UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
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Karen Mogus
Deputy Director
Division of Water Quality
State Water Resources Control Board
1001 I Street
Sacramento, California 95814

Transmitted by Email Only

Subject: Approval of New Water Quality Standards: California State Policy for Water Quality Control: Toxicity Provisions

Dear Deputy Director Mogus,

I am pleased to approve the new statewide water quality standards establishing aquatic toxicity objectives per the subject Provisions, consistent with the requirements of section 303(c) of the Clean Water Act (CWA) and 40 C.F.R. Part 131. This approval includes those portions of the subject Provisions that constitute new water quality standards and subject to EPA's authority to approve or disapprove under CWA section 303(c). The approved standards, which take effect immediately for CWA purposes, are shown in Enclosure A and EPA's analysis and rationale supporting its action are included in Enclosure B of this letter.

I look forward to our continued partnership to protect water quality in California. Please call me if you would like to discuss further, or your staff may contact Tina Yin at (415) 972-3579, yin.tina@epa.gov with specific questions concerning this approval.

Sincerely,
TOMAS TORRES
Digitally signed by TOMAS TORRES
Date: 2023.05.01 12:28:15 -07'00'
Tomás Torres
Director, Water Division

Enclosures

Enclosure A
Approved Standards

EPA approves the following Water Quality Standards (WQS) found in California's State Policy for Water Quality Control: Toxicity Provisions (Toxicity Provisions), pursuant to CWA Section 303(c)(3). The approved WQS establish statewide aquatic toxicity objectives (also known as water quality criteria) that define the thresholds for determining aquatic toxicity, including allowable error rates based on specific species in Table 1 described below. Additionally, III.C.1 extends the applicability of the state's existing mixing zone policy to the new numeric aquatic toxicity objectives. EPA's analysis and basis for approval is in Enclosure B.

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I. INTRODUCTION

This State Policy for Water Quality Control: Toxicity Provisions (TOXICITY PROVISIONS) was adopted by the State Water Resources Control Board (State Water Board) under authority provided by Water Code sections 13140 and 13170.[1] Except as otherwise indicated, the TOXICITY PROVISIONS establishes provisions for water quality that apply to all INLAND SURFACE WATERS, ENCLOSED BAYS, and ESTUARIES AND COASTAL LAGOONS of the state, including both waters of the United States and surface waters of the state. These TOXICITY PROVISIONS do not apply to OCEAN WATERS, including Monterey Bay and Santa Monica Bay. All terms that are defined in Appendix A are reflected in capital letters.

II. AQUATIC TOXICITY WATER QUALITY OBJECTIVES

II.A. Aquatic Toxicity

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

As used in Section II, 'ambient water' refers to a sample taken from the water body of concern that may or may not be influenced by a discharge.

II.B. Applicable Beneficial Uses

The following water quality objectives for chronic and acute aquatic toxicity establish minimum requirements to protect AQUATIC LIFE beneficial uses including, but not limited to, warm freshwater habitat (WARM); cold freshwater habitat (COLD); wildlife habitat (WILD); estuarine habitat (EST); preservation of rare, threatened, or endangered species (RARE); migration of aquatic organisms (MIGR); spawning, reproduction, or early development (SPWN); marine habitat (MAR); inland saline water habitat (SAL); and wetland habitat (WET).

[1] NOTE: The portions of the TOXICITY PROVISIONS that apply to waters for which water quality standards are required by the Federal Water Pollution Control Act and acts amendatory thereof or supplementary thereto (i.e., waters of the United States) will be incorporated into the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California. Future incorporation of those portions of the TOXICITY PROVISIONS, as adopted, into the water quality control plan will be considered non-substantive amendments. At that time, formatting and other organizational edits necessary for incorporation into the water quality control plan will be addressed.

II.C. Aquatic Toxicity Water Quality Objectives

II.C.1. Numeric Chronic Aquatic Toxicity Objective

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

H_o: Mean RESPONSE (ambient water) $\leq$ 0.75 • mean RESPONSE (control)

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

And where the following ALTERNATIVE HYPOTHESIS shall be used:

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

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

Attainment of the water quality objective is demonstrated by conducting CHRONIC AQUATIC TOXICITY TESTING as described in Section III.B.2 and rejecting this NULL HYPOTHESIS in accordance with the TEST OF SIGNIFICANT TOXICITY (TST) statistical approach described in Section III.B.3. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the chronic aquatic toxicity water quality objective. Failing to reject the NULL HYPOTHESIS (referred to as a "fail") is equivalent to an exceedance of the chronic aquatic toxicity water quality objective.

