assess compliance with water quality objectives or permit toxicity requirements. *C. dubia* should not be used as the most sensitive species until the accuracy of the reproductive test can be verified or improvements can be made to the test method to reduce the variability through a comprehensive study. |
| **SR J-4.002** | See SR J-1.001 for a discussion on identifying non-toxic samples as toxic, SR L.005 through SR L.011 for a discussion of the *C. dubia* study and SR F.008 and Section 5.4.3 of the Staff Report for a discussion on the implementation of *C. dubia* numeric effluent limitations during the *C. dubia* study. Also, see response “SR25.013” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on the term “accuracy” in relation to WET testing and statistical analysis. |
| 1.008 | CASA looks forward to working alongside State Water Board staff and other stakeholders to address and hopefully resolve this fundamental issue related to false indications of toxicity through development and implementation of the State Water Board’s *Ceriodaphnia*  toxicity study. |
| 2.011 | In conclusion, we support a *C. dubia* toxicity study that could identify sources of variability and improve *C. dubia* WET tests so that MMEL violations and TREs are not triggered by false indications of toxicity. Moreover, we support Option 4 to address *C. dubia* numeric effluent limits while a study occurs (Issue 3), as discussed at the November 15, 2019 State Water Board staff workshop. |
| 3.002 | 2. We support the SWRCB’s proposed special study to identify methods to improve the performance of the *Ceriodaphnia dubia* reproduction test within the constraints of USEPA Standard Methods. |
| 3.010 | **Comment No. 2 - We are supportive of the proposed special study to identify methods to improve the performance of the *Ceriodaphnia dubia* reproduction test**  Our CVCWA special study of toxicity results in the Central Valley clearly indicated that the *Ceriodaphnia dubia* reproduction test is the most prevalent indicator of toxicity for Central Valley POTWs, and the most prevalent reason for initiation of Toxicity Reduction Evaluations (TREs). Given the issues that have been well documented for this test, CVCWA fully endorses the need for a study to improve the reliability and accuracy of results for the *Ceriodaphnia dubia* reproduction test. CVCWA looks forward to working with State Board staff and other stakeholders in the design and implementation of the proposed study. |
| 6.028 | If the *C. dubia* chronic bioassay is to be used in the TST Test Method framework, a clear understanding of the variability and limitations of the test method as well as adequate training of laboratory personnel and permit writers are required and should be performed before this test (as well as other WET tests) is used to assess compliance with water quality objectives or permit toxicity requirements. For the foregoing reasons, LADWP requests that that *C. dubia* not be used as the most sensitive species until the accuracy of the reproductive test can be verified or improvements can be made to the test method to reduce the variability through a comprehensive study. |
| **SC J-5.001** | The cost savings of running only two samples in the TST “method” compared to running multiple dilutions required by other statistical methods may not be realized, since additional replicates are needed to achieve low within-test variability for the TST method. The use of multiple dilutions is more appropriate, offering the dose response relationship information that the TST does not offer. |
| **SR J-5.001** | Dischargers may choose to increase the number of replicates to increase test power. However, as explained in Appendix J of the Staff Report, for most laboratories in California conducting the chronic *C. dubia* reproduction toxicity test, increasing the number of replicates is not necessary to achieve a low probability of having a false positive. The utility of additional replicates is discussed in Appendix J and in “SR27.032” and “SR27.033” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). See Section 9.1.4 of the Staff Report for a discussion of the costs of increasing the number of replicates. However, the Staff Report notes that increasing the number of replicates is not required by the Toxicity Provisions.  Analysis of the dose-response curve was recommended for assessing the statistical endpoints for the NOEC statistical approach. However, the Toxicity Provisions use the TST statistical approach to address the question ''is the sample toxic at the IWC?'' The TST statistical approach provides a yes or no answer, which is determined using a hypothesis testing approach such as the TST statistical approach. Therefore, there is no value in testing multiple effluent concentrations and analyzing the data using the NOEC statistical approach and the TST statistical approach when answering the question “is the sample toxic at the IWC?” For further discussion on the dose-response curve, see response “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  For a discussion on the differences between test method and statistical approach, see response “SR25.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 6.026 | **6. The perceived cost benefit of using the TST statistical method may not be realized.**  The TST statistical method only requires testing of two samples, the control and the IWC sample. Thus, in comparison to other test methods that require the use of multiple dilutions and a control, there was a perceived cost benefit of testing less samples. However, by increasing the replicates in the control and the IWC sample, the within laboratory variability is decreased and the statistical power of the TST method is enhanced. One of the key findings of the SWRCB Staff (presented in Appendix J, Tables J1-J3) was that if the number of replicates was increased from 10 to 20, laboratories were able to achieve low within-test variability and meet the acceptable level of probability of a fail when the percent effect was less than 10. Therefore, the cost savings of running only two samples in the TST method compared to running multiple dilutions required by other statistical methods may not be realized, since additional replicates are needed to achieve low within-test variability for the TST method. The use of multiple dilutions as the EPA tests were originally developed and promulgated are more appropriate, offering the dose response relationship information that the TST does not offer. |
| **SC J-6.001** | The State Water Board is choosing the TST to fix deficiencies in laboratory performance rather than to identify “true toxicity” of the effluent. |
| **SR J-6.001** | There are several advantages of the TST statistical approach, as described in Section 5.3.1 of the Staff Report, which discusses the statistical approaches that were considered for the Toxicity Provisions and why the TST approach is the preferred option. The TST statistical approach is a statewide, consistent, uniform approach that can be used across all permits and regulatory program to determine if a sample is toxic. It simplifies toxicity data analysis, eliminates subjective data interpretation, and allows comparison of results from different dischargers and from different waterbodies. The TST statistical approach also provides high confidence in the test results as it incorporates both a false positive and a false negative rate. In addition to those advantages, the TST statistical approach provides dischargers with an incentive to produce high quality data. High quality data provides greater confidence in the outcome of any toxicity test, regardless of the approach used to assess the toxicity test data. Appendix J demonstrates that as laboratory performance improves, the TST approach is less likely to misidentify “true toxicity,” than the NOEC approach.  Appendix J provides an analysis of laboratory performance in California for the chronic toxicity *C. dubia* test. This analysis provides the probabilities of incorrectly identifying toxicity based on current laboratory performance. The analysis also demonstrates how better laboratory performance favors dischargers when using the TST approach, while poor laboratory performance favors dischargers using the NOEC approach. |
| 4.007 | 1Our prior comments have noted that the SWRCB proposal changes the null hypothesis from the traditional NOEC method (which utilizes a dilution series to establish statistically that an effluent causes toxicity) to the TST method’s null hypothesis (where the effluent (at the IWC) and a control are subjected to a statistical test to establish that an effluent, presumed to be toxic, does not cause toxicity). As we have previously noted, we are concerned that the SWRCB is choosing to apply a method designed to fix deficiencies in laboratory performance rather than to identify the “true toxicity” of the effluent. |
| **SC J-6.002** | Figure J-4 incorrectly identifies 2014 as the point in which the TST was required in LACSD permits. Two of the permittee’s facilities incorporated the TST in January 2015 and the other six in mid- to late-2015. As a result, the key findings that LACSD’s municipal laboratory performance increased upon use of the TST are not supported. |
| **SR J-6.002** | Figure J-4 contains a dotted line and arrow indicating when the TST started to be required in LACSD permits. In the first draft of Appendix J, the dotted line was located between the years 2013 and 2014. However, in the Second Revised Draft of the Staff Report, the dotted line was moved to the right, and is now located between the years 2014 and 2015.  Additionally, Appendix J states that “[b]oth the Fox et al. 2019 researchers and State Water Board staff found LACSD Municipal Laboratories improved their laboratory performance after 2012, as demonstrated by reductions in the control CVs and within-test variability.” This observation of the reduction in CVs is independent of when LACSD began using the TST.  The key finding that the TST statistical approach incentivizes laboratories to produce more precise data and increase statistical power, and that the San Jose Creek Laboratory test performance improved when they began using the TST statistical approach are valid conclusions based on the data observed in Appendix J. Regardless of the exact date that individual permits began incorporating the TST approach, Figure J-4 clearly shows that CVs for the LACSD Municipal Laboratory were consistently higher prior to 2014, when the NOEC was being used exclusively, and consistently lower in 2014, 2015, 2017, and 2018. As pointed out in Section 5.3.1 of the Staff Report, the TST approach provides dischargers with an incentive to produce high quality data to reduce within-test variability. |
| 1.009,  1.013 | Given the above, we suggest that modifications be made to these Appendices regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. Specifically: . . . Figure J-4 incorrectly identifies 2014 as the point at which the TST was required in the Sanitation Districts of Los Angeles County’s (LACSD) permits. Two (2) of this permittee’s eight facilities incorporated the TST in January 2015 and the other six (6) in mid to late 2015. As a result, the key finding that LACSD’s municipal laboratory performance increased upon use of the TST is not supported. |
| **SC J-6.003** | The purely statistical analysis presented in Appendix J does not account for the RMD proposed in the Provisions which states that any effect equaling 25 percent represents unacceptable toxicity and is automatically a “Fail”. Likewise, any chronic *C. dubia* effect less than 13 percent is not determined significantly different for the purpose of reporting toxicity according to U.S. EPA (2002) Guidance, because this is the minimum percent effect that can be reasonably achieved by most laboratories.  Appendix J states that using the NOEC statistical approach, there is approximately a 30 percent chance of declaring the sample toxic when there is a 10 percent effect. This statement is misleading, because U.S. EPA's promulgated method manual states that effluent samples should not be declared toxic when the percent effect for *C. dubia* reproduction is less than 13, even if the NOEC indicates that the difference is statistically significant. In making the statement that TST approach is "less likely to identify a sample as toxic when the biological effects are negligible (at or below 10 percent effect)” Appendix J did not apply the NOEC method in the manner prescribed by U.S. EPA. Rather than a 30 percent chance of the NOEC determining that the sample in this example is toxic, there is actually zero percent chance that this sample would be reported as toxic according to USEPA (2002) WET test Guidance.  The transparency in the interpretation of results presented in Appendix J should be improved by clarifying that the regulatory interpretation of the NOEC and TST differ from the statistical results discussed in Appendix J. |
| **SR J-6.003** | Commenters confuse the percent minimum significant difference (PMSD) lower bound of 13 percent with the percent effect and incorrectly apply the PMSD lower bound to test results discussed in Appendix J. The PMSD is not the same as the percent effect. The TST Technical Document defines the percent effect as the difference in mean response between the IWC and the control, divided by the mean control response, and multiplied by 100. The calculation is included in Section IV.B.1.d of the Toxicity Provisions.  The PMSD discussed in the U.S. EPA methods manuals is used to review the within-test variability when using the NOEC statistical approach. The PMSD is the smallest percentage decrease in growth or reproduction from the control that could be determined as statistically significant in the test. The PMSD is calculated as 100 times the minimum significant difference (MSD) divided by the control mean. The equation and examples of MSD calculations are shown in Appendix C of the U.S. EPA Chronic Freshwater Methods Manual. Table 6 on page 52 of the U.S. EPA Chronic Freshwater Methods Manual lists the upper and lower PMSD bound for the *C. dubia* survival and reproduction test. When using the NOEC, a test should not be considered a “pass” if the PMSD exceeds the upper PMSD bound of 47 percent, and should not be considered a “fail” if both the percent effect at the IWC and the PMSD are below the lower PMSD bound of 13 percent.  The Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms; 4th Edition (EPA 2002) is one of the U.S. EPA method manuals discussed in the Staff Report. The U.S. EPA method manuals do not indicate that any test with a percent effect of less than 13 percent should always be considered a “pass” when using the NOEC approach. Nor do the method manuals indicate that that 13 percent this is the minimum percent effect that can be reasonably achieved by most laboratories for the *C. dubia* chronic test method. Rather the U.S. EPA Chronic Freshwater Methods Manual includes directions and guidance on calculating the PMSD and applying the upper and lower PMSD bounds, when appropriate. As discussed in “SR25.007” in the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), the PMSD bounds were included to account for some of the shortcomings of the NOEC approach that are not needed when using the TST.  The statements made on page 5 of Appendix J are based on the simulated WET tests described in Fox et al. 2019. In these simulations, Dr. Fox applied the PMSD upper and lower bounds when determining which tests would result in a “fail” using the NOEC approach (as described on page 5 of Fox et al. 2019, in the “Methods” section). Therefore, the statements made on page 5 of Appendix J are not misleading and these tests would have resulted in a “fail” if using the NOEC approach to assess the toxicity test data. In addition, the results in Appendix J do demonstrate that the TST approach is "less likely to identify a sample as toxic when the biological effects are negligible (at or below 10 percent effect)."  The erroneous comparison of the PMSD value to the percent effect identifies another significant flaw with the NOEC statistical approach. The complexity of the NOEC analysis with multiple concentrations as well as the additional PMSD review and application has led to confusion and errors in interpreting the results.  Using the TST does not involve such complex interpretations. The TST statistical analysis can be performed in minutes on a simple spreadsheet, providing a definitive and unambiguous answer to the question “Is the sample toxic?” |
| 8.014 | **Comment 3: Appendix J does not accurately reflect how data interpretation is performed.**  Appendix J does not reflect the realities of WET test data interpretation according to the revised draft Toxicity Provisions or USEPA (2002) Guidance. The purely statistical analysis presented in the appendix also does not account for the Regulatory Management Decision (RMD) proposed in the revised draft Toxicity Provisions which states that any effect =25 percent represents unacceptable toxicity and is automatically a “Fail”. Likewise, any chronic *C. dubia* effect <13 percent is not determined significantly different for the purpose of reporting toxicity according to USEPA (2002) Guidance, because this is the minimum percent effect that can be reasonably achieved by most laboratories. The following statement on page 5 is therefore misleading, because it only considers the statistical analysis used to inform the NOEC and not the data interpretation elements of determining the NOEC (“Using the NOEC statistical approach (the dashed line), there is approximately a 30 percent chance of declaring the sample toxic when there is a 10 percent effect. Using the TST statistical approach (the solid line), there is less than one percent chance of declaring the sample toxic when there is a 10 percent effect.”) Rather than a 30 percent chance of the NOEC determining that the sample in this example is toxic, there is actually zero (0) percent chance that this sample would be reported as toxic according to USEPA (2002) WET test Guidance.  **Recommendation:**  Regional San recommends improving transparency in the interpretation of results presented in Appendix J by clarifying that the regulatory interpretation of the NOEC and TST differ from the statistical results discussed in Appendix J. For example, the “Probability of declaring toxicity” in Figure J-2 and Figure J-3 is 100% for the TST when the percent effect is =25 percent and is zero (0) for the NOEC when the chronic *C. dubia* effect <13 percent when interpreted based on USEPA (2002, 2010) Guidance. |
| 9.015 | The fifth finding, at the top of page 2, states that the TST approach is "less likely to identify a sample as toxic when the biological effects are negligible (at or below 10% effect)." That statement is grossly misleading because EPA's promulgated method manual states that effluent samples should not be declared toxic when the Percent Effect for *Ceriodaphnia dubia* reproduction is  less than 13% even if the NOEC indicates that the difference is statistically-significant. The authors of Appendix J did not apply the NOEC method in the  manner prescribed by EPA. |
| **SC J-6.004** | Comparative results for the NOEC and TST are spread over two different figures (J-5 and J-6). In addition, the bar graphs for test results showing test results between 10 percent and 25 percent is also split in two. All of this obscures a critically important point. The NOEC only failed 5 of 25 tests with a percent effect between 10 and 25 percent, while the TST failed 13 of 25 of these same tests, even though none of these tests exceeded the RMD threshold. In addition, the authors improperly classified failures with a percent effect below 13 percent as toxic despite instructions in EPA’s method manual. Three of the five tests classified as failures using the NOEC were below 13 percent and should not have been classified as toxic. After correcting this error, the NOEC failed only 8 percent of these tests, but the TST failed 52 percent of these tests. Thus, the TST is six times more likely to declare results below the RMD as toxic. |
| **SR J-6.004** | There are a variety of ways in which the data in Figures J-5 and J-6 could be presented. The way in which they are presented in Appendix J shows results for the data analyzed using the NOEC pass/fail results in Figure J-5 and the TST pass/fail results in Figure J-6. The figures are presented together in the appendix so that they can be easily compared and the text in the appendix discusses the results. Different bar graphs were provided for tests with a percent effect between 10 and 20 percent and tests with a percent effect from 20 to 25 percent. This was done to provide an easier comparison of the percent effects with the probabilities of declaring a sample toxic presented in Figure J-2 of Appendix J.  The TST Test Drive data were generated during the period when reducing within-laboratory variability and increasing the number of replicates was not incentivized. WET test results were originally derived to be analyzed only with the NOEC or point estimate statistical approaches for compliance determination. The number of replicates used was the U.S. EPA method-required minimum of 10.  Since 2011, there has been an increased clarification of the role within-test variability and number of replicates play in the confidence of statistical results when using the TST and NOEC. Reviewing the long-run median control CV for a laboratory is important to determine statistical power when using the TST or NOEC. When the TST Test Drive was conducted, the data were aggregated by NPDES facility, regardless of how many laboratories provided analyses for that facility. For this reason, it was not possible to include specific laboratory performance in the analysis. Additionally, NPDES *C. dubia* test results were disproportionally provided by the 6 sources. Three of the TST fails below the 25 percent effect level (23 percent of the 13 fails) were from one small facility, which only provided 6 total test results (3 percent) to the study.  Because the long-run control CV data are not available for the laboratories that provided the data for the TST Test Drive, there is no analysis of each laboratory’s long-run control CV data. Therefore, discussion of within-test variability and results are caveated by this laboratory data limitation. Since the minimum number of replicates required during that period equaled 10, one can look at the potential range of the probability of declaring toxicity for CVs in the range of 0.1 to 0.4, as shown in the bottom row in Figure J-2. When precision is high (small CV), the NOEC analysis has a greater chance of declaring a test a fail under the RMD of 10 percent effect (false positive) than the TST. When precision is low (large CV), the NOEC has a greater chance of declaring a test a pass at the RMD of greater than 25 percent effect than the TST.  The remainder of Appendix J provides an in-depth discussion of more recent laboratory performance while conducting compliance testing to be analyzed by the TST. Analysis by Fox et al. 2019 as well as the evaluation of current data show California laboratories can achieve the precision needed to meet the false probability of 5 percent. Increase in precision of test execution and/or increase in replicates reduces the probability of a fail below the 10 percent effect level, as well as fails between the 10-25 percent effect level.  The commenter attempts to draw a conclusion on likelihood of a fail using the TST approach compared to the likelihood of a fail using the NOEC based on a single set of data where the CVs are not known. Fox et al. 2019 provides a comprehensive analysis of the probabilities based on long run CVs.  Commenters incorrectly compare the PMSD value of 13 percent to the percent effect. See SR J-6.003 for a discussion of the difference between PMSD and percent effect. The fails using the NOEC that were below a 13 percent effect were not improperly classified. As stated in Section 3.7 of the TST Test Drive, “[a]ll of these tests had PMSD values above the lower bound of 0.13.” |
| 9.017 | Comparative results for NOEC and TST are spread over two different figures (J-5 & J-6) on two different pages. In addition, the bar graphs for test results in the  zone-of-ambiguity (>10% and <25% effect) are also inexplicably split in two. All of this combines to obscure a critically important point. The NOEC failed only 5 of the 25 tests with a percent effect >10% and <25%, but the TST failed 13 of 25 tests even though none of these tests actually exceeded the RMD threshold. In addition, as noted above, the authors improperly classified NOEC failures with a Percent Effect <13% as toxic despite instructions to the contrary in EPA's method manual. Three of the 5 failed NOEC tests exhibited a Percent Effect <13% and should not have been classified as toxic. After correcting this error, the NOEC failed only 8% of the tests with a Percent Effect <RMD but the TST failed 52% of these same tests. Thus, the data in Figures J-5 & J-6 of Appendix J indicates that the **TST is six times more likely than the NOEC to declare as result BELOW the RMD as toxic.** |
| **SC J-6.005** | The data presented in Figure J-2 of Appendix J indicates that the number of replicates would have to be doubled to maintain equivalency with the NOEC when the CV is 0.3 and tripled when the CV is 0.4. Since the CV cannot be known in advance, each test must begin with 2-3 times more organisms just in case. This greatly increases the total cost of WET testing and is an enormous waste of resources. This fundamentally alters the EPA-approved method by forcing laboratories and dischargers to increase the minimum number of replicates in order to produce functionally-equivalent results with the NOEC procedure EPA promulgated in the chronic WET test methods under 40 CFR Part 136. |
| **SR J-6.005** | As stated in the “Key Findings” section of Appendix J, most laboratories can meet the acceptable false positive probability without the need to increase the number of replicates beyond the method-required minimum of 10. Please see SR J-3.005 for more information.  Fox et al. 2019 explains that the control CV values used in the simulated WET tests (presented in Figure J-2) are parameters, not observed values. While it is true that the control CV for an individual test cannot be known in advance, the median long-run control CV for a laboratory can be known in advance. The results presented in Figure J-2 are based on CV parameter values, which are analogous to long-run median control CVs, not test-specific CVs for individual tests. If a laboratory has a long-run median control CV similar to one of the CV values in Figure J-2 or Table J-5, then that laboratory is expected to achieve the associated false positive probabilities, even if the laboratory occasionally experiences a much higher test-specific control CV. Therefore, it is not necessary for dischargers to conduct the *C. dubia* test with two to three times as many replicates “just in case.” Please see SR J-3.002 for more information.  Additionally, none of the laboratories studied in Appendix J had a long-run median control CV as high as 0.3 or 0.4. Figure J-2 demonstrates that if laboratories were to have consistently high CVs of 0.3 or higher, then additional replicates may be needed to maintain a low probability of a false positive while using the TST. However, Figure J-2 also demonstrated that when the CVs are below 0.2, the TST has a much lower probability of a false positive than the NOEC even with the minimum number of replicates. Please see SR J-1.009 for further discussion.  The Provisions would not alter the U.S. EPA-promulgated test method, nor would they require dischargers to increase the number of replicates used in toxicity testing. The test methods provide a minimum number of replicates for each test method. The methods allow dischargers to increase the number of replicates if they desire to increase the confidence in the outcome of each test.  For concerns regarding the potential costs associated with using additional replicates, please see SR J-5.001. |
| 9.009 | The authors of Appendix J argue that the statistical uncertainty associated with natural biological variability, and the related risk of false positives using the TST, can be mitigated by increasing the number of replicates assigned to each exposure group in a WET test. This may be a true statement; however, the data presented in Figure J-2 of the Appendix indicates that the number of replicates would have to be doubled to maintain equivalency with the NOEC when the CV is 0.3 and tripled when the CV is 0.4. |
| 9.010 | Since the CV cannot be known in advance, each test must begin with 2-3 times more organisms just in case. This greatly increases the cost of total cost of WET testing and is an enormous waste of resources. Indeed, the authors of Appendix J admit that the need to reduce the risk of false positives, when using the TST, creates an "incentive" to increase the number of replicates. But, in effect, this fundamentally alters the EPA-approved method by forcing laboratories and dischargers to increase the minimum number of replicates in order to produce functionally-equivalent results with the NOEC procedure EPA promulgated in the chronic WET test methods under 40 CFR Part 136. |
| **SC J-6.006** | For Figure J-2, if the minimum number of replicates were tripled, the NOEC has more than a 99 percent probability of declaring a sample to be toxic when the percent effect is greater than 25 percent. It is not reasonable to compare the performance of the NOEC using only 10 replicates with the performance of the TST using 2 or 3 times more replicates. |
| **SR J-6.006** | Figure J-2 does not compare the performance of the NOEC with 10 replicates to the performance of the TST with 20-30 replicates. Rather, it provides the probability of declaring toxicity using each statistical approach under the same sets of conditions (i.e. various combinations of parametric percent effect, parametric CV, and number of replicates used for the control and the IWC). Each graph has the exact same set of conditions for both the TST and the NOEC. |
| 9.011 | Figure J-2 also shows that, if the minimum number of replicates were tripled, the NOEC has more than a 99% probability of declaring a sample to be toxic when the Percent Effect is greater than 25%. It is not reasonable to compare the performance of the NOEC using only 10 replicates with the performance of the TST using 2 or 3 times more replicates. |
| **SC J-6.007** | Focusing only on the relatively few false positives that may occur with less than a 10 percent effect ignores the fact that many more false positives can and will occur with when the measured percent effect is greater than 10 percent and less than 25 percent. The key question should be: what is the probability that a TIE will be initiated based on TST failures that occur in response to random natural background variability where the observed percent effect is less than the RMD? Any TIE initiated based on random natural fluctuations in *C. dubia* reproduction is doomed to fail because the process cannot identify a toxic chemical that was never actually present to begin with. |
| **SR J-6.007** | Section 5.4.6 of the Staff Report explains that a TRE is a step-wise process that is used to identify the cause of effluent or ambient toxicity in a water body, while a TIE is a study that attempts to characterize, identify, and then confirm the specific cause of toxicity observed in aquatic toxicity testing. While the Provisions do not include a requirement for conducting TIEs, a discharger may incorporate a TIE as a part of a TRE.  False positives that occur because of high within-test variability are accounted for in the test methods, including the *C. dubia* chronic reproduction test. As stated in SR J-1.001, the U.S. EPA conducted a robust method variability study prior to promulgating the *C. dubia* chronic test method. Please see “SR25.014” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for information on the low false positive rates (the percentage of test results that indicated toxicity in blank samples) from the U.S. EPA variability study. In Edison Electric Institute et al. v. EPA, 391 F.3d 1267 (D.C. Cir. 2004), the Court of Appeals determined that the test methods did not produce unacceptably variable results. Please see SR J-3.007 for further discussion of why “natural background variability” is unlikely to result in a TST fail.  The probabilities of MMEL violations and TREs based on false positive rates presented in Section J-5 of Appendix J, are based on the probability of a fail at a percent effect of 10, which is the “negligible” level of toxicity used by the TST. Section 1.4 of the TST Technical Document defines “negligible” toxicity as having a 10 percent or less effect. This section of the TST Technical Document also explains that it was necessary to define a second, smaller level of toxicity as “negligible” (in addition to the “unacceptable” toxicity level of 25 percent effect) in order to control both false positive and false negative error rates. Tests with a percent effect of greater than 10 demonstrate a greater than negligible level of toxicity.  The Fox 2019 Memorandum explains further: “Toxicity occurs if the true percent effect is between 10 and 25, but for practical reasons, as a regulatory management decision, it was useful to select a value of 25 percent effect to use in the TST t-test.” Fox et al. 2019 (page 3, last paragraph of the “Background” section) explains that, for the purposes of their study, a false positive occurred when a test was incorrectly declared toxic when the “true” (i.e., parametric) percent effect was 10 or less. A parametric percent effect of 10 does not correspond to every individual simulated test having a percent effect of 10. This concept is explained further in Fox et al. 2019.  The “true” toxicity of real environmental samples is hypothetical and unknown. However, in statistical “power” calculations and simulated WET tests (such as those described in the TST Technical Document and Fox et al. 2019), the “true” level of toxicity is known, and statistical calculations are used in order to estimate false positive and false negative rates. For this reason, Section J.5 of Appendix J relies upon these types of analyses to estimate the probability of false positive test results leading to an MMEL violation and a TRE.  Section J.5 of Appendix J explains that the probability of false positive test results leading to an MMEL violation is very low, while the probability of false positive test results leading to a TRE is even lower. |
| 9.018 | All of the calculations used to show that the probability of initiating a TIE based on a statistical false positive are irrelevant to the actual regulatory issue before the Board. Focusing only on the relatively few false positives that may occur with less than a 10% effect ignores the fact that many more false positives can and will occur with when the measured Percent Effect is greater than 10% and less than 25%. So, the key question should be: what is the probability that a TIE will be initiated based on TST failures that occur in response to random natural background variability where the observed Percent Effect is LESS than the RMD? This is important because any TIE initiated based on random natural fluctuations in *Ceriodaphnia dubia* reproduction is doomed to fail because the process cannot identify a toxic chemical that was never actually present to begin with. |

## Category K – Appendix K

| **Comment Code** | **Comment** |
| --- | --- |
| **SC K-1.001** | Initiating three toxicity tests within a 30-day period is possible, but very difficult. This makes it for all practical purposes, infeasible on an on-going basis across the State. |
| **SR K-1.001** | As described in Section 5.4.3 of the Staff Report, median monthly effluent limitations (MMELs) are designed to address the possible effects of a discharge over a period of a calendar month. Ongoing routine monitoring of aquatic toxicity ensures protection of beneficial uses while providing some relief to dischargers from conducting multiple tests each calendar month if the initial routine monitoring test results in a “pass.” Affording dischargers up to three toxicity tests to determine compliance with the MMEL provides dischargers with two additional opportunities to demonstrate the effluent is not toxic to aquatic life whenever a routine monitoring test results in a “fail.” An alternative to using up to three toxicity tests within a calendar month would be to assess compliance with the MMEL using results from a single toxicity test within a calendar month.  The Los Angeles Regional Water Quality Control Board requires NPDES dischargers to complete three toxicity tests within a calendar month for MMEL compliance purposes. Dischargers have been able to comply with this requirement. The Toxicity Provisions do not require dischargers to complete three toxicity tests in a calendar month. Rather, the Toxicity Provisions require dischargers to initiate from one to three tests in a calendar month depending on the results of the first test. Any difficulties in initiating three toxicity tests within a calendar month can be alleviated with proper planning and management by the laboratories and dischargers. See responses “SR07.001” and “SR07.002” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) regarding the feasibility of initiating three toxicity tests in a calendar month.  Dischargers can work with their contract or in-house laboratories to obtain preliminary results and notification of fails in a timely manner. The laboratory survey results in Appendix K of the Staff Report demonstrate that initiating a routine monitoring test toward the beginning of the calendar month would provide the dischargers sufficient time to initiate three tests within a calendar month.  Additionally, language was added to the Toxicity Provisions to provide dischargers relief from receiving a permit violation if the toxicity tests cannot be initiated within the same calendar month due to circumstances outside the discharger’s control. A consistent yet flexible framework for monitoring toxicity is consistent with Project Goal #3 in Section 2.2 of the Staff Report. |
| 7.004 | Toxicity testing requires significant logistical resources and planning in order to be conducted in a timely manner. BACWA appreciates the State Water Board’s staff effort to research toxicity laboratory practices and include these findings in Appendix K of the Staff Report. As concluded in Appendix K and acknowledged by staff at the November 28, 2018, State Water Board Hearing and again at the recent January 10, 2020, Public Staff Workshop, initiating three tests within a 30 day period is possible, but very difficult. This makes it for all practical purposes, infeasible on an on-going basis across the State. |
| **SC K-1.002** | Using the practicable timeframe in Table K-1 to initiate three MMEL compliance tests in a calendar month, it is unlikely that the discharger would be able to initiate the second compliance test in the same calendar month. The practicable timeframe gives the discharger and the laboratory one day (in a 28-day calendar month) to collect the sample, transport the sample to the laboratory, and initiate the bioassay, which is not feasible. Table K-1 only considers what the laboratory could achieve once it has the sample and does not consider any constraints the discharger may have in work force, equipment, and logistical issues in collecting and shipping the sample to the laboratory once informed of the "fail" result.  Results from three Los Angeles County Sanitation District (LACSD) wastewater facilities using the TST statistical approach were analyzed. Although the three MMEL samples were initiated within the same calendar month, LACSD data suggest that it can take up to 21 days after the routine monitoring sample to collect the first MMEL compliance sample. The LACSD uses an in-house laboratory, and as such, communication and ease of transferring results between the facilities and the laboratory should be accelerated compared to using an outside laboratory. |
| **SR K-1.002** | Section IV.B.2.d.ii(D) of the Toxicity Provisions requires that the MMEL compliance tests shall be *initiated* within the same calendar month that the first routine monitoring test was initiated that resulted in the “fail.” After these comments were submitted, language was added to Section IV.B.2.d of the Toxicity Provisions to define “initiation” of a test to mean when the sample is collected. As explained in Section 5.4.4.1 of the Staff Report, initiation of a test for a grab sample begins once the grab sample has been collected. When collecting a composite sample, commonly collected over a 24-hour period, initiation of a test begins after the 24-hour period, when the composite sample has been collected. Therefore, if a discharger was not be able to initiate their second MMEL compliance test until day 27 in a 28-day calendar month, the discharger would still meet the initiation requirement in the Toxicity Provisions because the sample would be collected within 24 hours or less.  The LACSD laboratory was one of the respondents to the survey conducted for Appendix K. None of the respondents to the survey in Appendix K indicated that it would take up to 21 days after the routine monitoring sample to collect the first MMEL compliance sample. In Figure 1 provided by the commenter, the second MMEL compliance samples were collected well within the 30-day period and would have met the initiation requirement in the Toxicity Provisions. Additionally, the Los Angeles Regional Water Quality Control Board currently requires their dischargers to *complete* the three toxicity tests within a calendar month, whereas the Toxicity Provisions only require dischargers to *initiate,* not complete, up to three toxicity tests within a calendar month. The requirements for conducting MMEL compliance tests in permits issued by the Los Angeles Regional Water Quality Control Board are currently more stringent than the requirements in the Toxicity Provisions.  As noted by the commenter, for dischargers with in-house laboratories, communication and ease of transferring results between the facilities and the laboratory should be accelerated, compared to using an outside laboratory. Dischargers with in-house laboratories can receive test results faster and would be able to initiate another toxicity test sooner, making it more feasible for these dischargers to initiate three toxicity tests within a calendar month.  See SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month.  See SR K-4.003 for a discussion on the discharger’s logistical constraints. |
| 6.017 | The State Board provided a practicable timeframe for initiating three MMEL compliance tests in a calendar month that outlined when the tests would be initiated and when the test results would be available (Appendix K, Table K-1). The timeframe was based on two key summary responses from the surveyed laboratories: (1) 10 days was the longest time a discharger would have to wait for preliminary "pass/fail" results (i.e., *C. dubia* chronic bioassay) and (2) the additional MMEL compliance test could begin within 7 days of the discharger receiving the "fail" result.  Based on this information, the second additional MMEL compliance test could be initiated as late as day 28. This schedule only considers what the laboratory could achieve once it has the sample and does not consider any constraints the discharger may have in work force, equipment, and logistical issues in collecting and shipping the sample to the laboratory once informed of the "fail" result. Not all facilities operate 24/7, which could result in a delay in receiving the laboratory results and making necessary arrangements for collecting the next sample. For remote facilities, overnight shipping may not be available, also resulting in delays.  Using the practicable timeframe provided by the SWRCB to initiate three MMEL compliance tests in a calendar month, under the worst-case scenario of 10 days to receive preliminary results and 7 days to initiate the first additional compliance test, it is unlikely that the discharger would be able to initiate the second compliance test in the same calendar month. Under this scenario, the routine monitoring results are received on Day 10, the first additional compliance test is initiated on Day 17, and results are provided on Day 27. This gives the discharger and the laboratory one day (in a 28-day calendar month) to collect the sample, transport the sample to the laboratory, and initiate the bioassay, which is not feasible. |
| 6.018 | To provide some ground truthing to the proposed practicable timeframe, Los Angeles County Sanitation District's (LACSD) test data were analyzed.  The LACSD's wastewater facilities have been using the TST statistical approach since the Los Angeles Regional Board incorporated the method in the NPDES permits in 2014. Monthly "pass/fail" data for the *C. dubia* bioassay were analyzed for eight LACSD facilities from January 2015 through April 2019. When the MMEL monitoring sample resulted in a "fail," the number of days between the sampling dates of the first 24-hr composite sample for the additional two MMEL compliance samples was computed and compared to the practicable timeframe provided by the State Board.  Results for three facilities that had the most "fail" events between 2015 and 2019, Long Beach, SJC East and SJC West, are provided in Figure 1. |
| 6.019 | Each fail event represents when the routine monitoring sample resulted in a "fail" using the TST statistical method for *C. dubia* chronic reproductive bioassay. Data were derived from the spreadsheet apppendix\_j\_source\_data.xlsx."  For each sample, the top of the bar represents the day the first 24-hr composite was collected. The routine MMEL sample is collected on day 1. The first additional MMEL compliance sample was collected between 7 to 21 days after the routine monitoring sample. The second additional MMEL compliance sample was collected 1 to 7 days after the first additional compliance sample. |
| 6.020 | Although the three MMEL samples were initiated within the same calendar month, a couple of observations can be made. One observation is that the SWRCB's practicable timeframe for initiating the first MMEL compliance sample between Days 8 and 17 is optimistic since the LACSD data suggest that it can take up to 21 days to collect the sample. The LACSD uses an in-house laboratory, and as such, communication and ease of transferring results between the facilities and the laboratory should be accelerated compared to using an outside laboratory. |
| **SC K-1.003** | The “Practicable Timeframe for Initiating MMEL Compliance Tests” included in Table K-1 does not consider many factors that would require additional time to initiate three samples within a calendar month and should be modified to show longer time periods. For example, sampling may not be possible on the first day of every month, due to weekends, holidays and other sampling staff availability issues, especially at smaller POTWs. Under the “Less Optimistic Case,” based on the information presented in Appendix K, three samples cannot be taken in the required 30- or 31-day monthly window. This would result in non-compliance with this NPDES permit requirement. |
| **SR K-1.003** | Table K-1 is a practicable timeframe based on the laboratory survey results and has not been modified. Most laboratories and dischargers are capable of working together to be able to initiate the tests within or close to the timeframes shown for the “best case” time needed. Sampling would not be required on the first day of every month because Section IV.B.2.d.i of the Toxicity Provisions requires the Regional Water Board to consider relevant scheduling constraints identified by the discharger and applicable laboratories when setting the start of the calendar month. The “Less Optimistic Case” presented by the commenter includes two 7-day timeframes between results conveyed to the POTW and the start of the next sampling event to match laboratory capacity to begin the next test. This could be avoided with proper planning and communication between the discharger and the laboratory. Additionally, language was added to the Toxicity Provisions to provide dischargers relief from receiving a permit violation if the toxicity tests cannot be initiated within the same calendar month due to circumstances outside the discharger’s control. See SR K-1.001 and SR K-1.002 for further discussion on initiating three toxicity tests within a calendar month. |
| 2.022 | Furthermore, it is appropriate to adjust the testing timeframe projections in Appendix K to account for the factors discussed above. |
| 3.005 | The issue of the feasibility of initiating three chronic toxicity tests in a one-month period has been an ongoing topic between CVCWA, CASA, other POTW representatives and State Board staff for the past several years. The topic has also been discussed at workshops before State Board members. Based on the information presented in Appendix K, CVCWA believes that additional consideration should be given to this issue.  First, we assess the information presented in Appendix K and summarized in Table K-1. The findings from the survey of toxicity testing laboratories performed by State Board staff indicate the following for the *Ceriodaphnia dubia* reproduction test, the most commonly applied test for inland surface water discharges:   * Time to perform *Ceriodaphnia dubia* reproduction test: 6 to 8 days (Page 3, K.3) * Time for laboratory to perform *Ceriodaphnia dubia* reproduction test and produce preliminary results: 10 days (Page 1, K.2. Question 1) * Time to inform client regarding preliminary results: 1 to 2 days Page 1, K.2, Question 1) * Time to for a laboratory initiate a subsequent test upon direction from client: from one day to 7 days (Page 1, K.2, Question 2) |
| 3.006 | Based on these facts, the range in timing for performance of three *Ceriodaphnia dubia* reproduction tests is as follows:  **Best case**  Start first laboratory test – Day 2 (first full day of sampling occurs on Day 1 – laboratory testing begins on Day 2)  Start second laboratory test – Day 14 (first test completed on Day 11, results conveyed to POTW on Day 12, sampling initiated on Day 13, second test starts on Day 14)  Start third laboratory test – Day 26 (second test completed on Day 23, results conveyed to POTW on Day 24, sampling initiated on Day 25, third test starts on Day 26)  **Less Optimistic Case**  Start first laboratory test – Day 2 (first day of sampling occurs on Day 1 – laboratory testing begins on Day 2)  Start second laboratory test – Day 20 (first test completed on Day 11, results conveyed to POTW on Day 13, sampling starts on Day 19 to match lab capacity to begin next test, second test starts on Day 20)  Start third laboratory test – Day 38 (second test completed on Day 29, results conveyed to POTW on Day 31, sampling starts on Day 37 to match lab capacity, third test starts on Day 38)  As can be seen in the above, for the Less Optimistic case, based on the information presented in Appendix K, three samples cannot be taken in the required 30- or 31-day monthly window. This would result in non-compliance with this NPDES permit requirement.  Notably, we designate the second case above as “Less Optimistic,” as opposed to “Worst Case,” because of the following, which, if included, would add days to those shown for the “Less Optimistic” case:   * Sampling may not be possible on the first day of every month, due to weekends, holidays and other sampling staff availability issues, especially at smaller POTWs. * Weekends and holidays will likely impact (prolong) communications between the testing laboratory and the POTW management and sampling crews during the month. * Smaller POTWs will likely encounter difficulties in communication and in getting contractors out to take multiple mid-month samples and renewals on specific days. |
| 3.007 | The above results bring into question the information presented in Table K-1. Specifically, Table K-1 should be modified as follows to be consistent with the facts stated in Appendix K:  1. For the Routine Monitoring Test, Test Initiation should be changed from “Day 1” to “Day 2”; Test Results Available [to POTW] should be changed from “Day 7 to 10” to “Day 12 to 13”  2. For the first Compliance Test, the Test Initiation days should be changed from “Day 8 to 17” to “Day 14 to 20”; the Test Results Available [to POTW] should be changed from “Day 15 to 27” to “Day 24 to 31”.  3. For the second MMEL Compliance Test, the Test Initiation days should be changed from “Day 16 to 28” to “Day 26 to 38”; the Test Results Available [to POTW] should be changed from “Day 23 to 38” to “Day 36 to Day 49”.  To illustrate the above, we have prepared several diagrams. The first diagram (Figure 1) depicts the “Best Case” described above; the second diagram (Figure 2) depicts the “Less Optimistic Case” described above. A “Worst Case” condition is not depicted. |
| 8.022 | *Recommendation:*  The “Practicable Timeframe for Initiating MMEL Compliance Tests” included in Table K-1 does not account for most of these reasonable and common occurrences that prevent sample collection, and should be revised to present a more realistic timeframe. Please refer to Table 1 (Attachment B) for a visual representation of Regional San’s realistic workflow for WET testing. |
| **SC K-1.004** | Scheduling required MMEL compliance tests is not achievable in a calendar month when there are only 15 days of discharge. Dischargers who reclaim all or large portions of their effluent during the summer irrigation season may discharge for as few as 15 days in a given month, making this a relevant concern. Additionally, it is not possible to collect all samples for the three WET tests with *C. dubia* that would be needed. Test renewal samples are required every other day (USEPA 2002). Sampling every other day during 15 days of discharge would miss one of these required samples in the third test.  The calendar in Figure 1 provided by the commenter demonstrates that there is no time to review preliminary test results and thus make a decision whether to execute MMEL testing. Conducting MMEL testing must be assumed, a priori, and the first MMEL test must be initiated before routine toxicity test results are available. Also, the schedule presented in Figure 1 is optimistic because it does not consider diversions, maintenance, and other activities that would prevent sampling for toxicity testing as shown. |
| **SR K-1.004** | Section IV.B.2.d of the Toxicity Provisions states that when there is no effluent available to complete a routine monitoring test, or MMEL compliance test, the test shall not be required, and routine monitoring continues at the frequency specified in the permit. Section 5.4.4.2.4 of the Staff Report provides further explanation for when an MMEL compliance test is or is not required. If effluent is not available to conduct any MMEL compliance test, then one is not required, and the discharger would not be in violation of the MMEL for that calendar month. If effluent is available to conduct the first MMEL compliance test, then the discharger must initiate that test even if they anticipate that there will be insufficient effluent to initiate two MMEL compliance tests within that same calendar month.  As mentioned in SR K-1.001, while a discharger could initiate an MMEL compliance test before receiving the results from the routine monitoring tests, initiating a routine monitoring test toward the beginning of the calendar month would provide the dischargers enough time to initiate three tests within a calendar month. Conducting MMEL compliance testing is not always assumed a priori with proper planning and communication between the discharger and their laboratory. Figure 1 provided by the commenter appears to suggest that the three toxicity tests must be completed within the calendar month. However, the Toxicity Provisions only require the MMEL compliance tests to be initiated within the calendar month. See SR K-1.002 for further discussion.  See SR K-4.003 for a discussion on the discharger’s logistical constraints. |
| 2.014 | **a. Scheduling required MMEL compliance tests is not achievable for certain discharge scenarios.** A detailed activity schedule for planning, sampling, conducting, and reporting required toxicity tests in a calendar month is provided in **Figure 1**. This is a schedule for conducting three chronic *C. dubia* WET tests (USEPA 2002, method 1002.0) in a calendar month when there are only 15 days of discharge, as would be required (Toxicity Provisions Section IV.B.2.c.i.(A)). The calendar demonstrates that there is no time to review preliminary test results and thus make a decision whether to execute MMEL testing. Conducting MMEL testing must be assumed, a priori, and the first MMEL test must be initiated before routine toxicity test results are available. Dischargers who reclaim all or large portions of their effluent during the summer irrigation season may discharge for as few as 15 days in a given month, making this a relevant concern. Moreover, laboratories were not presented with this scenario when asked whether they could complete MMEL testing. |
| 2.015 | Also note that the schedule presented in Figure 1 is optimistic because it does not consider diversions, maintenance, and other activities that would prevent sampling for toxicity testing as shown. Even so, it is not possible to collect all samples for the three WET tests with *C. dubia* that would be needed. Test renewal samples are required every other day (USEPA 2002). Sampling every other day during 15 days of discharge would miss one of these required samples in the third test. |
| **SC K-2.001** | Initiating up to three toxicity tests in a calendar month may extend sampling and testing into the following month. For example, initiating the second *C. dubia* MMEL compliance test on the 28th day of the calendar month would require collecting some or most of the samples for this test in the next calendar month. To avoid overlap with the next routine test that must be scheduled in this next month, sampling for the next routine test in the second month would need to be delayed. This jeopardizes a discharger’s ability to conduct all routine and MMEL tests in the subsequent month. Other factors could further delay implementation of MMEL testing.  Another example of significant overlap in sampling days is shown in Figures 3 and 4 provided by the commenter. Figure 3 illustrates the case where the discharger just barely initiates three samples in a 30-day month and has a total of 22 unique sampling days over a two-month period. Figure 4 illustrates the case the discharger takes three samples in a six-week period and has a total of 15 unique sampling days over a two-month period. The sampling intensity (as measured by sampling days per two-month period) is different between the two approaches, but not radically so. On the other hand, the approach shown in Figure 3 is unproven in common practice, and is not reliably attainable based on the information presented in Appendix K. There are serious concerns regarding the ability to initiate three samples in a one-month approach, over the long haul of a five-year NPDES permit term, for POTWs of all sizes. |
