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8 Attorneys for Plaintiffs  
 9 CLEAN WATER SOCAL and  
 10 CENTRAL VALLEY CLEAN WATER  
 ASSOCIATION

11 UNITED STATES DISTRICT COURT  
 12 CENTRAL DISTRICT OF CALIFORNIA

13 CLEAN WATER SOCAL and  
 14 CENTRAL VALLEY CLEAN WATER  
 ASSOCIATION,

15 Plaintiffs,

16 v.

17 UNITED STATES ENVIRONMENTAL  
 18 PROTECTION AGENCY; and TOMAS  
 19 TORRES, DIRECTOR, WATER  
 20 DIVISION of UNITED STATES  
 ENVIRONMENTAL PROTECTION  
 AGENCY, REGION IX,

21 Defendants.

Case No. 2:2023-cv-3930

**COMPLAINT FOR  
 DECLARATORY JUDGMENT  
 AND INJUNCTIVE RELIEF**

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1 Plaintiffs Clean Water SoCal and Central Valley Clean Water Association  
 2 (“CVCWA”) (“Plaintiffs”) brings this action against Defendant United States  
 3 Environmental Protection Agency; Tomas Torres, Director, Water Division, United  
 4 States Environmental Protection Agency, Region IX; and Doe Defendants 1 to 10  
 5 (collectively referred to as either “USEPA” or “Defendants”), to challenge and  
 6 invalidate USEPA’s actions that violated the Administrative Procedures Act  
 7 (“APA”), 5 U.S.C. §§ 551 and 702 *et seq.*, and statute and regulations  
 8 implementing the Federal Water Pollution Control Act (commonly known as the  
 9 “Clean Water Act” or “CWA”), 33 U.S.C. § 1251 *et seq.*, and 40 C.F.R. Part 131,  
 10 and allege as follows:

### 11 I. INTRODUCTION

12 1. A full understanding of this case requires some history. In June of 2010,  
 13 the United States Environmental Protection Agency (“USEPA”) issued a new  
 14 guidance document discussing a new methodology for determining Whole Effluent  
 15 Toxicity (“WET”) tests, known as the Test of Significant Toxicity (“TST”). Not only  
 16 is this guidance non-binding by definition, but the TST Guidance document itself  
 17 explicitly included a disclaimer that stated that the guidance document “cannot  
 18 impose any legally binding requirements on EPA, states, NPDES<sup>1</sup> permittees, or  
 19 laboratories conducting or using WET testing for permittees” and “nor is this  
 20 document a permit or regulation itself.”

21 2. Notwithstanding this clear disclaimer, on March 17, 2014, USEPA has  
 22 urged use of the TST in regulatory contexts and, to enhance that ability, approved a  
 23 request from California’s water quality agency, the State Water Resources Control  
 24 Board (“State Water Board”), to use the 2010 TST Guidance method for conducting  
 25 chronic WET tests, urging a two-concentration TST approach instead of the  
 26

27 <sup>1</sup> This acronym stands for National Pollutant Discharge Elimination System  
 28 (NPDES). *See* 33 U.S.C. § 1342.

1 promulgated five-concentration dose-response review method, as a “limited use”  
2 Alternate Test Procedure (“ATP”) under 40 C.F.R. section 136.5.

3 3. USEPA’s March 17, 2014 action effectively promulgated a new ATP or  
4 a new method modification in contravention of federal law and regulations.  
5 Furthermore, USEPA’s March 17, 2014 action impermissibly exceeded USEPA’s  
6 authority by mandating the statewide use of the two-concentration TST in all new or  
7 revised National Pollutant Discharge Elimination System (“NPDES”) permits issued  
8 by the State Water Board and Regional Water Quality Control Boards and in any  
9 EPA-issued California permits that include WET provisions, for both inland and  
10 ocean dischargers. This mandate effectively overruled promulgated federal and state  
11 regulations, including, but not limited to, Water Quality Control Plans, such as the  
12 California Ocean Plan and regional Basin Plans.

13 4. Neither USEPA nor the State Water Board had the authority to impose  
14 or mandate the use of this two-concentration TST until that method has been  
15 promulgated by EPA as an approved method under federal regulations at 40 C.F.R.  
16 Part 136. Analytical results obtained by using a non-promulgated method cannot be  
17 used for monitoring or NPDES permit compliance determination purposes until that  
18 method has been properly approved under and incorporated into 40 C.F.R. Part 136.  
19 *See, e.g.*, 40 C.F.R. § 122.41(j)(4); § 122.44(i)(1)(iv).