II.C.2. Numeric Acute Aquatic Toxicity Objective

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

H_o: Mean RESPONSE (ambient water) $\leq$ 0.80 • mean RESPONSE (control)

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

And where the following ALTERNATIVE HYPOTHESIS shall be used:

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

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

Attainment of the water quality objective is demonstrated by conducting ACUTE AQUATIC TOXICITY TESTING as described in Section III.B.2 and rejecting this NULL HYPOTHESIS in accordance with the TST statistical approach described in Section III.B.3. When the NULL HYPOTHESIS is rejected, the ALTERNATIVE HYPOTHESIS is accepted in its place, and there is no exceedance of the acute aquatic toxicity water quality objective. Failing to reject the NULL HYPOTHESIS (referred to as a "fail") is equivalent to an exceedance of the acute aquatic toxicity water quality objective.

II.D. Interaction of Toxicity Provisions with Basin Plans and the State Implementation Policy

In accordance with Water Code section 13170, except where otherwise noted, the TOXICITY PROVISIONS automatically supersede any Regional Water Quality Control Plans (Basin Plans) for waters of the United States to the extent of any conflict.
Consistent with its authority in Water Code sections 13140 and 13142, the State Water Board has also determined that the TOXICITY PROVISIONS shall supersede any Regional Water Quality Control Plans (Basin Plans) for all waters of the state to the extent of any conflict. The TOXICITY PROVISIONS supersede section 4 of the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, also known as the State Implementation Policy or the SIP.

The TOXICITY PROVISIONS supersede Basin Plan toxicity provisions to the extent that:

(A) The Basin Plan provisions specify methods of assessing compliance with any numeric or narrative water quality objectives for acute or chronic aquatic toxicity; or
(B) The Basin Plan provisions regard aquatic toxicity testing or interpretation of aquatic toxicity testing results; or
(C) The Basin Plan provision is a numeric aquatic toxicity water quality objective that is not a site-specific water quality objective; or
(D) The Basin Plan provisions are in conflict with the TOXICITY PROVISIONS.

The TOXICITY PROVISIONS, notwithstanding the above, do not supersede the following Basin Plan provisions:

(A) The narrative toxicity water quality objectives (e.g., 'no toxic POLLUTANTS in toxic amounts'); or

(B) Any Basin Plan provisions regarding the application of narrative toxicity water quality objectives to derive chemical-specific limits, targets, and other thresholds; or
(C) Any site-specific toxicity water quality objective or site-specific toxicity implementation provisions established in a Basin Plan. In addition, the TOXICITY PROVISIONS do not apply to segments of the water body in which the site-specific toxicity water quality objective apply; or
(D) Any total maximum daily loads (TMDLs) related to aquatic toxicity, including their implementation provisions, established prior to the effective date of these TOXICITY PROVISIONS. Section III also applies to all dischargers subject to TMDL requirements except to the extent the PERMITTING AUTHORITY determines that any specific aquatic toxicity TMDL requirements are more protective than any comparable requirements of Section III in which case those specific TMDL requirements will apply in lieu of the comparable requirements of Section III. Nothing in this section limits the Regional Water Board's authority to reconsider a TMDL and its implementation provisions that were established prior to the effective date of these TOXICITY PROVISIONS.

III. AQUATIC TOXICITY PROGRAM OF IMPLEMENTATION

III.B. Required Toxicity Testing Methods and Analyses

III.B.2. Toxicity Test Methods

CHRONIC AQUATIC TOXICITY TESTS shall be conducted using one or more of the test species in Table 1 selected by the PERMITTING AUTHORITY in accordance with the TOXICITY PROVISIONS, and shall follow methods identified in the Code of Federal Regulations, title 40, part 136, or other U.S. EPA-approved methods, or included in the following U.S. EPA method manuals: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, Fourth Edition (EPA-821-R-02-013); Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition (EPA-821-R-02-014); and Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms, First Edition (EPA-600-R-95-136).

ACUTE AQUATIC TOXICITY TESTS shall be conducted using one or more of the test species in Table 1 selected by the PERMITTING AUTHORITY in accordance with the TOXICITY PROVISIONS, and shall follow methods identified in the Code of Federal Regulations, title 40, part 136, or other U.S. EPA-approved methods, or included in Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, Fifth Edition (EPA-821-R-02-012).

Table 1. Toxicity Test Methods, Regulatory Management Decision (RMD), β Error, and α Error

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

U.S. EPA Toxicity Test Method	Tier	RMD (b)	β Error	α Error
Americamysis bahia (mysid) Survival	II	0.80	0.05	0.10
Menidia berylina (inland silverside) Survival	II	0.80	0.05	0.10

Table 1 Notes: The bioequivalence value (b) is equivalent to the RMD. The β error is the probability of declaring a sample toxic when it is not toxic. The α error is the probability of declaring a sample non-toxic when it is toxic.

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

Test results shall be analyzed using the TST as described in Section III.B.3. To the extent that U.S. EPA-approved methods require that observations be made of organisms' RESPONSE in multiple concentrations of effluent or receiving water, the INSTREAM WASTE CONCENTRATION (IWC) shall be included as one of the selected concentrations, and the TST shall be conducted using the IWC and control as described in Section III.B.3.

III.B.3. Test of Significant Toxicity

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

Step 1: Conduct the aquatic toxicity test according to procedures in the appropriate test method manual, as described in Section III.B.2.