| **SR K-2.001** | If the second MMEL compliance test was initiated near or at the end of the calendar month and the test was to continue into the following calendar month, some of the renewal water samples may be collected in the next calendar month. An ongoing MMEL compliance test in one month would not prevent the discharger from initiating a routine monitoring test at the beginning of the subsequent calendar month. The routine monitoring test may be initiated before the final renewal water sample is collected for an MMEL compliance test initiated in the previous month, as long as the tests are conducted independent of each other. A single toxicity test cannot be used to determine compliance for an MMEL compliance test in one calendar month and a routine monitoring test in the next calendar month.  For dischargers with a quarterly or biannual routine monitoring frequency, overlapping compliance periods is less of a concern because there is more time between each required routine monitoring test. Dischargers with a monthly routine monitoring frequency may still be completing an MMEL compliance test when they initiate the routine monitoring test for the following month. This is not anticipated to happen often because of the low frequency of fails that have been observed for aquatic toxicity testing, and MMEL compliance tests are only required when a routine monitoring test results in a “fail.” As mentioned by two laboratories in the survey, laboratories try to start the routine monitoring test as close to the beginning of the monitoring period as possible so there is sufficient time to initiate two MMEL compliance tests within that calendar month if necessary. Additionally, Section IV.B.2.d.ii.(A)(1) of the Toxicity Provisions requires dischargers with a monthly monitoring frequency to initiate the routine monitoring test at a time that would allow any required MMEL compliance tests to be initiated within the same calendar month as the routine monitoring test. As demonstrated by the practicable timeframe for initiating MMEL compliance tests in Table K-1, dischargers can minimize or prevent the need for collecting renewal samples in the subsequent calendar month with proper planning and communication between the discharger and the laboratory.  See Section 5.4.4.2.4 of the Staff Report for an explanation on why the MMEL relies upon a calendar month instead of a 45-day time period.  See SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month.  See SR K-4.003 for a discussion on the discharger’s logistical constraints. |
| 2.018 | **d. Sampling and testing for up to three WET tests in a calendar month may extend into the following month to avoid overlapping sampling periods and/or to account for other scheduling conflicts.** Table K-1 supports this concern by indicating that the second MMEL compliance test may be initiated as late as the 28th day of the month. Initiating a *C. dubia* MMEL test on the 28th day of the calendar month would require collecting some or most of the samples for this test in the next calendar month. To avoid overlap with the next routine test that must be schedule in this next month, sampling for the next routine test in the second month would need to be delayed. This jeopardizes a discharger’s ability to conduct all routine and MMEL tests in the subsequent month. The factors discussed above could further delay implementation of MMEL testing. |
| 3.008 | Two additional diagrams illustrate a different point. A third diagram (Figure 3), illustrates the case where a discharger just barely complies with the three samples initiated in a 30-day month. Note that, in this case, there is a significant overlap in sampling days between months one and two. A total of 22 unique sampling days over a two-month period would result. A fourth diagram illustrates a sampling approach where three samples are taken in a 6-week period (an approach commonly used in Central Valley NPDES permits). This approach results in 15 unique sampling days over a two month period. The point to be made is that the sampling intensity (as measured by sampling days per two month period) is different between the two approaches, but not radically so. On the other hand, the approach shown in the third diagram is unproven in common practice, and, in fact, is shown to be likely to not be reliably attainable based on the information presented in Appendix K. As has been discussed with State Board staff by CVCWA and CASA representatives, and as documented in testimony by POTW laboratory leaders at the October 3, 2019 workshop, there are serious concerns regarding the ability to initiate three samples in a one month approach, over the long haul of a five year NPDES permit term, for POTWs of all sizes. |
| **SC K-2.002** | LACSD facilities have been subject to the TST and MMEL compliance tests since 2014. A review of past data shows that generally, when the routine monitoring sample resulted in a fail, the first additional MMEL compliance sample was collected 7 to 21 days after the routine monitoring sample. The second additional MMEL compliance sample was collected within 1 to 7 days after the first additional compliance sample. Although the three MMEL samples were initiated within the same calendar month, the data indicated that the second additional compliance sample was collected shortly after the first additional sample. For two fail events from San Jose Creek (SJC) West, the second additional compliance sample was collected within 24 hours of the first additional compliance sample. Since a MMEL compliance sample typically consists of three 24-hr composite samples collected over a 5- to 6-day period, when the two additional samples are collected within 1-3 days of each other, it is likely that the two additional compliance tests will overlap and thus will be representative of the same sampling period. Because of the time required to determine the first test produces a “fail” result, and to collect, transport, and initiate testing on additional samples, the proposed time constraints mean that the second and third samples are unlikely to be truly independent. |
| **SR K-2.002** | Dischargers may initiate the second MMEL compliance test before completion of the first MMEL compliance test, as long as the tests are conducted independent of each other. In this case, samples for the MMEL compliance tests may overlap. However, overlapping MMEL compliance tests should not occur often with proper planning and communication between the discharger and the laboratory. Additionally, this situation may be alleviated if dischargers initiate their routine monitoring test toward the beginning of the calendar month to provide the maximum amount of time to initiate three toxicity tests within a calendar month. In addition, current permit requirements for LACSD discharge facilities require that both MMEL compliance tests must be completed within the same calendar month as the initial routine monitoring test. The Toxicity Provisions only require the second MMEL compliance test to be initiated within the same calendar month, providing more time than is in the current permits.  See SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month.  See SR K-2.001 for a discussion on overlapping samples. |
| 4.010 | **2. Use of *Ceriodaphnia dubia* 7-day chronic test and meeting permit requirements**  The *C. dubia* bioassay is a short-term test for estimating the chronic toxicity of receiving waters and effluents (U.S EPA 2002). The *C. dubia* are exposed under static renewal conditions until 60% of the surviving control females produce three broods of offspring, which should occur within 7 to 8 days. Two additional effluent samples must be collected throughout the test period to “renew” the water used to test the organisms during the entire test. Under the proposed TST method, if the routine monitoring test results is a “fail,” the discharger is required to initiate two additional MMEL compliance tests within the same calendar month as the routine monitoring test. It may not always be feasible to meet these requirements with *C. dubia* using the TST method. |
| 4.011 | Based on a survey of California laboratories, the *C. dubia* chronic reproduction test has the longest turn-around time of 10 days from when the laboratory initiates the test to when the laboratory provides preliminary “pass/fail” results to the discharger. Under the proposed regulations with the TST method, if the routine monitoring test results in a “fail” the discharger is required to initiate two additional MMEL compliance tests within the same calendar month as the routine monitoring test. The feasibility of meeting these requirements with *C. dubia* and the TST method was tested using data Los Angeles County Sanitation District’s (LACSD) wastewater facilities that have been using the TST statistical approach since 2014 when it was a permit requirement. Monthly “pass/fail” data for the *C. dubia* bioassay were analyzed for eight LACSD facilities from January 2015 through April 2019.4 Generally, when the routine monitoring sample resulted in a fail, the first additional MMEL compliance sample was collected 7 to 21 days after the routine monitoring sample. The second additional MMEL compliance sample was collected within 1 to 7 days after the first additional compliance sample. Although the three MMEL samples were initiated within the same calendar month, the data indicated that the second additional compliance sample was collected shortly after the first additional sample. For two fail events from SJC West, the second additional compliance sample was collected within 24 hours of the first additional compliance sample. Since a MMEL compliance sample typically consists of three 24-hr composite samples collected over a 5- to 6-day period, when the two additional samples are collected within 1-3 days of each other, it is likely that the two additional compliance tests will overlap and thus will be representative of the same sampling period. If this occurs, then the second and third samples are not truly independent. |
| 4.015 | Finally, it is likely to be difficult to initiate two additional MMEL compliance tests for *C. dubia* within the same calendar month as the routine monitoring test. Because of the time required to determine the first test produces a “fail” result, and to collect, transport, and initiate testing on additional samples, the proposed time constraints mean that the second and third samples are unlikely to be truly independent. |
| 6.021 | Another observation is that the second additional compliance sample was collected shortly after the first additional sample. For SJC West, the second additional compliance sample was collected the next day for two fail events. Since a MMEL compliance sample typically consists of three 24-hr composite samples collected over a 5- to 6-day period, when the two additional samples are collected within 1-3 days of each other, it is likely that the two additional compliance tests will be representative of the same sample or sampling period. Although the real-time sampling data from LACSD demonstrate that it is possible to initiate three MMEL compliance samples within a calendar month, the data suggest that dischargers may be forced to collect these samples in a compressed period to meet the permit requirements, which could result in sacrificing sample integrity. |
| **SC K-2.003** | The revised draft Toxicity Provisions indicate that a retest (also known as a “replacement test”) for a test that fails to meet Test Acceptability Criteria (TAC) or other USEPA (2002) guidance validation requirements may be performed to evaluate the MMEL even if the sampling and testing occurs in the next calendar month. However, the Toxicity Provisions do not allow this retest to be used for compliance in the (subsequent) calendar month during which samples were actually collected. It is important to allow time for a retest when test method requirements or TAC are not met. However, scheduling an additional test in the second calendar month due to TAC failures or other validation issues will push the next monthly compliance test further into that calendar month and make it even more difficult to schedule, sample, and meet MMEL testing requirements in the second month. |
| **SR K-2.003** | Section IV.B.2.d.iv of the Toxicity Provisions was added to allow dischargers to initiate a required toxicity test outside the required time period without receiving a permit violation, if the Regional Water Board determines that the toxicity test was not initiated in the required time period due to circumstances that are outside of the discharger’s control. This allows dischargers to avoid a permit violation, under certain circumstances. As stated in Appendix K of the Staff Report, many laboratories expressed that failing to meet TAC does not happen often because they maintain high quality assurance. Other circumstances outside of the discharger’s control that would delay testing or require a replacement test are also expected to rarely occur. Typically, if a replacement test is required for a routine monitoring test, there would be sufficient time to initiate that replacement test within the same calendar month for which the routine monitoring test was required. If the replacement test results in a “pass,” MMEL compliance tests would not be required. If the replacement test results in a “fail,” then it is possible that the required MMEL compliance tests could be initiated in the subsequent calendar month. Also, if a replacement test is required for an MMEL compliance test, that replacement test may need to be initiated in the subsequent calendar month. The Toxicity Provisions require the replacement tests to be initiated as soon as possible. A replacement test that is not initiated in the required time period due to circumstances outside the discharger’s control is not subject to a permit violation, under certain circumstances.  For dischargers with a monthly routine monitoring frequency, because Section IV.b.2.d.iv requires replacement tests to be initiated as soon as possible, a replacement test for one calendar month may be run concurrently with a routine monitoring test or MMEL compliance tests in the subsequent calendar month. Running concurrent toxicity tests may present some logistical challenges but will allow dischargers to avoid receiving a permit violation and is not expected to occur often. However, the replacement test cannot be used to substitute for the required routine monitoring test, meaning that the replacement test must be run independent of the routine monitoring test. A replacement test for one calendar month cannot be used for compliance in the subsequent calendar month, even if the replacement test samples were collected in that subsequent calendar month. In this way, a single test could not be used to determine a violation for separate calendar months. See Section 5.4.4.4 of the Staff Report for further discussion.  See SR K-2.001 for a discussion on overlapping calendar months. |
| 2.019 | **e. Retesting due to TAC failures or other validation issues extends sampling periods.** If a WET test fails to meet Test Acceptability Criteria, or other validation requirement described in the USEPA (2002) guidance (e.g., test dissolved oxygen requirements are not met), then the revised draft Toxicity Provisions indicate that a retest may be performed to evaluate the MMEL even if the sampling and testing occurs in the next calendar month (State Water Board 2019b; Section IV.B.2.c.v – Routine Monitoring and MMEL Compliance Tests that Do Not Meet Test Acceptability Criteria). However, the Toxicity Provisions do not allow this retest to be used for compliance in the (subsequent) calendar month during which samples were actually collected. It is important to allow time for a retest when test method requirements or TAC are not met. However, scheduling an additional test in the second calendar month will push the next monthly compliance test further into that calendar month and make it even more difficult to schedule, sample, and meet MMEL testing requirements in the second month. |
| 8.021 | *e. Needs for retesting due to Test Acceptability Criteria (TAC) failures or other validation issues*  If a WET test fails to meet Test Acceptability Criteria (TAC), or other validation requirements described in the USEPA (2002) Guidance (e.g., test dissolved oxygen requirements are not met), then the revised draft Toxicity Provisions indicate that a retest may be performed to evaluate the MMEL, even if the sampling and testing occurs in the next calendar month (State Water Board 2019b; Section IV.B.2.c.v – Routine Monitoring and MMEL Compliance Tests that Do Not Meet Test Acceptability Criteria). Invalid or indeterminate tests include events such as an apparent problem noted with the condition of the test organisms that is not caused by toxicity, receiving water toxicity, PRT, or an unexpected failure of test equipment (e.g., where all required samples cannot be collected). Scheduling an additional test in the second calendar month will push the next monthly compliance test further into that calendar month and make it even more difficult to schedule, sample, and meet MMEL testing requirements in the second month. |
| **SC K-3.001** | The economic analysis performed in Appendix K is insufficient to understand the costs associated with conducting the specified number of tests in a calendar month. One cost not accounted for in Appendix K includes the cost to staff facilities during weekends such as weekend sample preparation and sampling, weekend toxicity testing, and hiring additional staff if planning and performing multiple tests in a calendar month required repeated weekends. Costs associated with overtime can be minimized when there is flexibility in the timing for toxicity tests.  Another cost not accounted for in Appendix K includes the cost of preparing for tests that may not be necessary. At a minimum, planning and associated costs will be incurred by a discharger for up to two additional MMEL compliance tests, even if only routine monitoring is ultimately required and reported. However, results from routine monitoring will not always be received by the discharger with sufficient time. Also, the results of the first MMEL compliance test may not be available prior to the date when the second MMEL compliance test must be initiated. Therefore, requiring up to three chronic WET tests in a calendar month will impose direct costs for tests that are ultimately unnecessary and lost opportunity costs.  The State Water Board should not consider its economic analysis of the impact of this increased testing complete, until these additional costs associated with logistics of completing the required number of tests is considered. |
| **SR K-3.001** | Appendix K of the Staff Report only reported the results from the laboratory survey and was not intended to include a complete economic analysis of costs associated with toxicity testing in the Toxicity Provisions. Section 9.1.4.2.2 of the Staff Report further explains the monitoring costs and comparisons from the laboratory survey and the 2020 Economic Report estimates the range of baseline aquatic toxicity monitoring costs under current permit requirements.  The number of toxicity tests each calendar month is not anticipated to change significantly due to “fails” as dischargers and laboratories currently need to conduct follow-up testing when there is an exceedance of a trigger. See SR K-2.003 for further discussion on providing dischargers relief from receiving permit violations due to circumstances outside their control. Currently most dischargers are required to conduct follow-up testing whenever a routine monitoring test results in a fail or exceeds a trigger. For some dischargers this consists of up to four additional aquatic toxicity tests. The Toxicity Provisions would only require up to two MMEL compliance tests when the routine monitoring test results in a fail. Therefore, for many dischargers, the requirement for MMEL compliance tests would not result in additional costs beyond the costs for follow-up testing already required in their current permits.  Appendix K of the Staff Report acknowledges that one laboratory may start charging extra for weekend and/or holiday work if the demand for testing increases significantly. Also, for toxicity tests that are cancelled or no longer needed, laboratories do charge for incurred expenses (e.g., cost of purchasing test organisms, courier fees, etc.) and may charge a prorated fee based on the time and effort the laboratory expended. Section 9.1.4.2.2 of the Staff Report was revised to consider these potential costs.  In addition, information provided in the laboratory survey indicates that toxicity testing results can be relayed to the discharger within one to two days. Better communication and coordination between laboratories and discharges can shorten the time needed between analyzing the results of one test and initiating a subsequent MMEL compliance tests when required. This can reduce or eliminate any need for staff to work weekends or overtime to meet compliance test demands. Costs associated with sample collection and transportation are discussed in Section 9.1.4.1.1 of the Staff Report.  See SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month. |
| 7.011 | On the issue of resources and costs associated with conducting up to three tests in a calendar month, BACWA supports the detailed comments submitted by Regional San, in particular comment 5 of their letter. |
| 8.026 | *Comment 5: The economic analysis performed in Appendix K is insufficient to understand the costs associated with conducting the specified number of tests in a calendar month.*  Appendix K includes a summary of laboratory responses to some cost-related questions associated with completing up to 3 MMEL toxicity tests. The range of questions include whether or not laboratories charge for unexpected or canceled tests and how much laboratories charge for each type of test. Regional San would like to reiterate that these questions do not adequately account for all of the costs that will be incurred by dischargers if the proposed MMEL schedule is implemented. Other costs that would be incurred include:  *a. Costs to staff facilities during weekends*  Sampling preparation and sampling may be required on weekends to meet the sampling and testing requirements in the revised draft Toxicity Provisions. Weekend overtime may be required for operators to prepare for testing (e.g., clean and flush lines prior to sampling), collect composite samples, transport, and for laboratory staff to conduct toxicity testing. Costs associated with overtime can be minimized when there is flexibility in the timing for toxicity tests. However, repeated weekends to plan and perform multiple tests in a calendar month would require hiring additional staff. |
| 8.027 | *b. Costs associated with preparing for tests that may not be necessary*  At a minimum, under the most optimistic scheduling scenarios, planning and associated costs will be incurred by a discharger for up to two additional MMEL compliance tests, even if only routine monitoring is ultimately required and reported. Up to two additional MMEL compliance tests are required if a routine monitoring test results in a “Fail”.  However, results from routine monitoring will not always be received by the discharger with sufficient time to order organisms, clean and flush sampling lines, conduct sampling and perform testing before the calendar month ends. Table K-1 indicates that these preliminary test results may not be available before day 10. Results from fathead minnow chronic WET testing may not be available to dischargers for at least 10 days from the start of testing under the conditions shown in Figure 1, and this can be up to 13 days from the start of testing due to weekends and holidays. If additional MMEL compliance testing is required, then both of these tests may need to be initiated. Results from MMEL-1 may not be available prior to the date when MMEL-2 must be started so that it is started within the calendar month. Ordering organisms, sampling, and initiating tests that are ultimately unnecessary, imposes costs on dischargers that were not considered in the State Water Board’s economic analyses. Therefore, requiring up to 3 chronic WET tests in a calendar month will impose direct costs and lost opportunity costs (e.g., deferred maintenance due to scheduling conflicts with toxicity sampling) that were not considered in the State Water Board’s economic analyses. |
| 8.028 | *Recommendation:*  The additional costs to dischargers for weekend overtime, the possibility of hiring additional staff, and canceled tests are not considered in Appendix K, nor were they covered in the economic analyses referenced in this appendix (State Water Board 2019a, Staff Report Section 9.1.4; Abt Associates and PG Environmental. 2018). The State Water Board should not consider its economic analysis of the impact of this increased testing complete, until these additional costs associated with logistics of completing the required number of tests is considered. |
| **SC K-4.001** | The commenter supports and thanks State Water Board staff for revising the proposed Toxicity Provisions to allow replacement toxicity tests, including replacement tests in a subsequent month, when required initial testing does not meet the test acceptability criteria (TAC). However, the reasons for granting the extension should include circumstances beyond the POTWs’ control in addition to tests that do not meet TAC. Atypical conditions, at times, could prevent a laboratory from performing all the required tests are not considered in Appendix K. As noted in Appendix K, results from the second MMEL compliance test may not be available until day 27 of the calendar month. This leaves agencies extremely vulnerable to small slippages in the timeline due to unforeseen events.  The State Water Board should reevaluate its MMEL requirements and the permitting authority should have the discretion to extend the allowable schedule for effluent testing if an agency can prove that they are unable to conduct their test for reasons outside of their control, such as atypical laboratory conditions, culture failure, lack of species availability, quality control failure, capacity contract laboratories, or any number of issues that could occur. Such discretion would allow dischargers the ability to collect and analyze the needed samples without the jeopardy of receiving a violation or wasting resources due to unnecessary testing. |
| **SR K-4.001** | After these comments were submitted, language was added to Section IV.B.2.d.iv of the Toxicity Provisions which states that any specific monitoring requirement is not required to be initiated in the required time period when the Regional Water Board determines that the test was not initiated in the required time period due to circumstances outside of the discharger’s control that were not preventable with the reasonable exercise of care, and the discharger promptly initiates, and ultimately completes, a replacement test. Section 5.4.4.4 of the Staff Report states that circumstances outside the discharger’s control may include a toxicity test not meeting TAC, but also includes dead or delayed shipment of ordered organisms, problems with shipment or transport of samples, laboratory power outage, etc. The Regional Water Board has the discretion to make this determination. See SR K-2.003 for further discussion on providing dischargers relief from receiving a permit violation due to circumstances outside of their control.  Comments regarding the MMEL requirements are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, see SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month and SR K-3.001 for a discussion on how the Toxicity Provisions do not result in “unnecessary testing” as dischargers and laboratories currently need to conduct follow-up testing when there is an exceedance of a trigger. |
| 2.020 | f. **Atypical conditions, at times, could prevent a laboratory from performing all the required tests are not considered in Appendix K.** For example, *C. dubia* cultures recently crashed at the same time at two private toxicity test facilities and replacement organism purchased from a supplier were so unhealthy that they failed to meet Test Acceptability Criteria. A few weeks were needed until laboratory testing with *C. dubia* could resume at either lab after restarting their cultures and validating their health. Appendix K does not discuss testing issues of this magnitude, nor identify the time needed (e.g., to setup a new contract) for the discharger to secure testing space at an alternative lab. |
| 2.023 | Given the challenges described, we recommend that the regulatory authority (i.e., Regional Water Boards) be given discretion to extend the time needed to conduct MMEL tests for any number of issues that could occur. |
| 7.005 | Per Appendix K, “dischargers will know if they need to initiate a second MMEL compliance test between day 15 and day 27 of the calendar month. The second MMEL compliance test could be initiated somewhere between day 16 and day 28 of the calendar month, if it is required.” As noted, results from the second MMEL may not be available until day 27 of the calendar month.  This leaves agencies extremely vulnerable to small slippages in the timeline due to unforeseen events. Dischargers are very much reliant on the labs to be efficient and to provide the results in a timely manner. Any delays on their part can jeopardize the discharger’s ability to initiate the third test within the same calendar month. And, if a result is obtained on a weekend or holiday or if other unavoidable issues are encountered at the POTW such that collection of a third sample is not obtained within a day of the receipt of results from the second MMEL compliance test, the discharger is again at risk of noncompliance with the Toxicity Provisions. |
| 7.007 | Similar consideration must be given to the very real possibility that a test may be invalidated due to laboratory error, quality control failure, and unavailability of test organism due to seasonal nature, and permittees are not able to meet the required time limits. |
| 7.008 | BACWA supports and thanks State Water Board staff for revising the proposed Toxicity Provisions to allow replacement toxicity tests, including replacement tests in a subsequent month, when required initial testing does not meet the test acceptability criteria (TAC). However, this allowance does not go far enough to recognize the breath of circumstances that can delay a successful toxicity test. |
| 7.009 | BACWA proposed that the proposed Toxicity Provisions retain the language allowing for tests to be run in a subsequent month, but broaden the reasons for granting  the extension to include circumstances beyond the POTWs control in addition to tests that do not meet TAC. BACWA requests that the Permitting Authority be given discretion to extend the allowable schedule for effluent testing if an agency can prove that they are unable to conduct their test for reasons outside of their control, such as lack of species availability, control failure, or capacity contract laboratories. Such discretion would allow dischargers the ability to collect and analyze the needed samples without the jeopardy of receiving a violation. |
| 7.010 | BACWA also requests that the State Water Board reevaluate its median limit requirements. The proposed Toxicity Provisions, as written, expose agencies to non-compliance due to factors outside their control in the worst case scenario, or waste of resources due to planning unnecessary testing under the best case scenario. |
| 8.016 | **Comments on Appendix K: Survey of Laboratory Toxicity Testing Logistical Capacities**  **Comment 4: Appendix K fails to consider logistical challenges to conducting the required MMEL compliance tests in a calendar month.**  Appendix K summarizes the results of a survey conducted by the State Water Board to assess the  ability of laboratories to comply with testing requirements in the draft Provisions. The State Water Board survey results summarized in Appendix K conclude that laboratories are generally capable of meeting test requirements proposed in the revised draft Toxicity Provisions that will require dischargers to conduct up to three (3) chronic WET tests in one calendar month. This conclusion may be true under normal laboratory conditions, but atypical conditions will occur (e.g., culture failure) that at times could prevent a laboratory from performing all the required tests. |
| 8.024 | Given the challenges likely to be encountered in meeting the testing requirements in the revised draft Toxicity Provisions, Regional San reiterates its recommendation to allow the regulatory authority (i.e., Regional Water Boards) discretion to extend the time needed to conduct these tests when extenuating circumstances prevent a discharger from collecting the required samples or prevent a laboratory from successfully completing the required WET tests. |
| **SC K-4.002** | Publicly available data indicate that it may not be possible to sample and test three sampling periods that would be independent and separate (rather than overlapping). If laboratories are unable to meet the required schedule, they may subcontract to another laboratory, introducing additional variability to the compliance testing. Subcontracting also requires additional time to review test results.  The use of subcontractors introduces another level of variability for compliance testing that is outside of the control of the prime laboratory and discharger (e.g., inter-laboratory variability). In the TST statistical method, the key factor to meeting the acceptable level of probability of a fail at or below 10 percent effect is to achieve a low level of within-laboratory variability. If the prime laboratory and the subcontracted laboratory do not have similar within-laboratory variability for the chronic *C. dubia* reproduction controls, it is possible that the two laboratories could have different pass/fail results from the TST method, particularly for samples where the percent effect ranges from 10 to 25.  Additionally, when using a subcontracted laboratory, the notification of the test results can be delayed to the discharger. When a subcontracted laboratory is used, the prime laboratory should review the results prior to releasing the results to the client. This additional time for communication between the prime laboratory and subcontracted laboratory and review can ultimately delay the results to the discharged and delay collection of another MMEL compliance sample if needed.  Therefore, additional time should be allowed for MMEL compliance testing and the calendar month should be revised to mean that MMEL compliance tests must be initiated 31 days from the date the routine monitoring results determine a fail. |
| **SR K-4.002** | Dischargers should select subcontracted laboratories with good laboratory performance, based on long-term coefficient of variation (CV), which is a robust measurement of a laboratory’s performance. Dischargers can request this information from the laboratories. Appendix J demonstrates that laboratories with similar CVs have similar probabilities of declaring a test a “pass” or “fail” when evaluating toxicity test data using the TST approach. See SR J-3.002 for further discussion on laboratory variability. Also, the Toxicity Provisions provide dischargers relief from receiving a permit violation due to circumstances that are outside their control. However, the laboratory survey results in Appendix K indicate that the laboratories can manage the volume of toxicity tests and do not need to send samples to a subcontracted laboratory often. See SR K-2.002 regarding overlapping samples.  The laboratory survey results in Appendix K also indicate that test results may be available one to two days after the completion of the toxicity test. Better communication and coordination among the dischargers, laboratories, and subcontracted laboratories would help avoid a delay in MMEL compliance testing, especially when a routine monitoring test results in a “fail.” Section 5.3.1 of the Staff Report explains that the TST approach provides clear pass/fail results that are easy to interpret and use to make a transparent determination of toxicity. Unlike the NOEC or point estimate approaches, the TST approach will not require the initial contracting laboratory to conduct a potentially complicated and time-consuming analysis of the test results.  See SR K-1.001 and SR K-1.002 for a discussion on the initiating three toxicity tests within a calendar month. See SR K-4.005 regarding the definition of the calendar month. |
| 4.004 | Second, publicly available data indicate that it may not be possible to sample and test three sampling periods that would be independent and separate (rather than overlapping). Additionally, if laboratories are unable to meet the required schedule, they may then subcontract to another laboratory, thereby introducing additional variability to the compliance testing. For this reason, we recommend that the SWRCB extend the timeframes for follow-up sampling and testing. |
| 4.012 | In addition, there is a concern that laboratories will have capacity limitations or other constraints. Under these circumstances, it becomes more likely that samples will be sent to a subcontracted laboratory. Achieving a low level of laboratory variability increases the statistical power of the TST method. If the two laboratories (the primary laboratory and the subcontracted laboratory) do not have similar levels of variability for the chronic *C. dubia* reproduction controls, it is possible that they could have different pass/fail results from the TST method. This is particularly likely for samples where the percent effect ranges from 10 to 25. Therefore, the use of subcontractors to provide the compliance testing introduces another level of inter-laboratory variability for compliance testing. It is not clear how conflicting results would be interpreted. |
| 4.016 | Furthermore, if a subcontractor laboratory were needed because the original laboratory could not perform the repeat testing, an additional level of inter-laboratory variability would be introduced into the process. Under these circumstances, it is not clear how conflicting results would be interpreted. For this reason, we recommend that additional time be allowed for MMEL compliance testing. |
| 6.024 | **5. Use of a subcontracted laboratory to meet additional testing demand of the TST statistical method provides another level of variability for compliance.**  When a laboratory has capacity limitations, scheduling limitations, or other constraints, the samples are sent to a subcontracted laboratory for testing. In the TST statistical method, the key factor to meeting the acceptable level of probability of a fail at or below 10 percent effect is to achieve a low level of within-laboratory variability. It has been shown that an increase in the number of replicates in the control and in the IWC sample decreases the variability and increases the statistical power of the TST method. If the prime laboratory and the subcontracted laboratory do not have similar within-laboratory variability for the chronic *C. dubia* reproduction controls, it is possible that the two laboratories could have different pass/fail results from the TST method, particularly for samples where the percent effect ranges from 10 to 25. Therefore, the use of subcontractors to provide the testing compliance introduces another level of variability for compliance testing that is outside of the control of the prime laboratory and discharger (e.g., inter-laboratory variability). |
| 6.025 | Another issue with using a subcontracted laboratory to meet an increase demand is that notification of the pass/fail results can be delayed to the discharger. When a subcontracted laboratory is used, the prime laboratory should review the results prior to releasing the results to the client. This additional time for communication between the prime laboratory and subcontracted laboratory and review can ultimately delay the results to the discharged and delay collection of another MMEL compliance sample if needed.  For the foregoing reasons, LADWP requests that the SWRCB revise the definition of "Calendar Month" to mean that MMEL compliance tests must be initiated 31 days from the date the routine monitoring results determine a fail. |
| **SC K-4.003** | Appendix K evaluates only the laboratory capability of performing up to three WET tests in a calendar month and does not consider logistical challenges faced by dischargers that will, at times, prevent them from collecting all the samples needed to perform required MMEL compliance testing within a calendar month. Some logistical challenges faced by discharges include sampling equipment maintenance and sample preparation, time to prepare organisms and initiate a laboratory test, time to receive and review laboratory data results, and availability of effluent to sample.  Dischargers will face violations of their permit requirements for failing to conduct and report all of the required tests, even if making every attempt to comply.  Clarify the purpose of Appendix K by indicating that it evaluates only the laboratory capability of performing up to three WET tests in a full calendar month and that potential discharger-related sample collection limitations are not addressed. |
| **SR K-4.003** | See SR K-2.003 regarding providing dischargers relief from receiving a permit violation due circumstances outside of a discharger’s control. Dischargers have the responsibility to manage circumstances that are within their control to collect toxicity test samples and transport them to laboratories when required. Dischargers may subcontract sample collection and transportation services if needed. A discussion of sample collection and transportation costs is included in Section 9.1.4.1.1 of the Staff Report.  For a discussion on the availability of effluent, see SR K-1.004 and response “SR07.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  Appendix K clearly states that it is a survey of laboratory capacity. The survey was conducted in response to comments raising concerns that laboratories are incapable of conducting three aquatic toxicity tests in a calendar month. Language was added to Appendix K to indicate that the Regional Water Boards may grant additional time to initiate the required monitoring tests due to circumstances outside the discharger’s control. Also, as stated in Section IV.B.2.d.i of the Toxicity Provisions, the Regional Water Board must consider relevant schedule constraints identified by the discharger and applicable laboratories when setting the start of the calendar month. |
| 2.013 | **Comment 3. Appendix K does not consider logistical challenges faced by dischargers that will, at times, prevent them from collecting all the samples needed to perform required MMEL compliance testing within a calendar month.** The State Water Board survey results summarized in Appendix K reports that laboratories are generally capable of meeting test requirements in the revised draft Toxicity Provisions to conduct up to three chronic WET tests in one calendar month. This finding does not consider discharger concerns that they may not be able to collect samples for these tests even if laboratories are capable of performing these tests. For reasons described below, the revised draft Toxicity Provisions requires testing that dischargers will not always be able to complete. Dischargers will face violations of their permit requirements for failing to conduct and report all of the required tests, even if making every attempt to comply. |
| 2.016 | **b. Constraints on scheduling MMEL WET tests associated with timing of laboratory notification.** POTW staff responsible for coordinating with and reviewing bioassay test results may not be available to immediately review test results issued to a discharger late in the afternoon on Thursday, Friday, Saturday, Sunday, or Mondays that fall on a holiday. These limitations are because some POTWs have augmented work schedules that routinely provide staff, including those designated with WET testing oversight, two Fridays off per month. Certain dischargers that receive test results at close-of-business on Thursday will not have access to email notifications from a contract WET laboratory until the following Monday (or Tuesday if Monday is a holiday). Furthermore, given the tight timeframe needed to schedule and conduct MMEL testing, initiating sampling or testing on the weekends may be necessary on short notice. If so, there will also be overtime costs for municipal utility staff to prepare for testing, collect composite samples, and ship these samples to a commercial laboratory. Therefore, reviewing results and sampling for MMEL tests cannot always occur immediately after notification or within the timeframes provided in Appendix K. Appendix K does not identify whether POTWs can meet these demands and thus fulfill MMEL testing requirements. |
| 2.017 | **c. Time is required to perform maintenance and prepare for sampling.** Dirty sampling lines have been demonstrated through TRE investigations to be sources of bacteria/pathogen related toxicity (PRT) or interference in WET tests. This issue is specific to contamination of sampling equipment and does not affect discharge quality. Therefore, many dischargers clean sampling lines and equipment prior to sampling (or between samples collected on alternate days for *C. dubia* testing). Scheduling consecutive sampling dates for multiple WET tests in a calendar month will not always be possible due to the need to clean and flush sampling lines between sampling events. The time needed to do this should be identified in Appendix K. Moreover, wastewater utilities must perform daily, monthly, quarterly, and annual plant maintenance and sampling for toxicity testing must be planned around these scheduled events. This is particularly relevant to dischargers who must conduct three MMEL tests within a month despite discharging for as few as 15 days (as shown in Figure 1). Time needed to schedule and properly prepare for up to three back-to-back MMEL sampling events may not always be possible. |
| 2.021 | Given the foregoing discussion, we recommend clarifying the purpose of Appendix K by indicating that it evaluates only the laboratory capability of performing up to three WET tests in a full calendar month and that potential discharger-related sample collection limitations are not addressed. |
| 8.017 | This appendix also fails to address the variety of other logistical challenges that dischargers may face that could affect their ability to conduct 3 WET tests in a calendar month. A detailed activity schedule illustrating the challenges that could be faced by Regional San’s wastewater treatment plant in scheduling, sampling, conducting, and reporting 3 toxicity tests in a calendar month are provided in Figure 1 (Attachment B). This example presents the conditions for chronic fathead minnow WET testing (USPEA 2002 method 1000.0) currently performed by Regional San and how the required MMEL compliance testing could be done. Specifically, concerns and challenges include:   1. *Time required to initiate a test*   Test preparation can begin up to 7 days before the start of testing. Ordering organisms is often the driving factor for test initiation as the order request must be submitted to the procurement department at least 48-hours prior to the order being made. There are no fathead minnow suppliers within California, so the test organisms must be shipped overnight from out-of-state. Shipments are not sent on Sundays or holidays and cannot be received by Regional San on weekends or holidays due to reduced weekend staffing. Once organisms are received, they are acclimated for 24-hours prior to testing to exclude any individuals that are displaying signs of stress from shipping. Since WET tests can only be conducted with larval fathead minnow that are not more than 48-hrs post-hatch, the available days when a test can be started are limited to Wednesday through Saturday. These logistical constraints must be considered when scheduling WET tests and will not always allow testing to begin at the same day of the month. |
| 8.018 | *b. Time required to receive sample results*  Results from fathead minnow chronic WET testing may not be available to dischargers for at least 10 days from the start of testing under the conditions shown in Figure 1, and this can be up to 13 days from the start of testing due to weekends and holidays.  Although Table K-1 in Appendix K indicates that test results would be available up to 10 days from the start of testing, testing laboratories and dischargers typically do not have supervisor staff that review, finalize, and report final test results to the discharger on weekends. Due to general staffing constraints, if a test is finalized on Friday or Saturday, a discharger may not reasonably find out about the test result until Monday or Tuesday (if Monday is a holiday), creating a delay in being able to prepare for and implement additional tests. Time needed to report results could leave less than 2 weeks remaining in the calendar month to schedule, prepare for, and initiate up to 2 MMEL compliance tests. |
| 8.019 | *c. Time required to clean and prepare sampling lines in between sampling events*  Scheduling consecutive sampling dates for multiple WET tests in a calendar month must consider the need to clean and flush sampling lines between sampling events. In previous TRE investigations, Regional San determined that contaminated sampling lines caused or contributed to impaired organism performance through pathogen related toxicity (PRT) in WET tests. This issue is an artifact of sampling equipment contamination and does not reflect discharge quality or the potential for effects in the receiving water. Regional San cleans these lines and equipment prior to sampling (or between samples collected on alternate days for *C. dubia* testing at a contract laboratory) to prevent this artifact of sampling from biasing test results. Line cleaning and preparation for sampling and testing must therefore be considered when scheduling WET tests. |
| 8.020 | *d. Availability of effluent to sample*  The schedule presented in Figure 1 (Attachment B) is optimistic, because it does not consider diversions, maintenance, and other activities that would prevent sampling for toxicity testing as shown. Colleting samples for test renewal on each day of a 7-day test, as recommended in WET test Guidance (USEPA 2002) when conducting tests on-site, would require sampling 24-days of the month. Scheduling these tests tentatively on the facility calendar at least one month in advance will severely limit and introduce conflicts with other required operations (e.g., maintenance and required diversions). Therefore, maintenance and operations costs may increase, if activities need to be scheduled on weekends when overtime is paid to avoid conflicts with toxicity sampling.  Sampling and WET testing is currently coordinated to occur when there is a discharge so that receiving water samples can be collected in the morning for concurrent toxicity testing, as required in Regional San’s NPDES permit. This would pose another facet of testing coordination and limitations that dictate scheduling (e.g., avoiding diversions) if receiving water monitoring concurrent with routine WET testing is required in a future permit and Toxicity Provisions are adopted as currently written. Operations, maintenance, and scheduled diversions must be considered when scheduling WET tests. |
| 8.023 | Regional San recommends clarifying the purpose of Appendix K by indicating that it evaluates only the laboratory capability of performing up to three WET tests in a calendar month and that there may be discharger-related sample collection limitations that prevent the toxicity tests required by the revised draft Toxicity Provisions from being performed. |
| **SC K-4.004** | As it stands now, every discharger subject to routine monitoring would be forced to begin their testing at the beginning of the month in order to allow sufficient time for the two additional compliance tests. This provides no operational flexibility for dischargers, who may not be able to collect a routine monitoring sample at the beginning of the month due to lack of available flow, staff availability, or unplanned system outages.  Additionally, this system ensures a huge demand on laboratories at the beginning of the month when all affected dischargers will be submitting their initial compliance tests for analysis. A rush of demand for laboratory services at the beginning of the month could lead to issues such as limited laboratory staff availability, logistical issues, or availability of sufficient test species. |
| **SR K-4.004** | Language was added to Section IV.B.2.d.i of the Toxicity Provisions stating that in setting the start of the calendar month, the Regional Water Board shall consider relevant scheduling constraints identified by the discharger and applicable laboratories. This is discussed further in Section 5.4.4 of the Staff Report. In addition, Section IV.B.2.d.i of the Toxicity Provisions states that for dischargers that conduct routine monitoring at a less than monthly frequency, the calendar month begins from the initiation of the routine monitoring test. This would provide these dischargers the flexibility to begin their calendar month at a time that allows them time to collect all samples as required by the test method.  See SR K-2.003 for a discussion on providing dischargers relief from receiving a permit violation due to circumstances outside the discharger’s control.  For a discussion on the availability of effluent, see SR K-1.004 and response “SR07.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 6.015 | **4. Initiating three MMEL compliance tests in a calendar month may not be feasible**  LADWP has concerns regarding the practicality of the requirement that a discharger initiate up to two median monthly effluent limitation (MMEL) compliance tests within the same calendar month as the routine monitoring test whenever a routine monitoring test results in a fail.  While good communication and coordination between the dischargers and their laboratories is important, LADWP suggests that situations may arise that make it impossible to collect two additional compliance tests within the same calendar month. As it stands now, every discharger subject to routine monitoring would be forced to begin their testing at the beginning of the month in order to allow sufficient time for the two additional compliance tests. This provides no operational flexibility for dischargers, who may not be able to collect a routine monitoring sample at the beginning of the month due to lack of available flow, staff availability, or unplanned system outages. |
| 6.016 | Additionally, this system ensures a huge demand on laboratories at the beginning of the month when all affected dischargers will be submitting their initial compliance tests for analysis. A rush of demand for laboratory services at the beginning of the month could lead to issues such as limited laboratory staff availability, logistical issues, or availability of sufficient test species. |
| 6.022 | All together these issues could lead to situations were dischargers are not able to initiate a routine monitoring test at the beginning of the month. |
| **SC K-4.005** | Revise the definition of “calendar month” to mean that MMEL compliance tests must be initiated 31 days from the date the routine monitoring results determine a fail. |
| **SR K-4.005** | Comments regarding the definition of the calendar month are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, see response “SR07.011” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 6.023 | By changing the requirement for the two additional compliance tests to be initiated within 31 days from the date of a fail test result, the SWRCB would reduce the demand placed on laboratories, and provide dischargers needed operational flexibility. For the foregoing reasons, LADWP requests that the SWRCB revise the definition of "Calendar Month" to mean that MMEL compliance tests must be initiated 31 days from the date the routine monitoring results determine a fail. |
| **SC K-4.006** | There are limited accredited laboratories available to perform toxicity testing; at present there are three in the San Francisco Bay Area. It is likely that at some point an agency will not be able to locate a laboratory able to accept their sample or turn around reports to meet the schedule stipulated.  Additionally, there are very few wild-caught organism suppliers providing these types of test organisms for bioassay labs. An issue such as this could impact all laboratories in the state and is a further example of the difficulties involved in potentially performing bioassay testing three times per calendar month. The proposed Toxicity Provisions should avoid penalizing an agency in this type of situation. |
| **SR K-4.006** | See SR K-2.003 regarding a possible extension for dischargers due to circumstances outside of their control.  Additionally, Section IV.B.2.b.iv of the Toxicity Provisions would provide the permitting authority discretion to allow temporary use of the next appropriate species if the discharger cannot secure a reliable supply of test organisms. See SR K-1.001 and SR K-1.002 for a discussion on initiating three toxicity tests within a calendar month. |
| 7.006 | Because of the level of complexity and expertise required to perform WET tests, most agencies send their sample to contract laboratories. There are limited accredited laboratories available to perform toxicity testing; at present there are three in the San Francisco Bay Area. It is likely that at some point an agency will not be able to locate a laboratory able to accept their sample, or turn around reports to meet the schedule stipulated. Department of Fish and Wildlife Scientific Collecting Permits are required for collecting certain wild (non-cultured) bioassay test organisms. These permits have become increasingly complex to apply for and are often delayed. Additionally, there are very few wild-caught organism suppliers providing these types of test organisms for bioassay labs. An issue such as this could impact all laboratories in the State, and is a further example of the difficulties involved in potentially performing bioassay testing three times per calendar month. The proposed Toxicity Provisions should avoid penalizing an agency in this type of situation. |
| **SC K-4.007** | The largest POTWs should switch from monthly sampling to bi-monthly sampling. The smallest POTWs should switch from quarterly sampling to a maximum of semi-annual sampling. Additionally, switch from a requirement to initiate three samples in a month to initiating three samples in a 45-day period.  This provides the much needed flexibility to address the real-world issues described above, reduces stress on sampling crews, laboratory managers and other staff involved in the logistics of the toxicity testing process, has been applied successfully, and will not significantly reduce the monitoring intensity for toxicity testing |