20 5. For these reasons, USEPA’s March 17, 2014 final agency action was  
21 judicially challenged. As a result, USEPA withdrew its March 17, 2014 ATP  
22 approval on February 11, 2015, effective immediately, prior to any ruling on the  
23 merits in the litigation.

24 6. Under the Clean Water Act, states must adopt water quality standards  
25 and submit them for approval by USEPA. 33 U.S.C. § 1313(2)(B); 40 C.F.R. § 131.6.  
26 USEPA must approve the new standards within sixty (60) days, or shall disapprove  
27 “not later than the ninetieth day after the date of submission of such standards” 33  
28 U.S.C. § 1313(c)(3). Once approved by USEPA, the state water quality standards

1 become effective and applicable under the CWA. 40 C.F.R. § 131.21(c). “Such  
2 standards serve the dual purpose of establishing the water quality goals for a specific  
3 water body and serve as the regulatory basis for establishment of water-quality-based  
4 treatment controls and strategies beyond the technology-based levels of treatment”  
5 required by the CWA. 40 C.F.R. § 131.2.

6 7. On December 1, 2020 (and as subsequently revised and readopted on  
7 October 5, 2021), the State Water Board adopted new toxicity water quality standards  
8 and related implementation provisions called the “State Policy for Water Quality  
9 Control: Toxicity Provisions” (the “Toxicity Provisions”). The Toxicity Provisions’  
10 new numeric WET water quality standards are based on the TST even though in over  
11 a decade USEPA has never formally promulgated the TST as part of the approved  
12 Part 136 methods. USEPA reviewed the Toxicity Provisions since their adoption in  
13 2021 despite a statutory requirement to make an approval/disapproval decision  
14 within sixty (60) or ninety (90) days respectively. 33 U.S.C. § 1313(c)(3); 40 C.F.R.  
15 § 131.21(a)(1)-(2).

16 8. On or about May 1, 2023, USEPA finally issued an approval decision  
17 on the water quality standards portion of the Toxicity Provisions, which then became  
18 effective for federal law purposes and useable as water quality standards and effluent  
19 limitations in NPDES permits. Petitioners seek declaratory relief as to the legality of  
20 USEPA’s final agency action to approve the Provision’s water quality standards, as  
21 well as injunctive relief to maintain the status quo pending a final decision on the  
22 merits in this case.

23 9. USEPA’s May 1, 2023 document, “Approval of New Water Quality  
24 Standards: California State Policy for Water Quality Control: Toxicity Provisions,”  
25 was issued despite being outside the statutory and regulatory decision-making  
26 windows of sixty or ninety days. Because of the extended length of USEPA’s delay,  
27 Plaintiffs’ counsel asked USEPA to defer any action a bit longer until after a state  
28 court challenge to the Toxicity Provisions could be heard on the merits on June 23,

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1 2023, less than 2 months after the USEPA final agency action was issued, to  
2 potentially avoid this federal litigation.

3 10. The Toxicity Provisions were not in effect for federal law purposes until  
4 USEPA approved them, which warrants an injunction since USEPA’s May 1, 2023  
5 approval was the final step in making the Toxicity Provisions fully effective.  
6 USEPA’s approval action failed to comply with the law and exceeded its statutory  
7 authority in improperly approving the toxicity water quality standards contained in  
8 the State Water Board’s Toxicity Provisions that mandate the use of the TST to  
9 determine compliance with toxicity water quality standards in all applicable  
10 waterbodies and through all relevant NPDES permits. A true and correct copy of  
11 USEPA’s May 1, 2023 approval letter is attached as **Exhibit A**.

12 11. Plaintiffs are trade associations with member agencies that own and  
13 operate wastewater treatment plants and water reclamation plants, often called  
14 Publicly Owned Treatment Works (“POTWs”), which are designed to collect and  
15 treat municipal and industrial wastewater. Many of Plaintiffs’ members operate  
16 pursuant to NPDES permits issued by the State Water Board, Regional Water Quality  
17 Control Boards, or USEPA that include chronic toxicity testing and compliance  
18 provisions.