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

If there is no variance in the ENDPOINT in both concentrations being compared, compute the PERCENT EFFECT, as described in Section III.B.4.

If the PERCENT EFFECT at the IWC is ≥ the RMD, the sample is declared toxic and the test result is "fail." If the PERCENT EFFECT at the IWC is < the RMD, the sample is declared non-toxic and the test result is "pass." Skip steps 3-7.

If there is variance in the ENDPOINT in either concentration being compared, follow Steps 3-7.

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

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

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

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

If $0 < RP < 1$,

then the angle (in radians) = $\arcsin(\sqrt{(RP)})$.

If $RP = 0$,

then the angle (in radians) = $\arcsin(\sqrt{1/4n})$,

Where n = number of ORGANISMS used for each REPLICATE.

If RP = 1

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

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

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

Where:

$\bar{Y}_c$ = Mean RESPONSE for the control
$\bar{Y}_t$ = Mean RESPONSE for the IWC
S_c^2 = Estimate of the variance for the control
S_t^2 = Estimate of the variance for the IWC
n_c = Number of REPLICATES for the control
n_t = Number of REPLICATES for the IWC
b = 0.75 for chronic tests; 0.80 for acute tests
(Note: b is equivalent to the RMD)

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

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

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

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

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

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

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

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

III.B.4. Percent Effect

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

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

III.C. Implementation for Non-Storm Water NPDES Dischargers

III.C.1. Instream Waste Concentration

The PERMITTING AUTHORITY may grant MIXING ZONES and DILUTION CREDITS for the numeric aquatic toxicity objectives to dischargers in accordance with Section 1.4.2 of the Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California (2005).

APPENDIX A: Glossary

Definitions from Appendix A of the California Toxicity Provisions that are associated with the approved water quality standards in this action

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

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

AQUATIC LIFE: Aquatic life refers to aquatic organisms.

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

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

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

ENCLOSED BAYS: Indentations along the coast that enclose an area of oceanic water within

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

ENDPOINT: A measured RESPONSE of a receptor to a stressor. An endpoint can be measured in a toxicity test or field survey.

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

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

INSTREAM WASTE CONCENTRATION (IWC): The concentration of effluent in the receiving water after mixing as determined by the PERMITTING AUTHORITY. For purposes of aquatic toxicity testing for NON-STORM WATER NPDES DISCHARGERS, the IWC shall be as described in Section III.C.1. For assessing whether receiving waters meet the numeric water quality objectives, the undiluted ambient water shall be used as the IWC in the TEST OF SIGNIFICANT TOXICITY (TST) as indicated in Section III.B.3.

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

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

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

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

PERMITTING AUTHORITY: The State Water Board or a regional water board that issues a permit, waste discharge requirements, water quality certification, or other authorization for the

discharge or proposed discharge of waste. To the extent that the action is delegable, the term "Permitting Authority" can include the Executive Officer or Executive Director.

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

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

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

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

STORM WATER: Same meaning set forth in 40 Code of Federal Regulations section 122.26(b)(13) (Nov. 16, 1990) which states, 'Storm water means storm water runoff, snow melt runoff, and surface runoff and drainage.

TEST OF SIGNIFICANT TOXICITY (TST): A statistical approach used to analyze aquatic toxicity test data, as described in Section III.B.3.

Enclosure B

EPA Review of California State Policy for Water Quality Control: Toxicity Provisions

Section 303(c) of the Clean Water Act (CWA), 33 U.S.C. § 1313(c), requires states to establish water quality standards (WQS), from time to time to review their WQS, and to submit any new or revised standards to EPA for review and approval or disapproval. EPA's implementing regulations at 40 C.F.R. Part 131, require, among other things, that WQS specify appropriate designated uses of the waters and water quality criteria that protect those uses. EPA reviews the WQS to determine if they are consistent with the factors listed at 40 C.F.R. § 131.5 and contain the minimum requirements listed at 40 C.F.R. § 131.6. California uses the term "beneficial use" to mean "designated use" under the CWA and the term "water quality objective" to mean "water quality criteria" under the CWA. The terms are used interchangeably in this document.

California's development of its new WQS regarding toxicity included opportunities for public input at more than three dozen meetings throughout the State since 2012. California solicited public comments and prepared responses to those comments on October 26, 2018; July 22, 2020; and September 30, 2021. In December 2020, California's State Water Resources Control Board (SWRCB) adopted State Policy for Water Quality Control: Toxicity Provisions (Toxicity Provisions). On October 5, 2021, the SWRCB adopted a resolution to confirm that the Toxicity Provisions were adopted as State policy for water quality control for all inland surface waters, enclosed bays, estuaries, and coastal lagoons of the state. The Notice of Final Rulemaking was filed March 18, 2022, and approved by the California Office of Administrative Law on April 25, 2022. California followed applicable legal procedures sufficient to meet 40 C.F.R. § 131.5(a)(6).