| **SR K-4.007** | From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see “SR07.015” for a discussion on routine monitoring frequency, “SR07.006” for a discussion on a 30-day compliance period instead of a 45-day compliance period to initiate three toxicity tests, and “SR07.003” for a discussion on additional time to initiate three toxicity tests for circumstances outside the discharger’s control. |
| 3.009 | Based on the above information, CVCWA recommends the following alternative:  Switch from monthly sampling to bi-monthly sampling as the most intensive sampling requirement. This would apply to the largest POTWs. As has been recommended previously by CVCWA, for the smallest POTWs, switch from quarterly to a maximum of semi-annual sampling.  Switch from a requirement to initiate three samples in a month to initiating three samples in a 45 day period. This would require a switch in terminology from a median monthly effluent limit to a 3-sample median effluent limit. CVCWA believes that this approach is legal, since it has been used in previously adopted (and EPA-approved) NPDES permits.  The above alternative provides much needed flexibility to address the real-world issues described above, reduces stress on sampling crews, laboratory managers and other staff involved in the logistics of the toxicity testing process, has been applied successfully, and will not significantly reduce the monitoring intensity for toxicity testing. We believe the tradeoffs in adopting this approach would be worthwhile, and would offer, at minimum, an appropriate starting point for implementation of the proposed Toxicity Provisions. |
| 7.002 | In addition to our comments herein, we support the alternative approach to the monitoring frequencies and timing of the three sample medians that are proposed by the Central Valley Clean Water Agencies in their respective comment letter. |

## Category L – Miscellaneous

| **Comment Code** | **Comment** |
| --- | --- |
| **SC L.001** | The Toxicity Provisions attempt to change the method required by the U.S. EPA. The exposure strategy, performance of the testing, and statistical assessment procedures are all part of the promulgated method. For example, the exposure strategy uses multiple (five) dilutions and control, which, together with the statistical assessment to evaluate the results, are an integral part of the promulgated method.  The U.S. EPA method manual states that the preferred statistical method is the point estimate method. Moving to a two-concentration test such as the TST is a fundamental change in the promulgated method.  U.S. EPA’s 2015 withdrawal of their approval for an ATP was the appropriate choice and consistent with both best science and the fully adopted method. The need for a second draft ATP (requesting that the two-concentration test design replace the five-concentration test design when the TST method is required) confirms that the TST (in its entirety) is a change in test method, rather than simply a change in statistical application.  The Staff Report’s statement that the U.S. EPA does not require a valid concentration response curve to determine toxicity is a misinterpretation of U.S EPA’s position regarding the guidelines for WET test procedures for measuring the toxicity of effluents and receiving waters. The U.S. EPA did not state that a valid concentration response curve was not needed to determine toxicity. Rather, U.S. EPA’s position is that it is not appropriate to establish a concentration response curve prior to determining toxicity using WET test methods. This statement from the U.S. EPA is largely based on the important point that for non-toxic effluents, there will not be a concentration response curve, because all concentrations will indicate no effect, and the response curve would be essentially flat. |
| **SR L.001** | From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see “SR25.003” regarding statistics as a choice separate from the promulgated WET test methods, “SR25.007” for a response to the comment that the TST is a change to the test method, and “SR25.012” regarding the comment about point estimate as the ‘preferred’ statistical approach. Also, please see Section 5.3.1 of the Staff Report for a discussion of the limitations of the point estimate approach.  Please see SR J-3.009 and Section 5.3.1 of the Staff Report for a discussion of why the use of the information obtained from a full dilution series is not necessary when using the TST.  Section 2.6.5 of the Staff Report explains that the ATP application is separate from the Toxicity Provisions. In other words, a new ATP application is not needed prior to approval and implementation of the Toxicity Provisions. U.S. EPA Region 9 did not object to several NPDES permits issued by the Regional Water Boards that include use of the TST for assessing whole effluent toxicity data, yet they have not submitted an ATP to U.S. EPA. Had use of the TST constituted a change in the U.S. EPA-approved test methods or U.S. EPA would have objected to the permits during the review process. This is consistent with U.S. EPA’s response to comments on the 2016 Method Update Rule (MUR), in which U.S. EPA clarified that a revision to the five effluent test concentration minimum requirement in the WET test methods is not necessary in order to allow for use of the TST, and the methods do not specify the statistical approach that must be used in analyzing the data generated from valid WET tests. The U.S. EPA MUR response to comments states that “[t]he TST can be used consistently with the current EPA WET test methods, as long as the permittee continues to meet the required condition in the Part 136 WET test methods to test five effluent test concentrations and a control – even though the TST statistical analysis uses the data from only one of those effluent concentrations plus the control … Again, no ATP is required for the use of the TST, as long as the requirement to test five effluent concentrations is met. An ATP would be required only to reduce the required number of concentrations to be tested to the one effluent concentration plus a control used in the TST statistical approach.” Please see “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for more discussion on U.S. EPA’s 2016 MUR.  Regarding the withdrawal of the 2014 ATP, the reasons for the withdrawal, as described in the February 11, 2015 memo from the U.S. EPA to the State Water Board, are clearly identified as procedural errors in the ATP submittal at the state level, as well as the U.S. EPA’s approval and procedural processes. It is important to note that U.S. EPA’s withdrawal of its approval of the ATP is not based on the scientific soundness of the TST statistical analysis or the one effluent concentration in aquatic toxicity test design. Please see “SR25.040” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for more information. |
| 26.008 | **The proposed toxicity test procedures differ from the Whole Effluent Toxicity (WET) test methods recommended as the preferred approach by the U.S. EPA**  Issue: New language added to the Staff Report asserts that changes to the proposed Toxicity Provisions do not change or require different procedures from the U.S. EPA recommended aquatic test methods for WET. The U.S. EPA-promulgated methods require the use of multiple concentrations, but the TST approach requires only one test concentration (the in-stream waste concentration, or IWC) plus a control. The Staff Report indicates that the SWRCB intends to submit an alternative test procedure (ATP) that would require a two-concentration exposure test (control and IWC) in lieu of the five-concentration exposure test required by the WET test method.    Staff Report, Section 2.6.5, 3rd paragraph, page 16.  “The Provisions do not change or require different procedures than the test methods.”  Staff Report, Section 2.6.5, last paragraph, page 18.  “While a new ATP application is not needed prior to approval or implementation of the Toxicity Provisions, the SWRCB is currently drafting an application for an ATP for the use of the two-concentration test design (one concentration plus the control) when the TST or a simple T-Test is the required statistical approach.”  Staff Report, Section 5.3.1, 2nd paragraph of Option 1, page 74.  “U.S. EPA has previously identified that a valid dose response curve is not needed to determine toxicity (U.S. EPA 2002d)..3    Discussion: We respectfully but strongly disagree with SWRCB’s assertion that the Toxicity Provisions do not change the method required by the U.S. EPA. As presented in the U.S. EPA chronic test method manual (USEPA 2002a), which was part of the official rulemaking, the exposure strategy, performance of the testing, and statistical assessment procedures are all part of the promulgated method. For example, the exposure strategy uses multiple (five) dilutions and control with equal separation between concentrations (e.g., 50% bisection of concentrations), which, together with the statistical assessment to evaluate the results, are an integral part of the promulgated method. Furthermore, it is noted in bold text that the preferred statistical method is the point estimate method (USEPA 2002a) .4 Moving to a two-concentration test such as the TST is a fundamental change in the promulgated method. |
| 26.009 | We further believe that U.S. EPA’s 2015 withdrawal of their approval for an ATP (which is noted in the Staff Report at p. 17) was the appropriate choice and consistent with both best science and the fully adopted method. In our view, the need for a second draft ATP (requesting that the two-concentration test design replace the five-concentration test design when the TST method is required) confirms that the TST (in its entirety) is a change in test method, rather than simply a change in statistical application. |
| 26.010 | The Staff Report’s statement that the U.S. EPA does not require a valid concentration response curve to determine toxicity is a misinterpretation of U.S EPA’s position regarding the guidelines for WET test procedures for measuring the toxicity of effluents and receiving waters (U.S. EPA 2002b). The U.S. EPA did not state that a valid concentration response curve was not needed to determine toxicity. Rather, U.S. EPA’s position is that it is not appropriate to establish a concentration response curve prior to determining toxicity using WET test methods (U.S. EPA 2002b). This statement from the U.S. EPA is largely based on the important point that for non-toxic effluents, there will not be a concentration response curve, because all concentrations will indicate no effect, and the response curve would be essentially flat. |
| 23.010 | The Staff Report asserts in several locations that the revised proposed Toxicity Provisions do not change or require different procedures than promulgated U.S. EPA test methods. {footnote 1: For example, newly added language in the Staff Report Section 2.6.5 (page 16) states, “The Provisions do not change or require different procedures than the test methods.” Staff Report Section 2.6.5 (page 18) states, “While a new ATP application is not needed prior to approval or implementation of the Toxicity Provisions, the SWRCB is currently drafting an application for an ATP for the use of the two-concentration test design (one concentration plus the control) when the TST or a simple T-Test is the required statistical approach.” } |
| 23.011 | The Staff Report also states that the SWRCB intends to pursue a new alternative test procedure (ATP) that would require a two-concentration exposure test (the IWC and a control) instead of the five-concentration exposure test required by the current WET test method. |
| 23.012 | The U.S. EPA chronic test method manual (U.S. EPA 2002) specifies the exposure strategy, performance of the testing, and statistical assessment procedures. These features are part of the promulgated method since the test method manual was part of the official rulemaking process. The promulgated method uses five dilutions and a control with equal separation between concentrations (e.g., 50% bisection of concentrations), and specifies the statistical assessment that should be used to evaluate the results. The promulgated method specifies that the preferred statistical method is the point estimate method (e.g., LC50, IC25). In effect, the sampling procedures, required dilution series, and statistical approach together constitute the accepted method, and “carving out” or disregarding a portion of the promulgated method is a fundamental change in the method itself. |
| 23.013 | LADWP notes further that U.S. EPA withdrew its approval for an ATP in 2015. The need for a new ATP requesting approval of the two-concentration test appears to be an acknowledgement that the TST constitutes a change in the method itself, rather than a simple change to the statistical procedures used to evaluate toxicity test data. |
| 23.014 | Finally, LADWP disagrees with the new assertion in the Staff  Report that U.S. EPA has “previously identified that a valid dose response curve is not needed to determine toxicity.” |
| **SC L.002** | The deleted language in Section III.B.4 of the Provisions, which clarifies that numeric effluent limitations for toxicity will not be included in permits for storm water NPDES dischargers, should be maintained, in order to avoid inconsistent application of the Provisions in storm water permits. The removal of this language exacerbates concerns about the potential implications of the Provisions. The commenter agrees with the discussion in the Staff Report and the conclusions of the Blue Ribbon Panel cited in the Staff Report that numeric effluent limitations for toxicity should not be applied in storm water permits at this time. |
| **SR L.002** | Section III.B.4 of the 2018 draft Provisions contained language that could have been interpreted to indicate that storm water NPDES permits must not include numeric effluent limitations for aquatic toxicity. This was not the intent of the 2018 draft Provisions. Based on comments received during the 2018 public comment period, this language was edited to clarify the intent of Section III.B.4. For more information, please see “SR10.020” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  The 2020 draft Toxicity Provisions do not state that numeric effluent limitations for aquatic toxicity must or must not be applied to storm water on a permit basis. Rather, they state that when the permitting authority requires monitoring with Table 1 species, the TST must be used to evaluate the data.  This is discussed further in Section 5.5.1 of the Staff Report. Option 1, the preferred option, explains that “[t]his option would not require mandatory toxicity testing or effluent limitations for storm water dischargers. The Water Board would have discretion whether to require stormwater dischargers to conduct aquatic toxicity monitoring or to include effluent limitations in permits. However, for storm water dischargers who are required to be enrolled in NPDES permits, if the Water Boards require chronic and/or acute toxicity testing, using test methods as described in Section IV.B.1.b. of the Provisions, then the TST approach would be required for analyzing the resulting data generated from the acute or chronic toxicity tests.”  The adopting resolution for the Toxicity Provisions will direct the staff, primarily within the Strategy to Optimize Resource Management of Stormwater (STORMS) program, to prioritize an evaluation and consideration of aquatic toxicity implementation requirements specific to storm water discharges. Please see SR L.003 for more information. |
| 15.010 | **COMMENT #2: MODIFY SECTION III.B.4 REGARDING APPLICATION OF PROVISIONS TO STORMWATER NPDES PERMITS**  As noted in Comment #1, CASQA continues to have concerns with the Revised Draft Toxicity Provisions that were not addressed in the modifications. Language CASQA supported regarding the incorporation of the Provisions into stormwater permits in Section III.B.4 was removed, thereby exacerbating concerns about the potential implications of the Toxicity Provisions. CASQA requests that the language that was deleted in Section III.B.4. that clarifies that numeric effluent limitations for toxicity will not be included in permits for Storm Water NPDES Dischargers be maintained. As noted in the Draft Staff Report “There are significant difficulties associated with numeric effluent limitations calculations and compliance monitoring. While a compliance schedule would aid implementation efforts, the highly variable nature of storm water, coupled with the multitude of point sources within a municipality, continues to caution against a blanket policy of imposing numeric effluent limitations.” CASQA agrees with the discussion in the Staff Report and the conclusions of the Blue Ribbon Panel cited in the Staff Report that numeric effluent limitations for toxicity should not be applied in storm water permits at this time. CASQA encourages the State Water Board to return the language to this section to avoid inconsistent application of the Provisions in storm water permits. |
| **SC L.003** | New language in the Staff Report indicates that storm water and nonpoint source dischargers must attain the water quality objectives, but no analysis is included to determine whether this is attainable during wet weather events, nor is there any discussion of the economic impacts to storm water and nonpoint source dischargers of switching from narrative to numeric water quality objectives.  Section 9.1 of the Staff Report (13241 analysis) was modified to include a discussion of hydrologic conditions, but did not include any discussion regarding the water quality that can be reasonably achieved through the coordinated control of all factors affecting water quality (Section 9.1.3). The added language in this section acknowledges that stormwater runoff can be a source of toxicity and the selected objectives address dry and wet weather, but does not address whether or not the same objectives could be achieved during storm events.  The commenter encourages the State Water Board to begin implementing procedures to consider the appropriate establishment of objectives for wet weather conditions at the beginning of any policy development process for future efforts.  The commenter is not advocating for removing requirements during wet weather, but rather considering the science underlying the objectives for appropriate application to provide effective beneficial use protection, the conditions under which the objectives should be applied, and the available technology to achieve the objectives during wet weather. Ultimately, these considerations will result in a better understanding of the appropriate protection of beneficial uses under all conditions and the level of effort that will be required to attain those objectives to better inform policy development.  The adopting resolution should direct staff to identify and prioritize a Strategy to Optimize Resource Management of Stormwater (STORMS) project or projects that will (1) create a model process for conducting a 13241 and 13242 analysis that specifically evaluates attaining water quality objectives in wet weather conditions, (2) create guidelines for determining the appropriate application of objectives during wet weather conditions, including, but not limited to, monitoring considerations, permit requirements, and compliance with permit provisions.  Additionally, the adopting resolution should state that during the period of implementation of the STORMS project(s), Regional Water Boards shall not include any new effluent or receiving water limitations for toxicity in storm water permits. |
| **SR L.003** | The Toxicity Provisions do not mandate that effluent limitations or receiving water limitations be included in NPDES permits for stormwater dischargers. For those stormwater dischargers in which the Permitting Authority include toxicity receiving water limitations, the use of the numeric aquatic toxicity objectives are not expected to result in an increase in the number of exceedances compared to the current water quality objectives.  Section 5.1.1 of the Staff Report points out that narrative water quality objectives for aquatic toxicity already exist in basin plans for each Regional Water Board. This section discusses the advantages of a numeric water quality objective assessed using the TST approach, including clear water quality objectives that are not subject to interpretation, and greater confidence in the outcome. The section also points out that the TST and other statistical approaches used to assess compliance with the narrative objectives come to the same conclusion more than 90 percent of the time and that the use of numeric objectives assessed using the TST approach is not anticipated to result in an increase in the number of exceedances of the aquatic toxicity water quality objectives. The numeric water quality objectives in the Toxicity Provisions are attainable and can reasonably be achieved during both wet weather events and dry weather conditions. As discussed in Chapter 9.1 of the Staff Report, higher instream flows during rainfall events or snowmelt may dilute other toxicants. Low instream flows during dry weather conditions may concentrate toxicants. The numeric water quality objectives for aquatic toxicity would ensure the protection of aquatic life uses in both wet and dry weather flow conditions as the objectives are based upon an assessment of the effect of a sample of concern at the IWC relative to a control. The IWC accounts for instream flow conditions as it is the concentration of effluent in the receiving water after mixing. For those water bodies that are not achieving compliance with the narrative water quality objectives, TMDLs either have been developed, or may be developed in the future with specific steps outlined for obtaining compliance with water quality objectives. In either wet or dry conditions, sources of toxicity need to be controlled to protect aquatic life beneficial uses. Chapter 6 describes a wide variety of possible toxicity controls that may be selected by a discharger to reduce toxicity in wet or dry weather conditions. Furthermore, the CASQA Stormwater BMP Handbook emphasizes source control and other methods as effective ways to reduce the potential toxicity of wet weather discharges.  Section 9.1.4.2 discusses the potential economic impact of the Toxicity Provisions on storm water and nonpoint source dischargers.  The adopting resolution for the Toxicity Provisions will direct the STORMS program to consider projects to address NPDES permitting issues related to storm water discharges including appropriate methods of assessing compliance with aquatic toxicity water quality objectives. |
| 15.002 | Throughout the Revised Draft Toxicity Provisions and the Response to Comments, statements are made that the Provisions do not establish any requirements other than monitoring for stormwater permittees and the associated economic analysis is based on this assumption. However, added language in the Staff Report makes it clear that stormwater permittees are responsible for attaining the water quality objectives. “All dischargers, including storm water dischargers, would be responsible for ensuring that their discharge does not cause or contribute to an exceedance of the aquatic toxicity water quality objectives or impair aquatic life beneficial uses in the receiving water.” (Section 5.5.1 on page 156 of Staff Report). While potential strategies for addressing toxicity in stormwater discharges are included in Section 6.4, no analysis is included to determine whether the numeric water quality objectives can be attained during wet weather conditions utilizing these strategies and whether the change from a narrative to numeric water quality objective will have economic impacts on stormwater permittees. |
| 15.003 | Section 9.1 of the Staff Report (13241 analysis) was modified to include a discussion of hydrologic conditions, but did not include any discussion regarding the water quality that can be reasonably achieved through the coordinated control of all factors affecting water quality (Section 9.1.3). The added language in this section just acknowledges that stormwater runoff can be a source of toxicity and the selected objectives address dry and wet weather. However, it does not address CASQA’s primary concern of whether or not the same objectives would have been proposed for toxicity during wet weather events had a thorough evaluation of the water quality conditions that could be reasonably achieved during storm events been conducted. |
| 15.005 | While these disconnects are unlikely to be resolved in the Toxicity Provisions, CASQA appreciates the discussion in the Response to Comments that the adopting resolution may contain some direction that could address some of CASQA’s concerns. Because the adopting resolution is not yet available for review, it is challenging to evaluate if that will ameliorate the remaining concerns with the Revised Draft Toxicity Provisions. As a result, CASQA is providing proposed resolution language for consideration. This language was previously provided to staff for consideration after discussions regarding CASQA’s concerns with the first revised draft of the Toxicity Provisions. |
| 15.006 | CASQA strongly encourages the State Water Board to begin implementing procedures to consider the appropriate establishment of objectives for wet weather conditions at the beginning of any policy development process for future efforts to avoid these concerns and future challenges with implementing objectives in stormwater permits and TMDLs. Establishing objectives that effectively consider potential differences between beneficial use protection and implementation in wet and dry conditions will streamline efforts to develop permits and identify waterbody impairments. CASQA is not advocating for removing requirements during wet weather, but rather considering the science underlying the objectives for appropriate application to provide effective beneficial use protection, the conditions under which the objectives should be applied, and the available technology to achieve the objectives during wet weather. Ultimately, these considerations will result in a better understanding of the appropriate protection of beneficial uses under all conditions and the level of effort that will be required to attain those objectives to better inform policy development. |
| 15.007 | To address Comment #1- The Toxicity Provisions Should Distinguish Between Dry and Wet Weather Conditions in CASQA’s December 2018 comment letter:  WHEREAS: The variable nature of stormwater runoff presents unique challenges in accurately characterizing water quality and potential receiving water impacts. The science required to effectively characterize the duration, exposure, and environmental impacts of toxicity during wet weather events is lacking, and the application of methods derived for continuous wastewater discharges is not appropriate. The challenges are not limited to the Toxicity Provisions and procedures for evaluating development and implementation of objectives during wet weather need to be developed.  THEREFORE, BE IT RESOLVED THAT THE STATE WATER BOARD: Directs staff to identify and prioritize a Strategy to Optimize Resource Management of Stormwater (STORMS) project or projects that will (1) create a model process for conducting a 13241 and 13242 analysis that specifically evaluates attaining water quality objectives in wet weather conditions, (2) guidelines for determining the appropriate application of objectives during wet weather conditions, including, but not limited to, monitoring considerations, permit requirements, and compliance with permit provisions. During the period of implementation of the STORMS project(s), Regional Water Boards shall not include any new effluent or receiving water limitations for toxicity in storm water permits. |
| 22.004e | Page 159 and 165- Throughout the Revised Draft Toxicity Provisions and the Response to Comments, statements are made that the Provisions do not establish any requirements other than monitoring for stormwater permittees and nonpoint source dischargers and the associated economic analysis is based on this assumption. However the following language was added to page 159 (stormwater permittees) and 165 (nonpoint source dischargers): "All dischargers, including storm water dischargers, would be responsible for ensuring that their discharge does not cause or contribute to an exceedance of the aquatic toxicity water quality objectives or impair aquatic life beneficial uses in the receiving water." While potential strategies for addressing toxicity in stormwater and nonpoint sources discharges are included in the staff report, no analysis is included to determine whether the numeric water quality objectives can be attained during wet weather conditions utilizing these strategies and whether the change from a narrative to numeric water quality objective will have economic impacts on stormwater and nonpoint source dischargers. |
| **SC L.004** | The new Economic Report still understates the regulatory costs for implementation, fails to account for increased costs associated with potential acute testing, omits important costs which are discernible, acknowledges utilizing significantly lower cost estimates to sample than the costs reported by municipal labs, and fails to attempt to account for the increased likelihood of incorrect determinations of toxicity resulting in violations.  The economic analysis excludes costs associated with potential increased violations, costs for general permittees, and costs for TRE/IEs. Similarly, the Economic Report did not estimate costs associated with flow-through toxicity testing systems or the expenses for collecting and shipping samples to contract laboratories.  There is potential for increases in violations associated with the imposition of numeric limits and the TST, and the economic analysis does not account for this reality. Staff acknowledged that imposition of the Toxicity Provisions likely will lead to an increase in toxicity violations at wastewater facilities, yet nowhere in the economic analysis is the concomitant financial impact of such violations acknowledged or quantified. Both permitting authority enforcement actions and third-party lawsuits impose significant costs on local agencies, and these need to be represented, estimated, and articulated in the economic analysis. Historical data for prior exceedances/violations should be used to estimate the costs of violations. The alternative of omitting any costs altogether for these is not satisfactory to account for the economic impact.  The municipal laboratory costs used within the economic modelling are underestimated. Appendix K (State Water Board laboratory survey) acknowledges this issue and that, “The municipal laboratory costs were universally higher than the commercial laboratory prices and the costs included in the 2020 Economic Report, as shown in Table 9-7,” which highlights a potential critical flaw or miscalculation in the Economic Report’s analysis and affirms that the costs of these regulations are still understated.  Table 9-7 in the Staff Report (page 334) shows that the municipal laboratory costs generally were reported to be 2 to 3 times higher than the 2020 Economic Report price range. And while the Staff Report notes the municipal laboratories did not provide a breakdown of their costs to show what expenses lead to these higher costs, such a significant disparity may warrant further inquiry by the State Water Board Staff so that the basis of this information could be relayed to the authors of the Economic Report and factored into the final economic analysis to ensure the official estimated costs for complying with these regulations is robust and accurate. Alternatively, simply setting the costs of samples used by municipal laboratories to 2.5 times what is currently utilized in the model could be another way to account for the disparity, instead of using the lower figures for commercial laboratories across the board when it is known that they are a fraction of the costs reported by the regulated community’s laboratories. |
| **SR L.004** | Regarding acute toxicity monitoring costs and costs associated with flow-through toxicity testing systems, estimates were not included in the 2020 Economic Report because the Toxicity Provisions leaves acute toxicity reasonable potential analysis and monitoring requirements, including those for flow-through systems, to the discretion of the permitting authority. This is equivalent to the status quo. Additionally, determining which and how many facilities would be required to conduct acute toxicity monitoring, the frequency at which that monitoring would be required and resulting costs is speculative. As stated in Section 9.1.4 of the Staff Report, the State Water Board is not required to engage in speculation or conjecture. Tables 9-2 and 9-3 of the Staff Report include summaries of costs for conducting an acute toxicity test using multiple and single concentration test designs. For further details, please see pages 4-3 and 4-4 of the 2020 Economic Report.  Regarding the estimates of municipal laboratory costs, the Staff Report includes costs reported through multiple surveys of California commercial laboratories as well as by municipal laboratories to the authors of the 2020 Economic Report. Further discussion is included in Section 9.1.4.2.2 of the Staff Report, which acknowledges that “…municipal laboratory costs were universally higher than reported commercial laboratory prices”, and that “municipal laboratories did not provide a breakdown of their costs to show what expenses lead to these higher costs.” Information regarding what components of municipal laboratory costs might make such costs higher than those prices charged by commercial laboratories are unavailable to the State Water Board and have not been provided. It is not known why dischargers that utilize municipal laboratories pay such higher costs instead of market prices as available through commercial laboratories. Given the assumptions that the majority of regulated entities would tend to pay a lower price for such services, and that the majority of regulated entities use commercial laboratory services and not on-site or municipal laboratories, it is reasonable to assume that the ranges of costs described in the 2020 Economic Report are appropriate to determine aggregated cost increases throughout the state.  Section 9.1.4.1.1 of the Staff Report provides a discussion of estimated costs related to sample collection and transport.  Regarding costs associated with potential increased violations, please see “SR09.002” and “SR09.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). While the Provisions could potentially result in increased violations, it is impossible to accurately predict which dischargers may receive future violations and the frequency at which violations may occur. Any attempt to predict future violations, and potential costs to dischargers for future violations would be purely speculative. Additionally, Water Code 13385 only subjects an NPDES discharger to mandatory minimum penalties (MMPs) for violations of an aquatic toxicity effluent limitation when the NPDES permit does not contain pollutant specific effluent limitations for toxic pollutants. As such, it would be unlikely that a discharger would be subject to MMPs for violations of the proposed aquatic toxicity numeric toxicity effluent limitation because most, if not all, NPDES permits contain effluent limitations for toxic pollutants. See SR P.007 of this document for further discussion of the economic considerations taken into account in Section 9 of the Staff Report.  Regarding “incorrect determinations of toxicity”, please see SR J-1.001.  Regarding costs for general permittees, there is a lack of sufficient information regarding the portion of general permittees that may or may not be required to change current practices under the Provisions. However, page 5-7 of the 2020 Economic Report states that “…compliance activities associated with those affected facilities covered by general permits are expected to be similar to those for individual permittees.” The State Water Board interprets “similar to” as proportional in increase to costs for point-source facilities on a per-test basis.  Regarding costs associated with TREs/TIEs, the Staff Report includes potential costs for TREs and TIEs as explained in Section 9.1.4.1.4. The data included costs for POTW facilities discharging above 5 MGD and indicated a wide range of costs per TRE. Additionally, Section 5.4.6 of the Staff Report explains that TREs are currently required by the SIP if a discharge causes or contributes to chronic toxicity in a water body. Therefore, TREs are already required in current NPDES permits, and neither the frequency nor the costs of TREs are expected to change as a result of the Toxicity Provisions. |
| 11.012 | **2. The new Economic Report still understates the regulatory costs for implementation, fails to account for increased costs associated with potential Acute Testing, omits important costs which are discernible, acknowledges utilizing significantly lower cost estimates to sample than the costs reported by municipal labs, and fails to attempt to account for the increased likelihood of incorrect determinations of toxicity resulting in violations.**  CASA is concerned that the economic analysis contained in the Economic Report supporting the proposed Toxicity Provisions still significantly underestimates the true annual costs of implementation. The current analysis projects the costs to range annually between $1.025 million and $2.823 million for total statewide chronic toxicity incremental routine monitoring. However, the Economic Report acknowledges several “key limitations” of the analysis in Exhibit 5-4 on page 66 of the Economic Report, and that section expressly states the forecasted impact may be “understated.” Specifically, the economic analysis excludes costs associated with potential increased violations, costs for general permittees, and costs for TRE/IEs. Similarly, the Staff Report states that the Economic Report did not estimate costs associated with flow-through toxicity testing systems, and too, the cost evaluation did not include the expenses for collecting and shipping samples to contract laboratories. |
| 11.013 | As noted elsewhere in these comments, we are concerned with the potential for increases in violations associated with the imposition of numeric limits, and the economic analysis does not account for this reality. The Economic Report should at least examine the historical data for costs related to violations, which would supply a baseline figure or value that could be utilized for more fully representing the cost impacts of the Toxicity Provisions. The alternative of omitting any costs altogether for these is not satisfactory to account for the economic impact.  As articulated by others in greater detail in their written comments for these rulemaking proceedings, the economic analysis still entirely fails to account for the potential cost of increased violations from imposition of numeric limits and the TST. Staff has acknowledged that imposition of the Toxicity Provisions likely will lead to an increase in toxicity violations at wastewater facilities, yet nowhere in the economic analysis is the concomitant financial impact of such violations acknowledged or quantified. Both Permitting Authority enforcement actions and third-party lawsuits impose significant costs on local agencies, and these need to be represented, estimated, and articulated in the economic analysis. Consequently, we suggest the aforementioned historical data for prior exceedances/violations, be used to estimate the costs of violations if it assumed that they will occur with the same frequency as they did historically. While they may in fact increase or decrease going forward, we would rather have this assumption for the model explained and the figures included in the models and Economic Report, than it being omitted and not considered. |
| 11.014 | Beyond the costs excluded from the calculation, are the values used within the economic modeling, and here we are still concerned the municipal labs costs for sampling are underestimated. Appendix K (SWB lab survey) acknowledges this issue and that, *“The municipal laboratory costs were universally higher than the commercial laboratory prices and the costs included in the 2020 Economic Report, as shown in Table 9-7,*” which highlights a potential critical flaw or miscalculation in the Economic Report’s analysis and affirms our sector’s concerns that the costs of these regulations are still understated.  More telling for this concern however is directly reviewing Table 9-7 in the Staff Report (page 334), for which it is shown that the municipal lab costs generally were reported to be 2 to 3 times higher than the 2020 Economic Report price range. And while the Staff Report notes the municipal laboratories did not provide a breakdown of their costs to show what expenses lead to these higher costs,” such a significant disparity may warrant further inquiry by the State Water Board Staff so that the basis of this information could be relayed to the authors of the Economic Report and factored into the final economic analysis to ensure the official estimated costs for complying with these regulations is robust and accurate. Alternatively, simply setting the costs of samples used by municipal labs to 2.5 times what is currently utilized in the model could be another way to account for the disparity, instead of using the lower figures for commercial labs across the board when it is known that they are a fraction of the costs reported by the regulated community’s labs. |
| 16.001 | The additional costs due to the provisions will be burdensome for our agency. |
| **SC L.005** | The *C. dubia* study should identify best practices that will demonstrably improve a laboratory's control performance, if needed, thereby increasing confidence in test results.  Each participating laboratory's *C. dubia* reproduction long-run control coefficient of variation, mean, and standard deviation and their upper percentiles (all calculated as instructed by Dr. John Fox, U.S. EPA, ORD) should first be made a matter of public record. All underlying raw data (biological, chemical, physical), calculations, and applicable standard operating procedures need to be included. Providing this complete, granular performance summary *a priori* to the public will firmly and transparently anchor your study in the indisputable fact of each toxicity laboratory's actual performance and estimated error rates under normal operating conditions testing NPDES effluents.  Providing this compilation will elevate public confidence if the State Water Board chooses to delay freshwater invertebrate protection by the *C. dubia* reproduction MMEL to conduct further study. If this basic information on laboratory control performance cannot be successfully summarized for the public before the study begins, the study's strict fidelity to the key facts of method performance and within-laboratory variability is already jeopardized.  Even the potential choice of SCCWRP to assist or guide execution of the study could seem problematic to the public: No expert freshwater toxicologist, biostatistician, or mathematical statistician is currently housed there to advise. Also, the most active arm of SCCWRP's JPA member agencies is dominated by powerful and influential permittees the Toxicity Provisions will regulate; and it is unrealistic to think SCCWRP can shed the interests and influences of its past and current associations, collaborations, and partnerships to secure the appearance of an impartially conducted study (see **Attachment 1.c;** June 21, 2019 SCCWRP regular commission meeting minutes, p. 3 of 8, paragraph #1 ). |
| **SR L.005** | As discussed in Section 5.4.3 of the Staff Report, the purpose of the *C. dubia* study is to investigate test conditions and factors that can be controlled to reduce within-test variability and improve a laboratory’s performance over time which thereby increases confidence in the test outcome of the *C. dubia* chronic reproduction toxicity test.  The State Water Board has entered a contract with the Southern California Coastal Water Research Project (SCCWRP). The contract contains 17 different Tasks. Task 12 concerns the *C. dubia* study. An [excerpt from the contract](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) (Task 12 and its associated Deliverables Schedule) is provided on the State Water Board’s toxicity program webpage.  Task 12.2 of the contract explains that SCCWRP “shall recruit and form an Expert Panel to assess study needs, review and edit the Study Work Plan (see Task 12.3), analyze and interpret the results of the study, and make final recommendations. Members shall have extensive experience as a principal investigator in their area of expertise and experience relevant to toxicity testing.”  Task 12.3 explains that the Study Work Plan will be developed by SCCWRP, in consultation with the Stakeholder Advisory Committee and the Expert Panel. The Study Work Plan may include an examination of control performance data from participating laboratories, as suggested by the commenter. |
| 10.007 | The sustained lack of confidence in *C. dubia* reproduction, most sharply articulated by California POTWs, dates back to U.S. EPA's 1995 proposed WET methods rule and is unlikely to change by the end of 2023, even in the context of your proposed delay for further study of *C. dubia* reproduction. Rather than a delay that is undermining Clean Water Act protections, this lack of confidence is best remedied through NPDES enforcement discretion and a strictly science-based study to improve the execution of *C. dubia* reproduction by those California toxicity laboratories identified as needing to improve (see, in your public record, Fox et al. 2019 addressing *C. dubia* reproduction error rates). The "eye on the prize" deliverable of this study needs to be the identification of metrics and best practices that will demonstrably improve a toxicity laboratory's control performance, if needed, thereby increasing confidence in test results evaluated against the provisions' WQBELs. |
| 10.008 | If you decide to conduct a *C. dubia* reproduction study, it is absolutely necessary that each participating toxicity laboratory's *C. dubia* reproduction long-run control coefficient of variation, mean, and standard deviation and their upper percentiles (all calculated as instructed by Dr. John Fox, U.S. EPA, ORD) first be made a matter of public record. All underlying raw data (biological, chemical, physical), calculations, and applicable standard operating procedures need to be included. Providing this complete, granular performance summary *a priori* to the public will firmly and transparently anchor your study in the indisputable fact of each toxicity laboratory's actual performance and estimated error rates under normal operating conditions testing NPDES effluents. Also, providing this compilation will elevate public confidence should you choose to delay freshwater invertebrate protection by the *C. dubia* reproduction MMEL to conduct further study-when policy development on this point is arguably being inordinately influenced by the very permittees the provisions will regulate (see **Attachments 1.a, 1.b, 1.d).** Even your potential choice of SCCWRP to assist or guide execution of the study could seem problematic to the public: No expert freshwater toxicologist, biostatistician, or mathematical statistician is currently housed there to advise; the most active arm of SCCWRP's JPA member agencies is dominated by powerful and influential permittees the toxicity provisions will regulate; and it is unrealistic to think SCCWRP can shed the interests and influences of its past and current associations, collaborations, and partnerships to secure the appearance of an impartially conducted study (see **Attachment 1.c;** June 21, 2019 SCCWRP regular commission meeting minutes, p. 3 of 8, paragraph #1 ). I will note, throughout this long and pressurized policy development process, your staff have tried very hard to maintain a high level of integrity to the science that underlies *C. dubia* reproduction error rates (see Fox et al. 2019; **Attachment 1.d).** Nonetheless, if this basic information on toxicity laboratory control performance cannot be successfully summarized for the public before your study begins, the study's strict fidelity to the key facts of method performance and within laboratory variability-firmly rooted in the voluminous data available for individual laboratory control performance-is already jeopardized. As members of the public, we each want to choose the best doctors, hospitals, and medical testing centers to safeguard our health. Similarly, the public expects permittees to choose the best toxicity laboratories to help safeguard the health of California's freshwater aquatic environments. |
| **SC L.006** | The Staff Report should specify that “inter-laboratory comparability” and “inter-laboratory variability” are within the scope of the *C. dubia* study. |
| **SR L.006** | The scope of the *C. dubia* study will be developed by SCCWRP, in consultation with the Stakeholder Advisory Committee and the Expert Panel. Task 12.3 of the [contract with SCCWRP](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) states that “[t]he Contractor [SCCWRP] shall create a Study Work Plan to document the study design to identify and confirm laboratory practices that can reduce within-test variability in the chronic *C. dubia* toxicity test.” Within-test variability is a major determinant of laboratory performance, as shown in Fox et al. 2019 and Appendix J. Additionally, laboratories are not required to meet any between-laboratory comparability benchmarks in order for WET tests to be used for NPDES compliance purposes. For these reasons, the Staff Report was not revised as suggested by the commenter. |
| 11.005 | **The Staff Report’s section on Effluent and the *C. dubia* study should mirror language elsewhere in the supporting materials for consistency and to clearly certify intra-test, intra-laboratory, and inter-laboratory variability are examined.**  While the intra-lab variability component (“within-test variability”) is referenced for the scope of the study, we think it is important for the Staff Report’s language also to formally acknowledge the inter-lab variability element (“comparability”), which also is part of the study, as was discussed in the staff workshop last month. This is crucial to understanding the proper scope and intent of the study itself. Thus, we want to ensure the critical comparability part of the study is not neglected or disregarded in the Toxicity Provisions’ supporting materials, as it would leave a major gap in the confidence and reliability of using the reproduction endpoint for regulatory purposes. |
| 11.010 | Additionally in this section of the Staff Report, we think it would be beneficial to add the term *inter-laboratory variability* (“comparability”), which is discussed above in #2, in regards to an essential aspect of the *C. dubia* study, which is not referenced or defined here, despite definitions for intra-laboratory variability (“within-laboratory”) and intra-test variability (“within-test”). We think it is important for the Staff Report’s language to formally and consistently acknowledge the inter-lab variability element (“comparability”). |
| **SC L.007** | Commenters support conducting a *C. dubia* Special Study Process, and request that the study be executed with stakeholder involvement such as a technical advisory group. |
| **SR L.007** | Comment noted. The *C. dubia* study will include a Stakeholder Advisory Committee, which will include representatives from the regulated community. Please see Task 12.1 of the [contract with SCCWRP](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) for more information about the Stakeholder Advisory Committee. |
| 13.002 | **2. ACWA and CMUA support conducting a *Ceriodaphnia dubia* Special Study Process.** |
| 13.004 | ACWA and CMUA request that the study be executed with stakeholder involvement such as a technical advisory group. |
| 23.003 | LADWP also recognizes and appreciates that SWRCB staff have adjusted the requirements of the provisions related to the use of *C. dubia* chronic toxicity tests and have planned a study that is intended to address these concerns. |
| 23.018 | LADWP appreciates the opportunity to work with SWRCB Staff to examine the concerns related to the use of *C. dubia* for chronic testing, and appreciates that the SWRCB is undertaking a study to examine the impacts of within-test variability on the TST toxicity test results. |
| **SC L.008** | The CASA “white paper” reviewed three studies that all demonstrated unacceptably high false determinations of toxicity in dilution water for this endpoint. Therefore, the *C. dubia* study should determine the rate at which false determinations of toxicity in dilution water occur. This information will be critical to the State Water Board in determining how to proceed with regulating toxicity using the *Ceriodaphnia* reproduction endpoint. |
| **SR L.008** | The *C. dubia* study is not designed to estimate the false positive or false negative rates using the TST, it is not a “blank” study, and it is not a study about “how to proceed with regulating toxicity using *C. dubia*.”  Please see SR J-1.001 for a response to the comments about “false determinations of toxicity.”  For a discussion of the “White Paper” prepared for CASA (Larry Walker Associates, 2018), please see “SR27.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  Please see SR L.005 through SR L.007 and SR L.009 through SR L.011 for additional comments regarding the *C. dubia* study. |
| 17.002 | ***The study should include determination of the rate at which false determinations of toxicity are made on laboratory dilution water.*** |
| 17.003 | At a January 9, 2019 Public Staff workshop, Board Members and Water Board staff spoke on the concept of a study of the *Ceriodaphnia* test. This study was proposed in response to considerable concern from the regulated community regarding the accuracy and precision of this particular toxicity test’s reproduction endpoint. Specifically, a California Association of Sanitation Agencies white paper1 reviewed three studies that all demonstrated unacceptably high false determinations of toxicity in dilution water for this endpoint. At the time of the workshop there was little detail as to what such a study would entail, but the Sanitation Districts strongly believe the study should determine the rate at which false determinations of toxicity in dilution water occur. We believe this information will be critical to the State Water Board in determining how to proceed with regulating toxicity using the *Ceriodaphnia* reproduction endpoint. |
| **SC L.009** | The *C. dubia* study should be limited to providing laboratory best practices for chronic toxicity testing using *C. dubia*, but should not delay in using *C. dubia* to demonstrate compliance with chronic toxicity requirements. The State Water Board should build from the results of Fox et al. 2019 and limit the scope of a forthcoming study to identify laboratory practices that will improve the quality of toxicity test data, rather than wasting time and resources to quantify laboratory variability that was already done in Fox et al. 2019.  The State Water Board should limit the scope of the study to provide a set of recommendations to ELAP to provide appropriate training and guidance to individual laboratories engaged in *C. dubia* toxicity testing. This will ensure that any study conducted by the State Water Board is timely, cost effective, and provides practical, effective guidance for laboratories conducting toxicity testing.  Recent studies demonstrate that chronic toxicity testing using *C. dubia* can achieve the desired 10 percent effect. Commenters acknowledge that economic circumstances have changed since discussions regarding the laboratory performance surrounding *C. dubia* have taken place, and question the necessity of a costly study during these economically uncertain times. The State Water Board can choose not to pursue the study and still use *C. dubia* to demonstrate compliance with chronic toxicity requirements based on current science and demonstrated laboratory practices that increase the confidence in *C. dubia* in toxicity test results. If the State Water Board chooses to pursue this study, the scope of the study should be done concurrently with use of *C. dubia* in chronic toxicity testing. |
| **SR L.009** | The State Water Board has committed to conducting the *C. dubia* study. The *C. dubia* study is a quality assurance study to determine whether laboratory best practices might be recommended to improve laboratory performance through reduced within-test variability and increased between-laboratory comparability for the *C. dubia* chronic toxicity test.  The study is not:   1. A method validation study. It is not a “blank” study to determine whether *C. dubia* should be used in California regulatory programs. 2. A study to estimate false positive or false negative rates using the test of significant toxicity (TST).   Fox et al. 2019 identified the long-run median control CVs for eight laboratories, based on data collected during or before 2015. Appendix J includes these results and provided more recent CV data for some of the same as well as other California laboratories. The State Water Board’s *C. dubia* study will expand upon the results presented in Fox et al. 2019 and Appendix J and will obtain more recent data from a larger number of participant laboratories.  Task 12.8 of the *C. dubia* study contract states that “The Contractor [SCCWRP] shall prepare a report that summarizes the study results and describe specific test procedures and quality assurance recommendations to improve toxicity data quality and comparability when conducting *C. dubia* toxicity testing.” This report may be used in the development of future training and/or guidance documents for laboratories engaged in toxicity testing using *C. dubia*.  Please see SR F.001 for information about the use of *C. dubia*. |
| 19.038 | Critically, *C. dubia* is the only freshwater invertebrate species used to test toxicity. Without the use of *C. dubia* to determine compliance where *C. dubia* is identified as the most sensitive species, chronic toxicity testing will not be adequately protective of aquatic health. We urge the final Provisions to require all discharges that identify *C. dubia* as the most sensitive species, even where *C. dubia* was not previously used in discharge permits, to comply with chronic *C. dubia* toxicity testing in order to demonstrate compliance with the Toxicity Provisions and ensure California’s freshwater ecosystems are adequately protected. |
| 19.044 | Any forthcoming study should be limited to providing laboratory best practices for chronic toxicity testing using *C. dubia*, but should not delay in using *C. dubia* to demonstrate compliance with chronic toxicity requirements. If a study regarding the use of C dubia in toxicity testing is to be conducted, even after the demonstrated confidence in the use of *C. dubia* for toxicity testing affirmed in Fox et. al the State Water Board should limit the scope of the forthcoming study to provide a best laboratory practices document for *C. dubia* toxicity testing based on the findings of Fox et al. As discussed in Appendix J, Fox et al. evaluated the error rates of *C. dubia* in WET test methods using the TST and NOEC statistical approaches and has assessed laboratory variability within California. |