19 12. Plaintiffs’ members are either currently or now imminently subject to  
20 the unjustifiably onerous impacts of the TST, a test procedure that relies upon a  
21 default statistical inference known as a “null hypothesis.” Under USEPA’s  
22 promulgated Part 136 toxicity test methods, the null hypothesis presumes all water is  
23 *not toxic* unless proven otherwise; similar to the legal presumption of innocence. The  
24 null hypothesis under the TST turns that normal presumption on its head by  
25 presuming water *is toxic* unless proven not to be so, which is highly problematic  
26 when applied in a strict liability context such as under the CWA. 33 U.S.C. §§ 1251,  
27 *et seq.*

28 13. USEPA’s failure to comply with the law, as set forth herein, subjects

1 that federal agency's actions to judicial review under the APA. In this case, Plaintiffs  
2 seek a declaration that USEPA acted contrary to the mandates of the APA, the CWA,  
3 and the regulations implementing the CWA, and exceeded its statutory authority. As  
4 a result, USEPA's actions must be declared unlawful and void. 28 U.S.C. § 2201;  
5 Fed. R. Civ. P. 57. Plaintiffs further seek a temporary restraining order, and  
6 preliminary and permanent injunctive relief to maintain the status quo pending  
7 adjudication, and to forestall irreparable injury to Plaintiffs' members and others in  
8 the meantime. 28 U.S.C. § 2202; Fed. R. Civ. P. 65.

## 9 II. JURISDICTION AND VENUE

10 14. This Court has jurisdiction over the subject matter of this final agency  
11 action pursuant to 28 U.S.C. section 1331 (federal question jurisdiction), section  
12 1346 (United States as a Defendant), section 2201 (authorizing declaratory relief),  
13 section 2202 (authorizing injunctive relief), and pursuant to 5 U.S.C. section 702  
14 (providing for judicial review of agency action under the APA).

15 15. Plaintiffs have standing to bring this suit on behalf of their members  
16 because at least one of their members would have standing to sue in its own right;  
17 the interests Plaintiffs seek to protect are germane to their purposes; and neither the  
18 claim asserted nor the relief requested requires an individual member to participate  
19 in this suit. *See Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497,  
20 507 (D.C. Cir. 2010).

21 16. Defendants have waived sovereign immunity pursuant to provisions of  
22 the APA, 5 U.S.C. sections 701-706.

23 17. Venue is proper in this Court under 28 U.S.C. section 1391(e) because  
24 this case represents an action against an agency of the United States; Plaintiff Clean  
25 Water SoCal maintains its principal place of business in this judicial district; and a  
26 substantial part of the events to implement the Toxicity Provisions at issue in this  
27 case will occur in this district.  
28

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**III. PARTIES**

18. Clean Water SoCal is a non-profit corporation organized to help ensure that regulations affecting POTWs and collection systems are reasonable, lawful, and in the public’s best interest. Clean Water SoCal provides leadership, technical assistance, and timely information to its members in order to promote regulations and regulatory programs that focus on the sustainable protection of the environment and public health, and acts to represent and advocate for the interests of its members on issues of importance where, as here, federal and state agencies veer from the requirements set forth in laws and regulations.

19. CVCWA is a non-profit industry trade association representing municipalities and other public entities located within the Central Valley region that provide wastewater collection, treatment, and water recycling services to millions of Central Valley residents and businesses. CVCWA participates in litigation where, as here, topics of import to the CVCWA membership are raised.

20. Defendant USEPA is the United States agency primarily responsible for the implementation of the Clean Water Act and for oversight of its regional offices, including USEPA Region IX, and the states acting or exercising permitting authority granted under the CWA. Defendant USEPA is also an agency of the United States charged with certain responsibilities under the APA.

21. Defendant Tomas Torres is the Water Division Director of USEPA Region IX of the USEPA and is signatory of the challenged May 1, 2023 water quality standards approval action. Mr. Torres is sued in his official capacity.

**IV. LEGAL BACKGROUND**

22. The CWA created a method for adopting water quality standards and a system for permitting wastewater discharges through the NPDES program that maintain such water quality standards. Under CWA sections 301 and 402, all facilities which discharge pollutants from any point source into waters of the United States are required to obtain an NPDES permit. Effluent limitations serve as the

1 primary mechanism in NPDES permits for controlling discharges of pollutants from  
2 point sources to receiving waters. Water quality standards are used as the basis for  
3 deriving the specific water quality-based effluent limitations in NPDES permits that  
4 supplement technology-based standards. 40 C.F.R. § 122.44(d); § 131.2.