The State transmitted the Toxicity Provisions to EPA dated April 27, 2022, including a Staff Report and Response to Comments. EPA finds that the submission and supporting materials meet the requirements of 40 C.F.R. § 131.6(b). A certification from the Attorney General for California dated April 25, 2022, states that the Toxicity Provisions were duly adopted pursuant to State law. 40 C.F.R. § 131.6(e). EPA finds the public participation procedures followed by the State in development and adoption of these statewide WQS are consistent with the procedural requirement set forth in 40 C.F.R. § 131.20(b).

Based on its review of the submittal and supporting documentation, EPA finds the portions of the Toxicity Provisions shown in Enclosure A are new WQS and are consistent with the CWA and 40 C.F.R. part 131. EPA approves the WQS specified in Enclosure A pursuant to CWA Section 303(c).

I. Background

The purpose of California's Toxicity Provisions is to provide for consistent protection of aquatic life beneficial uses from the effects of known and unknown toxicants, by establishing water quality objectives for both acute and chronic aquatic toxicity.

Aquatic toxicity is the adverse response of aquatic organisms from exposure to chemical or physical agents or the additive or synergistic effects of the toxicants in effluent or ambient water. Simply put, aquatic toxicity is a measurement used to determine whether the quality of the water presents an unacceptable risk to aquatic organisms. Aquatic toxicity is typically assessed in a laboratory setting by selecting specific species of fish, aquatic insects, aquatic plants or algae to be exposed to a sample of the water of interest (e.g., river water) for a period of time then measuring the test organisms' lethal (survival) or sub-lethal (e.g., growth or reproduction) response and comparing, through statistical analysis, the measurements to the survival, growth or reproduction of the same species of test organisms exposed to control water. If the test organisms exposed to the sample water respond similarly to those living in the control water, then the sample water is considered non-toxic. If there is a biologically significant reduction in the survival, growth or reproduction of the organisms exposed to the sample water compared to the test organisms in the control water, as determined through statistical analysis, then the sample water is considered toxic. CA SWRCB 2021 Toxicity Provisions Fact Sheet at 1. Acute aquatic toxicity refers to adverse response (typically lethality) from a short-term exposure. Chronic aquatic toxicity generally refers to longer-term exposure and measures both lethal and sub-lethal (typically growth or reproduction) adverse responses.

EPA has promulgated whole effluent toxicity (WET) test methods for measuring organism response in laboratory testing, which have been incorporated by reference in 40 C.F.R. Part 136. In addition to the WET test, which provides the biological data necessary for assessing toxicity, application of a statistical approach is necessary to determine whether those biological results are statistically significant. Toxicity may be caused by a variety of substances in a water sample and – unlike a pollutant such as mercury or copper – it is not measurable as an absolute amount or concentration. Accordingly, the biological results of a WET test must be analyzed through a statistical approach to determine whether any observed biological difference between a test sample and a control is statistically significant and can thus be attributed to toxicity. The Test of Significant Toxicity (TST) is one such statistical approach,[1] which the State has incorporated into its Toxicity Provisions, as discussed in more detail below.

[1] Because toxicity is not an absolute quantity but rather an effect that is determined relative to a control or reference sample, statistical analysis of toxicity test data is always necessary to determine whether a sample is toxic. EPA's promulgated WET test methods list certain recommended statistical approaches, but do not require the use of any particular statistical approach for analyzing WET test data. *See* 67 Fed. Reg. 69952, 69964 (Nov. 19, 2002) ("the statistical methods recommended in this manual are not the only possible methods of statistical analysis"). Accordingly, although the WET test methods do not specifically reference the TST, the methods allow for the use of statistical approaches other than those listed therein. Therefore, once the WET test has been conducted (using the requirements specified in the WET test methods), the TST statistical approach can be used to analyze the WET test results to determine whether the effluent is toxic. *See* US EPA 2010b TST Implementation Document at 3.

II. Toxicity Provisions Subject to EPA Review as WQS pursuant to CWA § 303(c)

EPA considers four questions when evaluating whether a particular provision is a new or revised WQS. US EPA 2012. The four questions are:

1. Is it a legally binding provision adopted or established pursuant to state or tribal law?
2. Does the provision address designated uses, water quality criteria (narrative or numeric) to protect designated uses, and/or antidegradation requirements for waters of the United States?
3. Does the provision express or establish the desired condition (e.g., uses, criteria) or instream level of protection (e.g., antidegradation requirements) for waters of the United States immediately or mandate how it will be expressed or established for such waters in the future?
4. Does the provision establish a new WQS or revise an existing WQS?

If the answer to all four questions is "yes," then the provision would likely constitute a new or revised WQS that EPA has the authority and duty to approve or disapprove under CWA Section 303(c). EPA must then determine whether the new or revised WQS are consistent with the factors listed at 40 C.F.R. § 131.5 and contain the minimum requirements listed at 40 C.F.R. § 131.6.