| 19.045 | We request the State Water Board build from the results of Fox et. al and limit the scope of a forthcoming study to identify laboratory practices that will improve the quality of toxicity test data, such as ensuring healthy cultures are used in toxicity testing and increasing replicates where necessary, rather than wasting time and resources to quantify laboratory variability that was already done in Fox et. al. The State Water Board should limit the scope of the study to provide a set of recommendations to the Environmental Laboratories Accreditation Program to provide appropriate training and guidance to individual laboratories engaged in *C. dubia* toxicity testing. This will ensure that any study conducted by the State Water Board is timely, cost effective, and provides practical, effective guidance for laboratories conducting toxicity testing. |
| 19.046 | While we support the overall development of new knowledge and improved laboratory practices to strengthen chronic toxicity testing, recent studies demonstrate that chronic toxicity testing using *C. dubia* can achieve the desired 10 percent effect. We further acknowledge that economic circumstances have changed since discussions regarding the laboratory performance surrounding *C. dubia* have taken place, and question the necessity of a costly study during these economically uncertain times. The State Water Board can choose not to pursue the study and still use *C. dubia* to demonstrate compliance with chronic toxicity requirements based on current science and demonstrated laboratory practices that increase the confidence interval of *C. dubia* in toxicity testing. If the State Water Board chooses to pursue this study, the scope of the study should be limited to the development of a best practices document and be done concurrently with use of *C. dubia* in chronic toxicity testing. |
| **SC L.010** | The commenter strongly supports the statement in the Staff Report that “the chronic *C. dubia* test is a reliable test” and echoes that “the study is not a necessary component of the Toxicity Provisions.”  As part of the *C. dubia* study, participating laboratories should be asked to supply performance data to assist in evaluation of their long-run control coefficient of variation as a measure of ongoing laboratory performance.  An independent science panel of national experts, including statisticians, will provide insights to how laboratories can achieve an acceptable level of performance. The commenter is committed to working with State Water Board staff on the study. |
| **SR L.010** | Comment noted and the commenter’s commitment to working on the study is appreciated. SR L.005 explains that the State Water Board has entered a contract with SCCWRP, and an [excerpt from the contract](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) is provided on the State Water Board’s toxicity program webpage. SR L.007 explains that the study will include a Stakeholder Advisory Committee. The Committee will be comprised of representatives from the following sectors:   * Non-Storm Water NPDES dischargers * Storm Water dischargers * Agricultural dischargers * Non-governmental organizations * Municipal laboratories * Commercial laboratories * U.S. EPA * State Water Board (Division of Water Quality; and ELAP) * Regional Water Boards   SCCWRP is currently in the process of forming the Stakeholder Advisory Committee. A list of Committee members’ names and affiliations will be posted on the State Water Board’s toxicity program webpage when available. If an individual wishes to provide input on the development of the study plan, they may contact one or more members of the Stakeholder Advisory Committee.  The study will also include an Expert Panel. Please see SR L.005 and Task 12.2 of the [excerpt from the contract with SCCWRP](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/excerpt_from_19-078-270.pdf) for further details about the composition of the Expert Panel. |
| 24.006 | We strongly support your statement in the Staff Report that “the chronic *C. dubia* test is a reliable test” and echo that “the study is not a necessary component of the Toxicity Provisions.” We also agree with State Board that the time-limited study should focus on improving laboratory performance for *C. dubia*. |
| 24.008 | We recognize that some stakeholders remain concerned about the reliability of *C. dubia* reproduction test endpoint in relation to false positive error rate and that the State Board is proceeding with further study to build public confidence. To further this goal, we recommend California ask participating laboratories to supply performance data to assist in evaluation of their long-run control coefficient of variation as a measure of ongoing laboratory performance. {footnote 1: For example, each accredited laboratory should provide their long-run control mean, standard deviation and coefficient of variation (CV) for the past 40 valid test results. A comparison of each laboratories control (CV) percentile values should then be compared to the percentiles of Fox et al. (2019), Tables 1 and 3 values.} We agree that an independent science panel of national experts, including statisticians, will provide insights to how laboratories can achieve an acceptable level of performance and support focusing the study in this area. EPA is committed to working with State Board staff on the study. |
| **SC L.011** | Until the concerns regarding the use of *C. dubia* for compliance monitoring are resolved, it is not appropriate to utilize this species for compliance monitoring.  Characterizing the *C. dubia* chronic test as reliable is premature when the State Water Board is currently sponsoring a multi-year study to further investigate test conditions and factors to reduce within-test variability and performance.  The statement in the Staff Report that “*C. dubia* is a reliable test” should be removed. |
| **SR L.011** | The *C. dubia* study is not a study about whether *C. dubia* will be used in California regulatory programs. As demonstrated in Fox et al. 2019 and Appendix J, the *C. dubia* chronic reproduction toxicity test is reliable. Therefore, the statement in the Staff Report that “*C. dubia* is a reliable test” has not been removed. Please see SR F.008 for discussion of the use of *C. dubia* for compliance monitoring during the study. Mandating the use of *C. dubia* statewide for compliance purposes is appropriate and necessary for the protection of aquatic life beneficial uses. The *C. dubia* test is a reliable test method.The statewide mandate to include effluent limitations using *C. dubia* is being delayed till January 1, 2024 for the limited reason of building stakeholder confidence in laboratory performance. Further discussion was added to section 5.4.3 of the Staff Report describing the appropriateness of effluent limitations using *C. dubia.* |
| 23.019 | Before the study is complete and available for public review, it is unsuitable to pre-determine the outcome of the study. Thus, LADWP disagrees with new language in the Staff Report that states that “the chronic *C. dubia* test is a reliable test,” as LADWP believes this statement may be premature. |
| 23.021 | Recommendation 1: LADWP requests that the SWRCB remove language from the Staff Report stating that the *C. dubia* chronic test is “a reliable test.” |
| 26.005d | Implementation of the current test protocol for the *C. dubia* chronic test, which is not reliable and should not be used with the TST method |
| 26.016 | **Current test protocol for the *Ceriodaphnia dubia* chronic test is not a reliable test and not applicable for the TST method** |
| 26.018 | ***C. dubia* chronic test may not provide reliable results for compliance monitoring**  Issue: The chronic test with *C. dubia* is currently being investigated to identify factors that would reduce within-test variability. We have previously submitted comments expressing significant concern with the use of *C. dubia* for compliance testing, and believe that until these concerns are resolved, it is not appropriate to utilize this species for compliance monitoring. We do not repeat these concerns here (they are contained in our prior comments) but focus instead on the new language proposed by the SWRCB.  Staff Report, Section 5.4.3, Option 1, 4th paragraph on page 116.  “During public comment periods and workshops, stakeholders expressed concerns about the reliability of the *Ceriodaphnia dubia* (*C. dubia*) chronic reproduction toxicity test in compliance monitoring programs. However, the chronic *C. dubia* test is a reliable test and is already being used as the most sensitive species in a number of existing California NPDES permits. The State Water Board is conducting a study to investigate test conditions and factors that can be controlled to reduce within-test variability…”  Discussion: Characterizing the *C. dubia* chronic test as reliable is premature when the SWRCB is currently sponsoring a multi-year study to further investigate test conditions and factors to reduce within-test variability and performance.  Recommendation: Remove the phrase “is a reliable test and” on page 116 of the Staff Report:  “During public comment periods and workshops, stakeholders expressed concerns about the reliability of the *Ceriodaphnia dubia* (*C. dubia*) chronic reproduction toxicity test in compliance monitoring programs. However, the chronic *C. dubia* test is already being used as the most sensitive species in a number of existing California NPDES permits. The State Water Board is conducting a study to investigate test conditions and factors that can be controlled to reduce within-test variability…” |
| **SC L.012** | The notes associated with Table 1 of the Provisions should be clarified to state that the alpha and beta errors refer only to “statistical” errors. |
| **SR L.012** | As stated in SR J-1.001, the proposed distinction between "statistical false positives" and "false determinations of toxicity” is inaccurate. All determinations of toxicity based on whole effluent toxicity (WET) testing are "statistical" because statistical analysis is necessary to determine whether a sample is toxic. See SR J-1.001 for further discussion on “statistical false positives” vs. “false determinations of toxicity.” |
| 17.009 | ***6. Table 1 Notes need to be corrected for accuracy.***  The revised Table 1 Notes state that the α and β errors are the probability of declaring a sample non-toxic when it is toxic and the probability of declaring a sample toxic when a sample is non-toxic, respectively. However, the α and β error are only statistical terms and these probabilities should not be confused with the overall probability of incorrectly identifying a sample as toxic or non-toxic, which would include the statistical error as well as other sources of error including intra- and inter-laboratory errors. In order to avoid any confusion, we request that this definition be altered to include the term “statistical” such that they read, “…is the statistical probability of declaring a sample non-toxic when it is toxic.” |
| **SC L.013** | Option 2 in Section 5.4.2 of the Staff Report should be removed because reasonable potential should be determined at the IWC, not 100% effluent. Option 2 in Section 5.4.2 of the Staff Report represents a condition that will not be reflective of the actual environmental exposure for an IWC less than 100%. Additionally, if a discharger has not previously conducted tests at the 100% effluent concentration, Option 2 may require a discharger to conduct additional testing. Also, Option 2 is not “less stringent” than Option 1. Without knowing the diluted concentration of IWC compared to 100% effluent, there is no basis to state that the requirement is “less stringent.”  Testing a single concentration conflicts with the U.S. EPA promulgated WET testing method which uses a dilution series, and reasonable potential testing should be conducted using conditions that are representative of conditions expected in the environment. Also, testing a dilution series provides important and necessary information to assess whether the measured effect is related to the concentration of effluent, and therefore, the dilution series should be used when making a reasonable potential determination.  The Toxicity Provisions should not rely on a 10% effect threshold for determining reasonable potential. |
| **SR L.013** | Option 2 in Section 5.4.2 of the Staff Report was added because stakeholders previously requested to have a reasonable potential process similar to the process described in the SIP for priority pollutants. In the SIP, the reasonable potential analysis for priority pollutants is conducted with 100% effluent, prior to applying any dilution credits. The approach in the SIP for determining reasonable potential does not consider if a discharger received a dilution credit. Ultimately, Option 2 was considered, but was not incorporated into the Toxicity Provisions and Option 1 remains as the preferred option. See Option 2 in Section 5.4.2 of the Staff Report for further discussion.  The statement in the Staff Report that this option is less stringent than the preferred option is specifically referring to those dischargers that do not have dilution credit. For those dischargers, Option 2 would determine reasonable potential using a pass/fail assessment at the IWC, which would be 100 percent effluent, compared to the preferred option which would determine reasonable potential based on both a pass/fail or a 10 percent effect at the IWC. When considering dischargers that do have dilution credit, the Staff Report states, “this option may or may not result in fewer dischargers than the preferred option having reasonable potential.”  Please see response “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on why a dilution series is not valuable when answering the question “is the effluent toxic” but is still required to be conducted according to the U.S. EPA methods manuals.  Please see response “SR21.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on the reasons for using a 10 percent effect for determining reasonable potential. |
| 26.021 | **Determination of reasonable potential does not evaluate representative environmental exposures**  The primary revision in Section 5.4.2 of the Staff Report for determining reasonable potential is the addition of Option 2. Option 1 (see table below) remains the preferred option recommended in the Staff Report. Both Option 1 and the newly added Option 2 require at least four (4) toxicity tests from Table 1 within five (5) years that are analyzed using the TST approach. A comparison of the two options for determining reasonable potential is provided below:  [See table on page 11 of comment letter #26] |
| 26.022 | **Reasonable potential should be determined at the IWC**  Issue: The TST approach requires one test concentration (the IWC) in addition to the control. The newly added Option 2 for determining reasonable potential as well as the preferred Option 1 both include testing only one concentration in addition to the control. Option 2 tests at 100% effluent while Option 1 tests at the IWC.  Staff Report, Section 5.4.2, Option 2, 3rd paragraph on page 105.  “The procedures for conducting a reasonable potential analysis under this option would be similar to the procedures under Option 1 except that the reasonable potential analysis would be conducted using all toxicity tests (with a minimum of four tests) conducted at 100 percent effluent rather than at the IWC.”  Discussion: Testing only one concentration does not provide sufficient information to evaluate whether a response relationship exists (i.e., whether the observed toxic effects are related to the effluent concentration). Because laboratory testing for toxicity cannot exactly match actual environmental conditions during discharge, a measured effect may be related to factors that affect the laboratory test conditions rather than toxicity caused by the effluent. Testing a dilution series provides important and necessary information to assess whether the measured effect is related to the concentration of effluent. |
| 26.023 | Further, the toxicity of an effluent in the environment can best be determined by evaluating conditions similar to those observed in the environment, including available dilution. Because Option 2 would test 100% effluent (rather than the IWC), Option 2 represents a condition that will not be reflective of the actual environmental exposure for an IWC less than 100%. Further elimination of the concentration response information (by using only a control and 100% effluent) exacerbates this problem, since it cannot be determined if an observed effect is related to the effluent or to extraneous laboratory factors.  Also, if a discharger has not previously conducted tests at the 100% effluent concentration, Option 2 may require a discharger to conduct additional testing.  Finally, testing a single concentration conflicts with the U.S. EPA promulgated WET testing method which uses a dilution series (see Comment 1.1), and reasonable potential testing should be conducted using conditions that are representative of conditions expected in the environment.  Recommendation: Reject Option 2 (use of 100% effluent) if 100% effluent is not consistent with the IWC. Consistent with prior comments and 5.2 below, delete the requirement that an effect of >10% response compared to control be used to indicate reasonable potential. Further, use the promulgated U.S. EPA toxicity testing method for WET testing to determine NPDES compliance, and allow use of information from the full concentration response curve to interpret test results. |
| 26.024 | **Option 2 is not “less stringent” than Option 1**  Issue: The Staff Report asserts that reasonable potential Option 2 is less stringent than Option 1.  Staff Report, Section 5.4.2, Option 2, last paragraph on page 107:  “The reasonable potential analysis under this option would always be conducted at 100 percent effluent. The IWC for non-storm water NPDES dischargers that do not have dilution credits would be 100 percent effluent. Therefore, for dischargers that do not have dilution credit, this option would be the same as conducting a reasonable potential analysis at the IWC using pass/fail results only. This option is less stringent than the preferred option because the reasonable potential analysis in the preferred option also includes a 10 percent effect threshold for determining reasonable potential. Therefore, this option is likely to result in fewer dischargers that do not have dilution credits having reasonable potential than the preferred option. This option would likely only require effluent limitations if these dischargers are causing an excursion above the water quality objective. This option would not assess if these dischargers have a reasonable potential to cause or contribute to an excursion above the water quality objective.”  Discussion: The Staff Report asserts that Option 2 is “less stringent” than Option 1 because it does not require the response to be within 10% of the control. This would only be less stringent if both options tested at 100% effluent (i.e., without dilution). Without knowing the diluted concentration of IWC compared to 100% effluent there is no basis to state that the requirement is “less stringent.”  The additional condition of Option 1 that the test response at IWC is greater than 10% of the control might only occur when the null hypothesis (of toxic effluent) is not rejected. The TST approach uses the null hypothesis that there is a significant difference between the IWC and the control responses (i.e., the difference is assumed to exist unless the data indicate a smaller difference in response). Depending on variability of the test endpoint and the number of replicates, the requirement to be within 10% of the control may not result in an additional requirement because rejecting the null hypothesis might only occur for responses close to the control (within 10%). There is no reliable way to predict whether this may occur without measured test data. This evaluation was not part of the toxicity test-drive exercise.  Recommendation: Discussion of Option 2 as preferable to Option 1 is not supported and should be removed. |
| 23.024 | LADWP requests that reasonable potential procedures be established that are consistent with both the expected environmental exposure and the statistical evaluations used in the provisions.  The Toxicity Provisions Staff Report includes a new alternative, Option 2, for performing reasonable potential analyses. Option 2 would involve determining reasonable potential at a concentration of 100% effluent, even if the IWC is less than 100% effluent. Because toxicity testing is intended to evaluate the conditions of the discharge, Option 2 (100%) represents a condition different than the exposure condition in the environment (if the IWC < 100%). If a discharger has not previously conducted testing at 100% effluent, Option 2 may also require a discharger to conduct additional testing.  In addition, as noted in Comment 1, testing only one concentration does not provide sufficient information to determine whether a concentration-response relationship exists, making it more difficult to determine if toxic tests observed in the reasonable potential evaluation are related to the effluent or to other factors that affect laboratory test conditions.  Recommendation: LADWP requests that Option 2 be removed from consideration for the evaluation of reasonable potential. LADWP further requests, consistent with Comment 1, that the SWRCB allow the discharger to consider information from the full dilution series in evaluating reasonable potential and interpreting toxicity test results. |
| **SC L.014** | The Staff Report should be revised to state that “one difference” (not “the primary difference” as currently stated) between chronic and acute tests is the inclusion of a sublethal endpoint for chronic tests and evaluation of survival only for acute tests. |
| **SR L.014** | Please see response “SR27.037” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion as to why the primary difference between chronic and acute tests is the inclusion of a sublethal endpoint for chronic tests and evaluation of survival only for acute tests. |
| 26.027 | **Clarify differences between chronic and acute tests**  Issue: The Staff Report states that “The primary difference between chronic and acute tests is the inclusion of a sublethal endpoint for chronic tests and evaluation of survival only for acute tests.” (Staff Report, Section 2.6.2, 1st paragraph, page 15).  While endpoints are a difference between acute and chronic toxicity tests, exposure time is the major difference. This is important because USEPA (1985) makes a distinction for the development of acute criteria as being short-term exposures and chronic criteria as being longer-term exposures. This concept should carry forward throughout the Staff Report, as was done in the introduction section of the Staff Report (Page 1, 1st paragraph), where exposure time is mentioned as a difference between acute and chronic toxicity tests in addition to the inclusion of sublethal endpoint for chronic tests.  Staff Report, Section 2.6.2, 1st paragraph, page 15.  “The primary difference between chronic and acute tests is the inclusion of a sublethal endpoint for chronic tests and evaluation of survival only for acute tests.”  Recommendation: Suggest changing the phrase “the primary difference” to “one difference” and adding exposure durations in the text on page 15 of the Staff Report:  “One difference between chronic and acute tests is the inclusion of a sublethal endpoint for chronic tests and evaluation of survival only for acute tests.” |
| **SC L.015** | The phrase "valid and representative" should be added to each of the four items in the bulleted list of possible reasonable potential analysis (RPA) outcomes in Section 5.4.2 of the Staff Report. If tests are not valid and representative of the IWC they are intended to characterize, they will not lead to appropriate and technically supported conclusions regarding the toxicity of the effluent. Deletion of the term “valid” implies that tests may be used even if not valid or representative. |
| **SR L.015** | Please see response “SR21.001” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for why the Staff Report does not include the term “valid” in this context. |
| 26.028 | **“Valid” removed as a descriptor of toxicity tests considered**  Issue: The word “valid” was removed from the list of four possible outcomes from implementation of the TST approach in Option 1 to determine reasonable potential.  Staff Report, Section 5.4.2, Option1, bullet list on page 100.   * “If any chronic or acute aquatic toxicity test at the IWC, analyzed using the TST approach, results in a fail, then the discharge has a reasonable potential to cause or contribute to an excursion above the toxicity water quality objectives. * If any chronic or acute aquatic toxicity test at the IWC, exhibits greater than a 10 percent mean effect, as compared to the mean control response, then the discharge has a reasonable potential to cause or contribute to an excursion above the toxicity water quality objectives. * If all chronic or acute aquatic toxicity tests at the IWC, analyzed using the TST approach, result in a “pass” and no test has a mean percent effect of greater than 10 percent, as compared to the mean control response, then the toxicity test data does not indicate reasonable potential to cause or contribute to an excursion above the toxicity water quality objectives. However, other relevant information may still be used by the Regional Board to consider if reasonable potential exists. * If a discharge does not have at least four chronic or acute aquatic toxicity tests at the IWC, analyzed using the TST approach, there is not enough information to determine reasonable potential. Additional testing needs to be conducted at the IWC and/or analyzed using the TST approach. Alternatively, aquatic toxicity test data at a higher concentration of effluent than the IWC could be used to assess reasonable potential.”   Discussion: If tests are not valid and representative of the IWC they are intended to characterize, they will not lead to appropriate and technically supported conclusions regarding the toxicity of the effluent. Deletion of the term “valid” implies that tests may be used even if not valid or representative.  Recommendation: Revise each of the four outcomes to include “valid and representative” chronic or acute aquatic toxicity tests. |
| **SC L.016** | Throughout the Staff Report and to a lesser extent in the Toxicity Provisions, the phrases “toxicity water quality objective” and “aquatic toxicity water quality objective” are used interchangeably when referring to numeric and narrative water quality objectives. The terms should be consistent in the Staff Report and in the Toxicity Provisions. The phrases should include the word “aquatic” for clarity because the issue being addressed is specifically aquatic toxicity. |
| **SR L.016** | The Toxicity Provisions were revised to add the word “aquatic” before toxicity in several locations to add clarity and consistency. In certain instances, the use of the term “toxicity water quality objective” (without the word “aquatic” preceding it) was intentional such as when describing narrative toxicity objectives in Basin Plans. Some of the narrative toxicity objectives in Basin Plans protect both human health and aquatic life beneficial uses. In those instances, including the term “aquatic” would mischaracterize the narrative toxicity objective. |
| 26.029 | **Inconsistent use of “toxicity water quality objective” and “aquatic toxicity water quality objective”**  Issue: Throughout the Staff Report and to a lesser extent in the Toxicity Provisions, the phrases “toxicity water quality objective” and “aquatic toxicity water quality objective” are used interchangeably when referring to numeric and narrative water quality objectives.  Examples can be found on Staff Report pages 10, 11, 14, 16, 46, 65, 66, 84, and 104 and Toxicity Provisions pages 4 and 5.  Recommendation: The terms should be consistent in the Staff Report and in the Toxicity Provisions. The phrases should include the word “aquatic” for clarity because the issue being addressed is specifically aquatic toxicity. |
| **SC L.017** | The Staff Report should clarify that “Table 1” refers to Table 1 of the Toxicity Provisions. |
| **SR L.017** | The Staff Report was revised to clarify that “Table 1” refers to Table 1 of the Toxicity Provisions. |
| 26.030 | **Clarity in reference to Table 1**  Issue: Table 1 in the Staff Report (page 11) refers to a Table 1 entitled “Toxicity Test Method, Regulatory Management Decision (RMD), ß Error, and a Error,” which is found in the Toxicity Provisions and should be referenced accordingly.  Recommendation: Add text to clarify to the reader that Table 1 in the Staff Report is referring to Table 1 in Toxicity Provisions. |
| **SC L.018** | Several tables in the Staff Report are not referenced in the text. |
| **SR L.018** | The Staff Report was revised to include references to all tables. |
| 26.031 | **Staff Report tables not referenced in text**  Issue: The Staff Report includes Tables 2-1 and 5-4, but they are not mentioned in the text.  Recommendation: Add reference to Tables 2-1 and 5-4 in the relevant sections of the Staff Report. |
| **SC L.019** | During the timeframe of the *C. dubia* study, the Toxicity Provisions should provide guidance for how to proceed or assess compliance in cases where split testing of the same sample(s) by two or more laboratories results in a disagreement on the determination of toxicity in the same sample. |
| **SR L.019** | If a split sample were sent to two or more laboratories, it is possible that the results from the different laboratories might disagree on the determination of toxicity in the sample. However, this is not unique to WET testing. It is a possibility with chemical-specific tests as well. Additionally, sending a split sample to two or more laboratories would provide no practical benefit to the permittee. All test results must be reported to the permitting authority. The MMEL in Section IV.B.2.e.iv and the MMET in Section IV.B.2.g.ii of the Toxicity Provisions state that no more than one (most sensitive species) chronic aquatic toxicity test initiated in a calendar month shall result in a “fail“ at the IWC for any endpoint. If a sample is sent to two different laboratories, and one laboratory reports a TST “fail” for the sample, that TST “fail” would require the discharger to conduct additional testing in order to assess compliance with the MMEL (per Section IV.B.2.d.ii.(D) of the Toxicity Provisions) or the MMET (per Section IV.B.2.d.iii(B) of the Toxicity Provisions). Because the Toxicity Provisions already provide clear MMELs and MMETs, which are based on TST “fails,” the Toxicity Provisions do not need to provide guidance for how to proceed or assess compliance when two laboratories provide different results for a split sample.  Regarding testing performed for reasons other than to determine compliance with NPDES permits, duplicate sample submittal can be used for quality assurance and proficiency testing and to evaluate intra- and inter-laboratory variability. These samples are prepared in a reference laboratory with a known toxicant. Evaluation of reference toxicants are examples of a required quality assurance procedure for laboratories conducting WET testing. However, this is not the same thing as compliance testing of an environmental sample. Reproducibility, which is verification of similar results between laboratories analyzing the same environmental sample (also known as a split sample), is not a requirement of compliance with NPDES for all analytes. Please see “SR27.021” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for further discussion. |
| 11.007 | **For the interim while the *C. dubia* Study is executed, the Toxicity Provisions should provide guidance for how to proceed or assess compliance in cases where split testing of the same sample(s) by two (or more) labs results in a disagreement on the determination of toxicity in the same sample.**  While the *C. dubia* study is being conducted and before its byproducts are available to dischargers to optimize testing, a number of wastewater treatment agencies will continue to have monthly maximum effluent limits (MMELs) using the reproduction endpoint toxicity test. (Revisions to Section IV.B.2.e.iv specify that the Permitting Authority shall require the use of the TST in assessing compliance with the MMEL.)  One potential tool for assessing and confirming accuracy in toxicity tests is to conduct split sample testing among multiple laboratories. If the results from the participating laboratories agree, there is little question regarding interpretation of compliance. However, if the laboratories do not agree, determining compliance becomes more challenging. Such ambiguous results create challenges and increase uncertainty for both dischargers and Permitting Authorities.  In the course of diagnosing elevated toxicity at treatment plants, CASA members have split samples among multiple laboratories and have received conflicting results, i.e., a sample that passes the TST according to one lab, but fails according to another lab. (See Appendix A in LACSD’s comment letter for a table of recent interlaboratory comparisons conducted on split final effluent samples.)  There is currently no guidance available on how to assess compliance in this situation, and we respectfully ask that such guidance be provided, so that the interpretation of results and response in this situation are consistent across the state. From our members’ experiences, we recommend that the most appropriate response is to repeat the test rather than relying on the conflicting results from one laboratory or the other. |
| 17.006 | ***3. The State Water Board should provide guidance on how to proceed or assess compliance in cases where split testing of the same sample(s) by two (or more) labs results in a disagreement on the determination of toxicity for the sample(s).***  Newly added Section IV.B.2.e.i includes provisions that are proposed to stay in effect until December 31, 2023, in order to allow time to conduct a study to improve the accuracy and reliability of the *Ceriodaphnia dubia* reproduction endpoint toxicity test. While the study is conducted, certain dischargers, including a number of wastewater treatment plants operated by the Sanitation Districts, may continue to have monthly maximum effluent limits (MMELs) using this endpoint; revisions to Section IV.B.2.e.iv specify that the Permitting Authority shall require the use of the TST in assessing compliance with the MMEL. In the course of diagnosing elevated toxicity at one of our treatment plants, the Sanitation Districts have split samples among multiple laboratories and have received conflicting results (i.e., a sample that passes the TST according to one lab, but fails according to another lab); see Appendix A for a table of recent interlaboratory comparisons conducted on split final effluent samples. Such ambiguous results create challenges and increase uncertainty for both dischargers and Permitting Authorities. As there is currently no guidance available on how to assess compliance in this situation, we request that such guidance be provided in the Draft Plan, so that the interpretation of results and response in this situation are consistent across the state. We believe that the most appropriate response is to repeat the test rather than relying on the conflicting results from one laboratory or the other. |
| **SC L.020** | Please see the individual comments below regarding the language about numeric objectives and effluent limitations that was added to the Staff Report. While a new option to consider a consistent narrative statewide objective was added to the Staff Report, it was not assessed in the project alternatives in Section 8. |
| **SR L.020** | From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR10.003” for a discussion on why numeric water quality objectives and effluent limitations are necessary and “SR15.003” for a discussion on water quality objectives using non-Table 1 species that may be more sensitive to certain types of pollutants than the Table 1 species. The feasibility of numeric effluent limitations is discussed in Section 5.4.3 of the Staff Report.  Chapter 8 of the Staff Report states that “(Cal. Code Regs., tit. 23, § 3777, subd. (b)(3)) require the SED to contain an analysis of a range of reasonable alternatives to the project and reasonably foreseeable methods of compliance that could feasibly meet the project objectives to avoid or substantially reduce any potentially significant adverse environmental impacts.”  No potentially significant impacts were identified in Chapter 7 related to the methods of compliance with the Provisions. Chapter 8 of the Staff Report includes a discussion of the alternatives that would avoid, or substantiality lessen the potentially significant impacts from the construction, operation, and maintenance of possible toxicity controls. As no potentially significant effects were identified from the reasonably foreseeable methods of compliance or the project, these alternatives are not those capable of avoiding or substantially lessening the significant environmental impacts of the project. This discussion is included for purposes of informing decision makers and the public of any possible effects, however unlikely, and associated alternatives that lessen the significant environmental effects of the possible toxicity controls: alternatives that reduce the identification of persistent aquatic toxicity.  Option 3 of section 5.1 of the Staff Report points out that a statewide narrative objective would not meet the project goal of adopting consistent, statewide water quality objectives for acute and chronic toxicity that are protective of California’s waters from both known and unknown toxicants. Section 5.1 further points out that statewide narrative water quality objectives can only be established where numeric water quality objectives cannot be established or to supplement numeric water quality objectives. Numeric water quality objectives can be established. Since statewide narrative water quality objectives would not meet the project goals, it is not a viable option compared to statewide numeric water quality objectives, and therefore they were not included in the analysis of alternatives that lessen the significant environmental effects of the possible toxicity controls in Chapter 8 of the Staff Report. |
| 22.004b | * Page 26 of the staff report includes the statement that "Without clear, enforceable objectives and effluent limitations the Water Boards could not effectively control and reduce toxicity in surface waters." without any justification or support. Our previous comment letters demonstrated that toxicity could be controlled without numeric objectives and effluent limitations. |
| 22.004c | * Page 27 of the staff report notes that numeric effluent limitations have been adopted by Regional Water Boards and that this "has demonstrated that the effluent limitations in the Provisions are both feasible and achievable for NPDES-permitted dischargers." The simple adoption of an effluent limitation does not demonstrate that it is feasible and achievable. No supporting information has been provided to justify these statements and the statements do not demonstrate the necessity for the numeric objectives and effluent limitations. |
| 22.004d | * Page 68-While we appreciate the inclusion and assessment of the new option as proposed by the Stakeholders to consider a consistent narrative statewide narrative objective, we disagree with the following statement: "This option would not ensure consistent application of the statewide narrative water quality objectives. Therefore, a disadvantage of this option is that it would not meet project goal I-to adopt consistent, statewide water quality objectives for acute and chronic toxicity that are protective of California's waters from both known and unknown toxicants." By establishing consistent implementation provisions with numeric triggers as outlined in our letter, the same goal as numeric objectives could be achieved. Additionally, the benefits discussed in this alternative would be achieved. For example, the objectives would not be limited to being assessed by Table 1 species. This is important to addressing future toxicants, such as pesticides, that are not being adequately captured by the current test species in Table 1. Finally, while this alternative was added in staff report, it was not assessed in the project alternatives in Section 8. |
| **SC L.021** | Remove the TST as it is an unapproved approach under 40 CFR Part 136. The State Water Board is bound to comply with regulations issued by U.S. EPA. The TST has specifically been disclaimed by U.S. EPA for the use that the State Water Board staff purposes and is inconsistent with the methods promulgated by the U.S. EPA. The Toxicity Provisions change the federally prescribed 2002 Methods in at least the following ways:   1. Changes the question for the hypothesis, 2. Alters the hypothesis 180 degrees from sample tested from being presumed not toxic to being presumed to be toxic, 3. Uses an unauthorized and discouraged “Pass/Fail” endpoint, instead of the prescribed NOEC or point estimates (IC/EC25) in 40 C.F.R. §136.3, Table 1A, 4. Does not follow the prescribed flow chart, 5. Does not use one of the 4 authorized statistics authorized in the methods manuals, 6. Ignores mandated dose concentration response curves and other safeguards that were the reason why the 2002 Methods were upheld in Edison Electric case, 7. Relies on a single concentration and control without an approved Alternative Test Procedure (ATP), and 8. Allows for single exceedance to be subject to formal enforcement despite EPA not recommending this approach.   Allow consideration of concentration-response data in interpreting toxicity test results because its use is important to determine when a toxic response is caused not by toxicity of an effluent but by organism variability or other laboratory factors. |
| **SR L.021** | No new language has been added to the Toxicity Provisions or Staff Report regarding the consistency between the TST and U.S. EPA’s WET test methods. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR25.003” for a discussion on the differences between test methods and statistical approaches, “SR25.029” for a discussion on the presumption of toxicity, and “SR25.007” and “SR27.014” for a discussion on the evaluation of the concentration-response curve. |
| 13.006 | **3. ACWA and CMUA suggest removal of the Test of Significant Toxicity (TST) as an unapproved approach under 40 CFR Part 136.**  As raised by several other commenters, ACWA and CMUA are concerned about use of an EPA guidance document regarding the TST to replace the requirements set forth in federally promulgated and binding regulations and incorporated manuals in Part 136. Table 1A in 40 C.F.R. section 136.3 clearly states “**Toxicity, chronic, fresh water organisms, NOEC or IC25, percent effluent**.” This federal regulation cannot be changed by the State Water Board since NPDES permit regulations require that monitoring and reporting (and compliance with the same) be in accordance with Part 136. *See e.g.,* 40 C.F.R. section 122.41(j)(4) and section 122.44(i)(iv). The TST does not qualify as a sufficiently sensitive test procedure approved under 40 CFR Part 136 since it does not result in one of the only two approved endpoints in 40 C.F.R. Part 136, namely NOEC or IC25. We suggest that one of the legally approved endpoints, either NOEC or IC25, replace the unpromulgated TST in the final version of the Toxicity Provisions. The response to comments failed to address this issue and merely argued that the TST was preferable. However, use of the TST would require modification of Section 136.3’s Table 1A. |
| 23.004 | LADWP respectfully disagrees with new language added to the provisions that asserts that the Test of Significant Toxicity (TST) is the preferred test method and is consistent with the Whole Effluent Toxicity (WET) test methods promulgated by the United States Environmental Protection Agency (U.S. EPA). LADWP suggests that language in the provisions and Staff Report be changed to more accurately represent current U.S. EPA test methods and to allow consideration of concentration-response data in interpreting toxicity test results. |
| 23.009 | The Toxicity Provisions and Staff Report should be changed to more accurately represent current U.S. EPA test methods and to allow consideration of concentration-response data in interpreting toxicity test results. |
| 23.015 | There are several reasons why it is important to consider the full concentration-response curve. One reason is to properly interpret toxicity data. Because organism responses are variable, use of a concentration-response curve is important to determine when a toxic response is caused not by the toxicity of an effluent but by organism variability or other laboratory factors. Another reason is that the information from a concentration-response curve is important to determining the cause of toxicity. |
| 23.016 | Recommendation: LADWP requests that the SWRCB eliminate language from the Staff Report stating, “The Provisions do not change or require different procedures than the test methods.” Consistent with LADWP’s prior comments, LADWP also requests that the SWRCB modify the Toxicity Provisions to allow a discharger to collect information from the full dilution series, and to use that information to assist with the interpretation of toxicity test results made using the TST method. |
| 25.006 | The Board Must Respect Federal Supremacy. We are aware of the Board’s many differences with federal agencies in terms of policy, including disputes currently in litigation. Regardless, the Board is bound to comply with regulations issued by USEPA until those regulations are changed. That practice is particularly important in a complicated and technical arena like toxicity where USEPA has issued literally thousands of pages of regulations and incorporated method manuals prescribing methods and standards. Here, portions of the Board Staff’s proposed method of analysis for toxicity has specifically been disclaimed by USEPA for the use that the Board Staff proposes. Consequently, the proposed use of the Test of Significant Toxicity (TST) and related requirements in the Toxicity Provisions is not legal.  As the most important example, State Board Staff continues to allege that the TST approach used in the proposed Toxicity Provisions does not modify the federal Part 136 promulgated methods.1 However, this allegation is false since the Toxicity Provisions change the federally prescribed 2002 Methods in at least the following ways:  Changes the question for the hypothesis,   1. Alters the hypothesis 180 degrees from sample tested from being presumed not toxic to being presumed to be toxic, 2. Uses an unauthorized and discouraged “Pass/Fail” endpoint, instead of the prescribed NOEC or point estimates (IC/EC25) in 40 C.F.R. §136.3, Table 1A, 3. Does not follow the prescribed flow chart, 4. Does not use one of the 4 authorized statistics authorized in the methods manuals, 5. Ignores mandated dose concentration response curves and other safeguards that were the reason why the 2002 Methods were upheld in Edison Electric case, 6. Relies on a single concentration and control without an approved Alternative Test Procedure (ATP), and   Allows for single exceedance to be subject to formal enforcement despite EPA not recommending this approach. |
| 26.001 | In our opinion, the SWRCB’s proposed use of the Test of Significant Toxicity (TST) as the statewide statistical approach for analyzing Whole Effluent Toxicity (WET) test data is inconsistent with the methods promulgated by the United States Environmental Protection Agency (U.S. EPA), which evaluate toxicity based on multiple test concentrations. |
| 26.002 | Further, the SWRCB has stated that it intends to eventually require toxicity testing at only one concentration (plus a control) and discontinue the traditional assessment methods, which require determining a concentration-response relationship. This would affect not only compliance testing, but also the determination of reasonable potential and effluent limitations, and would potentially reduce the available data to be used if a Toxicity Reduction Evaluation (TRE) is triggered. |
| 26.003 | These proposed changes represent a significant alteration to current toxicity testing procedures and methodology; as a result, the proposed Toxicity Provisions will reduce the information available regarding the cause of toxicity when toxicity is observed. |
| 26.005a | Nonetheless, we continue to have concerns. Specific content that we recommend the SWRCB re-evaluate includes the following:  Toxicity test procedures that differ from the Whole Effluent Toxicity (WET) promulgated test methods recommended as the preferred approach by the U.S. EPA |
| 26.005c | Use of limited toxic/not toxic output from the TST for complex issues such as reasonable potential evaluations, species sensitivity, effluent limitations, and TREs (when triggered) without the benefit of the concentration-response relationship data |
| 26.011 | Further, U.S. EPA (2002a)5 states, in bold type within the manual, the following: “NOTE: For the NPDES Permit Program, the point estimation techniques are the preferred statistical method in calculating end points for effluent toxicity tests.” Thus, although the TST is the preferred method in the Staff Report, we believe the TST method is not supported in the promulgated short-term chronic toxicity testing method. |
| 26.012 | Recommendation: Use the promulgated U.S. EPA toxicity testing method for WET testing to determine NPDES compliance and allow use of information from the full concentration response curve to interpret test results. See also prior comments submitted on December 21, 2018. |
| **SC L.022** | Consider the sensitivity of *C. dubia* to salinity. |
| **SR L.022** | Salinity may be a test condition that is considered in the *C. dubia* study. From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see response “SR25.003” for a discussion on the differences between test method and statistical approach, “SR27.006” for a discussion on the variability of *C. dubia,* and “SR25.022” for a discussion on false positives. |
| 23.006 | LADWP recommends that the Toxicity Provisions be modified to consider more explicitly the need to match salinity for toxicity testing conducted for discharges of freshwater into saline water bodies. |
| 23.023 | LADWP recommends that the Toxicity Provisions be modified to consider more explicitly the need to match salinity for toxicity testing conducted for discharges of freshwater into saline water bodies.  The Toxicity Provisions allow the Regional Water Boards the discretion to require dischargers to use freshwater test methods for dischargers of freshwater effluent into marine waters. This requirement could lead to a situation where the salinity of the control differs from the salinity of the IWC, which could lead to salinity-related impacts to test organisms.  EPA’s WET test guidance requires test organisms to be selected based on the salinity of the receiving water (i.e., freshwater organisms are used when the receiving water salinity is < 1 part-per-thousand (ppt); above this level, the choice of organism depends on permit requirements or water quality standards established by the state). For discharges to marine receiving waters or for high salinity effluents, the use of a salinity-sensitive species such as *C. dubia* could result in a false positive (i.e., a finding of toxicity that is caused by salinity, not by toxicants in the effluent). As noted in our prior comments, cations and anions associated with saline receiving waters may cause a toxic response.  Recommendation: LADWP requests that the SWRCB allows dischargers to evaluate the impacts of salinity (major cations and anions) on test organisms using well-established procedures. {Footnote 9: See, e.g., Goodfellow et al. (2000). Goodfellow WL, Ausley LW, Burton DT, Denton DL, Dorn PB, Grothe DR, Heber MA, Norberg-King TJ, Rodgers RH. 2000. Major ion toxicity in effluents: A review with permitting recommendations. Environmental Toxicology and Chemistry 19(1): 175-192.} LADWP also requests that the SWRCB require the Regional Water Boards to evaluate salinity impacts before establishing testing requirements for freshwater effluents that are discharged to marine waters. |
| 26.017 | **The sensitivity of *C. dubia* to salinity should be considered**  Issue: The Regional Water Boards require dischargers to use freshwater test methods for dischargers that discharge freshwater effluent into marine waters without considering the effect of salinity on sensitive organisms (e.g., *C. dubia*). This could lead to a condition where the salinity of the control and the salinity of the IWC differ, which could cause salinity-related impacts to test organisms.  Staff Report, Section 5.2.1, Option 1, 1st paragraph on page 71.  “The Regional Water Boards also have discretion to require dischargers to use freshwater test methods for dischargers that discharge freshwater effluent into marine waters, or inland saline waters. For example, this may be applied to discharges to inland saline waters that are located far from the coast, or to discharges to coastal waters when testing with freshwater species is considered protective of freshwater aquatic life beneficial uses in the receiving water.”  Toxicity Provisions, Section IV.B.1.a, 2nd paragraph on page 6.  “Dilution water and control water shall be prepared and used as specified by the test methods.”  Discussion: The U.S. EPA WET test guidance states that when the salinity of the receiving water is < 1 part per thousand (ppt), freshwater organisms are used regardless of the salinity of the effluent, and when the salinity is =1 ppt, the choice of the organism depends on the permit requirements or state water quality standards (USEPA 2002a). For marine receiving waters or when effluents are high in salinity, the use of a salinity-sensitive species such as *C. dubia* could produce a different outcome in the TST method compared to a more salinity-tolerant freshwater organism or an estuarine organism. Test organisms can be sensitive to salinity and any effect from the salinity of the ambient receiving water or the effluent on the test organism needs to be considered in the control. Not adjusting the control sample for the salinity could result in a false positive result (i.e., the effluent is categorized as toxic when it is not toxic) when salinity- sensitive species such as *C. dubia* are used in the WET testing framework. This is important when the potential toxicants impacting the *C. dubia* are only the major anions and cations that would be associated with the saline receiving waters. A discharger should not be required to treat for constituents that are naturally part of saline receiving waters.  Recommendation: Toxicity testing for freshwater discharges into marine waters should be evaluated carefully so that toxic effects due to salinity are not incorrectly attributed as an effect of the effluent. For example, an effluent should not be found to be toxic because it contains cations or anions that will naturally be present in a saline receiving water. Exponent recommends that the SWRCB allow dischargers to assess the impacts from the major anions and cations in the effluent using the mock effluent procedures that are well established and outlined in Goodfellow et al. (2000). |

## Category M – Statements of Support, Non-Support, and Support of Other Letters

| **Comment Code** | **Comment** |
| --- | --- |
| **SC M.001** | Commenters appreciate State Water Board staff’s efforts to work with stakeholders and improve the Toxicity Provisions. Many of the changes made to the Toxicity Provisions after discussion with stakeholders have resulted in improvements. |
| **SR M.001** | Comment noted. |
| 21.001 | We appreciate the efforts made by State Water Board staff to consider past comments and discussion from stakeholders in developing and revising this important policy. |
| 23.001 | First, LADWP wants to express its appreciation to the State Water Resources Control Board (SWRCB) staff, who met with stakeholders over a lengthy period to hear and address many comments. |
| 23.002 | LADWP supports many changes made to the Toxicity Provisions, including efforts to ensure consistency with the State Implementation Plan (SIP), especially related to dilution and in-stream waste concentration (IWC) determinations, changes to the monitoring frequency, and adjustments to language allowing the use of historical toxicity test data. |
| 26.004 | As detailed below, we appreciate the many opportunities we have had to work with SWRCB staff in the development of these provisions, and we believe that changes made to the provisions in response to stakeholder comments have improved the provisions significantly. |
| 26.006 | **We appreciate the SWRCB staff’s efforts to work with stakeholders and improve the Toxicity Provisions**  We want to recognize the efforts of SWRCB staff in meeting with stakeholders during workshops and individual meetings. We believe that many of the changes made to the Toxicity Provisions after discussion with stakeholders have resulted in improvements. For example, the requirements of the Toxicity Provisions that pertain to dilution credits have been made consistent with the requirements of the State Implementation Plan (SIP), and clarifications have been made to the requirements for effluent limitations and accelerated or follow-up monitoring. Adjustments to the required monitoring frequency have been made to reduce the burden on dischargers and allow greater use of existing data. Similarly, we appreciate that SWRCB staff have recognized the concerns that we and other stakeholders have expressed regarding the use of *C. dubia* chronic toxicity tests and have planned a study that is intended to address these concerns. |
| **SC M.002** | Commenters support California’s proposed draft Toxicity Provisions. |
| **SR M.002** | Comments noted. |
| 10.001 | **As a general rule, the proposed draft toxicity provisions set exemplary public policy for aquatic life protection in California's non-ocean surface waters.** |
| 20.001 | Given the small contribution of point source relatively to nonpoint sources, we do not expect adoption draft Toxicity Provisions to have much practical effect on the California portion of the Klamath Basin and thus we did not conduct a thorough review of the technical details of the changes between the October 2018 and July 2020 versions of Draft Toxicity Provisions to which the current public comment period is solely limited to. Nonetheless, we support the general approach outlined in the Toxicity Provisions and encourage their adoption in some form. We look forward to continuing to work with State Board and North Coast Regional Water Quality Control Boards to address water pollution in the Klamath Basin, including from nonpoint sources that arc the primary contributors in our geographic area of interest. |