5 23. USEPA is required to review and to approve or disapprove state-adopted  
6 water quality standards under the CWA. Under CWA section 303(c), “a water quality  
7 standard . . . consist[s] of the designated uses of the navigable waters involved and  
8 the water quality criteria for such waters based upon such uses. 33 U.S.C. §  
9 1313(c)(2)(A) (emphasis added). Generally, “uses” are the types of activities for  
10 which the water can be used (e.g., recreation, aquatic life), and “criteria” are the  
11 numeric or narrative water quality levels necessary to support the water’s designated  
12 uses. Numeric criteria are expressed as specific concentrations of individual  
13 pollutants (e.g., no more than 5 mg/l pollutant X). Narrative criteria (e.g., no toxics  
14 in toxic amounts) are the catch-all of water quality regulation, expressed as narrative  
15 statements describing a desired water quality goal.

16 24. Within the NPDES program, freshwater and marine acute and chronic  
17 whole effluent toxicity tests are used in conjunction with other chemical analyses to  
18 evaluate and assess the compliance of wastewater discharges and surface waters with  
19 water quality standards under the CWA.

20 25. “Whole effluent toxicity” or “WET” is a term used to describe the  
21 aggregate toxic effect of an aqueous sample (e.g., whole effluent wastewater  
22 discharge) as measured by a laboratory organism’s response upon exposure to the  
23 sample, including lethality or death (acute toxicity), or impaired growth or reduced  
24 reproduction (chronic toxicity). WET tests are designed to replicate the total effect  
25 and environmental exposure of aquatic life to toxic pollutants in an effluent without  
26 initially identifying the specific pollutants causing toxicity. Since WET is not a  
27 pollutant, more in-depth analyses, known as Toxicity Identification Evaluations  
28 (“TIEs”) and Toxicity Reduction Evaluations (“TREs”), are performed if toxicity is

1 detected in order to determine what pollutant or pollutants are likely causing the  
2 toxicity effect. Then, the pollutant(s) actually causing toxicity can be controlled.

3 26. Chronic toxicity testing is meant to assess *long-term* impacts to  
4 biological communities of organisms in the ambient receiving waters, not the impact  
5 of a single day's discharge. *See accord* 40 C.F.R. § 131.38(b)(l), fn. d. Acute toxicity  
6 is meant to assess short-term impacts on survival of aquatic organisms.

7 27. CWA Section 304(h) requires USEPA to “promulgate guidelines  
8 establishing test procedures for the analysis of pollutants that shall include the factors  
9 which must be provided in any certification pursuant to section 401 of [the CWA] or  
10 permit application pursuant to section 402 of [the CWA].” 33 U.S.C. § 1314(h).

11 28. USEPA regulations at 40 C.F.R. Part 136 prescribe the specific test  
12 procedures and methods that must be used for the analysis of pollutants in all  
13 applications and reports submitted under the NPDES program under section 402 of  
14 the CWA, as well as State certifications pursuant to section 401 of the CWA. 40  
15 C.F.R. §§ 136.1(a), 136.3; *see, e.g.*, 40 C.F.R. § 122.44(i)(iv) (monitoring to be done  
16 according to test procedures approved under 40 C.F.R. Part 136).

17 29. Under limited circumstances and subject to specific regulatory  
18 requirements, a person may request to use an Alternative Test Procedure (“ATP”)  
19 not previously approved and formally promulgated by USEPA. 40 C.F.R. § 136.3(a).  
20 The ATP process was designed to “encourage organizations *external to EPA* to  
21 develop and submit for approval new analytical methods.” *See Guide to Method*  
22 *Flexibility and Approval of EPA Water Methods*, USEPA Office of Water (Dec.  
23 1996) at p. 77. USEPA regulations at sections 136.4 and 136.5 describe the specific  
24 procedures and requirements for obtaining USEPA review and approval of ATPs. 40  
25 C.F.R. §§ 136.4, 136.5.

26 30. Under 40 C.F.R. section 136.6, a person may make limited minor  
27 modifications to an approved testing method included in 40 C.F.R. Part 136.3 without  
28 prior USEPA approval, including for example, changing purge volumes and

1 automating manual methods. However, changes to the determinative step, the quality  
2 control, or significant chemistry of the method, are outside the scope of modifications  
3 authorized by section 136.6. Additionally, the Method Modification approach under  
4 section 136.6 applies only to CWA chemical methods and cannot be used for  
5 “Method-Defined Analytes.” Specifically, USEPA regulations prohibit  
6 modifications of WET methods. 40 C.F.R. § 136.6(b)(3) (“Restrictions. An analyst  
7 may not modify an approved Clean Water Act analytical method for a method-  
8 defined analyte.”) (emphasis added). Whole effluent toxicity methods are *not*  
9 *chemical methods* and USEPA has previously declared that WET is a Method-  
10 Defined Analyte. *See* 67 Fed. Reg. 69,965 (“toxicity is inherently defined by the  
11 measurement system (a ‘method-defined analyte’) and toxicity cannot be  
12 independently measured apart from a toxicity test.”).