EPA reviewed the Toxicity Provisions using the 4-part test above and determined that the portions of the Toxicity Provisions included in Enclosure A constitute new WQS that the EPA has the authority and duty to approve or disapprove under CWA section 303(c). In brief, and as described in more detail below, portions of the Toxicity Provisions 1) are legally binding provisions adopted pursuant to state law; 2) address water quality criteria for toxicity; 3) establish the desired condition for California's waters; and 4) constitute new WQS for California waters that have not previously been approved by EPA.

1. The Toxicity Provisions are Legally Binding Provisions

California submitted a certification from the Attorney General for California dated April 25, 2022, which states that the Toxicity Provisions were duly adopted pursuant to State law.

2. The Toxicity Provisions Address Designated Uses and Water Quality Criteria; and,
3. Provisions Express or Establish the Desired Condition of Waters

Across California, all Regional Water Quality Control Plans (Basin Plans) currently contain narrative toxicity objectives that require all waters to be maintained free of toxic substances in concentrations that produce detrimental responses in human, plant, animal, or aquatic life (e.g., "no toxic pollutants in toxic amounts"). California determined that clearer and more specific numeric toxicity objectives were needed to help ensure consistent statewide protection of aquatic life and developed statewide numeric toxicity objectives. CA SWRCB 2021 Staff Report at 59. The new numeric toxicity objectives supersede existing Basin Plan toxicity provisions only to the extent that

they conflict, as described in section II.D.[2] The narrative toxicity objectives remain in place as described in section II.E., for example, to provide protection for human health or for aquatic life when assessing chemical-specific toxicity.

The Toxicity Provisions apply to all inland surface waters, enclosed bays, estuaries and coastal lagoons.[3] The Toxicity Provisions specifically address designated uses and criteria[4] to protect aquatic life beneficial uses including, but not limited to: warm freshwater habitat; cold freshwater habitat; wildlife habitat; estuarine habitat; preservation of rare, threatened, or endangered species; migration of aquatic organisms; spawning, reproduction, or early development; marine habitat; inland saline water habitat; and wetland habitat. Toxicity Provisions, page 1.

The water quality objectives in II.C. of the Toxicity Provisions require toxicity testing in accordance with EPA's aquatic toxicity test methods described in III.B.2[5] and analysis of the resulting data using the (TST) statistical approach in III.B.3. These sections, along with the other portions of the Provisions identified in Enclosure A, work together to establish the desired condition for California waters, as explained below.

California's Toxicity Provisions establish that when conducting aquatic toxicity testing in accordance with all requirements of the Provisions, ambient water is toxic if the adverse response (e.g., survival, reproduction, growth) of the test organisms in the ambient water sample is less than or equal to 75% or 80% of the test organisms' response in the control water sample (depending on whether analyzing for chronic or acute toxicity). The above percentiles, referred to as Regulatory Management Decisions (RMDs), define the degree of difference in organism response that is considered biologically significant. However, to define what is considered toxic – and thus, the desired condition of the waterbody – the Toxicity Provisions require that tests be conducted using specific methods identified in III.B.2 of the Toxicity Provisions and that the test data be statistically analyzed using the TST.

Specifically, the Toxicity Provisions require a null hypothesis that the ambient water is toxic if the difference between the sample and control is greater than or equal to the RMD – which means the sample can be found not toxic only if the null hypothesis is rejected in accordance with the TST. In

[2] California has identified the Regional Basin Plan objectives that are superseded by the Toxicity Provisions in Appendix E of the Staff Report, incorporated herein by reference.

[3] The Provisions do not apply to ocean waters including Monterey Bay and Santa Monica Bay. California defines Enclosed Bays and Estuaries as: "Indentations along the coast that enclose an area of oceanic water within distinct headlands or harbor works. Enclosed bays include all bays where the narrowest distance between headlands or outermost harbor works is less than 75 percent of the greatest dimension of the enclosed portion of the bay. This definition includes but is not limited to Humboldt Bay, Bodega Harbor, Tomales Bay, Drakes Estero, San Francisco Bay, Morro Bay, Los Angeles Harbor, Upper and Lower Newport Bay, Mission Bay, and San Diego Bay." Toxicity Provisions, Appendix A. Glossary.

[4] These provisions, in combination, translate the narrative criteria to protect the designated use, thus serving to establish a desired condition for the waters to which they apply.

[5] The EPA approved toxicity test methods resulted from many years of development and testing by EPA, States, municipalities, academia, and the regulated community. These Whole Effluent Toxicity (WET) test methods provide the biological data necessary to measure the acute and short-term chronic toxicity of ambient waters to aquatic plants, invertebrates, and vertebrates living in freshwater and marine environments.

addition, the Toxicity Provisions (at Table 1, Section III.B.2) include species-specific alpha and beta error rates[6] associated with the TST, setting maximum false positive and false negative rates for determining unacceptable toxicity. Therefore, the TST components reflected in the Toxicity Provisions (RMD, including error rates, and null hypothesis with presumption of toxicity) are integral to defining the difference in organism response that is considered toxic. In other words, the TST components as described in sections II.C, III.B.2 and III.B.3 together establish a level of statistical certainty that observed biological differences in organism response constitute toxicity, and thus define the desired condition of the waterbody (i.e., that the waterbody is not toxic).[7]