| 24.001 | EPA commends California’s efforts to develop provisions for toxicity control and supports the State Water Board’s plan to consider for adoption the proposed water quality standards (WQS) for toxicity. The proposed standards are based on robust science and years of stakeholder outreach and provide a consistent statewide framework, building on a long history of improving surface water quality in California. |
| **SC M.003** | The commenter hopes that Board members will look at these issues independently and with fresh eyes and stands ready to work with State Water Board staff to achieve the policy goals to which we are all committed: ensuring that all reasonable and feasible steps are taken to ensure that California’s water bodies are not toxic, either to humans or to our natural environment. |
| **SR M.003** | Comment noted. |
| 25.008 | We hope that the Board members will look at these issues independently and with fresh eyes. We stand ready – as we have throughout this process – to work with you and your Staff to achieve the policy goals to which we are all committed: ensuring that all reasonable and feasible steps are taken to ensure that California’s water bodies are not toxic, either to humans or to our natural environment. |
| **SC M.004** | Stakeholders support and concur with comments and concerns provided by other stakeholders and encourage the State Water Board to consider the comments submitted by these other stakeholders. |
| **SR M.004** | Comment noted. |
| 7.003 | BACWA also supports the comments submitted by the Sacramento Regional County Sanitation District (Regional San). |
| 8.002 | Regional San supports the comments provided by the California Association of Sanitation Agencies, the Central Valley Clean Water Association and the Bay Area Clean Water Agencies, in particular related to the issues of *C. dubia* testing and the feasibility of performing multiple chronic toxicity tests in one month. |
| 14.002 | In addition to our comments herein, we also support the comments provided by the California Association of Sanitation Agencies. |
| 25.001 | We write in support of the comments made by ACWA, CASA, and other permittees and trade associations related to the recent changes to the Toxicity Provision. |
| **SC M.005** | Commenters continue to have significant concerns regarding several aspects of the Toxicity Provisions. |
| **SR M.005** | Comment noted. Please see responses in the response to comment document posted on the [Statewide Toxicity Provisions web page](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/tx_ass_cntrl.html). |
| 7.001 | As we expressed in previous opportunities to comment on the proposed Toxicity Provisions (see letter dated December 21, 2018), BACWA has significant concerns regarding several aspects of the proposed Toxicity Provisions. The present letter is limited in scope to comments on Appendix K to the Draft Staff Report on the proposed Toxicity Provisions. We thank State Water Board staff for providing this comment opportunity. |
| 26.007 | As detailed below, we continue to have concerns with certain aspects of the proposed Toxicity Provisions, and we have focused our comments on those aspects that are new or modified from prior versions, or on new language that is provided to support and accompany the proposed Toxicity Provisions. |
| **SC M.006** | Commenters appreciate the efforts of the State Water Board to address stakeholder concerns regarding the probability of determining non-toxic water as toxic and regarding the logistics of performing all of the toxicity testing that will be required in order to meet the proposed median monthly effluent limit. However, Appendix J and K do not address the primary concerns regarding the frequency with which non-toxic samples will be incorrectly identified as toxic, nor of the long-term feasibility or practicability for agencies to complete the specified number of monthly toxicity tests. |
| **SR M.006** | Comment noted. See SR J-1.010 for a discussion on the frequency of non-toxic samples incorrectly identified as toxic. See SR K-1.001 for a discussion on the ability to initiate three toxicity tests within a calendar month. |
| 8.001 | Regional San has provided comments on past versions of the proposed Toxicity Provisions, and has met on several occasions with staff from the State Water Board to discuss the content. We appreciate the efforts of the State Water Board to address stakeholder concerns regarding the probability of determining non-toxic water as toxic and regarding the logistics of performing all of the toxicity testing that will be required in order to meet the proposed median monthly effluent limit (MMEL) by proposing to add these two appendices. Unfortunately, these appendices do not address our primary concerns regarding the frequency with which non-toxic samples will be incorrectly identified as toxic, nor of the long-term feasibility or practicability for agencies to complete the specified number of monthly toxicity tests. |

## Category N – Out of Scope Comments (Appendices J and K)

| **Comment Code** | **Comment** |
| --- | --- |
| **SC N.001** | *C. dubia* is sensitive to salinity and salinity can potentially affect the results of the TST Test Method if the salinity of the control is different from the salinity of the IWC. Therefore, the control exposures should be adjusted to a salinity equivalent to the salinity at the IWC. |
| **SR N.001** | The State Water Board received comments from the public according to the State Water Board’s Notice of Opportunity to Comment (December 24, 2019).  That notice stated that “[t]he State Water Board will accept input and recommendations on the content of the appendices through written comments. The State Water Board will also accept additional evidence directly related to the content of the appendices.  Written comments and evidence unrelated to the content of the appendices, including comments on any of the actual language in the draft Toxicity Provisions, will not be accepted.” As a result, comments regarding the effects of salinity on *C. dubia* and the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K. Appendix J discusses recent research and information on how laboratory performance affects the pass or fail results of the chronic *C. dubia* toxicity test when using the TST and NOEC statistical approaches. Appendix J does not discuss salinity concentrations of the control or IWC sample while running a toxicity test nor the potential causes of observed variability. However, salinity may be a test condition that is considered in the *C. dubia* study. From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see response “SR25.003” for a discussion on the differences between test method and statistical approach, “SR27.006” for a discussion on the variability of *C. dubia,* “SR25.007” and “SR27.014” for a discussion on evaluating the dose-response curve, and “SR25.022” for a discussion on false positives. |
| 4.002 | One primary concern is the sensitivity of the freshwater organism *C. dubia* to salinity. Naturally occurring salinity is both acutely and chronically toxic to *C. dubia*. A review of chronic toxicity data for *C. dubia* indicates that sodium chloride (a surrogate for salinity) can cause chronic toxic responses at a threshold concentration of 585 mg NaCl/L. Therefore, salinity can potentially affect the results of the TST Test Method if the salinity of the control is different from the salinity of the instream waste concentration (IWC). For this reason, we recommend that control exposures should be adjusted to a salinity equivalent to the salinity at the IWC. |
| 4.003 | In addition, since toxicity is dependent on the composition of the ions in solution, it is important that the salts used to adjust the salinity of a control be representative of the ionic mixture at the IWC. |
| 4.005 | The *C. dubia* short-term chronic reproductive test is one of the recommended bioassays to estimate the chronic toxicity of effluents and receiving waters and to assess compliance with effluent limitations (U.S. EPA 2002). There are several concerns with the utilization of *C. dubia* in the TST framework that could lead to erroneous conclusions regarding the toxicity of an effluent sample. |
| 4.006  6.004 | One issue is the sensitivity of the freshwater organism *C. dubia* to salinity. The U.S. EPA test guidance states “when the salinity of the receiving water is < 1%, freshwater organisms are used regardless of the salinity of the effluent” (U.S.EPA 2002). For effluents that are high in salinity, such as those from the petroleum, agro-food or tannery industries (Lefebvre and Moletta 2006), the use of a salinity-sensitive species such as *C. dubia* could produce a different outcome in the TST method compared to a more salinity tolerant freshwater organism or an estuarine organism. In San Francisco Bay, some effluents are discharged to receiving waters of salinity higher than *C. dubia* can tolerate. Thus, the perceived noncompliant levels of toxicity in the effluent, if due to salinity, needs to be taken into account. |
| 4.008  6.006 | Information provided by SWRCB in Appendices J and K of the Staff Report was drawn from to support our concerns with the variability of the *C. dubia* chronic test and its use as a test species in the TST method.  This memorandum is organized into sections including the issues associated with salinity of the effluent or receiving water in freshwater assessments; the general variability of *C. dubia* and the impacts to follow-up testing; policy options for *C. dubia* testing; and summary and conclusions. |
| 4.009  6.007  6.008  6.009 | **1. Impacts of salinity and ionic composition on *Ceriodaphnia dubia***  Background on Ion Toxicity  Natural trace levels of some cations and anions are essential for the health of aquatic organisms. The typical dissolved ions present in natural waters include Na+, K+, Ca2+, Mg2+, Cl-, HCO3-CO3-2, and SO42-. These ions can be collectively measured as conductivity or total dissolved solids (TDS). Conductivity and TDS are correlated properties, and for natural waters, TDS (with units of mg/L), can be approximated by multiplying conductivity in μS/cm by a factor of 0.6 (APHA et al. 2018). Because these ions are considered salts, salinity is another measure of the relative amount of these ions in natural waters. These ions can be from naturally occurring salts or from anthropogenic sources. When the concentrations of these ions reach elevated levels, they may affect freshwater aquatic organisms and laboratory organisms used in bioassays that are not acclimated to higher ionic concentrations. At some salinity levels, the tolerance of any organism will be exceeded, and acclimation is not possible. Ion toxicity has been correlated to measurements of salinity, conductivity and TDS (Ingersoll et al. 1992; Dwyer et al. 1992; Chapman et al. 2000; Clements and Kotalik 2016).  In addition to species sensitivity, it is well understood that the toxicity is also dependent on the ionic composition. While the gross metrics of salinity, conductivity, and TDS may be able to explain effects in a specific laboratory exposure, they cannot be used to predict toxicity across solutions of varying ion composition because they do not differentiate among the ions in the composition (Mount et al. 1997; Goodfellow et al. 2000; Weber-Scannell and Duffy 2007). Mount et al. (1997) realized that solutions containing two salts were sometimes less toxic than expected and sometimes more toxic. Similar toxicity effects were observed in *C. dubia* exposed to single salt solutions of NaCl and CaCl2; even though the concentration of the Cl- ion was identical, the toxic response differed. However, a mixture of these two salts with the same Cl- ion concentration was less toxic.  Other studies have demonstrated that water hardness influences toxicity (Soucek et al. 2011; Elphick et al. 2011). In most natural freshwaters, hardness is primarily the sum of the concentrations of calcium and magnesium expressed as mg CaCO3/L. In a study evaluating the role of background water chemistry, calcium was determined to have a major influence on the acute toxicity of other ion salts; anions also have some influence on toxicity (Mount et al. 2016).  To demonstrate that standard measures of conductivity and TDS are not good predictors of toxicity, Mount et al. (1997) exposed *C. dubia* to saline solutions constructed from different combinations of salts; other potential toxicants were not present. The data of Mount et al. (1997) can be used to examine the toxicity of *C. dubia* for over 2,100 ion solutions consisting of up to four different ions (two cations and two anions). In order to present the relationship in a straightforward manner, the percent survival statistics for *C. dubia* after 48-hour exposure to various ion solutions are plotted in Figures 1 and 2 for the corresponding concentrations of TDS and conductivity, respectively. For both TDS and conductivity, there is more than a two order of magnitude difference in concentration for 100% survival and 100% mortality, demonstrating that TDS and conductivity are not good predictors of toxicity.  Statistical mathematical models for predicting toxicity of aquatic organisms from exposure to solutions containing multiple ions have advanced over the years (Mount et al. 1997; Erickson et al. 2017; Erickson et al. 2018). The Multi-Ion Toxicity (MIT) model is a mechanistic electrochemical approach that has been in development since 2015 and has been applied to acute and chronic toxicity data for four species exposed to various ion solutions (EPRI 2018).  Effect of Salinity on Toxicity of *Ceriodaphnia dubia*  As noted above, the effect salinity has on the toxicity of *C. dubia* has been examined by using sodium chloride as a surrogate for salinity. Sodium and chloride are the dominant ions in natural waters and sodium chloride is often used as a reference toxicant in toxicological studies (Mount et al. 1997; Zalizniak et al. 2006). A cursory review of the literature was performed to identify comparable acute and chronic toxicity studies where the exposure time, organism age (e.g., neonates), hardness, and testing protocol were similar and therefore would not have a confounding influence on toxicity, but the concentration of NaCl (or salinity) varied. All endpoints were converted to mg/L as NaCl for ease of comparison. Four studies had comparable acute toxicity data (Table 1). The studies were conducted for a 48-h period using reconstituted moderately hard water (80 -100 mg/L as CaCO3) as the dilution water (U.S. EPA 2002). The LC50 values were within a factor of 1.62 of each other and ranged from 1,590 to 2,504 mg NaCl/L with a geometric mean value of 1,930 mg NaCl/L. In contrast, chronic studies were conducted for 7 days and showed greater variability compared to the acute studies (Table 2). For 28 chronic toxicity values, the endpoint observed was 50% mortality and/or 50% inhibition in reproduction. These chronic effects concentrations ranged from 280 to 1,940 mg NaCl/L, which is a factor of 6.9 and far outside the factor of 2 rule-of-thumb for comparison of ecotoxicity results (Figure 3). Five chronic studies reported No Observed Effect Concentrations (NOECs) ranging from 440 to 1,500 mg NaCl/L, which is a factor of 3.4 and outside the factor of 2 rule-of-thumb. The higher variability in the chronic endpoints compared to the acute endpoints suggests that the laboratory variability may be due to the longer exposure to environmental and experimental conditions (e.g., test water, temperature, food, etc.).  For many chemicals, the mechanisms of toxicity for acute and chronic toxicity are often different. Acute to chronic ratios (ACRs) are used in aquatic toxicity to understand the difference in chemical structure and trophic levels, particularly in determining if established safety factors are sufficiently protective. In criteria development, ACRs are used to estimate chronic endpoints from acute values when reliable chronic endpoints are not available. ACRs can also be used to define concentration ranges for chronic tests. To understand the magnitude of the difference between acute and chronic endpoints for salinity to *C. dubia*, ACRs were computed from paired data where the acute and chronic toxicity data were for the same chemical and the same species and were determined in the same test (i.e., under the same experimental conditions and in the same laboratory). Since the same chemical, NaCl, and species is being considered, the ACRs should be similar.  The acute endpoint considered in the ACR calculation was mortality. The chronic endpoints considered in the ACR calculation were IC25, the concentration that causes a 25% inhibition to reproduction of test organisms, and NOEC for reproduction. The IC25 was found to be comparable to a NOEC and therefore these values should give similar ACRs (Norberg-King 1988 as cited in Anderson et al. 1991). A summary of the data used for the ACR calculation is provided in Table 3. Data were available from studies performed by three laboratories. The ACRs were similar, ranging from 2.5 to 3.6 with a geometric mean value of 3.3. The good agreement in ACRs for NaCl to *C. dubia* gives confidence in the acute and chronic endpoints measured by the different laboratories. The low ACR suggests the acute and chronic mechanisms of toxicity are most likely similar, such that the use of acute data in addition to short-term chronic data for the evaluation of impacts to WET testing is appropriate.  To understand what effluent concentrations of salinity would potentially cause an impact to *C. dubia*, the relationship of the salinity concentration in the effluent and its potential impacts to salinity at the IWC (i.e., the dilution achieved after mixing with the receiving water) was calculated for both the acute and chronic thresholds (Figure 4). The acute salinity threshold was 1,930 mg/L (1.93 ppt), the geometric mean of the acute toxicity values for sodium chloride. The chronic salinity threshold was 585 mg/L (0.585 ppt), which was computed by applying the ACR of 3.3 to the acute salinity threshold. As an example, at a 10% IWC, an effluent salinity concentration of approximately 20 ppt or greater would potentially be acutely toxic to *C. dubia*.3 Similarly, at a 10% IWC, an effluent salinity of approximately 6 ppt or greater would potentially be chronically toxic, regardless of whether there is another toxicant in the effluent.  It is worth noting that the intent of compliance testing is to protect the organisms in the receiving water body. If the salinity of the receiving waterbody is higher than the effluent, and if the ionic composition of the effluent will not cause ionic imbalance to the point of toxicity in the receiving stream, then salinity of the effluent would not cause toxicity to organisms in the receiving water. Accordingly, the TST tests should be conducted such that the salinity of the effluent should not, by itself, result in toxicity to the test organisms—i.e., such that a toxic response caused by salinity alone is not be interpreted as a finding that the effluent is toxic.  Effect of Salinity on TST Test Method  The TST Test Method evaluates one concentration at the IWC. Mathematically, the method will almost always find a positive result (i.e., a toxic result) for chronic tests when the mean percent effect is > 25% at the IWC (U.S. EPA 2011). For acute tests, the threshold is >20% effect (U.S. EPA 2011). However, it is possible for salinity differences between the IWC and the control to cause an apparent toxic response, even when any other toxicant(s) is absent. Based on the review of the acute and chronic toxicity data for *C. dubia* due to sodium chloride (a surrogate for salinity), salinity can cause acute and chronic toxic responses at threshold concentrations of 1,930 and 585 mg/L as NaCl, respectively. The acute value is the geometric mean of the LC50 from multiple tests, so the TST Test Method, which uses an acute threshold of > 20% response compared to the control, could yield a positive result at salinity concentrations lower than 1,930 mg/L. Therefore, salinity can potentially affect the results of the TST Test Method if the control exposures are not adjusted to a salinity equivalent to the salinity of the IWC.  If control exposures are adjusted to a salinity similar to the IWC, the salt(s) used to achieve the salinity should not be toxic. As previously discussed, the toxicity of ion salts is variable and depends on other salts present in the solution. Mount et al. (1997) tested over 300 single salt solutions and found that K+ was the greatest driver of toxicity, followed by Mg2+, HCO3-, Cl- and SO42-. In follow up work on background chemistry of ions, it was demonstrated that Na has an effect on the toxicity of K salts, and Ca has an effect on the toxicity of Mg salts (Mount et al. 2016). Additionally, with the exception of CaSO4 and CaCO3, all single salt solutions tested by Mount et al. (2016) were acutely toxic to *C. dubia*, which reinforces the need to evaluate how salinity can be adjusted in the control exposures. Thus, whenever possible, it is important that the salts used to adjust the salinity of a control be representative of the ionic mixture at the IWC. |
| 4.013 | **3. Proposed Regulatory Options Due to Public Comment on Variability of *Ceriodaphnia dubia* chronic test**  Since *C. dubia* is often the most sensitive species, the 7-day chronic reproduction test would be required to determine compliance with effluent limitations under the SWRCB’s proposal. In response to public comments regarding the use of the TST Test Method with the *C. dubia* chronic test, the SWRCB has proposed three options:  • Option 1: No change and use *C. dubia* to assess compliance. Conduct a study to determine if changes to the *C. dubia* test method are needed to reduce variability.  • Option 2: Use *C. dubia* as a monitoring trigger and use the second most sensitive species to assess compliance with proposed effluent limitations. Include a date in the Provisions by which the *C. dubia* will be used as the most sensitive species to force a timely completion of the study.  • Option 3: Do not use *C. dubia* as a monitoring trigger or for effluent compliance until the study has been completed.  While these options were developed to further explore the concerns with *C. dubia* test variability, these options do not evaluate the potential impacts from salinity in the effluent and receiving waters. For example, the concern remains that the TST will yield erroneous conclusions when used to test effluents with salinity levels above chronic endpoints. Because the *C. dubia* chronic bioassay does not require adjustment of the control for salinity, for effluents with high salinity levels, a false positive may occur solely due to salinity (no other toxicants) if the salinity and ionic composition of the control are not adjusted to match the effluent. Toxicity observed solely because of salinity differences between the IWC and the control do not indicate that the effluent is toxic. As a result, any option evaluated by the SWRCB should consider explicitly the impact of salinity to *C. dubia*. |
| 4.014 | The *C. dubia* short-term chronic reproductive test is one of the recommended bioassays to estimate the chronic toxicity of effluents and receiving waters. The sensitivity of *C. dubia* to salinity is a primary concern with the use of this species and toxicity test in the proposed SWRCB TST method. Because the TST tests only a control and a single effluent concentration (the IWC), the statistical method does not accommodate considering a dose response relationship using many concentration treatments to assist in interpreting test results, including the potential effects of salinity.  Salinity is both acutely and chronically toxic to *C. dubia*. The influence of salinity causing an increase in false positives from the TST Test needs to be considered. The TST Test Method tests only at the IWC. Mathematically, the method will almost always find a positive result (i.e., a toxic result) for chronic tests when the mean percent effect is > 25% at the IWC compared to control. The *C. dubia* chronic bioassay does not require adjustment of the control for salinity and therefore, for effluents high in salinity, a false positive may occur since the difference in toxicity compared to the unadjusted control can be artificially high. Toxicity observed as the sole result of salinity differences between the IWC and the control do not indicate that the effluent is toxic. For effluents with elevated salinity, the appropriateness of using *C. dubia*, a freshwater organism, needs to be evaluated. |
| **SC N.002** | It is not necessary to reverse the null hypothesis or require use of the unpromulgated TST guidance to address the issue of inadequate test sensitivity. The State Water Board can improve NOEC performance by simply adopting more rigorous Test Acceptance Criteria (lower minimum PMSD or higher maximum CV for the control group). North Carolina and other states have also revised the *C. dubia* test termination criteria to significantly improve test sensitivity by reducing internal variability. |
| **SR N.002** | Comments regarding the NOEC statistical approaches are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  Appendix J discusses recent research and information on how laboratory performance affects the pass or fail results of the chronic *C. dubia* toxicity test when using the TST and NOEC statistical approaches. Appendix J does not evaluate toxicity test method options which could potentially lower variability, such as test termination criteria. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see “SR25.027” for a discussion on the reversal of the null hypothesis, “SR25.003” for a discussion of the differences between test method and statistical method, “SR25.007” for a discussion on the limitations of the NOEC with PMSD and high CV, and “SR27.006” for a discussion on the State Water Board study that will be designed to answer key questions about the best practices for conducting the *C. dubia* reproduction chronic toxicity test method. Additionally, see SR L.005 through SR L.011 for further discussion of the *C. dubia* study. |
| 9.012 | It is not necessary to reverse the null hypothesis or require use of the unpromulgated TST guidance to address the issue of inadequate test sensitivity. The State Board can improve NOEC performance by simply adopting more rigorous Test Acceptance Criteria (lower minimum PMSD or higher maximum CV for the control group). North Carolina has also revised the *C. dubia* test termination criteria to significantly improve test sensitivity by reducing internal variability.5  The latter approach was described in federal guidance and has been accepted for use in other states (WA, CO, WI) by EPA.  5All four states allow a chronic *Ceriodaphnia dubia* test to continue until 80% of the organisms assigned to the control group have had three broods. EPA's method manual specifies that the test should conclude when only 60% of the control organisms have released three broods. See EPA; Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under NPDES. EPA-833-R-00-003 (June, 2000); pg. F-5. |
| **SC N.003** | The variability of the *C. dubia* test method and the sensitivity of *C. dubia* to salinity are two concerns with the use of this species and toxicity test in the proposed SWRCB TST method, which tests only at the IWC and is proposed to take the place of the current methods that require multiple concentrations. Without the benefit of a dose response relationship using many concentration treatments to assist in the interpretation of the toxicity response from increasing effluent concentrations, it is difficult to understand whether the single effluent concentration response is representative. |
| **SR N.003** | Comments regarding the sensitivity of *C. dubia* to salinity is outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, salinity may be a test condition that is considered in the *C. dubia* study.  From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see “SR25.003” for a discussion on the differences between test method and statistical approach, “SR25.007” and “SR27.014” for a discussion on the dose-response relationship, and “SR27.006” for a discussion on the variability of the *C. dubia* test. |
| 6.001 | Our first concern is that the TST method uses only one test concentration at the instream waste concentration (IWC) and a control and is proposed to take the place of the current methods that require multiple concentrations. |
| 6.027 | The *C. dubia* short-term chronic reproductive test is one of the recommended bioassays to estimate the chronic toxicity of effluents and receiving waters. The variability of this test method and the sensitivity of *C. dubia* to salinity are two concerns with the use of this species and toxicity test in the proposed SWRCB TST method, which tests only at the IWC. Without the benefit of a dose response relationship using many concentration treatments to assist in the interpretation of the toxicity response from increasing effluent concentrations, it is difficult to understand whether the single effluent concentration response is representative. |
| **SC N.004** | The *C. dubia* 7-day chronic reproduction test is often the most sensitive species and will be used to determine compliance with effluent limitations under the Toxicity Provisions. |
| **SR N.004** | Comments regarding the use of *C. dubia* as the most sensitive species are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, Section 5.4.1 of the Staff Report discusses species sensitivity screening requirements in the Toxicity Provisions. Section 5.4.3 of the Staff Report points out that non-storm water NPDES permits in the Los Angeles Region already have MMELs and MDELs using the most sensitive species. Under the Toxicity Provisions, when *C. dubia* is identified as the most sensitive species it will be used for determining compliance with the numeric effluent limitations or targets. |
| 6.002 | Since *C. dubia* is often the most sensitive species, the 7-day chronic reproduction test would be required to determine compliance with effluent limitations under the State Water Resources Control Board (SWRCB’s) proposal (U.S. EPA 2002). |
| **SC N.005** | The MMEL compliance testing requirement should be changed. Suggestions presented below in the individual comments include:  1) a single TST fail should result in a MMEL violation, given the additional precision and safeguards against a false positive that the TST statistical approach affords over the NOEC.  2) use a six-week or 45-day compliance period instead of a calendar month.  3) the MMEL could be a rolling median limit, similar to how median chronic toxicity triggers are currently implemented in Region 2 NPDES permits. |
| **SR N.005** | Comments regarding the MMEL compliance testing requirement are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), see “SR10.002” for a discussion on why a single TST fail does not result in a MMEL violation, “SR07.006” for a discussion on why the Toxicity Provisions include a calendar month compliance period instead of a six-week or 45-day compliance period to initiate three toxicity tests, and “SR10.005” for a discussion on chronic toxicity triggers. Additionally, see Section 5.4.4.2.4 of the Staff Report for an explanation on why the MMEL relies upon a calendar month instead of a 45-day time period. |
| 2.024 | We also support CVCWA’s recommendation for flexibility to perform the required testing over a six-week period (see comment 5 from Debbie Webster on the draft Toxicity Provisions, submitted to the State Water Board on December 21, 2018). |
| 3.001 | 1. For Appendix K, we offer an alternative approach to the monitoring frequencies and timing of the three sample medians that are currently proposed in the Toxicity Provisions |
| 3.004 | **Comment No. 1 – We recommend an alternative to the monitoring approach currently proposed in the Toxicity Provisions.**  The current proposal is to require chronic toxicity testing to occur in a one-month (i.e. 30-day) period, with monitoring frequencies ranging from monthly to quarterly, depending on the size of the discharge.  The CVCWA recommendation would modify the compliance testing requirement to a 45-day testing period, with monitoring frequencies ranging from bi-monthly to semi-annual, or greater, depending on the magnitude of discharge. |
| 5.004b | To prevent and address pervasive toxicity in California’s waters, we support a single fail as a median monthly effluent limitation (MMEL) violation, given the additional precision and safeguards against a false positive that the TST statistical approach affords over the NOEC. The draft Toxicity Provisions, however, state that more than one TST test fail in a calendar month is a MMEL violation, and two violations in a month or in two consecutive months will result in a requirement to conduct a TRE which provides even further safeguards against a false positive testing result. |
| 7.012 | For these reasons, instead of a median monthly limit, BACWA recommends that the Toxicity Provisions implement a rolling median limit, similar to how median chronic toxicity triggers are currently implemented in Region 2 NPDES permits. |
| 8.025 | Regional San also would support CVCWA’s recommendation for flexibility to perform the required testing over a six (6) week period (see comment 5 from Debbie Webster on the draft Toxicity Provisions, submitted to the State Water Board on December 21, 2018) as a reasonable alternative. |
| **SC N.006** | The commenter strongly supports the effort to transition to enforceable numeric toxicity objectives using the WET test methods and the TST statistical approach. Enforceable numeric toxicity objectives that utilize WET test methods and the TST statistical approach is the most protective regulatory strategy for aquatic life and human health. |
| **SR N.006** | Comments regarding support for numeric toxicity objectives and the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on Appendices J and K.  However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR25.003” and “SR25.004” for a discussion on the TST statistical approach and “30.002” for a discussion of the numeric water quality objectives. |
| 5.001 | Given that California waterbodies in all nine regions have experienced chronic toxicity, we strongly support the effort of the State Water Resources Control Board (State Water Board) to transition to enforceable numeric toxicity objectives using the whole effluent toxicity (WET) test methods and the Test of Significant Toxicity (TST) statistical approach. Of 992 sites assessed by the State Water Board’s Surface Water Ambient Monitoring Program (SWAMP) in 2010, 473 sites (48%) had at least one sample where toxicity was observed, and 129 sites (13%) were classified as highly toxic. Waterbodies listed as impaired for toxicity has further increased from 225 waterbodies in 2010 to 326 waterbodies in 2016, 1 despite the implementation of narrative toxicity limits by each of the nine Regional Water Quality Control Boards (Regional Water Boards). Consistent with the federal Clean Water Act and discussions that have taken place since 2003 to address this chronic toxicity in California, 2 enforceable numeric toxicity objectives that utilize WET test methods and the TST statistical approach is the most protective regulatory strategy for aquatic life and human health. |

## Category O – Out of Scope Comments (Differences between 2018 and 2020 Drafts)

| **Comment Code** | **Comment** |
| --- | --- |
| **SC O.001** | The Staff Report should update the definitions for false positive and false negative and add the concept of inter-laboratory variability (“comparability”). A false positive is not the same as a false indication of toxicity. CASA’s white paper highlights the concerns with false indications of toxicity in clearly non-toxic blank samples. Statistical false positives do not seem to be related to false indications of toxicity in non-toxic blank samples. A significant proportion of laboratories conducting toxicity tests on these known non-toxic samples seem to identify unacceptably large effects (>25%) at an unacceptably high frequency. The Staff Report should add clarification by using the term “statistical false positive” to distinguish it from a false determination of toxicity. |
| **SR O.001** | The State Water Board received comments from the public according to the State Water Board’s Notice of Opportunity to Comment (July 7, 2020). That notice stated that “[t]he State Water Board will receive written comments, input, recommendations, and additional evidence directly related to the differences between the October 2018 versions and the July 2020 versions of the Toxicity Provisions and the Staff Report. Any specific written comment or evidence that is unrelated to the differences between the October 2018 Toxicity Provisions and Staff Report and the July 2020 Toxicity Provisions and Staff Report will not be accepted.”  As a result, comments on Appendix J are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, please see SR J-1.001, SR J-1.002, and SR J-3.003 for a discussion of “statistical false positives” and “non-toxic blank samples” and the CASA white paper. |
| 11.009 | **6. The Staff Report’s definitions for Relevant Statistical Concepts should add the concept of Inter-Laboratory Variability (“comparability”) and update the definitions for False Positive and False Negative to reflect their differences from a False Indication of Toxicity.**  As explained in our Comment Letter on Appendix J, which is attached, a statistical “false positive” is not the same thing as a “false indication of toxicity.” With regard to Relevant Statistical Concepts in the Staff Report (p.447-48 by page number, or p. 460-61 of 494), we think it would be helpful to notate and clarify the difference in the “false positive” and “false negative” paragraphs to ensure their meaning is not conflated to mean false indications of toxicity.  CASA submitted a white paper to the Water Board and staff in 2018 entitled *Ceriodaphnia dubia Short-term Chronic Reproduction Test: Understanding the Probability of Incorrect Determinations of Toxicity in Non-toxic Samples*, which highlighted our concerns with false indications of toxicity in clearly non-toxic blank samples.  Although CASA does not see any significant shortcomings in the statistical analysis as conducted in Appendix J, the analysis unfortunately failed to take into account several important factors which limit its applicability.  Moreover, occurrences of statistical false positives which can be ameliorated through careful laboratory controls on within test variability (as described in Appendix J) do not appear to be related to actual false indications of toxicity in non- toxic blank samples. Instead, a significant proportion of laboratories conducting toxicity tests on these known non-toxic samples seem to identify unacceptably large effects (>25%) at an unacceptably high frequency.  Because the definition of a “false positive” in Appendix J is statistically based, we would recommend clarification by using the term “statistical false positive” for the State Water Board’s to distinguish it from a false determination of toxicity. Given the above, we suggest that modifications to the Staff Report be made as proposed in our February 2020 comment letter for Appendix J, which is attached, regarding how the results of the analysis are communicated and summarized, to ensure that the results are used appropriately in decision-making relating to the proposed statewide toxicity regulations. |
| **SC O.002** | The Toxicity Provisions will result in unwarranted violations from inaccurate toxicity results that do not reflect actual water quality impairments and will only act to damage the public confidence in sanitation services and Title 22-equivalent recycled water. Labeling recycled water as “toxic,” even if only related to protection of aquatic life beneficial uses, is a major hurdle to widespread adoption and use of recycled water in the state. For the *C. dubia* chronic test, non-toxic blank samples have been declared toxic at relatively high frequencies. |
| **SR O.002** | Comments regarding unwarranted violations are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR25.029” for a discussion on “unwarranted violations from inaccurate toxicity results and responses” “SR19.006” and “SR25.030” for a discussion on recycled water. Additionally, see SR J-1.001 for a discussion regarding the claim “non-toxic blank samples declared toxic at relatively high frequencies.” |
| 13.003 | Our organizations have been concerned that Title 22-equivalent effluent may incur violations of aquatic toxicity effluent limitations and be regarded as “toxic” in the public’s perception. The same water is distributed for beneficial reuse as recycled water throughout our member agencies’ districts, and this has been communicated in past comments that labeling recycled water as “toxic,” even if only related to protection of aquatic life beneficial uses, is a major hurdle to widespread adoption and use of recycled water in the state. Our organizations recognize the concerns raised by the California Association of Sanitary Agencies (CASA), the Central Valley Clean Water Agency (CVCWA), and Robertson-Bryan, Inc. in current and past comments with regards the chronic *C. dubia* test; particularly that non-toxic blank samples have been declared toxic at relatively high frequencies with this test. The same test issues could cause non-toxic recycled water to be declared “toxic,” but the public will perceive toxicity in recycled water as being caused by toxic chemical constituents. |
| 16.002 | Even in the absence of these cost increases, we are concerned that these new provisions will result in unwarranted violations from inaccurate toxicity results that do not reflect actual water quality impairments and will only act to damage the public confidence in the sanitation services CVWD provides. |
| **SC O.003** | All dischargers that identify *C. dubia* as the most sensitive species can use *C. dubia* to determine compliance with both the MDEL and MMEL, with the appropriate level of confidence. The Regional Water Boards have inconsistently established and monitored toxicity effluent limitations throughout the state. The State Water Board’s work to establish the TST statistical approach statewide sets a consistent, actionable measure of toxicity statewide. The TST statistical approach provides an unambiguous “pass” or “fail” measurement of toxicity and its low false positive and false negative rates provide increased statistical power to accurately identify a test concentration as either toxic or non-toxic. This increases the confidence of both those regulated by these provisions and the public in the results of toxicity testing, including the use of chronic *C. dubia* tests. |
| **SR O.003** | See SR F.002 for a discussion on using *C. dubia* for compliance purposes.  Comments regarding the advantages of the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, see SR J-1.005 for a discussion on the TST statistical approach. |
| 19.032 | 2. All dischargers that identify *C. dubia* as the most sensitive species can use *C. dubia* to determine compliance with both the MDEL and MMEL, with the appropriate level of confidence. Toxicity testing in California has generally used the no observed effect concentration (NOEC) approach and TST statistical approach on an individual permit basis. Given that no statewide standard for the implementation of toxicity limitations has been clearly defined, Regional Water Boards have inconsistently established and monitored toxicity effluent limitations throughout the state. The State Water Board’s work to establish the TST statistical approach statewide sets a consistent, actionable measure of toxicity statewide. Importantly, the statistical approach provides an unambiguous “pass” or “fail” measurement of a test concentration’s toxicity, and its low false positive and false negative rates provide increased statistical power to accurately identify a test concentration as either toxic or non toxic which in turn, increases the confidence of both those regulated by these provisions and the public in the results of toxicity testing. Specifically, the NOEC is more likely to declare a sample toxic than the TST when within test variability and the percent effect is low. Meanwhile, when within test variability and the percent effect is high (i. greater than or equal to 25 percent and therefore toxic the NOEC is less likely to declare a sample toxic, while the TST will always declare the sample toxic, demonstrating the precision of the TST statistical approach. The TST further improves controls for false negatives and actually identifies occurrences of toxicity that may degrade California’s waterways. As described in the study of the City and County of Honolulu’s TST test drive: “[T]oxic effects of effluents on *C. dubia* reproduction are difficult to detect with the NOEC approach because of the inherent within test variability of this chronic WET test. The alternative TST procedure controls false negatives and identifies toxicity that may have potential adverse environmental effects.” 24 |
| 19.033 | We strongly support the use of the TST statistical approach statewide to increase the precision of toxicity testing and to decrease the presence of false positives, which in turn increases the overall confidence of toxicity testing throughout the state including the use of chronic *C. dubia* tests. |
| **SC O.004** | Given the existing range in laboratory performance for chronic *C. dubia* toxicity testing and the need for accurate testing to uphold the integrity of the forthcoming Toxicity Provisions, laboratories should strive to decrease test variability. Multiple studies, including Fox et al. 2019 and Appendix J of the Staff Report, have concluded that increasing replicates will improve laboratory accuracy when using *C. dubia* for chronic toxicity testing. With this demonstrated ability to increase laboratory precision to the acceptable 10 percent effect by increasing replicates, dischargers and the public alike have confidence in chronic toxicity testing results using *C. dubia*. |
| **SR O.004** | Comments regarding Appendix J are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, see SR J-3.005 for a discussion on adding additional replicates. From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR25.013” for a discussion the use of the term “accuracy” in relation to WET testing and statistical analysis. |
| 19.034 | a. Increasing replicates can increase laboratory precision and overall confidence in chronic *C. dubia* testing results. The reliability of laboratory data is critical to uphold the numeric toxicity limitations in the forthcoming Toxicity Provisions. Given the existing range in laboratory performance for chronic *C. dubia* toxicity testing, and need for accurate testing to uphold the integrity of the forthcoming Toxicity Provisions, we do not dispute that laboratories should strive to decrease test variability. Fortunately, multiple studies have concluded that increasing replicates will improve laboratory accuracy when using *C. dubia* for chronic toxicity testing. For example, the City and County of Honolulu study found: “The failures [in the 15 to 25 percent effect range] declared by TST in this study were very rare excursions caused by an episode of unusually poor *C. dubia* culture performance. While blocking by parentage minimizes within test variability, the effect of limited fecundity or mortality of even a single organism may be remarkable. For this reason, there must be an extremely thorough oversight of laboratory protocols to ensure consistent organism vigor. In addition, increased replication in the control and in the sample at the IWC may be adopted to decrease variance.” |
| 19.035 | Further, Fox et al. (2019) 25 examined data from a subset of California laboratories, and found that four of the six laboratories examined had low within test variability and could attain the acceptable false positive probability of five percent using 10 test replicates. Critically, Fox et al. found that if the number of replicates were increased to 20, then five of the six laboratories would meet the acceptable false positive probability. Meanwhile, as reported in Appendix J, State Water Board staff performed an independent review of recent data from four California laboratories, finding that three of four laboratories had low within test variability and could attain the acceptable probability of a fail at or below 10 percent effect of five percent using 10 replicates. If the number of replicates were increased to 20, then all four laboratories would meet the acceptable probability proposed in the draft Toxicity Provisions. With this demonstrated ability to increase laboratory precision to the acceptable 10 percent effect by increasing replicates, dischargers and the public alike have confidence in chronic toxicity testing results using *C. dubia*. |
| **SC O.005** | The Toxicity Provisions provide numerous safeguards against false positives, as seen by the low probability of an MMEL violation at or below 10 percent effect. To prevent and address pervasive toxicity in California’s waters, a single fail should be a median monthly effluent limitation violation, given the additional precision and safeguards against a false positive that the TST statistical approach affords over the NOEC. Also, all dischargers found with an MMEL violation should be required to conduct a TRE even if a concurrent study is conducted alongside these Provisions.  The Toxicity Provisions include other safeguards against poor samples and test interferences to protect dischargers from false positives. These include the use of Test Acceptability Criteria, which allow new tests to be conducted to determine compliance for those tests that do not meet the Test Acceptability Criteria, and discretion to use another test species when a discharger encounters unresolvable test interference or cannot secure a reliable supply of test organisms. Therefore, the likelihood a discharger will be held responsible for inaccurate test result is very low. |
| **SR O.005** | Comments regarding Appendix J are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, see SR J-1.006 for a discussion on the “safeguards against false positives.” Also, see response “SR10.002 from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), for a discussion on why a single fail does not result in a median monthly effluent limitation violation. |
| 19.036 | b. The proposed Toxicity Provisions provide numerous safeguards against false positives, as seen by the low probability of an MMEL violation using the percent effect at or below 10. To prevent and address pervasive toxicity in California’s waters, we support a single fail as a median monthly effluent limitation (violation, given the additional precision and safeguards against a false positive that the TST statistical approach affords over the NOEC. The draft Toxicity Provisions, however, state that more than one TST test fail in a calendar month is a MMEL violation, and two violations in a month or in two consecutive months will result in a requirement to conduct a Toxicity Reduction Evaluations TRE which provides even further safeguards against a false positive testing result. As is discussed and demonstrated by Dr. Fox, the probability of determining a single MMEL violation based on TST “fails” of *C. dubia* with a percent effect at or below 10 is very low. The probability of being required to conduct a TRE based on TST fails with a percent effect at or below 10 is even lower. Given the probability of receiving a MMEL violation using *C. dubia* and actually being required to conduct a TRE is extremely low, and that increasing replicates improves laboratory accuracy of chronic toxicity testing using *C. dubia* it is critical that all dischargers found with an MMEL violation actually be required to conduct a TRE even if a concurrent study is conducted alongside these Provisions to improve laboratory performance for chronic *C. dubia* toxicity testing in order to actually address discharges that are likely to be significant sources of toxicity. |
| 19.037 | Further, the proposed Toxicity Provisions provide a number of safeguards against poor samples and test interferences to protect dischargers from false positives. These include the use of Test Acceptability Criteria, which allow new tests to be conducted to determine compliance for those tests that do not meet the Test Acceptability Criteria, and discretion to use another test species when a discharger encounters unresolvable test interference or cannot secure a reliable supply of test organisms. Couple these safeguards with the inherent structure of the TST statistical approach and the MMEL compliance structure of the proposed Toxicity Provisions where a single fail does not constitute a violation, nor triggers a TRE the likelihood a discharger will be held responsible for an inaccurate test result is very low. |
| **SC O.006** | Under this draft of the Toxicity Provisions, it still will be logistically difficult for small facilities and their labs to comply in circumstances where an entity is required to conduct three full tests within a calendar month. In Appendix K of the Staff Report and at the July 29, 2020 workshop, it was acknowledged that initiating three tests within a 30-day period is theoretically possible, but very difficult for small laboratories. There is some concern that the methodology and respondents that the survey utilized in Appendix K showing compliance within a 30-day period is possible were not a representative sample of entities in the State. Also, Appendix K’s findings about the feasibility of the calendar month is limited only to other large facilities or commercial labs surveyed, but not the predominant type or size of entities regulated by the Toxicity Provisions.  The State Water Board’s Response to Comments regarding these issues fails to grasp the resource constraints and real-world operations of the small wastewater agencies.  In order to address the concerns of these smaller agencies and other stakeholders, provide a modified calendar, such as calendar proposals provided by CVCWA and Regional San, to entities most adversely impacted by the requirement to initiate three tests in a specified period. |
| **SR O.006** | Comments regarding Appendix K and the definition of a calendar month are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  Appendix K surveyed all 23 laboratories accredited by ELAP to conduct chronic whole effluent toxicity testing in California, in which 20 of the laboratories responded to the survey. The surveyed laboratories include small, medium, and large laboratories. The surveyed laboratories also included commercial and municipal laboratories.  From the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR07.006” and Section 5.4.4.2.4 of the Staff Report for a discussion on why the compliance period to initiate three toxicity tests is 30 days and not 45 days. Also, see responses “SR07.001” and “SR07.002” regarding the feasibility of initiating three toxicity tests within a calendar month. |
| 11.001 | Unfortunately, many of our previously expressed concerns regarding fundamental elements of the Toxicity Provisions remain unresolved. Likewise, several new aspects have been added to the Toxicity Provisions that present their own challenges for numerous smaller permittees to practicably implement compliance mechanisms on the ground in labs and communities across the state. |
| 11.011 | **1. The Toxicity Provisions should address further the implementation issues relating to a Calendar Month timeframe for conducting routine monitoring tests for small wastewater agencies.**  We appreciate that the State Water Board has attempted to address the practical issues related to conducting multiple toxicity tests in a limited window with the addition of Section IV.B.2.d.iv (“replacement tests”) and other changes to the Toxicity Provisions (e.g. allowing start dates to be varied among the regulated community and cross over months). Under this draft of the Toxicity Provisions, it still will be logistically difficult for small facilities and their labs to comply in circumstances where an entity is required to conduct three full tests within a calendar month.  To be certain about this point, a key finding on page 4 from Appendix K (the SWB’s study of labs) is that:  *“The size of the laboratory and laboratory staff availability impact the feasibility of conducting multiple toxicity tests in a calendar month. Compared to larger laboratories, smaller laboratories generally require more time to obtain test species, set up tests, and start unscheduled tests due to fewer staff, capacity, and resources.”*  This point was acknowledged by State Water Board Staff in their presentation (p. 21 of 24) during the workshop on July 29, that initiating three tests within a thirty-day period is theoretically possible, but very difficult for small labs. We are concerned that the methodology and respondents that the survey utilized in Appendix K showing compliance within a thirty day period is possible were not a representative sample of entities in the State.  Thus, the reliability of Appendix K’s findings about the feasibility of the calendar month is limited only to the other large facilities or commercial labs surveyed but not the predominant type and size of entities regulated by the Toxicity Provisions. As such, Appendix K’s applicability as a decision-making tool for developing the timeframes for statewide toxicity regulations is limited.  Here, we seek the State Water Board’s recognition and understanding of the very real challenges and costs that this timetable thrusts upon the regulated community. This issue was raised previously, and language in the Response to Comments indicated “dischargers are ultimately responsible for ensuring that monitoring is conducted in accordance with monitoring requirements,” “dischargers can work with their contract or in-house laboratories to ensure the laboratories are running proper quality control procedures and are able to have an adequate supply of organisms should the discharger need to conduct MMEL compliance tests,” and “dischargers may develop contingency plans to use other laboratories in case their primary laboratory will not be able to obtain a supply of organisms to run MMEL compliance tests when needed.” These responses seem to fail to grasp the resource constraints and real world operations of the small wastewater agencies.  Accordingly, in order to address the concerns of these smaller agencies and other stakeholders, CASA would prefer for the State Water Board to provide for an alternative approach at least to the entities most adversely impacted by the Toxicity Provisions’ current requirement to initiate three tests in a specified period. We recommend the State Water Board consider the proposals submitted by both CVCWA and Regional San in their comment letters, and to examine the utility and benefits in providing a modified calendar for smaller dischargers, due to the challenges for them to comply. The alternative timetables recommended by CVCWA and others appear to be workable, provide equivalent information, and do not undermine the purposes or intent of the Toxicity Provisions. |