13 31. In November of 2002, USEPA promulgated in the Federal Register  
14 through a formal rulemaking process short-term chronic WET test methods for use  
15 in monitoring compliance with NPDES permit limitations in accordance with 40  
16 C.F.R. Part 136. *See* Guidelines Establishing Test Procedures for the Analysis of  
17 Pollutants; Whole Effluent Toxicity Test Methods; Final Rule, 67 Fed. Reg. 69,952  
18 (Nov. 19, 2002) (the “2002 Rule”). These methods specifically include two  
19 endpoints: the No-Observed-Effect-Concentration (“NOEC”) and the 25% Inhibition  
20 Concentration (“IC25”). The 2002 Rule incorporated by reference USEPA’s WET  
21 methods documents (namely USEPA, Short-term Methods for Estimating the  
22 Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA–  
23 821–R–02–013. Fourth Edition, October 2002; “2002 Methods”). 40 C.F.R. §  
24 136.3(a), Table IA, fn 26. Where the rule’s 2002 Methods allow hypothesis testing,  
25 a null hypothesis is specified that presumes an effluent sample is non-toxic, and  
26 requires testing to determine compliance with an NPDES effluent limitation  
27 consisting of a control group and a minimum of five effluent concentrations in order  
28 to evaluate the validity of the dose-response relationship. *See* 2002 Rule, 67 Fed.

1 Reg. 69,962-63. The 2002 Methods also specify the four allowable types of statistics  
2 that can be used, and do not mention the TST or provide that the TST may be used  
3 as part of an approved method. In addition, the USEPA in the 2002 Rule and 2002  
4 Methods specifically “recommends the use of point estimation techniques over  
5 hypothesis testing approaches for calculating endpoints for effluent toxicity testing.”  
6 *Id.* at 69,958.

7 32. In June of 2010, USEPA issued a guidance document regarding a  
8 potential new supplemental statistical method for use in WET testing called the TST.  
9 *See* National Pollutant Discharge Elimination System Test of Significant Toxicity  
10 Implementation Document, EPA 833-R-10-003 (June 2010). The TST procedure is  
11 designed for the toxicity test to be performed on test organisms using two test  
12 concentrations: a control group and an effluent-exposed group. The TST statistical  
13 method was merely confined to a guidance document, which was not promulgated  
14 through notice and comment rulemaking and which includes an explicit disclaimer  
15 in that guidance document specifically confirming that the document is not “a permit  
16 or a regulation itself.” In fact, that guidance document stated:

17  
18 The document does not and cannot impose any legally binding  
19 requirements on EPA, states, NPDES permittees, or laboratories  
20 conducting or using WET testing for permittees (or for states in  
21 evaluating ambient water quality). EPA could revise this document  
22 without public notice to reflect changes in EPA policy and guidance.

23 33. In 2012, USEPA amended the whole effluent toxicity test methods in its  
24 modifications to the Promulgated Guidelines Establishing Test Procedures for the  
25 Analysis of Pollutants under the Clean Water Act: Analysis and Sampling  
26 Procedures. Final Rule, 77 Fed. Reg. 29758 (May 18, 2012). These amendments did  
27 *not* incorporate the TST, even though the TST approach had been available as  
28 guidance for nearly two years. Several other amendments to the Part 136 methods  
were made over the next decade, yet none included the TST.

## V. FACTUAL BACKGROUND

1  
2 34. USEPA Region IX has been urging the State of California to utilize the  
3 TST approach in NPDES permits over the past decade or longer. Permit holders have  
4 objected to the use of the TST approach since this approach is based solely on  
5 informal guidance documents, not on any formally promulgated and publicly vetted  
6 rule, and using pass/fail bioequivalence methods never before used in compliance  
7 determinations under the Clean Water Act.