In the context of the Toxicity Provisions, the TST components, together with the other Toxicity Provisions identified in Enclosure A, constitute water quality standards, as they in fact *establish* the desired condition of the waterbody. This is because, as discussed above, the desired condition here is "not toxic," and unlike chemical-specific pollutants, toxicity cannot be measured as an absolute amount. Rather, as specified in the Toxicity Provisions, the desired condition here (not toxic) is defined and measured by specified application of the TST components, which establish whether an observed biological difference in organism response is or is not toxic. In other words, because "not toxic" does not have an inherent meaning, the application of the TST components is used to define what constitutes "not toxic" and thus the desired condition of the waterbody.[8]

For the reasons provided above, EPA has determined that the portions of the Toxicity Provisions identified in Enclosure A work together to address water quality criteria and establish the desired condition of the water, and thus the answer to questions 2 and 3 is yes.

4. <u>The Toxicity Provisions Include New or Revised WQS</u>

Addressing question four of the 4-part test, a provision that EPA has not previously approved as a WQS is considered a "new" WQS. A provision that has the effect of changing an existing WQS is considered a "revised" WQS. The portions of the Toxicity Provisions identified in Enclosure A have not been previously approved by EPA under section 303(c) and are therefore all new WQS that satisfy the fourth question of EPA's 4-part test.

In summary, EPA has evaluated the Toxicity Provisions under the 4-part test for evaluating whether a provision is a new or revised WQS and found the portions of the Toxicity Provisions identified in Enclosure A to be new WQS subject to EPA review under CWA section 303(c).

[6] Alpha error occurs when the null hypothesis is erroneously rejected when it is in fact true, and beta error occurs when the null hypothesis is erroneously not rejected when it is in fact not true.

[7] EPA understands the RMD components to be both the bioequivalence values (b) and the alpha and beta error rates listed on Table 1.

[8] EPA notes that published results (*see*, Diamond et al. (2013)) regarding the efficacy of the TST have relied on using all of the TST statistical approach components (RMDs, null hypothesis presuming toxicity, species-specific error rates), further supporting EPA's consideration of these components in the Toxicity Provisions as a package that together define the desired condition of the waterbody.

III. Review of Provisions Found to be New WQS for Consistency with the CWA and Implementing Regulations

CWA section 303(c)(3) provides that EPA will either approve or disapprove new or revised WQS, based on whether the submitted WQS are consistent with the applicable requirements of the CWA. EPA's regulations provide for the Regional Administrator to notify the state that the WQS are either approved or disapproved. 40 C.F.R. § 131.21(a). As specified in 40 C.F.R. § 131.21(b), the Regional Administrator's action is to be based on the requirements of the CWA as described by the implementing regulation at 40 C.F.R. §§ 131.5 and 131.6. Those sections refer to additional portions of 40 C.F.R. Part 131, including section 131.11. Principally at issue here are the requirements at 40 C.F.R. § 131.11(a): "States must adopt those water quality criteria that protect the designated use. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." As explained below, EPA finds that the Toxicity Provisions identified in Enclosure A meet the requirements of the CWA and 40 C.F.R. Part 131, and these Toxicity Provisions are approved for CWA purposes.

EPA reviewed the Toxicity Provisions to determine if they are consistent with the relevant factors listed at 40 C.F.R. § 131.5 and contain the relevant minimum requirements listed at 40 C.F.R. § 131.6.

The relevant factors at 40 C.F.R. § 131.5(a) are:

> (2) Whether the State has adopted criteria that protect the designated water uses based on sound scientific rationale consistent with 40 C.F.R. § 131.11.

The regulations at 40 C.F.R. § 131.11 further specify that criteria must protect the designated use based on a sound scientific rationale and scientifically defensible methods. 40 C.F.R. §§ 131.11(a) and (b)(1)(iii). EPA finds all these factors have been met, as explained below in section III.A.

> (6) Whether the State has followed applicable legal procedures for revising or adopting standards.

This factor has been met as discussed above.

> (8) Whether the State submission meets the requirements included in 40 C.F.R. § 131.6.

The relevant requirements in 40 C.F.R. § 131.6 specify that the State's submission must include the State's methods and analyses and a certification from the Attorney General. 40 C.F.R. §§ 131.6(b) and (e). EPA has determined these factors have been met as discussed above. 40 C.F.R. § 131.6(c) specifies that the State's submission must include criteria sufficient to protect uses. EPA finds this factor has been met as explained in section III.A below. Lastly 40 C.F.R. § 131.6(f) specifies that the State submission must include any general policies that may affect the application of the WQS. EPA finds this factor has been met as described section III.C below. *See also* 40 C.F.R. § 131.13.