| **SC O.007** | The issue of the feasibility of initiating three chronic toxicity tests in a one-month period has been an ongoing topic for the past several years. The findings from the survey of toxicity testing laboratories do not consider many factors that would require additional time to initiate three samples within a calendar month. Under the “Less Optimistic Case,” based on the information presented in Appendix K, three samples cannot be taken in the required 30- or 31-day monthly window. This would result in non-compliance with this NPDES permit requirement.  Additionally, in Figures 3 and 4 provided by the commenter, there is significant overlap in sampling days. Figure 3 illustrates the case where the discharger just barely initiates three samples in a 30-day month and has a total of 22 unique sampling days over a two-month period. Figure 4 illustrates the case the discharger takes three samples in a six-week period and has a total of 15 unique sampling days over a two-month period. The point to be made is that the sampling intensity (as measured by sampling days per two-month period) is different between the two approaches, but not radically so. On the other hand, the approach shown in Figure 3 is unproven in common practice, and is not reliably attainable based on the information presented in Appendix K. There are serious concerns regarding the ability to initiate three samples in a one-month approach, over the long haul of a five-year NPDES permit term, for POTWs of all sizes. |
| **SR O.007** | Comments regarding Appendix K are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see SR K-1.001 for a discussion on the feasibility of initiating three toxicity tests within a calendar month, SR K-1.003 for a discussion on the ability to initiate three toxicity tests under the “Least Optimistic Case,” and SR K-2.001 for a discussion on unique sampling days. |
| 12.008 | The issue of the feasibility of initiating three chronic toxicity tests in a one-month period has been an ongoing topic between CVCWA and State Board staff for the past several years. Laboratory supervisors from various Central Valley POTWs have provided consistent, pragmatic input to the Board on their concerns regarding the logistics of meeting this requirement, month after month, year after year. The topic has also been discussed at workshops before State Board members. CVCWA believes that additional consideration should be given to this issue. The following provides our detailed assessment of the logistics of the proposed sampling regimen (which has been previously provided to the Board): The findings from the survey of toxicity testing laboratories performed by State Board staff indicate the following for the *Ceriodaphnia dubia* reproduction test, the most commonly applied test for inland surface water discharges: • Time to perform *Ceriodaphnia dubia* reproduction test: 6 to 8 days (Page 3, K.3) • Time for laboratory to perform *Ceriodaphnia dubia* reproduction test and produce preliminary results: 10 days (Page 1, K.2. Question 1) • Time to inform client regarding preliminary results: 1 to 2 days Page 1, K.2, Question 1) • Time for a laboratory to initiate a subsequent test upon direction from client: from 1 day to 7 days (Page 1, K.2, Question 2) |
| 12.009 | Based on these facts, the range in timing for performance of three *Ceriodaphnia dubia* reproduction tests is as follows: Best case • Start first laboratory test – Day 2 (first full day of sampling occurs on Day 1 – laboratory testing begins on Day 2) • Start second laboratory test – Day 14 (first test completed on Day 11, results conveyed to POTW on Day 12, sampling initiated on Day 13, second test starts on Day 14) • Start third laboratory test – Day 26 (second test completed on Day 23, results conveyed to POTW on Day 24, sampling initiated on Day 25, third test starts on Day 26) Less Optimistic Case • Start first laboratory test – Day 2 (first day of sampling occurs on Day 1 – laboratory testing begins on Day 2) • Start second laboratory test – Day 20 (first test completed on Day 11, results conveyed to POTW on Day 13, sampling starts on Day 19 to match lab capacity to begin next test, second test starts on Day 20) • Start third laboratory test – Day 38 (second test completed on Day 29, results conveyed to POTW on Day 31, sampling starts on Day 37 to match lab capacity, third test starts on Day 38) As can be seen in the above, for the Less Optimistic case, based on the information presented in Appendix K, 3 samples cannot be taken in the required 30- or 31-day monthly window. This would result in non-compliance with this NPDES permit requirement. Notably, we designate the second case above as “Less Optimistic,” as opposed to “Worst Case,” because of the following, which, if included, would add days to those shown for the “Less Optimistic” case: • Sampling may not be possible on the first day of every month, due to weekends, holidays and other sampling staff availability issues, especially at smaller POTWs. • Weekends and holidays will likely impact (prolong) communications between the testing laboratory and the POTW management and sampling crews during the month. • Smaller POTWs will likely encounter difficulties in communication and in getting contractors out to take multiple mid-month samples and renewals on specific days. |
| 12.010 | The above results bring into question the information presented in Table K-1. To illustrate the above, we have prepared several diagrams. The first diagram (Figure 1) depicts the “Best Case” described above; the second diagram (Figure 2) depicts the “Less Optimistic Case” described above. A “Worst Case” condition is not depicted. Two additional diagrams illustrate a different point. A third diagram (Figure 3), illustrates the case in which a discharger just barely complies with the three samples initiated in a 30-day-month. Note that in this case there is a significant overlap in sampling days between months one and two. A total of 22 unique sampling days over a two-month period would result. A fourth diagram (Figure 4) illustrates a sampling approach where three samples are taken in a 6-week period (an approach currently used in Central Valley NPDES permits). This approach results in 15 unique sampling days over a two-month period. The point to be made is that the sampling intensity (as measured by sampling days per two-month period) is different between the two approaches, but not radically so. On the other hand, the approach shown in the third diagram is unproven in common practice, and in fact is shown to likely not be reliably attainable based on the information presented in Appendix K. As has been discussed with State Board staff by CVCWA, and as documented in testimony by POTW laboratory leaders at the October 3, 2019 workshop, there are serious concerns regarding the ability to initiate three samples in a one-month approach, over the long haul of a five-year NPDES permit term, for POTWs of all sizes. |
| 26.005f | Monitoring requirements for non-stormwater NPDES dischargers that are restrictive and may be logistically difficult to meet. |
| **SC O.008** | Modify the compliance testing requirement to initiate three toxicity tests within a 30-day testing period to a 45-day testing period. Also, change the monitoring frequencies to range from every other monthly to semi-annual, or greater, depending on the magnitude of discharge and other circumstances. For example, switch from monthly sampling to sampling every other month for the largest POTWs. For the smallest POTWs, switch from a quarterly to a semi-annual sampling. These alternatives provide the much-needed flexibility to address the real-world issues, reduces stress on sampling crews, laboratory managers, and other staff involved in the logistics of the toxicity testing process. Additional consideration should be given to this issue because of changes to the Toxicity Provisions that will result in up to 4 or more required toxicity tests in a calendar month. |
| **SR O.008** | Please see response “SR07.015” and “SR07.016” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on routine monitoring frequency.  Comments regarding the compliance period are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see Section 5.4.4.2.4 of the Staff Report and response “SR07.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on a 30-day compliance period instead of a 45-day compliance period to initiate three toxicity tests and SR K-1.001 for a discussion on the feasibility of initiating three toxicity tests within a calendar month. For a discussion on complying with the monitoring requirements using replacement tests, see SR K-2.003 and response “SR07.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 12.001  18.003 | • **Monitoring Approach:** We urge an alternative approach to the monitoring frequencies and timing of the three sample medians. As proposed, the frequency and schedule create unnecessary duplication and increase costs. |
| 12.007 | **We Urge the Board to Revise the Monitoring Approach to a 45-day Test Period.**  The proposed Toxicity Provisions would require all chronic toxicity testing (the initial test and up to two follow-up tests) to be initiated in a one-month (i.e. 30-day) period, with monitoring frequencies ranging from monthly to quarterly to semi-annually, depending on the size of the discharge. We recommend modifying the compliance testing requirement to a 45-day testing period, with monitoring frequencies ranging from bi-monthly to semi-annual, or greater, depending on the magnitude of discharge and other circumstances. |
| 12.011 | Based on the above information, CVCWA recommends the following alternative: • Switch from monthly sampling to bi-monthly sampling as the most intensive sampling requirement. This would apply to the largest POTWs. As has been recommended previously by CVCWA, for the smallest POTWs, switch from quarterly to a maximum of semi-annual sampling. • Switch from a requirement to initiate three samples in a month to initiating three samples in a 45-day period. This would require a switch in terminology from a median monthly effluent limit to a 3-sample median effluent limit. CVCWA believes that this approach is legal, since it has been used in previously adopted (and EPA-approved) NPDES permits. The above alternative provides much needed flexibility to address the real-world issues described above; reduces stress on sampling crews, laboratory managers, and other staff involved in the logistics of the toxicity testing process; has been applied successfully; and will not significantly reduce the monitoring intensity for toxicity testing. We believe that the tradeoffs in adopting this approach would be worthwhile, and offer, at a minimum, an appropriate starting point for implementation of the proposed Toxicity Provisions. |
| 18.020 | **Monitoring Approach**  The proposed Toxicity Provisions would require chronic toxicity testing to occur in a one-month (i.e. 30-day) period, with monitoring frequencies ranging from monthly to quarterly to semi-annually, depending on the size of the discharge. We recommend modifying the compliance testing requirement to a 45-day testing period, with monitoring frequencies ranging from bi-monthly (sampling once every 2 months) to semi-annual, or greater, depending on the magnitude of discharge and other circumstances.  The issue of the feasibility of initiating three chronic toxicity tests in a one month period has been an ongoing topic of debate between Regional San, CVCWA, CASA, other POTW representatives and State Board staff for the past several years. Laboratory supervisors from various Central Valley POTWs have provided consistent, pragmatic input to the Board regarding their concerns regarding the logistics of meeting this requirement. The topic has also been discussed at workshops before State Board members. Regional San believes that additional consideration should be given to this issue because of changes to the Toxicity Provisions that will result in up to 4 or more required toxicity tests in a calendar month. |
| **SC O.009** | The Toxicity Provisions must be applied equally to all dischargers that have the reasonable potential to cause or contribute to toxicity, including storm water dischargers and non-point source dischargers. At a minimum, the Provisions should be incorporated into all industrial stormwater permits. Please see the individual comments below regarding storm water and non-point source dischargers. |
| **SR O.009** | Comments on storm water and non-point source dischargers are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR24.006” for a discussion on storm water dischargers and “SR18.001” for a discussion on non-point source dischargers. |
| 19.005 | However, in order to protect aquatic life and associated beneficial uses in California waters from ongoing toxicity and degradation, and to ultimately meet the goals of these Provisions, the State Water Board must:  *Apply the Provisions to all dischargers, including stormwater, agricultural, and other nonpoint source dischargers that have the reasonable potential to cause or contribute to toxicity. At a minimum, these Provisions should be incorporated into all industrial stormwater permits.* |
| 19.012 | **I. THE STATE WATER BOARD SHOULD APPLY THE PROVISIONS TO ALL DISCHARGERS, INCLUDING STORMWATER, AGRICULTURAL, AND NONPOINT SOURCE DISCHARGERS, WHERE REASONABLE POTENTIAL TO CAUSE TOXICITY EXISTS.** |
| 19.013 | Stormwater and agricultural discharges are known sources of toxicity in California waterbodies.4 This is especially true for industrial stormwater discharges, which comprise of highly hazardous chemicals, heavy metals, oil and grease, and bacteria that discharge into California’s waterways and affect the overall health of the state’s aquatic ecosystems. Meanwhile, discharges from irrigated agriculture are the largest source of pollution in California’s Central Valley. The State Water Board’s own 2018 Integrated Report Clean Water Act Section 303(d) List /305(b) Report identifies roughly 910 waterbody impairments in the Central Valley with agriculture identified as the source of over 80 of these impairments with hundreds more unknown, covering over 1,572 waterway miles. Further, an assessment of 313 sites conducted by the Central Valley Regional Board in 2010 revealed that toxicity to aquatic life was present at 63 percent of the monitored sites. |
| 19.014 | Our organizations have worked on the development of the forthcoming Toxicity Provisions since the early 2000’s and provided comments on several drafts and iterations of the Provisions with the purpose that the final Provisions comply with state and federal laws and ultimately provide strong, consistent permit requirements statewide to protect California’s aquatic ecosystems from the impacts of cumulative toxicity. The proposed Toxicity Provisions, however, do not properly meet Clean Water Act requirements by failing to apply to stormwater, agricultural, and other nonpoint source discharges and perpetuates inconsistent permit requirements across the Regional Water Boards. |
| 19.015 | Stormwater discharges regulated by NPDES permit must adhere to waste load allocations in TMDLs with appropriate effluent limits, conditions, and requirements. 5 Specifically for industrial discharges, permitting agencies must ensure that NDPES permits authorizing stormwater discharges associated with industrial activities include both 1) technology based protections *and* 2) water quality based effluent protections in the form of water quality based effluent limitations (WQBELs). The Clean Water Act further requires effluent limitations for whole effluent toxicity (i.e., aquatic toxicity) when the permitting authority determines that a discharge “causes *or has the reasonable potential*” to cause an exceedance of a numeric whole effluent toxicity water quality objective.6 |
| 19.016 | Meanwhile, final Toxicity Provisions should apply to any discharge, including agricultural or nonpoint source discharges, that cause or contributes to acute or chronic toxicity. Specifically, the State Water Board’s Nonpoint Source Policy expressly recognizes “that the most successful control of nonpoint sources is achieved by prevention or by minimizing the generation of nonpoint source discharges.”7 Further, California Water Code sections 13260, 13263 and 13269, and the Nonpoint Source Policy (2)(c) all require current and proposed nonpoint source discharges be regulated, by one or a combination of administrative tools, that include waste discharge requirements (WDR), waivers of WDRs, or prohibitions to achieve water quality objectives. |
| 19.017 | Further, while discharges regulated by the Water Boards may meet the requirements of the limited list of California Toxic Rule (CTR) priority pollutants, this is not sufficient to protect against known or unknown toxicants. Currently, the CTR only contains 126 priority pollutants, despite the fact that tens of thousands of chemicals are in use in a given year. Additionally, only a small subset of these 126 priority pollutants are included in permits with effluent limits. 8 Nationally, there are only a handful of chemicals that are regulated under Toxic Substances Control Act (TSCA), despite the nearly 85,000 chemicals known to exist in chemical inventory, including approximately 62,000 chemicals that were grandfathered in without sufficient information or analysis regarding the toxicity of these chemicals when the original TSCA was passed in 1976.9 Together, even low concentrations of multiple contaminants can have a negative synergistic and/or cumulative impact on ecological health. For this reason, toxicity water quality objectives are a critical safety net in discharge permits to identify potential impacts from these aggregate effects through toxicity testing. To achieve the State Water Board’s goal to achieve statewide consistency and protection of ecological health – and to ensure actual achievement of water quality objectives – we recommend that the Draft Provisions require toxicity monitoring and toxicity effluent limits for all dischargers where a reasonable potential to contribute toxicity exists. |
| 19.018 | As reflected in the Staff Report, however, only some stormwater dischargers are currently required to conduct toxicity monitoring, and these monitoring requirements vary among permits and dischargers with only some using the TST approach to analyze toxicity test data.10 The Staff Report rationalizes that because a panel report presented to the State Water Board in 2006 concluded that it “was not feasible, *at that time*, to set enforceable numeric effluent limitations for municipal stormwater discharges” and that numeric limits may only be feasible for some stormwater dischargers, and because the “appropriateness of numeric effluent limitations for stormwater discharges continues to evolve,”11 requiring numeric toxicity effluent limitations for NPDES stormwater dischargers with reasonable potential is not the preferred scope of these Toxicity Provisions. Since the release of this 2006 expert panel report, however, the U.S. EPA has since issued a memorandum that noted the increased information available to the permitting agencies after more than a decade of experience with setting waste load allocations (WLA) and effluent limitations and proposed that numeric waste load allocations should be translated into effective, measurable effluent limitations that will achieve standards including, where appropriate, numeric effluent limitations. Further, individual NPDES stormwater permits have increasingly imposed numeric effluent limits in California, and statewide numeric effluent limits (NEL) were incorporated into the Industrial General Permit to reflect TMDL receiving water limitations in 2018. Therefore, it is feasible and reasonable to require toxicity limits in stormwater permits to ensure all permits issued in California comply with the Clean Water Act to prevent the discharge of pollutants that impact receiving waters. |
| 19.019 | **Requested Action**: The State Water Board should issue final Toxicity Provisions that apply to all NPDES stormwater discharges and nonpoint source discharges where feasible, unless it is otherwise demonstrated that the discharge does not have the reasonable potential to cause toxicity. At a minimum, the Provisions should be incorporated into all industrial stormwater permits. |
| 19.022 | Finally, while the Provisions do not require stormwater and nonpoint source dischargers to conduct chronic or acute toxicity monitoring, those dischargers that are required by the Regional Water Boards to conduct toxicity testing must do so in accordance with the new Provisions. Regional Water Boards must not be precluded or prevented from setting effluent limits for stormwater or nonpoint source dischargers, when deemed feasible. As discussed above, the mere act of monitoring is not protective of human health or aquatic life as monitoring allows discharge of pollutants that already exceed limits imposed by the California Toxics Rule in receiving waters, until that pollutant is detected in a monitoring program, reported to a Regional Water Board, and included in the next iteration of the NPDES permit issued to the discharger. Imposing effluent limitations is an effective and proactive approach to prevent toxicity from occurring and we recommend the following language to uphold the intent of these provisions to apply when Regional Water Boards impose new toxicity water quality objectives for stormwater or nonpoint source dischargers that would not otherwise fall under the scope of the Provisions. |
| 19.023 | **Requested Language** *(Suggested language in red)*: **Section IV.B.3 (p. 41)**  If after the effective date of these TOXICITY PROVISIONS, the PERMITTING AUTHORITY issues new or reissued chronic or acute aquatic toxicity monitoring requirements or toxicity effluent limits 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. |
| **SC O.010** | POTWs of any size with reasonable potential should be assigned numeric effluent limits, while POTWs of any size without reasonable potential should be assigned numeric target. The establishment of toxicity numeric limits does not yield any water quality benefits beyond those provided by numeric target. The only additional consequence of having numeric limits, rather than targets, is the threat of a violation in the case of a WET test failure, with the associated Federal liabilities. |
| **SR O.010** | Comments regarding assigning chronic toxicity effluent limitations to POTWs based on the size of the POTW, without the need for a reasonable potential analysis are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR10.003” and “SR21.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), for a discussion on why the Toxicity Provisions contain numeric effluent limitations rather than numeric triggers or targets and why certain dischargers are required to have numeric effluent limitations. |
| 14.001 | BACWA reaffirms our position that the establishment of toxicity numeric limits does not yield any water quality benefits beyond those provided by numeric target. In either case, numeric limits or targets, after the observation of apparent toxicity, the sole route available to a discharger is to investigate and reduce the observed toxicity to the extent feasible. The only additional consequence of having numeric limits, rather than targets, is the threat of a violation in the case of a WET test failure, with the associated Federal liabilities. Since the 2020 Draft Toxicity Provisions already include numeric targets for facilities that are below 5 mgd and without a determination of reasonable potential. BACWA recommends that this approach is extended to all POTWs, regardless of size. **We request that POTWs of any size with Reasonable Potential would be assigned numeric effluent limits, while POTWs of any size without Reasonable Potential would be assigned numeric target.** |
| **SC O.011** | Reasonable potential procedures should be established that are consistent with both the expected environmental exposure and the statistical evaluations used in the provisions. |
| **SR O.011** | Comments regarding the reasonable potential determination are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR21.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), for a discussion on the reasonable potential procedures. |
| 23.007 | LADWP recommends that reasonable potential procedures be established that are consistent with both the expected environmental exposure and the statistical evaluations used in the provisions. |
| 26.005e | Determination of reasonable potential in a manner that does not evaluate representative environmental exposures |
| **SC O.012** | The State Water Board has set an appropriate and protective threshold for determining whether a discharge has the reasonable potential to cause an exceedance of a toxicity water quality objective. The threshold is to ensure toxic discharges are detected, addressed, and ultimately prevented to protect water quality, beneficial uses, and aquatic habitat. Anything less will fail to meet the overarching goals of the Toxicity Provisions by failing to impose requirements and a program of implementation to control toxicity on discharges that have the potential to exceed toxicity water quality objectives in California waters. |
| **SR O.012** | Comments regarding the reasonable potential determination threshold are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR21.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), for a discussion on the reasonable potential determination threshold. |
| 19.025 | The Clean Water Act explicitly requires effluent limitations for whole effluent toxicity (i.e., aquatic toxicity) when the permitting authority determines that a discharge “causes *or has the reasonable potential*” to cause an exceedance of a numeric whole effluent toxicity water quality objective.13 Therefore, the threshold for determining whether a discharge has the reasonable potential to cause an exceedance of a toxicity water quality objective – and thereby impact the aquatic health of receiving waters – must be protective of aquatic health. |
| 19.026 | By determining that reasonable potential exists if any of the toxicity tests results in a “fail” or if the percent effect at the IWC is greater than 10 percent for both chronic and acute toxicity – in addition to other factors such as the occurrence of fish die-offs or presence of endangered or sensitive species or habitat – the State Water Board has set an appropriate and protective threshold to ensure toxic discharges are detected, addressed, and ultimately prevented to protect water quality, beneficial uses, and aquatic habitat. Anything less will fail to meet the overarching goals of the Toxicity Provisions by failing to impose requirements and a program of implementation to control toxicity on discharges that have the potential to exceed toxicity water quality objectives in California waters. |
| **SC O.013** | The insignificant discharger exemption must clarify what constitutes a “very low threat to water quality.” |
| **SR O.013** | Comments regarding the threshold for an insignificant discharge exemption are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR13.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion on what constitutes a “very low threat to water quality.” |
| 19.068 | 2. The insignificant discharger exemption must clarify what constitutes a “very low threat to water quality.” Section IV.B.2.k.i provides an exemption for insignificant dischargers; however, the Provisions remain unclear regarding which dischargers may qualify under this exemption. The term “insignificant discharges” is defined as “NPDES discharges that are determined to be a very low threat to water quality by the permitting authority.”39 However, there is no clear criteria for what constitutes a “very low threat.” Given that even small discharges can still have a significant effect on ecological health, the final Provisions should clarify what constitutes a “very low threat to water quality,” and provide criteria for Regional Water Boards to evaluate when making such a determination. The State Water Board should provide parameters for the currently vague definition of the insignificant discharger exemption, including but not limited to, the following factors to determine whether the facility is in fact a "very low threat to water quality”:   * Size of the average effluent outfall (e.g., less than 1 MGD); *and* * Presence of industrial activities within the POTWs jurisdiction; *and* * Level of the treatment plant (e.g., tertiary versus secondary treatment); *and* * Demonstrated performance of that facility (e.g., consistent ‘pass’ of toxicity testing).   Providing such parameters will provide Regional Water Boards with an appropriate level of guidance to make this determination and ensure that an exemption is not granted to a discharge that may otherwise impact aquatic health. |
| **SC O.014** | Concerns remain regarding the use of numeric limits and the TST. |
| **SR O.014** | Resubmittal of prior comments are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR10.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), for a discussion on use of the TST statistical approach with numeric effluent limitations. Also, see SR J-1.001 and SR J-3.002 for further discussion on the TST statistical approach in Appendix J. Further responses to the prior comment letter can be found in [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 11.002 | However, our unresolved concerns remain regarding the use of numeric limits and the Test of Significant Toxicity (TST), and our prior comment letter addressing them is attached. |
| **SC O.015** | The Board should foster collaborative solutions. A compromise solution might be: (i) to use effluent concentration triggers for additional testing, (ii) to require all permittees go through a reasonable potential analysis, and (iii) to mandate use of the promulgated point estimate approach (EC/IC25) instead of the unpromulgated Test of Significant Toxicity (“TST”). |
| **SR O.015** | Comments regarding the point estimate approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR10.003” for a discussion on triggers, “SR21.008” for a discussion on the reasonable potential analysis, “SR25.003” for a discussion on test methods and statistical approaches, and “SR25.012” for a discussion on the point estimate approach. |
| 25.007 | The Board Should Foster Collaborative Solutions. The two of us have – collectively –practiced before the Board, representing many different public and private clients, for more than a half-century. The Board best serves the people of California when it fosters collaborative and cooperative solutions, not when it seeks to resolve issues through enforcement or “one size fits all” regulations. Notwithstanding the contentious history of the Toxicity Provisions, we believe that there is a productive and collaborative way to proceed, specifically:  The goals of the Toxicity Provisions should be: (i) to determine in a scientifically sound and legally defensible way whether there is persistent toxicity in effluent that could adversely affect receiving waters, (ii) to determine the cause(s) of that toxicity, and (iii) to fix the problem as quickly and as cost-effectively as possible, recognizing that inordinate costs of compliance prevent POTW dischargers from undertaking other projects that protect the public and the environment.  A compromise solution might be: (i) to use effluent concentration triggers for additional testing, (ii) to require all permittees go through a reasonable potential analysis, and (iii) to mandate use of the promulgated point estimate approach (EC/IC25) instead of the unpromulgated Test of Significant Toxicity (“TST”). |
| **SC O.016** | All POTWs discharge at a rate substantially less than authorized in their NPDES permit. These facilities are typically permitted for discharge to surface water based on the facility’s design average dry weather flow (ADWF) capacity. In general, a POTW is designed to provide treatment capacity for decades of growth, meaning actual flows are often much lower than design flows. Also, the volume of water treated (i.e., influent) can be significantly higher than the volume of effluent discharged to surface water due to demands for recycled water. Therefore, throughout the Toxicity Provisions, change the term “authorized discharge rate” to “average discharge rate.” |
| **SR O.016** | Comments regarding the term “authorized rate of discharge” are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, as stated in Section 5.4.4.2.1 of the Staff Report, the routine monitoring frequency for chronic aquatic toxicity testing would be determined by the authorized rate of discharge in the NPDES permit. Regional Water Boards will be responsible for determining the authorized rate of discharge. In doing so, Regional Water Boards may designate the average dry weather flow specified in the NPDES permit as the authorized rate of discharge. The average dry weather flow is typically the design flow the treatment facility is capable of biologically treating on an average basis under dry weather flow conditions. Regional Water Boards should not use a flow that is calculated to be less than the average dry weather flow as the authorized rate of discharge. Additionally, Section 5.4.2 of the Staff Report explains why POTWs authorized to discharge at a rate equal to or greater than 5 MGD and are required to have an industrial pretreatment program are required to have effluent limitations. |
| 21.025 | **Comment 7. Flow Averaging Period for Routine Monitoring Frequency Categorization, – Revised Draft Toxicity Provisions Section IV.B.2.d.ii.(A)(1).**  As stated above, members of the State Water Board recognized that less frequent monitoring for smaller POTWs was justified, and this resulted in changes to the revised draft Toxicity Provisions. These changes should be expanded so that the monitoring frequency is identified based on actual POTW flows, not the authorized discharge rate. Currently, the revised draft Toxicity Provisions specify monitoring frequencies are identified based on POTW “authorized discharge rate.” The term “authorized discharge rate” is not defined in the revised draft Toxicity Provisions. Without defining it differently, the authorized discharge rate appears to mean the permitted discharge rate because NPDES permits “authorize” discharge to surface water and include a flow prohibition or effluent limitation. |
| 21.026 | All POTWs discharge at a rate substantially less than authorized in their NPDES permit. Many POTWs provide a substantial volume of their Title 22-equivalent recycled water to users via reclamation infrastructure. Uses include industrial cooling water, municipal landscape irrigation, residential irrigation supply, non-potable uses such as toilet flushing, and agriculture irrigation. These facilities are typically permitted for discharge to surface water based on the facility’s design average dry weather flow (ADWF) capacity. In general, a POTW is designed to provide treatment capacity for decades of growth, meaning actual flows are often much lower than design flows. Moreover, the volume of water treated (i.e., influent) can be significantly higher than the volume of effluent discharged to surface water due to demands for recycled water. Examples include the following.   * City of Roseville Pleasant Grove WWTP (PGWWTP; Figure 2). The PGWWTP has a permitted flow of 9.5 MGD, on an ADWF basis. During the seasonal reclamation period, there is a significant difference between influent and effluent flows, demonstrating the substantial volume of Title-22 equivalent recycled water from PGWWTP used by the City. The annual average effluent discharge rate is 6.1 MGD. However, the rate decreases to 4.5 MGD during the summer reclamation period, and it will decrease further in the future due to planned expansion of the City of Roseville’s recycled water distribution system. * City of Lodi White Slough Water Pollution Control Facility (WSWPCF; Figure 3). The WSWPCF has a permitted flow rate of 8.5 MGD, but discharge to surface water is seasonal due to high recycled water usage. The annual average effluent discharge rate is 2.2 MGD. * City of Brentwood Wastewater Treatment Plant (BWWTP; Figure 4). The BWWTP has a permitted flow of 5 MGD. Effluent discharges to surface water vary seasonally due to recycled water demand. The annual average discharge rate is 3.1 MGD. Brentwood is expanding their recycled water usage and storage capacity. * El Dorado Irrigation District’s El Dorado Hills Wastewater Treatment Plant (EDHWWTP; Figure 5). The EDHWWTP has a permitted flow of 4 MGD. Effluent discharges to surface water varies seasonally due to recycled water demand. The annual average discharge rate is 0.96 MGD.   [See Figures 2 – 5 on pages 15 – 17 of Comment Letter #21] |
| 21.027 | Since the revised draft Toxicity Provisions rely upon authorized discharge rates to categorize POTWs and their associated toxicity monitoring requirements, they do not incentivize POTWs to recycle greater quantities of water. Moreover, this approach penalizes public agencies for constructing POTW upgrades that will increase the authorized discharge rate due to the need for expanded housing within their region; although, the actual average discharge rate may not exceed the authorized discharge rate thresholds defined in the revised draft Toxicity Provisions for decades. It is in the interest of all people of the State for the State Water Board to incentivize recycled water use and public projects, prudent use of public funds, and access to affordable housing.  Requested Change to Address Comment 7:  We request that the term “authorized discharge rate” be changed throughout the Toxicity Provisions to “average discharge rate” as shown in this example from Section IV.B.2.d.ii.(A)(1).  “For NON-STORM WATER NPDES DISCHARGERS that have an average discharge rate equal to or greater than 5.0 MGD, the frequency of ROUTINE MONITORING shall be specified in the NPDES permit as follows: …” |
| **SC O.017** | Change the term “non-storm water NDPES discharger” to “NPDES dischargers other than stormwater” to avoid confusion with non-stormwater provisions in stormwater NPDES permits and with the definition in the Ocean Plan. |
| **SR O.017** | Comments regarding the definition of the term “non-storm water NPDES discharger” are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. The term “non-storm water NPDES discharger” is used in a specific sense, for the Toxicity Provisions, to describe dischargers that are regulated pursuant to one or more NPDES permits, but excluding discharges subject to the United States Code title 33 section 1342(p) and excludes dischargers that discharge a combination of treated municipal or industrial waste water and storm water. The term of “non-storm water discharge” in the Ocean Plan is separate and specific to its use in that water quality control plan. |
| 15.013 | **COMMENT #3: MODIFY THE NON-STORMWATER NPDES DISCHARGER TERM TO AVOID CONFUSION WITH NON-STORMWATER PROVISIONS IN STORMWATER NPDES PERMITS**  The Revised Draft Toxicity Provisions have inadvertently created confusion by utilizing the term “non-stormwater” to define a category that primarily includes discharges from wastewater treatment plants. For storm water permittees, the term non-stormwater has typically been utilized in a different manner to define discharges of dry weather flow from storm drains. In fact, “non-stormwater discharge", is a term that is already defined in the Ocean Plan specific to runoff, not discharges from wastewater treatment plants. The Ocean Plan definition is as follows: “Non-storm water discharge is any runoff that is not the result of a precipitation event. This is often referred to as “dry weather flow”.”  The Ocean Plan definition is commonly used in stormwater permits to establish non-stormwater permit requirements. The Revised Draft Toxicity Provisions use of the term non-stormwater to cover discharges from wastewater and other permittees creates confusion and may inadvertently create conflicts with the Ocean Plan definition.  CASQA recognizes this comment is not on the changes made to the provisions and therefore may be outside the scope of the comments provided in the July 7, 2020 notice. However, the potential conflict between the definitions was identified after the previous comments were submitted. As this would be a clarification and not a substantive change to the Provisions, we request your consideration of the recommended changes.  ***CASQA Recommendation:***  • Change the term “non-storm water NPDES dischargers” to a term that does not include non-stormwater, namely “NPDES dischargers other than stormwater”. |
| **SC O.018** | The commenter strongly supports the effort to transition to enforceable numeric toxicity objectives using the WET test methods and the TST statistical approach. A number of Regional Water Boards have begun to incorporate numeric toxicity limitations into regulatory permits since 2012, but this implementation has been inconsistent and incomplete statewide.  Iterations of these Provisions have only been weakened with numerous concessions made to limit the scope and application of the final Provisions. For example, the final Provisions cannot be weakened further by rolling back requirements for existing permits that already use *C. dubia* for compliance with water quality objectives. |
| **SR O.018** | Comments regarding support for the use of numeric toxicity limitations and the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see response “SR20.002” for a discussion on statewide numeric toxicity limitations and “SR25.001” for a discussion on the TST statistical approach.  The Toxicity Provisions are consistent with Project Goal #1 which is to adopt consistent, statewide water quality objectives that are protective of California’s waters from both known and unknown toxicants. The Toxicity Provisions are also consistent with Project Goal #3 which is to create a consistent, yet flexible framework for monitoring toxicity and laboratory analysis. Please see SR F.002 for a discussion on requirements for existing permits that already use *C. dubia* for compliance. |
| 19.001 | California waterbodies in all nine regions have experienced chronic toxicity. Of 992 sites assessed by the State Water Resources Control Board (State Water Board) Surface Water Ambient Monitoring Program (SWAMP) in 2010, 473 sites (48%) had at least one sample where toxicity was observed, and 129 sites (13%) were classified as highly toxic. Waterbodies listed as impaired for toxicity has further increased from 225 waterbodies in 2010 to 326 waterbodies in 2016,1 despite the implementation of narrative toxicity limits by each of the nine Regional Water Quality Control Boards (Regional Water Boards). Consistent with the federal Clean Water Act and discussions that have taken place since 2003 to address this chronic toxicity in California,2 enforceable numeric toxicity objectives that utilize whole effluent toxicity (WET) test methods and the Test of Significant Toxicity (TST) statistical approach is the most protective regulatory strategy for aquatic life and human health. |
| 19.002 | A number of the Regional Water Boards have begun to incorporate numeric toxicity limitations into regulatory permits to address, detect, and manage toxicity since 2012. However, this implementation has been inconsistent and incomplete statewide. In order to appropriately assess and address toxic waters throughout California, there must be consistent and strong statewide numeric water quality objectives for both acute and chronic toxicity. |
| 19.003 | To protect aquatic life from the acute, accumulative, and chronic effects of toxicity, the stated goals of these Provisions are: 1. Adopt consistent, statewide water quality objectives for acute and chronic toxicity that are protective of California’s waters from both known and unknown toxicants; 2. Adopt a program of implementation to control toxicity in discharges and achieve and maintain the toxicity water quality objectives in California waters; 3. Create a consistent, yet flexible framework for monitoring toxicity and laboratory analysis; and 4. Incorporate a statewide statistical approach to analyze test results that will provide a transparent determination of toxicity with high confidence in those results, and provide an incentive for dischargers to generate valid, high quality test data.3 |
| 19.004 | The Toxicity Provisions have been in development for over fifteen years over which time, iterations of these Provisions have only been weakened with numerous concessions made to limit the scope and application of the final Provisions. The Provisions are long needed to supersede the ineffective toxicity control provisions in the SIP and clarify the appropriate form of WET effluent limits and impose numeric effluent limits for toxicity in NPDES permits and WDRs. |
| 19.073 | Addressing the chronic presence of toxicity in California waterways is critical and long overdue. The final Toxicity Provisions are needed to enact consistent, statewide water quality objectives for acute and chronic toxicity that are protective of California’s waters to proactively prevent the introduction of known or unknown toxicants, and to ultimately manage and eliminate discharge of the numerous pollutants that continue to plague California’s waterways. The Toxicity Provisions, however, have been substantially weakened with each draft iteration of the Provisions this includes, but is not limited to: The exceptionally limited scope of the Provisions to non stormwater NPDES discharges; The significant reduction of monitoring frequency from monthly monitoring for all facilities greater than or equal to 1 MGD; The reduction of species sensitivity screening from occurring at a minimum of once over 10 years to now being done at a minimum of once every 15 years; Delaying the use of *C. dubia* in toxicity testing to determine compliance with effluent limits. |
| 19.074 | The State Water Board has an affirmative duty to protect beneficial uses, including but not limited to aquatic beneficial uses, and to enact permit requirements that actually achieve water quality objectives. The final Provisions cannot be weakened further by rolling back requirements for existing permits that already use *C. dubia* for compliance with water quality objectives. To rollback and delay these requirements threatens the integrity of these Provisions and the overall health of aquatic ecosystems that the State Water Board has a duty to protect. We request your consideration of these comments to ensure the Water Boards take meaningful action to address the persistent presence of toxic contaminants in California’s waterways by adopting consistent, statewide provisions that are protective of aquatic health. |
| **SC O.019** | The commenter supports the use of a minimum of four tests conducted at the IWC and the use of the ten percent effect threshold to determine reasonable potential. |
| **SR O.019** | Comments regarding the minimum number of tests and the reasonable potential determination are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, comment noted. |
| 24.002 | EPA continues to support the recommendation to analyze reasonable potential with a minimum of four aquatic toxicity tests conducted at the permitted instream waste concentration (IWC). |
| 24.003 | More importantly, we support determining the potential to cause an excursion of WQS resulting from any test that generates an effect at the IWC greater than 10 percent. |
| **SC O.020** | The commenter supports a unified and coordinated statewide approach to address toxicity and supports the adoption of the statewide toxicity water quality standards. |
| **SR O.020** | Comments regarding a statewide approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, comment noted. |
| 24.004 | EPA looks forward to implementation of the acute and chronic toxicity water quality standards to evaluate the interaction of chemicals in ambient waters in a consistent and clear approach throughout California. The current approach for addressing aquatic toxicity relies on a patchwork of toxicity objectives and differing policies for implementation. A uniform approach will provide much needed clarity. |
| 24.012 | In closing, EPA truly appreciates the hard work State Board staff put into creating a more unified and coordinated statewide approach to address toxicity and supports adoption of the state-wide toxicity water quality standards. |

## Category P – Comments on the 2018 Responses

| **Comment Code** | **Comment** |
| --- | --- |
| **SC P.001** | The Response to 2018 Comments and changes to the Staff Report failed to address the concerns about the potential implications of the numeric toxicity objectives and waterbody impairment assessments on stormwater permittees, inadequate consideration of wet weather in establishing the objectives, and continued confusion about the methods for implementing the Revised Draft Toxicity Provisions in stormwater permits.  While SR 30.009 states “Additionally, the Provisions do not mandate receiving water limitations for storm water dischargers,” the State Water Board mandated receiving water limitation language in stormwater permits in Order WQ 2015-0075 and as a result, any water quality objectives established by the Board will become receiving water limitations in stormwater permits. |
| **SR P.001** | The State Water Board received comments from the public according to the State Water Board’s Notice of Opportunity to Comment (July 7, 2020). That notice stated that “[t]he State Water Board will receive written comments, input, recommendations, and additional evidence directly related to the differences between the October 2018 versions and the July 2020 versions of the Toxicity Provisions and the Staff Report. Any specific written comment or evidence that is unrelated to the differences between the October 2018 Toxicity Provisions and Staff Report and the July 2020 Toxicity Provisions and Staff Report will not be accepted.” As a result, comments on the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, regarding the requirements for storm water discharges, please see responses “SR24.003,” “SR24.004,” and “SR24.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). Also, see Section 5.5.1 of the Staff Report and Section IV.B.3 of the Toxicity Provisions. |
| 15.001 | **COMMENT #1: INCLUDE SUGGESTED LANGUAGE TO ADDRESS CASQA’S PRIMARY CONCERNS IN THE ADOPTING RESOLUTION**  …However, CASQA continues to be concerned about the potential implications of the numeric toxicity objectives and waterbody impairment assessments on stormwater permittees, inadequate consideration of wet weather in establishing the objectives, and continued confusion about the methods for implementing the Revised Draft Toxicity Provisions in stormwater permits. The Response to Comments and edits to the Staff Report largely fail to address CASQA’s continued concern that disconnects regarding the relationship between the establishment of statewide policies and water quality objectives and stormwater permitting and implementation remain. |
| 15.004 | Response to Comment SR 30.009 states “Additionally, the Provisions do not mandate receiving water limitations for storm water dischargers.” The State Water Board, however, has mandated receiving water limitation language in stormwater permits in Order WQ 2015-00751. As a result, any water quality objectives established by the State Water Board will become receiving water limitations in stormwater permits. |
| **SC P.002** | The Toxicity Provisions could result in 303(d) listings based on intermittent toxicity or false positives that do not indicate a beneficial use impairment and cannot be effectively addressed by a TMDL. These listings could trigger unintended actions for permittees and Water Board staff and modifications to the 303(d) List may be warranted to address these concerns.  Add language to the adopting resolution for the State Water Board to direct staff to review the application of the numeric objectives during the next two integrated reporting cycles and consider if clarifications or modifications to the 303(d) List are needed. Staff should determine how many additional toxicity listings result from the objectives and how many of the listings are based on one or less exceedances on average within a three-year period. If there is a significant number of listings and/or if sporadic exceedances are causing a significant number of listings, the Listing Policy provisions for toxicity shall be reevaluated. |
| **SR P.002** | Comments regarding the 303(d) List are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR05.001” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 15.008 | To Address Comment #2- The Toxicity Provisions Must Provide Toxicity Specific Guidelines for Evaluating Waters for Placement on the Section 303(d) List for Aquatic Toxicity Alone in CASQA’s December 2018 Comment Letter  WHEREAS: Concerns have been raised that the Toxicity Provisions could result in 303(d) listings based on intermittent toxicity or false positives that do not indicate a beneficial use impairment and cannot be effectively addressed by a TMDL. These listings could trigger unintended actions for permittees and Water Board staff. Modifications to the Water Quality Control Policy for Developing California’s Clean Water Act Section 303(d) List may be warranted to address these concerns.  THEREFORE, BE IT RESOLVED THAT THE STATE WATER BOARD: Directs staff to review the application of the numeric objectives during the next two integrated reporting cycles and consider if clarifications or modifications to the Water Quality Control Policy for Developing California’s Clean Water Act Section 303(d) List are needed. As part of the review, the staff will determine how many additional toxicity listings result from the objectives and how many of the listings are based on 1 or less exceedances on average within a three-year period (e.g., only 2 exceedances within a six-year listing cycle). If a significant increase in the number of listings is observed and/or if sporadic exceedances are causing a significant number of the listings, the Listing Policy provisions for toxicity shall be reevaluated. |
| **SC P.003** | Under the Strategy to Optimize Resource Management of Storm Water (STORMS), the State Water Board will develop a statewide framework for urban pesticides reduction (Urban Pesticides Amendments) to establish a program of implementation for pesticide and pesticide-related toxicity water quality objectives. The Urban Pesticides Amendments program will also establish consistent statewide requirements for MS4 permittees to manage MS4 contributions to pesticide-related toxicity and create a comprehensive, coordinated statewide monitoring framework for pesticides and toxicity in urban runoff and receiving waters that improves resource efficiency, usefulness of data, and coordination of data collection to support management decisions.  Add language to the adopting resolution for State Water Board to direct staff to propose Urban Pesticides Amendments that can serve as the program of implementation for the Toxicity Provisions for municipal storm water permittees. Since the rationale in the Response to 2018 Comments stated that Urban Pesticide Amendments are not yet developed and therefore cannot be considered within the Toxicity Provisions, modify Section III.B.4 of the Toxicity Provisions to provide a linkage to the Urban Pesticides Amendments when they are developed. |
| **SR P.003** | Comments regarding the Urban Pesticides Amendments are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, regarding the requirements for storm water discharges, please see responses “SR24.003,” “SR24.004,” and “SR24.005,” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). Also, see Section 5.5.1 of the Staff Report and Section IV.B.3 of the Toxicity Provisions.  Additionally, the proposed resolution adopting the Toxicity Provisions includes direction to State Water Board staff primarily within the STORMS program to prioritize an evaluation and consideration of aquatic toxicity implementation requirements specific to storm water discharges. The suggested revisions have not been made to the Toxicity Provisions. If any implementation provisions specific to storm water are developed by the State Water Board in the future, the State Water Board would specify how the implementation provisions are to be used by the permitting authority. It is premature to assume the content of the implementation provisions or that the permitting authority would only be required to consider storm water specific implementation provisions. |
| 15.009 | To Address Comment #4 - Integrate Implementation Requirements for Municipal Storm Water Dischargers Regulated Pursuant to NPDES Permits Through the Urban Pesticides Plan Amendments in CASQA’s December 2018 Comment Letter  WHEREAS: The primary cause of surface water toxicity statewide is pesticides. A Phase I project under the Water Board Strategy to Optimize Resource Management of Storm Water (STORMS) is to develop a statewide framework for urban pesticides reduction (Urban Pesticides Amendments) to establish a program of implementation for pesticide and pesticide-related toxicity water quality objectives. The Urban Pesticides Amendments will formally implement a multi-agency pesticides management approach that has been informally implemented for the last decade. This approach involves cooperation between the Water Boards, municipalities, and state and federal pesticide regulators to support attainment of water quality objectives for pesticides and toxicity in urban receiving waters and to prevent or readily address future water quality impairments due to MS4 pesticide contributions through implementation of a statewide program for urban pesticides source control. The Urban Pesticides Amendments program will also establish consistent statewide requirements for MS4 permittees to manage MS4 contributions to pesticide-related toxicity and create a comprehensive, coordinated statewide monitoring framework for pesticides and toxicity in urban runoff and receiving waters that improves resource efficiency, usefulness of data, and coordination of data collection to support management decisions. The Urban Pesticides Amendments will build on the recently updated Management Agency Agreement (MAA) between the Department of Pesticide Regulation (DPR) and the Water Boards that coordinates their activities and authorities to solve water quality problems related to pesticide use by promoting the development of practices that reduce or eliminate impacts on water quality or preventing pesticide use that may impact water quality.  THEREFORE, BE IT RESOLVED THAT THE STATE WATER BOARD: Directs staff to propose Urban Pesticides Amendments that can serve as the program of implementation for the Toxicity Provisions for municipal storm water permittees. |
| 15.011 | Additionally, CASQA’s request to utilize the upcoming Urban Pesticides Amendments as the implementation provisions for stormwater permittees was not incorporated. While we understand the rationale provided in the Response to Comments that the Urban Pesticides Amendments are not yet developed and can therefore not be considered within the Provisions, CASQA requests some modifications to Section III.B.4 to provide a linkage to the Urban Pesticides Amendments when they are developed. |