8 35. In order to overcome stakeholder objections, on February 12, 2014, the  
9 State Water Board requested USEPA Region IX approval of “a two-concentration  
10 test design when using the Test of Significant Toxicity (TST) hypothesis testing  
11 approach” “[p]ursuant to Code of Federal Regulations, title 40, section 136.4.” On  
12 March 17, 2014, USEPA Region IX, in turn and in record time, approved a statewide,  
13 limited use ATP under 40 C.F.R. Part 136.5. *See* EPA ATP Approval Letter from  
14 Eugenia McNaughton, Ph.D. to Renee Spear, SWRCB (March 17, 2014).

15 36. USEPA Region IX went beyond approving the limited use ATP request  
16 to apparently *mandating* the use of the two-concentration TST, stating that “it will  
17 apply to all new or revised NPDES permits issued by the State Water Board and  
18 Regional Water Quality Control Boards and any EPA-issued California permits that  
19 include whole effluent toxicity provisions.” *See* USEPA ATP Approval Letter from  
20 Eugenia McNaughton, Ph.D. to Renee Spear, SWRCB (March 17, 2014) (emphasis  
21 added). Further, USEPA applied this ATP to non-ocean and ocean waters, even  
22 though application to ocean waters was not requested by the State Water Board in its  
23 ATP request.

24 37. This action was challenged in federal court by Clean Water SoCal’s  
25 predecessor organization. As a result, USEPA withdrew its ATP approval document.  
26 However, USEPA continued to encourage use of the TST in permitting and water  
27 quality standards by California’s Water Boards, which have delegated authority to  
28 regulate under the CWA subject to USEPA oversight.

1           38. The State Water Board adopted its Toxicity Provisions initially on  
2 December 1, 2020. Those Toxicity Provisions were revoked and superseded by the  
3 State Water Board and were ultimately approved by the State Water Board a year and  
4 a half ago, on October 5, 2021, and were submitted to USEPA for approval soon  
5 thereafter. The Toxicity Provisions became effective for state law purposes on April  
6 25, 2022, but were not effective under federal law until approved by USEPA on May  
7 1, 2023.

8           39. Clean Water SoCal, along with other petitioners/plaintiffs, challenged  
9 the Toxicity Provisions under the State Water Code, Government Code, and  
10 California Environmental Quality Act (“CEQA”) in state court with a hearing on the  
11 petition for writ of mandate set for June 23, 2023. Plaintiffs’ counsel was in contact  
12 with USEPA’s counsel on a regular basis, asking that USEPA wait to act on the  
13 approval or disapproval of the Toxicity Provisions’ water quality standards until after  
14 the state court ruled on the legality under state law. Despite the extensive review  
15 period already undertaken, far longer than authorized by statute, USEPA failed to  
16 agree with Plaintiffs’ counsel’s request to wait a bit longer and issued an approval  
17 letter on May 1, 2023, less than two months before a merits hearing on the  
18 petitioners/plaintiffs’ state petitions for writ of mandate and complaint.

## 19           **VI. LEGAL ISSUES WITH REQUIREMENTS BASED ON THE TST**

### 20           **A. The Approved Toxicity Provisions Unlawfully Modify USEPA’s** 21 **Promulgated Methods.**

22           40. Whole Effluent Toxicity (WET) test procedures were promulgated and  
23 approved as standardized test methods by EPA in 2002 as required by Section 1314  
24 of the Clean Water Act. 67 Fed. Reg. 69,952 (Nov. 19, 2002). The actual test  
25 procedures are described in a series of method manuals. *Id.* at p. 69,971. These  
26 manuals, and the related procedures for each WET test method, are now specified by  
27 rule at 40 C.F.R. § 136.3, Table 1A, No. 10, which as shown below specifies only the  
28 endpoints of “NOEC or IC25, percent effluent” for chronic toxicity; not Pass/Fail

1 units using TST. Similarly, Table IA, No. 8. excerpted below, only specifies  
 2 “Toxicity, acute, fresh water organisms, LC50, percent effluent”; not TST.

3 Table IA—List of Approved Biological Methods for Wastewater and Sewage Sludge

4 Parameter and units	5 Method <sup>1</sup>	6 EPA	7 Standard methods	8 AOAC, ASTM, USGS	9 Other
10 Aquatic Toxicity					
11 8. Toxicity, acute, fresh water organisms, LC <sub>50</sub> , percent effluent	12 Water flea, Cladoceran, <i>Ceriodaphnia dubia</i> acute	13 2002.0 <sup>25</sup>			
14 10. Toxicity, chronic, fresh water organisms, NOEC or IC <sub>25</sub> , percent effluent	15 Fish, Fathead minnow, <i>Pimephales promelas</i> , larval survival and growth	16 1000.0 <sup>26</sup>			

17 <sup>25</sup> Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, EPA-821-R-02-012. Fifth Edition, October 2002. U.S. EPA; and U.S. EPA Whole Effluent Toxicity Methods Errata Sheet, EPA 821-R-02-012-ES. December 2016.