A. Analysis of the Scientific Rationale Pursuant to EPA's WQS Regulations

EPA regulations at 40 C.F.R § 131.5(a)(2) establish that EPA review of adopted WQS involves a determination that the criteria protect designated uses based on sound scientific rationale consistent with 40 C.F.R. § 131.11. EPA considered the scientific justification included in the submittal and supporting documentation and also reviewed EPA Technical Documents and additional peer-reviewed science (see references). Based on review of the material, and as described below, EPA concludes the portions of the Toxicity Provisions identified in Enclosure A are based on a sound scientific rationale.[9]

California's Toxicity Provisions require that waters be assessed for aquatic toxicity using EPA-approved toxicity test methods.[10] Because toxicity is not an absolute quantity but rather an effect that is determined relative to a control or reference sample, statistical analysis of toxicity test data, either through hypothesis testing or a point estimate approach, is always necessary to determine whether a sample is toxic. In this case, California has chosen to require the use of the TST statistical approach, a form of hypothesis testing. The TST statistical approach is based on a type of hypothesis test referred to as bioequivalence testing. Bioequivalence testing has long been used in many contexts, from evaluating clinical trials of pharmaceutical products, to evaluating the attainment of soil cleanup standards for contaminated sites, to evaluating the effects of pesticides in experimental ponds. US EPA 2010a TST Technical Document at 4. US EPA 2023 Staff File Memo at 6.

The TST Statistical Approach

The TST is a hypothesis testing approach which builds on previous work conducted by EPA in the NPDES WET Program and other researchers (Erickson and McDonald 1995; Shukla et al. 2000; Berger and Hsu 1996). EPA developed the TST to provide increased confidence in toxicity data assessment by controlling for specific types of errors that are typical in hypothesis testing. With a hypothesis testing approach, two types of decision errors can occur: (1) fail to reject the null hypothesis when in fact it is incorrect (i.e., beta error) or (2) reject the null hypothesis, when in fact it is correct (i.e., alpha error). US EPA 2023 Staff File Memo at 2.

In 2010 EPA issued the TST Technical Document and TST Implementation Document describing the TST as another statistical approach for permit writers to consider incorporating into NPDES

[9] As explained above, criteria should be revised from time to time as new scientific data or methodologies are developed. CWA section 303(c) and 40 C.F.R. § 131.20. Factors such as technological feasibility, social and economic costs, and the benefits of achieving criteria levels are not directly involved in the process of developing water quality criteria. In contrast economic considerations may be relevant in establishing a designated use. *See* e.g., 40 C.F.R. § 131.10.

[10] The Toxicity Provisions require that waters be tested following test methods found in 40 C.F.R. Part 136 or other U.S. EPA-approved methods, or included in the following U.S. EPA method manuals: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, Fourth Edition (EPA-821-R-02-013); Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition (EPA-821-R-02-014); and Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to West Coast Marine and Estuarine Organisms, First Edition (EPA-600-R-95-136).

permits. US EPA 2010a TST Technical Document and US EPA 2010b TST Implementation Document.

In certain hypothesis testing approaches such as the No Observed Effect Concentration (NOEC)[11] approach, the null hypothesis is that the sample being tested is non-toxic (i.e., the organism response in the sample water is equal to or better than the response in the control water). The alternative hypothesis is that the sample water is toxic (i.e., the organism response is worse in the sample water than in the control and therefore, there may be a risk to aquatic life). Fox et al. (2019). Under hypothesis testing approaches developed prior to the 2010 TST, EPA recommends that alpha errors (i.e., false positives where the water is declared toxic when actually it is not) be no more than 5%, but does not explicitly address beta errors (i.e., false negatives where the water is declared non-toxic when it is actually toxic). The beta error rate implicitly depends on test variability and number of replicates. US EPA 2010a TST Technical Document.

In contrast, the TST statistical approach is an example of a test of noninferiority or "proof of safety" hypothesis approach that controls for both alpha and beta errors and in which the null and alternative hypotheses are opposite of what they are under other hypothesis testing statistical approaches for toxicity. Fox et al. (2019). The null hypothesis using the TST statistical approach is that the sample water is toxic, and the alternative hypothesis is that the sample water is non-toxic. As a result, for the TST statistical approach, the alpha error represents false negatives, and the beta error represents false positives. According to the peer-reviewed literature described in EPA's TST Technical Document and WET methods, defining both alpha and beta error rates accounts for normal method variability and provides greater confidence that truly non-toxic water samples are identified as non-toxic and truly toxic water samples are identified as toxic. US EPA 2010a TST Technical Document and US EPA 2010b TST Implementation Document; US EPA 2002a, b, and c; US EPA 2010a TST Technical Document at Appendix C. When using EPA-approved toxicity test methods and species, analyzing the resulting data with the TST statistical approach reduces the likelihood of missing true toxicity when it occurs (false negative), and also reduces the likelihood of declaring a sample toxic when there is a biologically insignificant effect (false positive result) as compared to other hypothesis testing (i.e., NOEC). Fox et al. (2019); and CA SWRCB 2021 Staff Report, Appendix J.