| 15.012 | Add the following text to Section III.B.4: For STORM WATER NPDES DISCHARGERS, the PERMITTING AUTHORITY shall consider statewide guidance and implementation provisions3 that are effective at the time of permit issuance prior to establishing effluent limitations, receiving water limitations, other permit requirements based on these provisions. In order to include limitations or other permit requirements, the PERMITTING AUTHORITY shall make a finding about the necessity for the requirements and demonstrate that other available implementation provisions have been considered and are insufficient to address toxicity. |
| **SC P.004** | The revised Staff Report and Responses to Comments did not adequately address the stakeholder's comments. As previously commented on, the Revised Draft Toxicity Provisions should use narrative objectives with implementation procedures for non-stormwater (i.e., wastewater) dischargers that include narrative effluent limitations and consistent numeric triggers for accelerated monitoring and Toxicity Reduction Evaluations (TREs) along with provisions for interpreting the narrative objectives for the purposes of 303(d) listing and TMDL target development. Additionally, previous drafts of the Toxicity Provisions failed to recognize the implications of numeric objectives to stormwater and agriculture dischargers, particularly in the context of TMDLs.  Stakeholders encourage the State Water Board to better incorporate consideration of the scientific basis of the objectives under different conditions and for different types of dischargers, how water quality objectives are utilized in waste discharge requirements for all types of dischargers, and implications for the waterbody assessment process when establishing future water quality objectives. |
| **SR P.004** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR30.002” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 22.004a | **Comment #4-Staff Report and Response to Comments did not Adequately Address the Stakeholder's Comments**  As noted in our previous comment letters, the Stakeholders have requested that the Revised Draft Toxicity Provisions use narrative objectives with implementation procedures for non-stormwater (i.e., wastewater) dischargers that include narrative effluent limitations and consistent numeric triggers for accelerated monitoring and Toxicity Reduction Evaluations (TREs) along with provisions for interpreting the narrative objectives for the purposes of 303(d) listing and TMDL target development. Additionally our comments expressed concern that the previous drafts of the Toxicity Provisions failed to recognize the implications of numeric objectives to stormwater and agriculture dischargers, particularly in the context of TMDLs. As these earlier recommendations have not been included in the Revised Draft Toxicity Provisions, our fundamental concerns remain unaddressed.  We recognize that the key concerns above are not available for comments based on the notice. However, do not feel that our previous comments were adequately addressed in the response to comments and edits to the staff report that were made in response to our comments. As a result, we are including some examples of the issues with the responses to our previous comments that we would like to note for the record…  The examples above, while not a comprehensive summary of the concerns with the response to our comments, highlight our continuing concern with the general approach taken to establish the Revised Draft Toxicity Provisions. While we recognize the approach will not be modified in response to these comments, the Stakeholders encourage the State Water Board to better incorporate consideration of the scientific basis of the objectives under different conditions and for different types of dischargers, how water quality objectives are utilized in waste discharge requirements for all types of dischargers, and implications for the waterbody assessment process when establishing future water quality objectives. |
| **SC P.005** | Few, if any, of the extensive comments and changes provided by the commenter in 2018 have been made in the July 2020 Second Revised Draft Toxicity Provisions. Staff often misunderstood or misconstrued the comments and simply failed to respond. The Response to Comments fails to adequately address the comments made by lumping similar comments together and providing a short answer to the parts of the comments to which the staff wishes to respond. This “summary” strategy has the effect of making the arguments appear to be less credible. This approach is factually and legally inadequate as many comments have not been adequately responded to and got lost. Such failure to respond does not comply with the Board’s requirements to consider and respond to all substantive comments under Porter-Cologne and other applicable law. Nor does it comport with our past experience with the Board where, even in the most contentious matters, Board Staff have gone out of their way to respond to all comments in a thorough and professional way. |
| **SR P.005** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  The responses to comments do not entail an inadequate response or format. Specifically, response to comments need only “summarize the public’s views, significant comments, criticisms and suggestions.” (Code of Fed. Regs, title 40, part 25.8.) The response to comments documents goes beyond the minimum, by both summarizing and identifying the specific comments. In addition, the response to comments documents provide a response to each group of comments. The “summary response” is a specific response to all the comments grouped under the summary comment. The response to comments documents also include written responses to the significant environmental issues raised in comments. (23 CCR § 3779.) For further discussion and specific responses to previously submitted comments, please see the specific responses in this category (i.e., Category P. Comments on 2018 Responses to Comments), other responses to comments in this document, and other response to comments documents.  In addition, the request for additional time could have been made prior to the conclusion of the comment period and was not timely. However, a time extension was not necessary as comments on the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are out of scope and there was sufficient time to review and comment on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. |
| 25.002 | We are also providing the Board with our detailed comments on the Staff’s Response to Comments (“RTC”), which are attached hereto as Exhibit A. Our review of indicates that few – if any – of the extensive comments and changes that we provided to the Board in 2018 on these issues have been made in the 2020 Toxicity Provisions. |
| 25.003 | A copy of our 32-page comment letter and attachments from 2018 is attached for your reference as Exhibit B for the benefit on the newer Board members. |
| 25.004 | As you will see, Staff have often misunderstood or misconstrued our comments and have often –especially in connection with some of the most important comments – simply failed to respond. Such a failure to respond to detailed comments does not comply with the Board’s requirements to consider and respond to all substantive comments under Porter-Cologne and other applicable law. Nor does it comport with our past experience with the Board where, even in the most contentious matters, Board Staff have gone out of their way to respond to all comments in a thorough and professional way. |
| 25.010 | The Response to Comments (“RTC”) fails to adequately address the comments made by lumping similar comments together and providing a short answer to the parts of the comments to which the staff wishes to respond. This approach is inadequate as many comments have not been adequately responded to and got lost in the 541 page RTC table. While Staff included the EPA text of the regulations and guidance quoted in our comments, they failed to include the actual reference citations associated with the text and footnotes in our comment letters. As such, staff's RTC document fails to acknowledge that the key quoted material actually came from EPA, not the stakeholders. This RTC “summary” strategy has the effect of making the arguments appear to be less credible. |
| 25.011 | The following replies to some of the responses included in the table to demonstrate that these responses were both factually inaccurate and legally inadequate. This is not a comprehensive reply to each response as there was not adequate time to prepare that level of reply in the just over 30 days provided for thousands of pages of new text and changed documents. Additional time should have been allowed to adequately review and comment on the entirety of the new materials provided in July. |
| **SC P.006** | The proposed Toxicity Provisions must be substantially revised to make them compliant with state and federal law. The Water Board should continue its currently binding precedential orders, with 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). |
| **SR P.006** | Comments regarding the State Water Board precedential orders are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, please see responses “SR06.005,” “SR06.007,” “SR10.003,” “SR10.009,” “SR10.010,” “SR20.007” and “SR30.002”from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  Further discussion on the impracticability of average weekly limitations was added to Section 5.4.3 of the Staff Report. Please also see Section 5.4.3 of the Staff Report for further discussion on the feasibility of numeric effluent limitations. |
| 25.009 | 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). As we have for the last 18 years working on this policy, we stand ready to assist in modifying the Toxicity Provisions to meet the State Water Board’s goal of consistency without placing permittees and water/recycled water purveyors in compliance jeopardy. |
| **SC P.007** | The City of Tracy case represents a binding authority upon the State Water Board since the case was never appealed (see full comment #25.012 below). Water Code section 13241 imposes an affirmative obligation on the State Water Board, when establishing water quality objectives, to take into account various factors, including the economic costs of complying the proposed objective. |
| **SR P.007** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  The commenter’s previous comments on the “cost of compliance” and *City of Tracy v. State Water Resources Control Bd,* Sacramento Superior Court Case No 34-2009-80000392, *City of Burbank v. State Water Resources Control Board*, Los Angeles County Superior Court Case No. BS 060960 (April 4, 2001), and *Communities for a Better Environment v State Water Resources Control Bd* (2003) 109 Cal.App 4th 1089 were made regarding the impracticability or infeasibility of effluent limitations. (Please see Comment 22.074 and Comment 22.021.) The July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) responded to these comments in “SR10.011” and “SR10.010”. Further discussion on the impracticability of average weekly effluent limitations was added to Section 5.4.3 of the Staff Report. Please also see Section 5.4.3 of the Staff Report for further discussion on the feasibility of numeric effluent limitations.  However, of note, *City of Tracy v. State Water Resources Control Bd,* Sacramento County Superior Court Case No 34-2009-80000392, is a superior court case, related to a different proceeding and constitutes only the law of the case. The State Water Board complied with the decision and filed a return to the writ. As a superior court case, it has no precedential value. Furthermore, *Communities for a Better Environment v. State Water Resources Control Bd* (2003) 109 Cal. App 4th 1089 affirmed the State Water Board’s interpretation of “infeasible” as used in 40 Code of Federal Regulations section 122.449k)(3) to mean “not appropriate.” As a superior court case, *City of Tracy* does not affect the holding in *Communities for a Better Environment v. State Water Resources Control Bd.* Additionally, as mentioned by the commenter, the California Supreme Court’s decision in *City of Burbank v. State Water Resources Control Board* (2005) 35 Cal.4th 613, did not address the trial court’s rulings on whether the permit improperly imposed daily maximum limitations rather than weekly or monthly averages because the issue was unchallenged on appeal. Therefore, the trial court’s ruling on that issue only constitutes the law of the case and the Regional Water Board complied with that decision. As a superior court case, it has no precedential value.  Now the commenter is expanding on previously submitted comments to discuss *City of Tracy* *v. State Water Resources Control Bd* and the California Supreme Court’s decision in *City of Burbank v. State Water Resources Control Board* (2005) and “cost of compliance” as it relates to the analysis required under Water Code section 13241 when establishing water quality objectives. As required by Water Code section 13241, Section 9.1.4 of the Staff Report contains an analysis of economic considerations, including cost of compliance.  In taking into account economic considerations as required under Water Code section 13241, Section 9.1.4 of the Staff Report includes estimated economic costs for non-storm water NPDES dischargers and for storm water and nonpoint source dischargers. The possibility that any given discharger would implement a specific toxicity control as a method of complying with the requirements in the Provisions is speculative. Whether a discharger would choose to implement additional toxicity controls as a result of the Toxicity Provisions to address toxicity would depend, in part, on whether the discharger already needs to comply with existing toxicant-specific monitoring requirements, effluent limitations, or receiving water limitations. Many dischargers already implement toxicity controls, making an upgrade unlikely. Whether a discharger chooses to implement additional toxicity controls may also depend on the nature, type, and persistence of any toxicity detections, and whether the cause of the toxicity or the identity of the toxicant is determined. In addition, any additional toxicity control may result from existing pollutant specific requirements, rather than the Provisions. The Water Boards do not mandate the manner of compliance (see Water Code section 13360(a)), so any discharger that chooses to implement a toxicity control is free to select any particular toxicity control or combination of toxicity controls. If a discharger chooses to implement an additional toxicity control, the discharger’s selection of one or more particular toxicity controls would depend on the type of facility, the type of toxicity controls already in place at the facility, and the quality of the existing effluent of the discharger. The type of toxicity control selected by the discharger could also depend on whether the cause of the toxicity (e.g., malfunctioning equipment) or the toxicant (e.g., identification of high copper concentrations in the effluent) are identified. It is more likely that dischargers would select toxicity controls that are less expensive and have lower environmental impact (e.g., institutional toxicity controls or optimization of existing structural toxicity controls) rather than toxicity controls that are more expensive and have higher environmental impacts (e.g., new structural toxicity controls). Ultimately, however, it is unclear which discharger would implement a toxicity control and which toxicity control would be selected by any specific discharger. Therefore, a range of costs were included in the Staff Report. Section 9.1.4 of the Staff Report provides examples of the costs of facility upgrade projects. In addition, Section 9.1.4 of the Staff Report takes into account the costs associated with monitoring, conducting TREs, and other economic considerations consistent with *City of Burbank v. State Water Resources Control Board* (2005). As previously indicated, *City of Tracy v. State Water Resources Control Bd,* Sacramento County Superior Court Case No 34-2009-80000392, is a superior court case, related to a different proceeding and constitutes only the law of the case. The State Water Board complied with the decision and filed a return to the writ. As a superior court case, it has no precedential value.  Taking into account economic considerations, the “cost of compliance” has not traditionally been associated with the cost of penalties/enforcement. It is important to note that violations of effluent limitations do not automatically subject a discharger to mandatory minimum penalties. Additionally, it would be unlikely that a discharger would be subject to mandatory minimum penalties for violations of the proposed aquatic toxicity numeric effluent limitations because most, if not all, NPDES permits contain effluent limitations for toxic pollutants. Please see response “SR11.002” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). In discretionary civil liability, by the very nature of the enforcement action being discretionary, it is speculative to determine whether a penalty would be applied and how substantial that penalty would be. The Toxicity Provisions do not change the process or frequency in which enforcement actions are taken by the Water Boards. Since it is not possible to predict which facilities may have violations, or how often, or what penalties may be assessed if there is a violation, any attempt to estimate costs associated with increased violations would be purely speculative.  Since a numeric effluent limitation provides clear and consistent interpretation of results, it is possible that the Toxicity Provisions could lead to a violation for those dischargers that do not currently have to comply with numeric effluent limitations. However, as discussed in Section J.5 of Appendix J, SR J-1.009, and SR J-3.002, violations are unlikely to occur unless effluent samples are truly toxic. Additionally, Section 5.3.1 of the Staff Report explains why the TST is the preferred statistical approach to determine compliance with the numeric effluent limitations in the Provisions. Violations and the costs associated with penalties would depend on the quality of effluent. To the extent penalties are issued, dischargers would usually take steps to correct the violation. Penalties are an appropriate and important tool to prevent or reduce toxicity. The numeric aquatic toxicity water quality objectives and numeric effluent limitations, and any costs, including penalties, are entirely appropriate, necessary, and reasonable to prevent toxicity. See also “SR10.004” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). If there are unusual or unanticipated significant costs to a discharger, as before, these issues can be raised with the permitting authority at the time of permit issuance and a possible solution could include a compliance schedule.    Please see responses “SR09.002,” “SR09.008,” “SR11.002,” “SR25.029,” and “SR25.024” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.005 | In this very complicated policy arena, we believe it is important for the Board to focus on several key principles:  The Board Must Comply with Applicable Law. The California Supreme Court in its decision in City of Burbank v. State Water Resources Control Board, as well as the trial court in its decision in City of Tracy v. State Water Resources Control Board have found that the Board must consider the cost of compliance as part of its efforts to promulgate water quality objectives. Other decisions, most notably Communities for a Better Environment v. State Water Resources Control Board have found that the Board must consider whether compliance is feasible in promulgating water quality objectives. The Toxicity Provisions fail to engage in these analyses, despite our prior comments highlighting these concerns. Such lack of analysis is itself troubling, especially in connection with the RTC’s failure to reflect controlling law. |
| 25.012 | **Category 1 – 13241 Analysis**  The City of Tracy case (*City of Tracy v. SWRCB*, Statement of Decision, Sac. Superior Case Number: 34-2009-80000392 (May 10, 2011) (“*Tracy*”) represents a binding authority upon the State Board since this case was never appealed.1 {footnote 1: **#SR19.005** states: “Note, the City of Tracy v. California State Water Resources Control Board cited by the commenter is a superior court case and does not establish precedent.” While it may not be precedential on other agencies, these rulings on legal issues are certainly binding on the State Water Board through res judicata and claim preclusion.} Both that case and the California Supreme Court endorsed the view that section 13241 requires consideration of the “cost of compliance “ (See *City of Burbank v. SWRCB*, 35 Cal 4th at 625 [finding the “plain language” of section 13241 requires the board to consider the “cost of compliance”]) As described above. Water Code section 13241 imposes an affirmative obligation on the State Board, when establishing water quality objectives, to take into account various factors, including the economic costs of complying the proposed objective. (See *Tracy* decision citing Water Code § 13241 and Atwater Memorandum.) |
| **SC P.008** | The 13241 analysis, required of the State Water Board under Water Code section 13170, must take into consideration not only economics and the cost of compliance, but also the *environmental characteristics* of the hydrographic unit under consideration. Thus, the State Water Board must consider the differences between wet and dry weather and natural toxicity and make the regulations reflect those differences. |
| **SR P.008** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, for a discussion on wet and dry weather information to inform the Water Code section 13241 analysis, please see “SR01.001” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). In addition, regarding the 13241 analysis, please see Section 9.1 of the Staff Report.  As already indicated, the proposed numeric water quality objectives for aquatic toxicity would ensure the protection of aquatic life beneficial uses in the state’s inland surface waters, enclosed bays, and estuaries in both wet and dry weather flow conditions. The Toxicity Provisions propose numeric water quality objectives for chronic and acute aquatic toxicity that are expressed as null hypotheses and incorporate a regulatory management decision (RMD). The RMDs represent the allowable error rates and thresholds that would result in an unacceptable risk to aquatic life. For chronic toxicity, the RMD is set at 25 percent and for acute toxicity, the RMD is set at 20 percent. This is not an over-protective nor unreasonable consideration of unacceptable risk. As toxicity data considers the cumulative and synergistic effects of all toxicants on test organisms, such data can be used directly to evaluate the overall potential impact of the effluent on the biological integrity of the aquatic community in the receiving water.  If a waterbody shows toxicity naturally, it would be expected that the waterbody would lack aquatic life susceptible to the natural toxicants or toxic conditions, and some or all aquatic life beneficial uses would not apply to the waterbody.  For example, a waterbody fed by natural hot springs may be toxic to fish but not algae or other aquatic plants.  The permitting authority may select test species from Table 1 of the Toxicity Provisions, in accordance with Section IV.B.1.b of the Toxicity Provisions, that are most representative of the waterbody when comparing waterbody conditions to the numeric aquatic toxicity water quality objectives.  To continue the above example, the permitting authority may select *Selenastrum capricornutum*, a green alga.  Furthermore, if a beneficial use is not present in a waterbody, but the waterbody is designated with the use, a Regional Water Board may consider a basin plan amendment to change the beneficial use.  The Toxicity Provisions are reasonable and necessary for all the reasons cited in the Staff Report and the response to comments documents. |
| 25.013 | This 13241 analysis, required of the State Board under Water Code section 13170, must take into consideration not only economics and the cost of compliance, but also the *environmental characteristics* of the hydrographic unit under consideration*, including the quality of the water thereto*. Water Code §13241(b). Thus, the State Board must consider the differences between wet and dry weather and make the regulations reflect those differences (e.g., more dilution in wet weather, no aquatic life when creek runs dry). Also, if the water body shows toxicity naturally (due to high temperature, salinity, or other factors), that must be considered when the objective is adopted. Nowhere in the Toxicity Provisions is there any analysis of this so the toxicity objectives in the Salton Sea are the same as those in a pristine Sierra creek. This is illogical and contrary to law. Staff Comment **#SR01.001** states that “The proposed numeric water quality objectives for aquatic toxicity would ensure the protection of aquatic life beneficial uses in the state’s inland surface waters, enclosed bays, and estuaries in both wet and dry weather flow conditions.” However, just because a stringent objective could protect both wet and dry weather does not answer the question as to whether that stringent objective year-round is reasonable or unnecessarily over-protective. |
| **SC P.009** | The State Water Board must consider the water quality conditions that could *reasonably* be achieved *through the coordinated control of all factors which affect water quality in the area*. By only regulating POTWs and other non-stormwater NPDES discharges (even though there is no evidence that these discharges are actually more toxic than others not being regulated), this action is arbitrary, capricious, and fails to meet the requirements of section 13241(c) since there is no reasonableness or coordinated control of all factors affecting water quality. Section 13000 of the Water Code requires “activities and factors which may affect the quality of the waters of the state shall be regulated to attain the highest water quality which is reasonable. The proposed Toxicity Provisions are not reasonable. |
| **SR P.009** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, regarding the 13241 analysis, please see Section 9.1.3 of the Staff Report.  The commenter inaccurately states that the Water Boards only regulate POTWs and other non-storm water NPDES discharges. The Toxicity Provisions include specific implementation requirements for non-storm water NPDES dischargers; however, the Toxicity Provisions do not indicate that other dischargers would not be regulated by the permitting authority. When regulating other dischargers, such as NPDES storm water dischargers and non-point source dischargers, the permitting authority is obligated to implement all relevant water quality control plans, including the numeric aquatic toxicity water quality objectives in the Toxicity Provisions.  The Toxicity Provisions are reasonable and necessary for all the reasons cited in the Staff Report and the response to comments documents. |
| 25.014 | In addition, the State Board must consider the water quality conditions that could *reasonably* be achieved *through the coordinated control of all factors which affect water quality in the area*. Water Code §13241(c). Staff Comment #SR01.001 states that “Factors that affect aquatic toxicity in the state’s inland surface waters, enclosed bays, and estuaries are municipal and industrial point sources, storm water, and natural and human-caused non-point sources….In either wet or dry conditions, sources of toxicity need to be controlled to protect aquatic life beneficial uses.” By only regulating POTWs and other non-stormwater NPDES discharges (even though there is no evidence that these discharges are actually more toxic than others not being regulated), this action is arbitrary, capricious, and fails to meet the requirements of section 13241(c) since there is no reasonableness or coordinated control of all factors affecting water quality. Reasonableness is mandated through sections 13140 and 13240 as well, which requires that water quality controls “plans shall conform to the policies set forth in Chapter 1 (commencing with Section 13000).” Section 13000 requires “activities and factors which may affect the quality of the waters of the state shall be regulated to attain the highest water quality which is reasonable, considering all demands being made and to be made on those waters and the total values involved, beneficial and detrimental, economic and social, tangible and intangible.” (All emphasis added). For the many reasons cited by the commenters over the last decade, which are incorporated herein by reference, the proposed Toxicity Provisions are not reasonable. |
| **SC P.010** | Response SR05.001 in the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) states that when making decisions regarding listing a waterbody as impaired under Clean Water Act section 303(d), if there is a concern that the fails are due to false positives, the quality of the data may be considered. However, the quality of the data is ignored in the context of permit compliance. This is highly inconsistent and unreasonable. |
| **SR P.010** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, data quality is reasonably considered in the context of permit compliance. First, the required toxicity testing methods provide quality assurance and quality control measures. Second, the TST statistical approach provides an incentive for more precise toxicity test execution since statistical variability is reduced with more precision. Third, when considering permit compliance in terms of a MMEL violation, the median of two or three toxicity tests is used to determine a violation. Two fails out of two or three tests is a clear indication that toxicity exists in the effluent. It is statistically improbable that two out of three toxicity tests would result in fails through false positive probability error alone, especially given the low false positive rate incorporated into the TST statistical approach. When considering permit compliance in terms of a MMEL violation using *C. dubia*, there is less than a one percent probably of a violation of the MMEL due to false positives, given a five percent probably of a false positive using the TST statistical approach (see Section J.5 in Appendix J of the Staff Report for additional discussion).  Additionally, the 303(d) listing process is separate from the process of determining compliance with effluent limitations in NPDES permits. The two processes serve different purposes and do not need to use the same procedures to account for data quality and potential false positives.  Finally, regarding the listing process, SR05.001 in the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) responds to concerns that a water body may be listed as impaired if there are two fails of the TST, out of 24 toxicity tests/samples. The 34 percent probability of an incorrect listing is only applicable when there are exactly 24 samples, with a 10 percent effect for each sample that resulted in a fail, and when out of those 24 samples exactly two samples results in a fail. In a listing determination, it is unlikely that each failed sample collected would have a 10 percent effect and that exactly 24 samples would be collected for each listing. If there are more than two fails out of 24 samples, the probability of an incorrect listing decreases (regardless of the percent effect of each sample that results in a fail). Likewise, if you have two fails with less than 24 samples, then the probability of an incorrect listing decreases (regardless of the percent effect of each sample that results in a fail). There are various factors that impact the likelihood of an incorrect listing (change in number of samples, number of fails, and the percent effect of those samples that resulted in a fail). The false positive rate of 5 percent was determined taking into account a population and a true percent effect of 10. Therefore, the commenter’s calculation is only applicable to very specific and theoretical sample set.  Listing a water body on the CWA section 303(d) list serves as a backstop to ensure state water quality standards are met. Early steps in addressing a listing include identifying the scope of the problem, compiling and assessing the data that led to the listing as well as other existing data, identifying data gaps, and developing a project plan to fill critical data gaps. Should a water body be listed per the scenario described above, additional toxicity testing could be used to increase the statistical confidence in the listing determination and to better understand the conditions (temporal and spatial) of the water body in terms of aquatic toxicity.  To clarify the statement in SR05.001 of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) that “[i]f there is concern that the fails are due to false positives, as potentially indicated by 2 fails out of 24 samples with both fails at a 10 percent effect, the quality of the data may be considered before a listing decision is made,” assessment of data quality in the listing process is applicable to all test results regardless of methods. Section 6.1.4 of the Listing Policy states that “[e]ven though all data and information must be considered, the quality of the data used in the development of the section 303(d) list shall be of sufficient high quality to make determinations of water quality standards attainment. Data supported by a Quality Assurance Project Plan (QAPP) pursuant to the requirements of 40 CFR 31.45 are acceptable for use in developing the section 303(d) list.” This section of the Listing Policy also explains that a QAPP (or equivalent documentation) must describe the methods used for sample collection and handling, quality assurance and quality control requirements, and a description of personnel training, among other things. |
| 25.015 | **Category 5 – 303(d) Listing**  Staff Response **#SR05.001** states “If there is concern that the fails are due to false positives, as potentially indicated by 2 fails out of 24 samples with both fails at a 10 percent effect, the quality of the data may be considered before a listing decision is made. The quality of the data used in the development of the 303(d) list shall be of sufficient high quality to make determinations of water quality standards attainment.” (Emphasis added.) It is interesting that the quality of the data will be considered for 303(d) listing purposes, but those same data quality issues are being ignored in the context of permit compliance. This seems highly inconsistent and unreasonable. |
| **SC P.011** | The evidence does not support the statement in the Staff Report that the overall number of exceedances of toxicity water quality objectives is not expected to increase using the TST approach when compared to other statistical approaches, because staff is relying on flawed data. |
| **SR P.011** | Comments regarding the expected number of exceedances of the toxicity water quality objective are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, the Staff Report discusses the results from the TST Test Drive, which demonstrated that no increase in the number of exceedances of the water quality objective is expected. Appendix J was added to the Staff Report and includes a comprehensive analysis of the probabilities of false positives when conducting the chronic *C. dubia* test. Appendix J discusses the Fox et al. 2019 study (a peer-reviewed and published paper), which demonstrates that as laboratories improve the quality of their data the probability of false positives decreases. When variability is low the TST statistical approach is less likely than the NOEC statistical approach to identify a sample as toxic when biological effects are negligible (at or below a 10 percent effect) and will always identify a sample as toxic the percent effect is at or above a 25 percent effect level. In addition, several dischargers have been using the TST approach to evaluate their aquatic toxicity test data over the past several years. There is no evidence that dischargers have experienced an increase in the number of fails when using the TST approach.  For further discussion of data quality, please see SR P.010 and “SR25.009” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.016 | As further stated: “the Staff Report explains that the overall number of exceedances of the toxicity water quality objective is not expected to increase using the TST approach when compared to using other current statistical approaches.” The evidence does not support this allegation because staff is relying upon flawed data, which was pointed out in comments previously submitted, but not addressed. |
| **SC P.012** | See the individual comment below regarding the Responses to 2018 Comments inadequately considering the comments and inaccurately characterizing the comments made regarding the false positive rate. |
| **SR P.012** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see “SR05.001” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  As discussed in “SR05.001,” “…data from ambient water toxicity tests are currently analyzed using a standard t-test, which has a false positive rate of 5 percent. This 5 percent false positive rate is the recommended false positive rate for aquatic toxicity tests and is standard for statistical approaches used to evaluate aquatic toxicity data.”  See “SR25.014” regarding the acceptability of WET testing for Clean Water Act regulatory purposes and the acceptable 5 percent false positive rate. See “SR25.029” regarding the Edison case and successful defense of WET testing procedures with an acceptable degree of variability. Chemical testing also includes the potential for false positives. The Listing Policy accounts for the possibility of false positives for chemical pollutants and associated listings have not been challenged on the false positive probability of each chemistry test.  The response in “SR05.001” specifically addresses a comment from CASQA, expressing a concern that using the TST will lead to an increase in the number of water bodies listed as impaired. As stated in “SR05.001,” “[s]taff is not aware of a similar concern about incorrect listings using the current approach. Furthermore, Section 5.1.1 of the Staff Report explains that the overall number of exceedances of the toxicity water quality objective is not expected to increase using the TST approach when compared to using other current statistical approaches.” Comments 06.019 through 06.021 do not include any specific examples of how the current approach has led to incorrect listings due to false positives. The TST incorporates an additional statistical component of evaluating the variability of the data when determining a “pass’ or “fail.” The probability of a TST “fail” below 10 percent effect can be reduced by increasing replication and/or decreasing within-test variability. Please refer to the TST Technical Document ([EPA 833-R-10-004](https://www3.epa.gov/npdes/pubs/tst-techdoc.pdf)), Fox et al. 2019, and Appendix J of the Staff Report for more information.  See also SR P.010 regarding quality assurance considerations for using data for listing. |
| 25.017 | This section on pages 17-18 also states that “This 5 percent false positive rate is the recommended false positive rate for aquatic toxicity tests and is standard for statistical approaches used to evaluate aquatic toxicity data. Staff is not aware of a similar concern about incorrect listings using the current approach.” (Emphasis added.) Yet, *on the very next page*, discussing comments 06.019-06.021, the public comment was included that “Notwithstanding concerns specific to the TST which have been documented in previous comment letters related to these Draft Toxicity Provisions, the concern regarding false positive aquatic toxicity test results are applicable to all common statistical approaches for interpretation of aquatic toxicity testing, yet the concerns regarding false positives are minimal for almost all pollutants (e.g. chemical parameters, bacterial indicators).” (Emphasis added.) This demonstrates both that the RTC inadequately considered the comments and inaccurately characterized the comments made. |
| **SC P.013** | Staff mischaracterizes and incorrectly makes assumptions about comments made. For example, SR06.006 states that the State Water Board assumes that the commenter is using the term “false failure” to mean “false positive.” A false failure means an inaccurate indication of toxicity that causes a test to be deemed a “fail” and thus creates a potential violation of the objective or the permit requirement. These false indications of toxicity have been demonstrated to be between 14 percent and 50 percent (based on the California Association of Sanitation Agencies’ (CASA) comment letter submitted on the Toxicity Provisions and their attached study).  Appendix J improperly assumes that only tests that failed the TST with less than a 10 percent effect are considered a potential “false positive.” Comments submitted showed a very real possibility that effects much larger than 10 percent will occur due solely to random and natural biological fluctuations in *Ceriodaphnia dubia* reproduction, even when there is no actual difference in the chemical composition of the sample waters. This problem has not been remedied and makes many of the assumptions made in the environmental document suspect. |
| **SR P.013** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  The commenter’s attempt to clarify the comment and the definition of “false failure” was not helpful because it is unclear how the Staff Report’s definition of “false positive” (declaring an effluent toxic when the percent effect is less than or equal to 10 percent) should be distinguished from the commenter’s definition of “false failure.”  As stated in SR J-1.001, an environmental sample can never be found to be “truly non-toxic.” There is no way to know whether any toxicity test of an environmental sample results in an inaccurate indication of toxicity (e.g. a true false positive).  The U.S. EPA conducted a blank study in 2001 in which multiple WET test methods were performed on non-toxic “blank” samples. The study showed low false positive rates. Please see “SR25.014” in the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for more information. False positive rates have not increased with the use of the TST. See Appendix J.  The attached study from the CASA comment letter submitted on the Toxicity Provisions relies on data presented in Moore et al. 2000. Please see SR J-1.010 for a discussion of the limitations of the Moore et al. 2000 study. Please see “SR27.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion of the CASA White Paper. Additionally, please see SR J-1.001, SR J-1.002, and SR J-3.003 for a discussion of “false indications of toxicity.” Also, see response “SR06.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.018 | **Category 6 – CEQA/SED**  Besides not specifically and inaccurately responding to previous comments related to CEQA and the SED, in this section, Staff mischaracterizes and incorrectly makes assumptions about comments made. For example, in Staff Response #SR06.006, staff states on pages 33-34 that “State Water Board assumes that the commenter is using the term ‘false failure’ to mean ‘false positive.’ The ‘false failure’ rate is not between 14% and 50%.’” This assumption is incorrect because this is not what the commenter meant. A false failure means an inaccurate indication of toxicity that causes a test to be deemed a “Fail” and thus creates a potential violation of the objective or the permit requirement. These false indications of toxicity have been demonstrated to be between 14% (which was the comparable percentage for the NOEC before EPA added additional safeguards to reduce that percentage to 5% - the percentage increases because those safeguards have been removed through the Toxicity Provisions’ use of the two-concentration TST) and 50% (based on see California Association of Sanitation Agencies (CASA) comment letter submitted on the Toxicity Provisions and attached study). |
| 25.019 | The data analysis presented in Appendix J improperly assumes that only tests that failed the TST with less than a 10% effect are considered potential “false positive,” when these really showed “false indications of toxicity.” Comments submitted showed a very real possibility that effects much larger than 10% will occur due solely to random and natural biological fluctuations in *Ceriodaphnia dubia* reproduction, even when there is no actual difference in the chemical composition of the sample waters. This problem has not been remedied and makes many of the assumptions made in the environmental document suspect. |
| **SC P.014** | The CEQA document/SED does not adequately consider alternatives. The Staff Report does not appear to evaluate an option in which numeric triggers and TRE initiation requirements consistent with the Draft Toxicity Provisions are included in place of numeric effluent limitations along with a clear definition of what constitutes a violation. This option would provide the same advantages as the numeric effluent limitations option (clearly defining what constitutes a violation and eliminating inconsistencies that could lead to different interpretations of statewide policy and guidance and an inequitable distribution of violations and compliance costs) while also offering the advantage of not considering the non-stormwater discharger in violation ahead of the ability to take any action to identify the toxicant or address the toxicity. The Response to Comments ignores comment 07.047, which mentions this issue. |
| **SR P.014** | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  Chapter 8 of the Staff Report states that “(Cal. Code Regs., tit. 23, § 3777, subd. (b)(3)) require the SED to contain an analysis of a range of reasonable alternatives to the project and reasonably foreseeable methods of compliance that could feasibly meet the project objectives to avoid or substantially reduce any potentially significant adverse environmental impacts.” No potentially significant impacts were identified in Chapter 7 related to the methods of compliance with the Toxicity Provisions. Chapter 8 of the Staff Report includes a discussion of the alternatives that would avoid, or substantiality lessen, the potentially significant impacts from the construction, operation, and maintenance of possible toxicity controls. As no potentially significant effects were identified from the reasonably foreseeable methods of compliance or the project, these alternatives are not those capable of avoiding or substantially lessening the significant environmental impacts of the project. This discussion is included for purposes of informing decision makers and the public of any possible effects, however unlikely, and associated alternatives that lessen the significant environmental effects of the possible toxicity controls: alternatives that reduce the identification of persistent aquatic toxicity.  One of the project goals is to adopt a program of implementation to control toxicity in discharges and achieve and maintain the toxicity water quality objectives in California waters. As mentioned in Section 5.4.3 and 9.3 of the Staff Report, numeric triggers and TRE initiation requirements are not effluent limitations. As discussed in Section 5.4.3 of the Staff Report and responses “SR10.009” and “SR10.010” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), it is appropriate and feasible to establish numeric effluent limitations. Also from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), please see responses “SR10.003,” “SR20.003,” and “SR20.007” and Sections 3.1.1 and 5.4.3 of the Staff Report for a discussion on why numeric effluent limitations are necessary. See also “SR10.004” of the Responses to 2018 Comments which states: **“**Section 3.3 of the Staff Report explains that 323 California water bodies (excluding ocean waters and open bays) are listed as impaired because of known or unknown toxicity, according to the 2016 California Integrated Report. This suggests that further incentives (beyond the current narrative limitations, numeric TRE triggers, and costs) are necessary to protect water quality in California. Enforcement is a critical ingredient in creating the deterrence needed to encourage the regulated community to anticipate, identify, and correct violations, and numeric effluent limitations provides a clear manner in which to determine whether a discharger’s effluent is toxic and to correct the non-compliance.  Since statewide numeric effluent triggers would not meet the project goals, and since numeric effluent limitations are appropriate and necessary, narrative effluent limitations and numeric effluent triggers alone were not included as a separate option in Chapter 8 of the Staff Report in lieu of numeric effluent limitations. As indicated in Section III.B.4 of the Toxicity Provisions, the permitting authority has the discretion to include narrative effluent limitations in addition to numeric effluent limitations.  No potentially significant impacts were identified in Chapter 7 related to the methods of compliance with the Provisions. Chapter 8 of the Staff Report includes a discussion of the alternatives that would avoid, or substantiality lessen the potentially significant impacts from the construction, operation, and maintenance of possible toxicity controls. The commenter has not indicated how this option would lessen the significant impact to the environment from the construction, operation, and maintenance of possible toxicity controls. |
| 25.020 | The CEQA document/SED does not adequately consider alternatives. For instance, the SED and the RTC ignore the following comment in 07.047, which states: “The Draft Staff Report does not appear to evaluate an option in which numeric triggers and TRE initiation requirements consistent with the Draft Toxicity Provisions are included in place of numeric effluent limitations along with a clear definition of what constitutes a violation (e.g., failure to prepare and submit an initial TRE Work Plan within 90 days after permit issuance, failure to conduct specific steps in the TRE Work Plan at the specified frequency). This option would provide the same advantages as the numeric effluent limitations option (clearly defining what constitutes a violation and eliminating inconsistencies that could lead to different interpretations of statewide policy and guidance and an inequitable distribution of violations and compliance costs) while also offering the advantage of not considering the non-stormwater discharger in violation ahead of the ability to take any action to identify the toxicant or address the toxicity.” |
| **SC P.015** | The summary response SR07.006 does not adequately demonstrate why an average monthly or average weekly effluent limitation is impractical to justify the use of maximum daily and median monthly effluent limitations. Without a demonstration of impracticability, average monthly and average weekly limits must be used. |
| **SR P.015** | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR07.006,” “SR10.009,” and “SR10.011” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  In addition, the issue description in Section 5.4.3 of the Staff Report has been updated to explain why average weekly limitations are impracticable. |
| 25.021 | **Category 7 – Compliance Monitoring**  Staff Response **#SR07.006** first correctly states: “The NPDES regulations in 40 Code of Federal Regulations section 122.45(d) require that for continuous dischargers, permit limitations be expressed as average monthly discharge limitations, and a maximum daily discharge (for non POTWs) or an average weekly discharger limitation (for POTWS) unless impracticable.” However, the next statement is contrary to this clear regulatory requirement, and says: “While averaging is not possible with a pass/fail result, it is not impractical to express the effluent limitation as a median monthly discharge limitation. MMELs are already included in non-storm water NPDES permits throughout California and in other states and are not considered impracticable. Allowing a six-week or 45-day monitoring period to be used to determine compliance with the MME(d) would also create challenges.” This statement does nothing to demonstrate that an average monthly (AMEL) or average weekly (AWEL) limit is “impracticable” to thereby justify the imposition of a maximum daily effluent limit (MDEL), or a Monthly Median Effluent Limit (MMEL). Without a demonstration of impracticability, AMEL and AWEL limits must be used. The practicability (i.e., not impracticable) of issuing an MMEL is not the appropriate or required analysis. |
| **SC P.016** | Water Code section 13050, subdivision (j) provides that a water quality control plan shall include a program of implementation needed for achieving water quality objectives. The State Board has failed to consider how municipal POTW dischargers would be able to consistently comply with the toxicity objectives, failed to include a time schedule for actions to be taken, and failed to describe surveillance to be used to determine instream compliance. Therefore, just as found in the *Tracy case*, the State Board’s program of implementation for the Toxicity Provisions is insufficient to meet the requirements of Water Code section 13242.  Instead of including a compliance schedule to allow time to meet the new objective, the RTC merely cites to the Compliance Schedule Policy which is inadequate to comply with section 13242. A similar successful challenge could lie here since the Toxicity Provisions assume compliance with the new objectives (*Id*.) and provide no specified actions, time schedule, or surveillance to ensure standards are being met in the receiving waters, where the objectives apply. Deferring such schedules to the time of permit issuance ignores the legal requirement to adopt such schedules when water quality objectives are adopted. |
| **SR P.016** | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  *City of Tracy v. State Water Resources Control Bd,* Sacramento County Superior Court Case No 34-2009-80000392, is a superior court case, related to a different proceeding and constitutes only the law of the case. The State Water Board complied with the decision and filed a return to the writ. As a superior court case, it has no precedential value.  As indicated in “SR20.009” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), the Toxicity Provisions include a program of implementation to control aquatic toxicity, including requirements for non-storm water NPDES dischargers, storm water dischargers, and nonpoint source dischargers. In compliance with Water Code section 13242, the Toxicity Provisions include a description of actions necessary to achieve compliance with the water quality objectives. This can be found at Section IV.B of the Toxicity Provisions. The Toxicity Provisions also include a time schedule for the actions to be taken. For non-stormwater NPDES dischargers, the requirements must be included upon permit issuance reissuance, renewal, or reopening (if the reopening is to address toxicity requirements). More specific timing for actions to be taken can be found throughout Section IV.B of the Toxicity Provisions. For example, an initial species sensitivity screening for chronic aquatic toxicity must be conducted either prior to, or within 18 months after, the first issuance, reissuance, renewal, or reopening (if the permit reopening is to address toxicity requirements) of the permit after the effective date of the Toxicity Provisions. In addition, the compliance policy as a stand-alone policy provides an additional option for a schedule of actions to be taken. For storm water and non-point source dischargers, the permitting authority shall issue a Water Code section 13267 Order(s) within one year of the effective date of the 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. Additionally, the Toxicity Provisions include a description of monitoring to be undertaken to determine compliance with the water quality objectives, specifically in Section IV.B.2.d of the Toxicity Provisions.  Consistent with Policy for Compliance Schedules in National Pollutant Discharge Elimination System Permits (Resolution No. 2008-0025), a discharger who seeks a compliance schedule must demonstrate to the satisfaction of the Water Board that the discharger needs time to implement actions, such as designing and constructing facilities or implementing new or significantly expanded programs and securing financing, if necessary, to comply with a more stringent permit limitation. Some facilities may not require this extra time because of their current performance. This is a facility-specific and permit-specific determination, and therefore shall be determined by the permitting authority. |
| 25.022 | **Category 8 – Compliance Schedules**  Water Code section 13050, subdivision (j) provides that a water quality control plan shall include a program of implementation needed for achieving water quality objectives. (Water Code § 13050(j).) Under Water Code section 13242, the program of implementation shall include (i) a description of the nature of actions necessary to achieve the objectives, including recommendations for appropriate action by public or private entities; (ii) a time schedule for the actions to be taken; and (iii) a description of surveillance to be undertaken to determine compliance with the objectives. (Water Code § 13242.)  Despite claims to the contrary in **#SR20.009**, the State Board has failed to consider how municipal POTW dischargers would be able to consistently comply with the toxicity objectives, failed to include a time schedule for actions to be taken, and failed to describe surveillance to be used to determine instream compliance. Therefore, just as found in the *Tracy case*, the State Board’s program of implementation for the Toxicity Provisions is insufficient to meet the requirements of Water Code section 13242.  The implementation plan must describe the nature of the actions necessary for such entities to consistently achieve the toxicity objectives in the receiving water, provide a reasonable time schedule for the actions to be taken, and include a description of the surveillance required to determine compliance in the waterways with the new objectives. In the *Tracy case*, the Court issued a writ compelling the Board to adopt an adequate program of implementation that describes the nature of the actions necessary for municipal dischargers to achieve the EC objectives (including recommendations for appropriate action by them), provides a reasonable time schedule for the actions to be taken, and includes a description of the surveillance required to determine their compliance. *Tracy* at 46. Further, the Court enjoined any action to enforce the provisions of the 2006 Bay-Delta Plan relating to the EC objectives against Tracy and other municipal dischargers pending an adequate program of implementation that meets the requirements of Water Code § 13242.  Instead of including a compliance schedule to allow time to meet the new objective, the RTC merely cites to the Compliance Schedule Policy (*see* **#SR08.001**), which is inadequate to comply with section 13242. A similar successful challenge could lie here since the Toxicity Provisions assume compliance with the new objectives (*Id*.) and provide no specified actions, time schedule, or surveillance to ensure standards are being met in the receiving waters, where the objectives apply. Deferring such schedules to the time of permit issuance ignores the legal requirement to adopt such schedules when water quality objectives are adopted. |