18 <sup>26</sup> Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA-821-R-02-013. Fourth Edition, October 2002. U.S. EPA; and U.S. EPA Whole Effluent Toxicity Methods Errata Sheet, EPA 821-R-02-012-ES. December 2016.

21 41. According to USEPA, the TST represents “an alternative statistical  
 22 approach for analyzing and interpreting valid WET data.” USEPA, National  
 23 Pollutant Discharge Elimination System Test of Significant Toxicity Technical  
 24 Document, EPA-833-R-10-004 (June, 2010) p . 60. Consequently, the TST provides  
 25 a new and different determinative technique for the way in which the analyte toxicity  
 26 is identified and quantified. For method-defined analytes, the statistical technique  
 27 used to determine the presence or absence of toxicity is part of the method. Any  
 28 change to these techniques constitutes an impermissible modification to the approved

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1 method. Such modifications can only be authorized through a formal USEPA  
2 rulemaking process like the one used to promulgate the original WET test methods.  
3 33 U.S.C. § 1314(h); 40 C.F.R. § 136.4.

4 42. The State Water Board in the administrative record for the Toxicity  
5 Provisions acknowledged that “for a small number of tests, the TST approach may  
6 determine a different outcome than other statistical approaches.” Toxicity Provisions,  
7 2021 Staff Report at 181. If there were no difference in outcome, then there would  
8 be no reason to use or approve the TST in lieu of the promulgated statistical methods.  
9 However, the number of times the TST reaches a different outcome is not “small.”  
10 In fact, data from the State Board’s “Test Drive” study showed that the TST came to  
11 a different conclusion in about 8% of all *Ceriodaphnia dubia* reproduction tests (the  
12 single most common species used to evaluate wastewater discharges to freshwater  
13 streams in California). In these tests, the TST was nearly twice as likely to label the  
14 sample “toxic” compared to the NOEC endpoint. Moreover, the TST is three times  
15 more likely to label the sample as “toxic” compared to the IC-25 procedure that  
16 EPA’s 2002 Methods manual states is the preferred approach for NPDES permitting.  
17 See 2002 Methods at p. 41, section 9.5.1 (Attachment 2). Such discrepancies  
18 demonstrate that the TST does not qualify as a “sound scientific rationale” or a  
19 “scientifically defensible method” since the TST does not provide performance  
20 equivalent to that of USEPA’s promulgated methods and cannot be used to set water  
21 quality standards or assess compliance with NPDES permit limits pertaining to  
22 toxicity.

23 43. The TST statistical hypothesis test consistently “detects” the existence  
24 of toxicity more frequently than the NOEC statistical hypothesis test, especially for  
25 freshwater test species. See State Water Board, *Effluent, Stormwater and Ambient*  
26 *Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST)* (“State Board  
27 Test Drive”) (Dec., 2011) (see, e.g., Chronic Freshwater results in Table E-1).  
28

1 However, one should not assume that greater statistical *sensitivity* equates with  
2 improved *accuracy* in WET testing.

3 44. Reanalysis of data from USEPA’s inter-laboratory WET variability  
4 study indicates that the TST statistical hypothesis test also “detects” toxicity in clean  
5 blank samples at a rate up to three times higher than the NOEC statistical test. USEPA,  
6 *Final Report: Interlaboratory Variability Study of EPA Short-term Chronic and*  
7 *Acute Whole Effluent Toxicity Test Methods*, Vol. 1; EPA-821-B-01-004 (Sept.,  
8 2001). Blank samples are those comprised solely of laboratory dilution water that is  
9 known to be non-toxic before the test begins. Such inaccuracies demonstrate that the  
10 TST does not provide performance “acceptably equivalent” to that of the standard  
11 methods that were promulgated in 40 C.F.R. Part 136 in the 2002 Methods.