The TST statistical approach is used to analyze data collected by EPA-approved toxicity testing methods to determine whether the response of test organisms in the sample water is less than a predetermined fraction (the RMD) of the control response that is considered unacceptably toxic. The RMD, including the error rates, represents the toxicity threshold beyond which there are unacceptable risks to aquatic life. Incorporating the RMD in the hypothesis equation accounts for the inherent variability in the growth, survival and reproduction of organisms due to factors unrelated to toxicity of the sample water. US EPA 2010a TST Technical Document at 4; Staff Report at 61. The Toxicity Provisions include RMDs consistent with EPA's peer-reviewed Technical Documents and scientific literature (0.75 for chronic and 0.80 for acute toxicity). US

[11] NOEC is a statistical approach to determine the highest concentration of toxicant to which organisms are exposed that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

EPA 2010a TST Technical Document at xii; Denton et al. (2011). Using a threshold of 0.75 (i.e., 25% difference in effect) as the RMD value is also consistent with other accepted biological effect thresholds for determining short-term chronic toxicity, such as the IC_{25} (25% inhibition concentration). US EPA 2010a TST Technical Document. EPA's scientific, peer-reviewed technical documents support the use of a 25% difference in effect as a toxic threshold above which ecological effects are likely, meaning that if there is a 25% or greater difference in adverse effect on the test organisms in the sample as compared to the control, then chronic toxicity is confirmed. US EPA 1991; US EPA 2010a TST Technical Document. The 0.80 (or 20% difference in effect) threshold for identifying acute toxicity is lower (hence a smaller percent difference from the control), and thus more conservative than the 25% threshold for chronic because of the more severe environmental implications of acute toxicity (lethality).

Diamond et al. (2013) evaluated the efficacy of the same TST statistical approach compared to the NOEC approach. Analyzing thousands of data points, these authors concluded that the TST statistical approach was better at identifying toxicity and distinguishing between significant toxicity and biologically insignificant effects. US EPA 2023 Staff File Memo at 4.

For the reasons described above, EPA concludes the Toxicity Provisions identified in Enclosure A are based on sound scientific rationale consistent with 40 C.F.R. § 131.5(a)(2) and 40 C.F.R. § 131.11.

B. Definitions

Definitions are often inextricably linked to how any WQS that use the corresponding terms will operate in practice. Certain definitions from the *Appendix A Glossary* of the Toxicity Provisions, identified in Enclosure A of this document, provide context for corresponding terms used in the portions of the Toxicity Provisions that EPA has determined are part of the new WQS. EPA has context for how the definitions described in Enclosure A will be used in the future in association with these WQS and for this reason, EPA is also approving those definitions as new WQS pursuant to Section 303(c) of the Act.

C. General Policies

States may, at their discretion, include in their WQS, policies generally affecting their application and implementation, such as mixing zones, low flows and variances. Such policies are subject to EPA review and approval. 40 C.F.R. § 131.13; *see also* 40 C.F.R. § 131.6(f). California has included in Part III.C.1 of the Toxicity Provisions the authority to grant mixing zones for toxicity effluent limits derived from these WQS in accordance with Section 1.4.2 of the Policy for Implementation of Toxics Standards for Inland Surface Water, Enclosed Bays, and Estuaries of California (2005).[12] EPA is approving the mixing zone authorizing policy in Part III.C.1 of the Toxicity Provisions consistent with 40 C.F.R. § 131.13.

[12] EPA approved the mixing zone policy in this section in 2001.

IV. Endangered Species Act (ESA)

Section 7(a)(2) of the ESA states that each federal agency shall ensure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered or threatened (listed) species or result in the destruction or adverse modification of critical habitat. EPA's review of a state's WQS is subject to section 7 of the ESA. EPA reviewed the submittal has determined that this action will have no effect on listed species or their critical habitat.

V. Consultation with Indian Tribes

EPA upholds its trust responsibility to federally recognized tribal governments consistent with the "*2011 EPA Policy on Consultation and Coordination with Indian Tribes*" (https://www.epa.gov/tribal/epa-policy-consultation-and-coordination-indian-tribes). Meaningful communication and coordination with appropriate tribal leadership on a government-to-government basis prior to EPA taking actions or making decisions that may affect tribal interests is a fundamental principal of this Policy.

On October 12 and 13, 2021, EPA provided letters offering consultation to tribes whose interests may be affected by this action. This included all tribes in California and in watersheds bordering California. The Tuolumne Band of Me-Wuk Indians requested Government-to-Government Consultation by email on October 14, 2021. Despite numerous attempts to get in contact, tribal and EPA staff were unable to successfully schedule consultation. EPA concluded the consultation opportunity by letter dated February 23, 2023. No other tribes requested consultation.

VI. Conclusion

Based on EPA's review, the Water Quality Standards of California's Toxicity Provisions identified in Enclosure A of this document are consistent with the requirements of the Clean Water Act and 40 C.F.R. Part 131 and are approved pursuant to Section 303(c) of the Act.

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