| SC P.017 | Please see the individual comment below regarding the economic analysis. |
| SR P.017 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. See SR P.007 above for further discussion.  Regarding statements in “SR09.005” of the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), the commenter was requesting that the State Water Board update the economic analysis in the future, after adoption and implementation of the Toxicity Provisions. The response points out that future tracking of ongoing costs associated with implementation of water quality objectives, once adopted, is not required by either the Water Code or the California Code of Regulations. |
| 25.023 | **Category 9 - Economic Analysis**  **SR#09.002** states “The 2020 Economic Report, as well as the Staff Report, no longer bases estimates of costs on a representative sample of dischargers. The 2020 Economic Report includes calculations of average increases in individual facility costs associates with changes in routine monitoring frequencies for aquatic toxicity.” The average cost of monitoring is not the proper determination of the economic impact of the new Toxicity Provisions as monitoring is just one part of the equation. The more expensive part is compliance.  The RTC merely shrugs off this issue, stating on page 90 “The Staff Report does not estimate potential costs associated with violations or penalties. It is not possible to predict which dischargers will have violations and how often they may occur, although, as discussed in Appendix J, violations are unlikely to occur unless effluent samples are truly toxic. Future costs for violations and penalties would depend on a discharger’s effluent quality. Any penalties assessed by a permitting authority would depend on a variety of factors.” **SR#09.005** incorrectly states “The State Water Board is not obligated to track future, ongoing costs associated with implementation of water quality objectives, once adopted.” Those are ongoing costs of compliance that do need to be considered now. |
| SC P.018 | Please see the individual comments below regarding the economic analysis. |
| SR P.018 | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see Section 9.1 of the Staff Report for an analysis of “economic considerations,” including cost of compliance. See also SR P.007 above for further discussion on “cost of compliance” in a Water Code section 13241 analysis.  *City of Tracy v. SWRCB,* Sacramento County Superior Court Case No 34-2009-80000392, is a superior court case, related to a different proceeding and constitutes only the law of the case. The State Water Board complied with the decision and filed a return to the writ. As a superior court case, it has no precedential value.  As discussed in Appendix J.5 of the Staff Report, SR J-1.009, and SR J-3.002, violations are unlikely to occur unless effluent samples are truly toxic. Please see the responses “SR10.003,” “SR10.009,” “SR10.010,” “SR20.003,” and “SR20.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Sections 3.1.1 and 5.4.3 of the Staff Report for a discussion on how numeric effluent limitations are appropriate and necessary. |
| 25.024 | Related to the economic considerations required under section 13241(d) and Section 13170, the *Tracy* Court flatly rejected the State Board’s argument that it is a matter entirely within the Board’s discretion to determine what it means to take “economic considerations” into account. While the Court noted that section 13241 does not specify precisely how the Board must go about considering the factors in section 13241, this does not mean courts should abdicate their constitutional role to independently construe the meaning of the statute. (See *Tracy, citing California Hospital Association v Maxwell-Jolly* (2010) 188 Cal App.4th 559, 570-571, 573-577 [department abused discretion by failing to adequately consider the impact of a contemplated Medicaid rate change on the statutory factors of efficiency, economy, quality, and access to care]) The State Board’s interpretation was just one among several tools available to the court in judging the interpretation of the text of the statute, but the State Board’s interpretation is not binding. In the *Tracy* case, the Court found the State Board’s interpretation that a “socioeconomic” analysis of a project’s environmental impacts is sufficient to be clearly erroneous. While the State Board may disagree that section 13241 requires consideration of the “cost of compliance,” the California Supreme Court has endorsed the view that it does (See *City of Burbank*, supra, 35 Cal.4th at p.625 [finding the “plain language” of section 13241 requires the board to consider the “cost of compliance”].) |
| 25.025 | The cost of compliance includes all costs, including costs of enforcement actions taken against a permittee for alleged noncompliance and none of those costs are considered even though **#SR09.008** “acknowledges that the Toxicity Provisions will likely lead to an increase in the number of violations of effluent limitations.” Although potentially not subject to Mandatory Minimum Penalties (“MMPs”) as discussed in **#SR09.008** and **#SR11.002**, all of these violations (even if for false indications of toxicity) would be subject to discretionary penalties and citizen suits.2 {footnote 2: **#SR11.002** seems to imply on page 146 that citizen suits are unlikely, but since the cause of toxicity is often unknown or unknowable, such allegations that the violations are intermittent and recurring would allow such suits to proceed. Further, if the allegations are related to false indications of toxicity, there is no polluting to continue.} If these enforcement costs and penalties were considered (at over $54,000 per day per violation plus attorney’s fees, and $10,000 per gallon plus staff costs), the costs would be substantial and would weigh in favor of the trigger approach instead for all the reasons provided by the commenters over the last few decades, which are incorporated herein by reference. |
| SC P.019 | Please see the individual comment below regarding the alternative test procedure (ATP). |
| SR P.019 | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  See “SR25.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) regarding the difference between U.S. EPA approved and promulgated WET methods and statistical choices.  Please see response “SR25.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) regarding the use of the TST with existing U.S. EPA approved methods and that an ATP would be required only to reduce the required number of concentrations to be tested to the one effluent concentration plus a control used in the TST statistical approach.  No WET ATP protocol existed or was required in 2014 when the State Water Board submitted the WET ATP that was approved. Please see response “SR25.040” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).The three reasons for withdrawal of the State Water Board ATP approval by U.S. EPA, as described in the February 11, 2015 memo, are clearly identified as procedural errors in the ATP submittal at the state level, as well as the U.S. EPA’s approval and procedural processes. The lack of a WET ATP protocol was not listed as a reason for the withdrawal.  A protocol for a WET ATP is not listed in the revised ATP language at 40 CFR 136.5 as a requirement for submittal of a limited use ATP. This is consistent with the 2016 U.S. EPA Methods Update Rule (MUR) response to comments. The U.S. EPA is charged with implementing and interpreting its own regulations and the U.S. EPA will have an opportunity to decide whether to approve the new ATP after it is submitted. |
| 25.026 | In **SR#09.012**, the RTC states: “a new alternative test procedure (ATP) application is not needed prior to approval or implementation of the Toxicity Provisions, the State Water Board is currently drafting an application for an ATP for the use of the two-concentration test design (one concentration plus the control) when the TST or a simple t-test is the required statistical approach.” This demonstrates that the Toxicity Provisions DO change the EPA promulgated methods, or such an ATP would not be required. This cannot wait until after the Toxicity Provisions are adopted, a valid ATP is needed for use of the two-concentration TST approach since hypothesis, the statistics, the endpoint, and the use of concentration-dose response are all different from the Part 136 requirements.  Even if once again applied for, 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 EPA Memo (Oct. 22, 2013)(“we do not yet have guidance for requesting or evaluating WET ATP requests…”). In sum, the Toxicity Provisions conflict with federal regulations and are unlawful as proposed. |
| SC P.020 | The 2018 RTC incorrectly claims that narrative effluent limitations with numeric triggers would not provide clarity and consistency. Staff is suggesting an interim MMET for *C. dubia*, which demonstrates that numeric triggers are a valid option. An effluent limitation would only result in additional enforcement, not better water quality.  The goals of the Toxicity Provisions should be: 1) determining if there is persistent toxicity in the effluent that could adversely affect the receiving water, 2) determining the cause of that toxicity, and 3) fixing the problem.  Instead of relying on enforcement actions, the Water Boards should set up a more collaborative approach to solving any potential toxicity problem through compliance assistance instead of enforcement actions.  In the *Tracy* case, the Court rejected any suggestion that effluent limitations are required to be numeric and pointed out that the definition of “effluent limitation” in the Clean Water Act refers to “any restriction,” and may include a “schedule of compliance.”  In *Communities for a Better Environment*, the First Appellate District Court of Appeal specifically rejected the argument that the federal regulations mandate numeric WQBELs in all circumstances. Rather, the Court found, Congress intended a “flexible approach” including alternative effluent control strategies. |
| SR P.020 | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  *City of Tracy v. State Water Resources Control Bd,* Sacramento County Superior Court Case No 34-2009-80000392, is a superior court case, related to a different proceeding and constitutes only the law of the case. The State Water Board complied with the decision and filed a return to the writ. As a superior court case, it has no precedential value.  The numeric aquatic toxicity water quality objectives and numeric effluent limitations, and any costs, including penalties are entirely appropriate, necessary, and reasonable to prevent toxicity. See also responses “SR10.003,” “SR10.004,” “SR10.009,” “SR10.010,” “SR20.003,” and “SR20.007”from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), Sections 3.1.1 and 5.4.3 of the Staff Report, and P.007 above.  Revisions to Section 5.4.3 of the Staff Report were made to explain how in the short-term only, the statewide inclusion of MMELs using *C. dubia* in non-stormwater NPDES permits is not feasible (i.e., “not appropriate”) in certain circumstances specified in Section IV.B.2.e.i of the Toxicity Provisions between the effective date of the Provisions and January 1, 2024. (See *Communities for a Better Environment v. State Water Resources Control Board* (2003) 109 Cal. App.4th 1089 affirming the State Water Board’s interpretation of “infeasible” as used in 40 Code of Federal Regulations, section 122.44(k)(3) to mean “not appropriate”). It is feasible and appropriate that on and after January 1, 2024, all accredited laboratories conduct the reliable and promulgated *C. dubia* chronic reproduction toxicity test. It is also feasible to include the *C. dubia* MDEL without delay, because laboratory performance is less of a concern for stakeholders due to the higher effect level required for a violation of the MDEL. However, for certain laboratories, the application of an MMET using *C. dubia* instead of an MMEL using *C. dubia* prior to January 1, 2024, will provide an opportunity for improvements in laboratory performance, as needed. See Section 5.4.3 of the Staff Report. As discussed in Appendix J, SR J-1.009, and SR J-3.002, violations are unlikely to occur unless effluent samples are truly toxic. See response “SR 10.010” and “SR25.024” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). If any specific discharger needs time to implement actions, such as designing and constructing facilities or implementing new or significantly expanded programs and securing financing, if necessary, to comply with a more stringent permit limitation, then that discharger can request a compliance schedule from the permitting authority. This is a facility-specific and permit-specific determination, and therefore shall be determined by the permitting authority.  Revisions to Section 5.4.3 of the Staff Report were made adding further explanation on why average weekly effluent limitations are impracticable. The U.S. EPA is charged with implementing and interpreting its own regulations and the U.S. EPA will have an opportunity to decide whether average weekly effluent limitations are “impracticable” in this particular context when asked to approve the Toxicity Provisions. |
| 25.027 | Category 10 – Effluent Limitations  Staff Response **#SR10.003** contains several errors. For instance, it states: “Numeric effluent limitations provide clarity and consistency, unlike accelerated monitoring or narrative effluent limitations which must be interpreted and can be applied differently across the state.” Numeric Effluent Triggers (e.g., 1 TUc) would provide the same clarity and consistency and would not require any more interpretation than an effluent limit. Since the Staff is suggesting an Monthly Median Effluent Trigger (MMET) in the interim during the *Cerio* study, this demonstrates that effluent triggers are a valid option and have been utilized successfully since 2003 with no noted instances in the record as to why these triggers are not equally effective. This is even being proposed where no limits are required: “In addition, for non-stormwater NPDES dischargers that are not required to comply with the numeric effluent limitations specified in the Provisions, language has been added to the Provisions requiring the permitting authority to include monitoring and targets for determining a TRE.” There should be an even playing field where everyone monitors at a frequency based on size and historic compliance record, the triggers would then require identification of the problem and a remedy. |
| 25.028 | A limit only results in additional enforcement, not better water quality. The goal of this policy should be: 1) determining if there is persistent toxicity in the effluent that could adversely affect the receiving water, 2) determining the cause of that toxicity, and 3) fixing the problem. Enforcement actions both by the Water Boards and third parties do not change these steps and merely penalize a discharger for inaccurate indications of toxicity or for toxicity sources that may be beyond their reasonable control. Instead, the Water Boards should set up a more collaborative approach to solving any potential toxicity problem through compliance assistance instead of enforcement actions. POTWs have an excellent track record of voluntarily taking action, even without the threat of enforcement. |
| 25.029 | **#SR10.003** also states: “Numeric effluent limitations are feasible as demonstrated by the several Regional Water Boards that have already required numeric effluent limitations for acute and chronic toxicity effluent limitations in NPDES permits.” Apparently, this is a response to a comment that the federal regulations allow best management practices (BMPs) in lieu of numeric limits if such limits are infeasible. 40 C.F.R. §122.44(k)(3). Just because a numeric limit is able to be calculated or imposed is not the issue; the issue is whether *compliance with the limit is feasible.* A court opinion binding on the State Board has so held. *City of Tracy v. SWRCB*, Statement of Decision, Sac. Superior Case Number: 34-2009-80000392 (May 10, 2011).  In the *Tracy* case, the Court rejected any suggestion that effluent limitations are required to be numeric and pointed out that the definition of “effluent limitation” in the Clean Water Act refers to “any restriction,” and may include a “schedule of compliance.” (33 U.S.C. §1362(11); 40 C F.R. § 122.2.) The term “schedule of compliance” means a “schedule of remedial measures,” including an enforceable sequence of interim requirements leading to compliance with an effluent limitation or standard.” (33 U.S.C. § 1362(17); 40 C.F.R § 122.2.) |
| 25.030 | In *Communities for a Better Environment*, the First Appellate District Court of Appeal specifically rejected the argument that the federal regulations mandate numeric WQBELs in all circumstances. Rather, the Court found, Congress intended a “flexible approach” including alternative effluent control strategies. (*Communities for a Better Environment v State Water Resources Control Bd* (2003) 109 Cal. App 4th 1089, 1105; *Communities for a Better Environment v State Water Resources Control Bd. (2005)* *132 Cal.App 4th 1313, 1318; see also Divers’ Environmental Conservation Organization v State Water Resources Control Bd (2006)* 145 Cal.App.4th 246, 262 [following *Communities for a Better Environment*.) Thus, numeric effluent limitations are not necessary to meet the requirements of the federal Clean Water Act. {*Communities for a Better Environment, supra,* 109 Cal.App.4th at p. 1093.) Indeed, federal regulations expressly permit non-numeric effluent limitations ~ such as best management practices ~ when numeric effluent limitations are “infeasible.” (40 C.F.R. § 122 44(k)(3); see also State Board Order WQ 2006-0012, p. 16.)  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, the Court in the *Tracy* case (which is binding on the State Board since not appealed) determined this argument is unfounded and not supported by case law or by the Board’s own Water Quality Orders. The Court held that “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.)  The *Tracy* Court rejected the argument that in determining the “propriety” of numeric effluent limitations, the Board may not consider the ability (or inability) of the discharger to comply with such limitations. The ability to comply is a critical factor in determining the “propriety” of numerical limitations. *Id*. at 43.  The *Tracy* Court also pointed out that, in Water Quality Order 2003-0012, related to chronic toxicity, 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. Nothing has changed since 2003 to make stringent pass/fail or numeric limits feasible to comply with, particularly given the technical issues raised. In fact, the State Board staff continue to rely upon data to propose these Provisions, despite clear and obvious mistakes made therein, which were pointed out in comments but not corrected. These facts make numeric limits infeasible and triggers (MMET) should be used instead. |
| 25.031 | **#SR10.003** also states: “Additionally, the U.S. EPA Technical Support Document for Water Quality-Based Toxics Control states that “[t]he NPDES regulations at 40 CFR 122.45(d) require that all permit limits be expressed, unless impracticable,3 {footnote 3: Under federal law, “impracticable” is not defined, but “practicable” means “technologically possible, able to be put into practice, and economically viable.” 40 C.F.R. §131.3(n). Effluent limitations requiring continuous compliance with the chronic toxicity objectives as defined in the Toxicity Provisions are not practicable.} as both average monthly and maximum daily values for all dischargers other than POTWs and as average weekly and average monthly limits for POTWs… in lieu of an [average weekly limitation] for POTWs, EPA recommends establishing an MDL (or a maximum test result for chronic toxicity) for toxic pollutants and pollutant parameters in water quality permitting.” *See also* **#10.009**, which states “Section 5.2.3 of U.S. EPA’s Technical Support Document indicates that average weekly limitations are impractical for POTWs.”  This shows that, again, Board staff is attempting to use guidance to improperly overrule a regulation, which is not authorized. (*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, the Water Board’s previous reliance on USEPA’s Technical Support Document guidance was overturned, and the permit was remanded. The RTC’s similar reliance is misplaced as well, and this controlling authority was not responded to in the RTC.  No authority exists 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 federally promulgated test procedures). |
| SC P.021 | See the individual comment below regarding numeric limits. |
| SR P.021 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  See response “SR20.007” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a discussion of impaired waters and how numeric water quality objectives for chronic and acute aquatic toxicity will provide a more consistent assessment of toxicity in ambient surface waters with greater confidence in the results.  Penalties are an appropriate and important tool to prevent or reduce toxicity. The numeric aquatic toxicity water quality objectives and numeric effluent limitations, including any associated enforcement are both necessary, appropriate, and reasonable to prevent toxicity. See also “SR10.003,” “SR10.004,” “SR10.009,” “SR10.010,” “SR11.002,” “SR20.003,” “SR20.004,” and “SR20.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). As discussed in Appendix J.5 of the Staff Report, SR J-1.009, and SR J-3.002, violations are unlikely to occur unless effluent samples are truly toxic. Please see Sections 3.1.1 and 5.4.3 of the Staff Report for a discussion on how numeric effluent limitations are appropriate and necessary. |
| 25.032 | **#SR10.004** was supposed to be responding to the concerns over numeric limits. The response states in full: “ Section 3.3 of the Staff Report explains that 323 California water bodies (excluding ocean waters and open bays) are listed as impaired because of known or unknown toxicity, according to the 2016 California Integrated Report. This suggests that further incentives (beyond the current narrative limitations, numeric TRE triggers, and costs) are necessary to protect water quality in California. Enforcement is a critical ingredient in creating the deterrence needed to encourage the regulated community to anticipate, identify, and correct violations, and numeric effluent limitations provides a clear manner in which to determine whether a discharger’s effluent is toxic and to correct the non-compliance. In addition, please see Section 5.4.3 of the Staff Report and SR10.003 regarding the need for numeric effluent limitations.” This ignores that the majority of waterbodies listed as impaired for toxicity do NOT have POTWs or industries identified as the source, and in many cases are from agricultural or stormwater discharges not covered by the Toxicity Provisions. This also ignores that the data for these listings can be more than a decade old. Thus, these impairments do not provide a justification or demonstrated need for further incentives or enforcement against non-stormwater NPDES discharges. We are unaware of any toxicity enforcement actions needed or taken in the last decade for these stated purposes. In fact, we are unaware of any discretionary enforcement taken against permittees that have WET numeric limits and exceedances of the same because most of those permits have been appealed and that would provide proof of harm that the permittees could use in those appeals. A MMET can just as easily identify who needs to do additional work (e.g., a TRE) to determine the source of any persistent toxicity so that cause can be remedied. |
| 25.033 | The State Board has previously held in WQO 2003-0012 that 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.” (Emphasis added.) Numeric limits based on the TST do not improve the clarity or the enforceability, they just create a greater likelihood of non-compliance not due to any action or inaction on the part of the permittee. |
| SC P.022 | See the individual comment below regarding effluent limitations and reasonable potential. |
| SR P.022 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  The objectives in the Toxicity Provisions are numeric water quality objectives. See Sections 2.6.1 and 5.1.1 of the Staff Report.  Please see “SR21.008” and “SR10.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Section 3.1 of the Staff Report for further discussion on how states are not precluded from omitting or modifying any provisions of the Clean Water Act to impose more stringent requirements, and Section 5.4.2 of the Staff Report for further discussion on why the Toxicity Provisions require POTW dischargers that are authorized to discharge at a rate equal to or greater than 5 MGD and are required to have a pretreatment program by the terms of 40 CFR § 403.8(a) (effective January 1, 2020) to have effluent limitations.  See “SR10.008” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for a response indicating that 40 Code of Federal Regulations section 122.44(d)(1)(v) does not preclude the state from imposing numeric aquatic toxicity effluent limitations and why chemical-specific water quality objectives are not sufficient to protect aquatic life beneficial uses from aquatic toxicity. |
| 25.034 | **#SR10.006 and #10.007** state “the Clean Water Act requires effluent limitations for whole effluent toxicity (aquatic toxicity) when the permitting authority determines that a discharge causes or has the reasonable potential to cause an exceedance of a numeric whole effluent toxicity water quality objective. (40 CFR §122.44(d)(1)(iv).)” This statement is not completely accurate and is overly simplified. Section 122.44(d)(1)(iv) states that “When the permitting authority determines, using the procedures in paragraph (d)(1)(ii) of this section, that a discharge causes, has the reasonable potential to cause, or contributes to an instream excursion above the numeric criterion for whole effluent toxicity, the permit must contain effluent limits for whole effluent toxicity.” (Emphasis added.) Thus, this section first requires a formal reasonable potential analysis, which is currently not being performed for POTWs above 5 mgd, and second requires the likelihood of an instream excursion above a numeric criterion. It is not entirely clear whether the Toxicity Provisions “Pass/Fail” objectives would be considered narrative or numeric. Further, the current provisions as proposed have little to do with determining actual instream excursions since focused entirely on the effluent. In addition, this response ignores that where chemical-specific limits are sufficient to attain and maintain applicable numeric and narrative water quality standards, then limits for WET are not necessary. 40 CFR §122.44(d)(1)(v). |
| SC P.023 | See the individual comment below regarding qualifications exempting insignificant dischargers. |
| SR P.023 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see Section IV.B.2.k.i of the Toxicity Provisions and Section 5.7.4 of the Staff Report regarding exemptions allowed for insignificant discharges. |
| 25.035 | Although **#SR10.008** states “If a discharger can demonstrate that they have a limited number of chemical-specific toxicants that may cause or contribute to toxicity in their effluent and they have specific effluent limitations for each of these chemicals in their NPDES permit, the permitting authority may consider exempting them from some or all of the implementation requirements in the Provisions as an insignificant discharger,” this provision is not clearly set forth in the Provisions and should be added as a clear term. |
| SC P.024 | Please see the individual comment below regarding the U.S. EPA 2002 WET test methods. |
| SR P.024 | Comments regarding the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see “SR10.009” and “SR25.029” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) regarding the Edison case and the successful defense of WET testing procedures with an acceptable degree of variability.  It should be noted that for years, prior compliance decisions for NPDES WET tests were often based on a single test using both NOEC and point estimate statistical approaches, and in the last 4 years, the TST statistical approach.  The Edison ruling supported the findings of the U.S. EPA Method Variability Study, where the inherent variability of WET testing was acceptable and within the 5 percent false positive range. U.S. EPA accounted for the variability by setting the method replicate number to 10 to meet the required number of biological responses to provide statistical confidence in meeting the 5 percent false positive probability.  Fox et al. 2019 and Appendix J provide direct evidence that California laboratories can execute the *C. dubia* test with a level of precision to meet the false positive probability of 5 percent for a single test when using the TST statistical approach.  Furthermore, the methods manuals clearly state that statistical approaches are a choice. Please see response “SR25.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx).  It should be noted that the two-concentration test design and the t-test are included as Appendix H of the freshwater organisms methods manual (U.S. EPA, 2002b), which states, “[t]o statistically compare a control with one concentration, such as 100 percent effluent or the instream waste concentration, a t-test is the recommended analysis.” These are recommendations and are not binding.  As to the commenter’s references to the SIP and the Los Angeles Region Water Quality Control Plan, the Toxicity Provisions supersede Section 4 of the SIP and supersede the Regional Water Board Basin Plan to the extent of any conflict and as further described in Section III.B.3 of the Toxicity Provisions. |
| 25.036 | **#SR10.009** states: “The United States Court of Appeals ruling in the case of *Edison Electric Institute, et al v. US EPA*, (D.C. Cir. 2004) 391 F.3d 1267, did not caution against the use of a single toxicity test failure to bring enforcement actions, as stated in Comment 12.011. In particular, the court stated that ‘[n]othing we have written thus far, and nothing we write in the balance of this opinion forecloses consideration of the validity of a particular test result in an enforcement action. *See* 33 U.S.C. § 1369(b)(2). That issue is not before us. The case involves only the validity of the WET test methods.’” This ignores that the 2002 Methods approved and incorporated into Part 136 state: 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**.  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.”4 {footenote 4: *See* USEPA, *Whole Effluent Toxicity: Guidelines Establishing Test Procedures for the Analysis of Pollutants - Supplementary Information Document* (SID) at pg. 28 (Oct. 2, 1995).} 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).)  The RTC does not respond to these comments that were made in 2018 and previously. |
| SC P.025 | See the individual comment below regarding the term “endpoint.” |
| SR P.025 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, as pointed out in “SR16.002” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), the Toxicity Provisions only use the term “endpoint” as it is defined within the Toxicity Provisions, as a measured biological effect. This is consistent with the way in which the term “endpoint” is used in the TST Technical Document, and the way in which the term is used in the U.S. EPA method manuals. The method manuals also discuss the NOEC, LOEC, and point estimates as endpoints. Because neither the NOEC nor point estimate approaches are used to assess compliance with the numeric water quality objectives or the numeric effluent limitations in the Toxicity Provisions, the term “endpoint” is not defined in terms of identifying endpoints associated with those statistical approaches. |
| 25.037 | **Category 16 – Glossary Terms**  The RTC failed to respond to the need for two definitions of ENDPOINT, one biological and one method/statistic related. While **#SR16.002** discusses the biological effect endpoint (e.g., survival, reproduction, growth), there is no definition of the test endpoint, which under 40 C.F.R. Part 136 is either NOEC or IC25. |
| SC P.026 | See the individual comment below regarding MMELs and MDELs in Los Angeles Regional Water Quality Control Board non-storm water NPDES permits that have been appealed to the State Water Board. |
| SR P.026 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR9.008,” “SR10.003,” “SR10.004,” “SR10.009,” “SR10.010,” “SR11.001,” and “SR25.024” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). Also see Sections 5.5.1 and 5.4.3 of the Staff Report.  See “SR06.005” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) for discussion on current petitions being held in abeyance. It should be noted that a stay on the effect of the action was not issued for any of these permits and therefore compliance with numeric limitations using the TST statistical approach continue to be required.  For a discussion of the need for numeric effluent limitations, please see “SR10.003,” “SR20.003,” and “SR20.007” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Sections 3.1.1 and 5.4.3 of the Staff Report. In addition, only a small fraction of available pollutants are individually monitored by NPDES dischargers. Demonstrating compliance with those few pollutants that are monitored does not guarantee that an effluent does not contain toxicants that can be detected using WET test methods. See “SR10.008” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) on how chronic toxicity testing and effluent limitations would maintain the biological integrity of receiving waters by acting as a backstop against the additive and synergistic effects of known and unknown pollutants. As discussed in section J.5 of Appendix J, SR J-1.009, and SR J-3.002, violations are unlikely to occur unless effluent samples are truly toxic. Additionally, Section 5.3.1 of the Staff Report explains why the TST is the preferred statistical approach to determine compliance with the numeric effluent limitations in the Provisions. |
| 25.038 | **Category 19 – Other Topics**  **#SR19.005** states: “Additionally, the Los Angeles Regional Water Board includes MMELs and MDELs in their non-storm water NPDES permits which are similar to those in the Toxicity Provisions. These effluent limitations have been demonstrated to be both reasonable and attainable for dischargers.” This ignores that most all of these permits have been appealed to the State Water Board, and that several of the plants to which these limits apply went from having perfect compliance records to no longer having that title due solely to numeric chronic toxicity limits. |
| SC P.027 | See the individual comment below regarding the feasibility of using the promulgated methods in conjunction with the Toxicity Provisions. |
| SR P.027 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR10.003,” “SR10.009,” and “SR10.010” from the [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Section 5.4.3 of the Staff Report regarding the feasibility of the numeric effluent limitations. Also, see Section 2.6.5 of the Staff Report and response “SR25.003” regarding the differences between test method and statistical approach. |
| 25.039 | **#SR19.009** states: “The provisions do not prevent a discharger from using U.S. EPA-promulgated test methods; rather, the provisions specify the numeric water quality objectives and numeric effluent limitations that are to be used in conjunction with those methods.” Since the TST is not part of the promulgated methods and include a hypothesis, endpoint (NOEC, IC25), statistic, and just one concentration (instead of 5) as compared to the control, there is no feasible way to use the promulgated methods (besides the care and feeding of the organisms) in conjunction with the Toxicity Provisions. |
| SC P.028 | See the individual comment below regarding the numeric effluent limitations described in the Toxicity Provisions, and the State Water Board precedential orders. |
| SR P.028 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report.  However, please see responses “SR10.003,” “SR10.009,” and “SR10.010” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx), and the Section 5.4.3 of the Staff Report regarding the feasibility of numeric effluent limitations. Additionally, please see responses “SR06.005,” “SR10.009,” and “SR20.007” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and the Staff Report regarding the precedential orders and the determination the numeric effluent limitations are appropriate. |
| 25.040 | **Category 20 – Project Goals**  **#SR20.003** states in part: “The discussion of current conditions in this section of the Staff Report indicates that many non-storm water NPDES permits in California do not include effluent limitations for aquatic toxicity. This demonstrates the need for clear statewide requirements for numeric effluent limitations.” Just because some permits do not include effluent limits does not signal a problem. If that discharger has no reasonable potential, then no limit would be required and that would be a good thing since that discharger has shown no likelihood to cause or contribute to toxicity in the waterways. Also, the lack of limits does not demonstrate a need for numeric limits, just effluent limits. Limits need not be numeric as is evidenced by the four precedential orders related to chronic toxicity. Order No. 2003-0012 (Long Beach/Los Coyotes) and 2003-0013 (Whittier Narrows)(replacing the numeric limit with a narrative stating “There shall be no chronic toxicity in the effluent discharge.”), *see also* WQO 2008-08 (City of Davis), and WQO 2012-0001 (City of Lodi). |
| SC P.029 | See the individual comment below regarding the Toxicity Provisions conflicting with or contradicting the Clean Water Act, the APA, court decisions, and federal regulations. |
| SR P.029 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. Where the commenter previously made specific comments on instances of conflict, please see responses to those comments for a discussion on how the Toxicity Provisions do not conflict with or contradict existing statutes, court decision, or other provisions of law. |
| 25.041 | **#SR20.008** states “The Toxicity Provisions do not conflict with or contradict existing statutes, court decision, or other provisions of law,” even though numerous instances have been pointed out where the Toxicity Provisions conflict with or contradict the Clean Water Act, the APA, court decisions, and federal regulations. The RTC continuing to repeat this statement does not make it true. |
| SC P.030 | See the individual comment below regarding statistical approaches in the methods manuals and requirements prescribed by federal law. |
| SR P.030 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, for a discussion of why the statistical approach is not a part of the test method please see response “SR25.003” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Section 2.6.5 of the Staff Report. |
| 25.042 | This section **#SR20.008** also states “the numeric aquatic toxicity water quality objectives in the Toxicity Provisions do rely on biological monitoring and assessment methods listed in Table 1 of the Toxicity Provisions, consistent with U.S. EPA test method manuals.” But Table 1 states as follows: . . .  [See table on page 13 of comment letter #25, Exhibit A]  Since only “NOEC and IC25, percent effluent” are prescribed, this is not consistent with the regulations, or with the manuals that prescribe only the use of 4 specified statistics, not including the TST.  The California Supreme Court held that the supremacy clause of the federal Constitution requires state law to yield to federal law. (*Burbank*. at p.618.) In other words, state water quality laws cannot be used to impose pollutant restrictions less stringent or different than required by federal law. As Justice Brown’s concurrence aptly points out in the *Burbank* case, that “seems a pretty self-evident proposition” (*City of Burbank*, *supra*, 35 Cal 4th at p.629.) Here, the federal law prescribes NOEC or IC25, no other hypothesis test or point estimate is allowed. |
| SC P.031 | Staff continues to clump all WET test species and methods (acute and chronic) together when making their case that the TST performs as well or better than the NOEC. However, even their own peer reviewer stated that while the conclusion might be true for TST as a whole, it is not true for the *Ceriodaphnia dubia* reproduction method, which performs substantially worse when using the TST. |
| SR P.031 | Comments regarding the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see Appendix J of the Staff Report for a discussion of California laboratory performance when executing the *C. dubia* chronic test method, and the TST results when analyzing the data. |
| 25.043 | **Category 25 – Test of Significant Toxicity**  Staff continues to clump all WET test species and methods (acute and chronic) together when making their case that the TST performs as well or better than the NOEC. However, even their own peer reviewer stated that while the conclusion might be true for TST as a whole, it is not true for the *Ceriodaphnia dubia* reproduction method, which performs substantially worse when using the TST. |
| SC P.032 | See the individual comments below regarding the claim that the use of the TST changes the test methods in 40 CFR 136. |
| SR P.032 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see the following responses from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx):  Response “SR27.012” explains that the selection of the statistical approach is based on the question being asked.  Response “SR27.021” explains that the rephrased null hypothesis provides a positive incentive for the permittee to generate high quality data with low test variability, increasing the confidence that correct determinations are made.  Response “SR25.003” explains that the statistical approaches recommended in the test method manuals are not the only possible methods of statistical analysis.  Response “SR25.007” explains that there is no value in examining the full dose-response curve when using the TST and how revision to the five effluent test concentration minimum requirement in the WET test methods is not necessary in order to allow for use of the TST.  Response “SR10.009” explains that MDELs and the additional threshold of a 50 percent effect are included to be certain the magnitude of toxicity is high enough to warrant a permit violation from results of a single toxicity test and that the State Water Board is not precluded from establishing an MDEL. |
| 25.044 | **SR#25.002** says: “The use of the TST approach does not alter or replace U.S. EPA promulgated or approved toxicity test methods.” **SR#25.003** says “the TST approach does not change the U.S. EPA aquatic toxicity test methods. Rather, it is a statistical approach used to analyze the data generated by aquatic toxicity test methods. The TST statistical approach is an option that U.S. EPA has added to the previously available statistical choices. Use of the TST approach does not alter the approved requirements of the test method, such as specified biological and laboratory procedures.” **SR#25.004** says: “Since the Toxicity Provisions do not change the U.S. EPA approved WET test methods, a comprehensive review of the WET methods is not required as part of the development of the Toxicity Provisions.”  As pointed out in 2018 comments, the Toxicity Provisions’ use of the TST changes the Part 136 methods in numerous ways. As a method-defined analyte, the interpretation and analysis of test data directly defines the test result. EPA has recognized for decades that WET is a method-defined parameter, and the RTC does as well (as described elsewhere). Thus, how one conducts and interprets the toxicity test defines the result.  Despite claims in the RTC to the contrary, as set forth in the cover letter, the Toxicity Provisions change the 2002 Methods in the following ways:  1) Changes the question for the hypothesis, 2) Alters the hypothesis 180 degrees from presumed not toxic to toxic, 3) Uses an unauthorized and discouraged “Pass/Fail” endpoint, 4) Does not follow the prescribed flow chart, 5) Does not use one of the 4 authorized statistics in the methods manuals, 6) Ignores mandated dose concentration response curves and other safeguards that were the reason why the 2002 Methods were upheld in *Edison Electric*, 7) Relies on a single concentration and control without an approved ATP, and 8) Allows for single exceedance to be subject to formal enforcement despite EPA not recommending this approach. |
| 25.056 | Finally, the RTC frequently attempts to distinguish the “test method” from the statistical approach or “procedures.” However, the plain language of 40 CFR §136.3(a) draws no such distinction between test methods and analytical procedures. That section states that: “Parameters or pollutants, for which methods are approved, are listed together with test procedure descriptions in Tables 1A … the full texts of the referenced test procedures are incorporated by reference into Table 1A… The discharge parameters values for which reports are required must be determined by one of the analytical test procedures incorporated by reference and described in Table 1A…” The “statistical approaches [are] included in the WET test method ‘measurement system’” (*see* 67 Fed. Reg. 69,968 (attached above)) and, therefore, cannot be modified without changing the regulations or through an ATP. |
| SC P.033 | The NOEC, EC/IC25 and LC50 have undergone formal promulgation and are codified in the CFR, unlike the TST. The TST is not included in the list of possible statistical approaches listed in the U.S. EPA method manuals. For method-defined analytes, the statistical technique used to determine the presence or absence of toxicity is part of the method. The TST Technical Document states that the intent of the document was to introduce a new alternative method of analyzing data collected during a valid WET analysis (not a replacement), and was not to be used for permitting. |
| SR P.033 | Comments regarding July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, for a discussion of the differences between the promulgated or approved WET test methods and acceptable statistical approaches, please see responses “SR25.003” and “SR25.005” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Section 2.6.5 of the Staff Report. |
| 25.045 | **#SR25.005** states: “NOEC, EC/IC25, and LC5O have not undergone formal promulgation, nor is formal promulgation required prior to using a statistical approach. While Table 1A in 40 CFR 136.3 mentions NOEC, EC/IC25, and LC5O as possible “units” of measurement, the table does not indicate a “required” statistical approach. Instead, it indicates that the U.S. EPA test method manuals should be used to conduct chronic toxicity and acute toxicity testing. The U.S. EPA method manuals recommend statistical approaches, but do not require any specific statistical approach. The U.S. EPA method manuals indicate that: “[T]he statistical methods recommended in the manual are not the only possible methods of statistical analysis.” This is completely incorrect. The NOEC, EC/IC25 and LC50 have undergone formal promulgation and are codified in 40 C.F.R. Section 136.2, Table 1A. These are not just possible “units” of measurement, they are the only ones authorized. Similarly, there are 4 statistical procedures that can be used, but those are the only ones. The citation to the 2002 Methods saying “[T]he statistical methods recommended in the manual are not the only possible methods of statistical analysis” has been repeated by USEPA in litigation over the TST many times, but both EPA and the State Board staff are selectively reading that passage to say what they want to hear. This quote ignores that the passage also says that “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.” However, in the end, they chose ONLY the statistical methods contained in the manual, no others were selected or authorized even though EPA realized they exist. In addition, the 2002 Methods stated in bold: “**NOTE: For the NPDES Permit Program, the point estimation techniques are the preferred statistical methods in calculating end points for effluent toxicity tests.**” It is unclear why the EC/IC25 promulgated method cannot be used in lieu of an unpromulgated one until such time as the TST is formally promulgated. |
| 25.046 | **SR#25.003** mischaracterizes the plain language of the 2002 Methods by saying “The methods manuals state that the statistical approaches recommended in the manuals are not the only possible methods of statistical analysis. The manuals go on to offer guidance regarding several possible statistical approaches that were commonly used at the time of publication to analyze test data.” For method-defined analytes, the statistical technique used to determine the presence or absence of toxicity is *part of the method.*  While the approved 2002 Methods and the “aquatic toxicity test method manuals specify testing parameters such as test temperature, organism age, feeding regime, test duration, test design, and test species to be used for conducting the test” (as discussed in **SR#25.003**), the manuals also describe the statistics that can be used. |
| 25.047 | Section 9.4.1.2 of the 2002 Methods states that “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.” Only four were authorized. Neither the TST nor any other statistical methods besides those specified in section 9.5.1 of the 2002 Methods and discussed in detail in Section 9.6 of the 2002 Methods are authorized. |
| 25.048 | The RTC did not respond to this clear language in the 2002 Methods, or to the language in the 2010 USEPA guidance document, *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document*, EPA 833-R-10-003, which introduced the TST protocol for analysis of chronic toxicity testing data and made it clear in numerous places that the intent of the guidance was to introduce a new alternative method of analyzing data collected during a valid WET analysis (not a replacement), and was not to be used 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) |
| SC P.034 | Citations in SR25.003 to the ATP regulations or the West Coast Methods for estuarine and marine organisms of the Pacific Ocean are inapplicable as there is no approved ATP, and the ISWEBE Plan does not apply to those waters, which are covered by the Ocean Plan and prescribe NOEC. |
| SR P.034 | Comments regarding the West Coast Methods and the Ocean Plan are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR25.003,” “SR25.007,” "SR25.034,” and “SR25.040” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.049 | Citations in **SR#25.003** to the ATP regulations or the West Coast Methods for estuarine and marine organisms of the Pacific Ocean are inapplicable as there is no approved ATP, and the ISWEBE does not apply to those waters, which are covered by the Ocean Plan and prescribe NOEC. |
| SC P.035 | The response SR25.006 states that “the state has discretion to select the statistical approach that is most appropriate for compliance and reporting purposes.” However, this is incorrect as 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 CF.R. §122.41(j)(4); 40 C.F.R. §122.21(j)(5)(viii)). |
| SR P.035 | Comments regarding changes to the test method are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see response “SR25.003” and “SR26.006” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.050 | **#SR25.006** states that “the state has discretion to select the statistical approach that is most appropriate for compliance and reporting purposes.” However, this is incorrect as 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 CF.R. §122.41(j)(4); 40 C.F.R. §122.21(j)(5)(viii)). |
| SC P.036 | See the individual comment below regarding modification of an EPA-approved Clean Water Act analytical method for method-defined analytes. |
| SR P.036 | Comments regarding an analytical method for method-defined analytes are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses ”SR25.003,” “SR25.007,” “27.004,” and “SR27.010” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx) and Section 2.6.5 of the Staff Report on how use of the TST statistical approach is not a change to the test method. |
| 25.051 | **SR#25.013** Regarding the “accuracy of tests,” the Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule (U.S. EPA, 2002) explains that “[b]ecause toxicity is inherently defined by the measurement system (a ‘‘method defined analyte’’), and toxicity cannot be independently measured apart from a toxicity test, accuracy as a performance characteristic is not completely applicable.” **SR#27.004** “For a method-defined analyte such as toxicity,…”  Previous comments stated that, 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).) The RTC failed to address this critically important comment. |
| SC P.037 | See the individual comment below regarding the IC25 and percent effect. |
| SR P.037 | Comments regarding the IC25 are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR25.005,” “SR25.012,” “SR25.015,” “SR25.029,” “SR25.037,” “SR25.039,” “SR27.008,” “SR27.010,” and “SR27.011” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.052 | The RTC falsely claims that the NOEC is used to decide if a sample is toxic and the IC25 is used to determine how much toxicity is in the sample. Attached below is an excerpt from EPA’s 2002 rulemaking for the WET method, which expressly states that the 25% difference (measured by the IC25) is used to declare a sample toxic, just as the TST does. [See the image on page 17 of comment letter #25, Exhibit A] |
| SC P.038 | See the individual comment below regarding the TST statistical approach. |
| SR P.038 | Comments regarding the TST statistical approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see Sections 5.1, 5.2, 5.3.1 and Appendix J of the Second Revised Draft Staff Report. Also, see Categories 25 and 27 from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). |
| 25.053 | Another quote highlighted earlier on the same page that states the “statistical approaches included in the WET test method measurement system ensure that measured responses can be reliably distinguished from background noise.” Several detailed comment letters previously submitted clearly show that the TST procedure is incapable of doing the same. |
| SC P.039 | See the individual comment below regarding Appendix J comment letters and responses to those comments. |
| SR P.039 | Comments regarding the responses to comment letters on Appendix J are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see SR J-1.001 through SR J-6.007 for responses to the comments received on Appendix J. |
| 25.054 | The RTC continues to reference the “new” data and analysis presented in Appendix J. Several comment letters were filed in January of 2020 that described numerous data entry errors and other mathematical problems in that Appendix. However, to date, the State Board Staff has not published any Response to the very detailed comments filed most recently. |
| SC P.040 | See the individual comment below regarding confidence in the IC25 approach. |
| SR P.040 | Comments regarding the IC25 approach are outside the scope of the comments the State Water Board will receive for its consideration on the differences between the October 2018 and July 2020 Toxicity Provisions and Staff Report. However, please see responses “SR25.005,” “SR25.012,” “SR25.015,” “SR25.029,” “SR25.037,” “SR25.039,” “SR27.008,” “SR27.010,” and “SR27.011” from the July 22, 2020 [Summary of Comments and Responses on the 2018 Draft Toxicity Provisions and 2018 Draft Staff Report](https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/toxicity_2018_rtc.docx). Also, see also Sections 5.1, 5.2, and 5.3 from the Second Revised Draft Staff Report.  As mentioned in Section 5.3.1 of the Staff Report, “[t]he U.S. EPA toxicity test manuals state: ‘It should be noted that software used to calculate point estimates occasionally may not provide associated 95 percent confidence intervals’ (U.S. EPA 2002c). A confidence interval is needed to know the reliability of the calculated point estimate value. Because the methods manuals don’t require the inclusion of confidence intervals and state permits do not require the additional calculation of confidence intervals, there is no statistical confidence and reliability in the calculated point estimate value. However, under this option, point estimate models could be developed which incorporate confidence intervals which would include statistical confidence in the outcome. This would be time consuming, costly and require additional peer review.” |
| 25.055 | The RTC **(#SR25.012** at pg. 348) states that, “for the IC25, there is no statistical confidence and reliability in the calculated point estimate values. While point estimate models could incorporate confidence intervals, it would be time consuming, costly and require additional peer review…. The IC25 approach provides no confidence in the in test result since the within-test variability is not assessed.” This is a FALSE statement. Appendix M of EPA’s chronic WET method manual for freshwaters expressly states that the IC25 procedure “allows traditional quantitative assessment of the precision of the endpoint, such as confidence limits for the endpoint of a single test…” (see App. M., §1.1 at pg. 324 and §6.4.1.). Section 5 of Appendix M (at pg. 325) describes how such confidence intervals are easily computed using the “bootstrap method.” It should be noted that confidence intervals for the IC25 endpoint are already computed by both EPA original software and by other statistical software package (e.g. CETIS or ToxCalc) commonly used by every WET lab in the country. As such, EPA’s method manual states that bootstrap “computations are easily done with a computer program such as the revision of the BOOTSTRP program (USEPA, 1988; USEPA, 1989) which is now called “ICPIN” which is described below in subsection 7.” IC25 confidence intervals, which are a measure of precision and reliability, are part of the DATA OUTPUT already provided by existing EPA software (see *id*. at §7.5.1 at pg. 329). Attached below is an example of the standard IC25 output for a *Ceriodaphnia dubia* reproduction test, which highlights the 95% confidence intervals with a red box. |