12 45. Federal courts have held that where USEPA utilizes a guidance  
13 document to compel regulated parties to “enhance the monitoring required in  
14 individual permits beyond that contained in State or federal emission standards even  
15 when those standards demand some sort of periodic testing, EPA has in effect  
16 amended [the regulation.] This it cannot legally do without complying with the  
17 rulemaking procedures . . .” *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028  
18 (D.C. Cir. 2000; *see also Iowa League of Cities v. EPA*, 711 F.3d 844, 876 (8th Cir.  
19 2013); *Nat’l Min. Ass’n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (“An  
20 agency action that purports to impose legally binding obligations or prohibitions on  
21 regulated parties—and that would be the basis for an enforcement action for  
22 violations of those obligations or requirements—is a legislative rule.”).)

23 46. The approved 2002 Methods also clearly require a multi-concentration  
24 test design with dose-response evaluation. The 2002 Methods manual states:

25 The tests recommended for use in determining discharge permit  
26 compliance in the NPDES program are multi-concentration, or  
27 definitive, tests which provide (1) a point estimate of effluent toxicity in  
28 terms of an IC25, IC50, or LC50, or (2) a no-observed-effect-

1 concentration (NOEC) defined in terms of mortality, growth,  
2 reproduction, and/or teratogenicity and obtained by hypothesis testing;

3 The concentration-response relationship generated for each multi-  
4 concentration test must be reviewed to ensure that calculated test results  
5 are interpreted appropriately; and

6 “Tables 1, 3, and 4 (labeled as 3) - SUMMARY OF TEST  
7 CONDITIONS AND TEST ACCEPTABILITY CRITERIA WITH  
8 EFFLUENTS AND RECEIVING WATERS (TEST METHODS  
9 1000.0, 1002.0, AND 1003.0): Test concentrations: Effluents: 5 and a  
10 control (required minimum).”

11 *See* 2002 Methods manual at pp. 36, 50, Sections 8.10.1, 10.2.6.2 (all emphasis  
12 added). In addition, the 2002 Manual also makes clear that consideration of PMSD  
13 is a required element of the procedure by stating:

14 When NPDES permits require sublethal hypothesis testing endpoints  
15 from Methods 1000.0, 1002.0, or 1003.0 (e.g., growth or reproduction  
16 NOECs and LOECs), within-test variability must be reviewed and  
17 variability criteria must be applied as described in this section.

18 (*Id.* at Section 10.2.8.2) (emphasis added).

19 47. For the purposes of evaluating within-test variability, the approved  
20 2002 Methods consistently rely on use of the PMSD as a tool. A higher PMSD is  
21 equivalent to greater within-test variability while a lower PMSD indicates lower  
22 within-test variability. The 2002 Manual describes mandatory criteria using the  
23 PMSD for interpreting and validating sublethal hypothesis test results using the  
24 PMSD metric. *See* 2002 Manual at p. 51 (Section 10.2.8.2, 10.2.8.2.1) (“To measure  
25 test variability, calculate the percent minimum significant difference (PMSD)  
26 achieved in the test.”). As quoted above, the approved 2002 Methods require review  
27 of the PMSD for any NPDES chronic toxicity hypothesis tests. The TST is a form  
28 of hypothesis test conducted on a chronic/sublethal endpoint (albeit one not  
authorized by the 2002 Manual), and is not subject to the PMSD criteria described

1 in the 2002 Manual.

2 48. In fact, the Toxicity Provisions do not reference or use the PMSD  
3 criteria and ignore the mandated steps for quality assurance in the 2002 Manual. The  
4 Toxicity Provisions provide no authority for, or even guidance documents  
5 recommending, exclusion of the use of PMSD criteria. Thus, USEPA's approval of  
6 these revised water quality standards contrary to the mandated test methods are  
7 inconsistent and contradictory to specific requirements contained in the approved  
8 Part 136 methods, and reduce the reliability of the test result.

9 49. USEPA has had ample opportunity to approve the TST in its Part 136  
10 regulations, including in its most recent rulemakings, but has not done so. *See U.S.*  
11 *v. Riverside Bayview Homes*, 474 U.S. 121, 137 (1985) (An action not to include  
12 modifications of which the entity was aware can be read as a presumption that the  
13 modifications were not intended to be included). In fact, although USEPA recently  
14 proposed amendments to the Part 136 methods, including specific changes to the  
15 2002 Methods, the TST was not included. *See, e.g.*, Federal Register Notice,  
16 <http://www.govinfo.gov/content/pkg/FR-2019-10-22/pdf/2019-223437.pdf> (Oct.  
17 22, 2019). Numerous amendments to Part 136 have occurred since 2010, and none  
18 have included the TST. If USEPA truly believed that the TST was a more effective  
19 and worthy test method, then the TST would or should have been proposed for  
20 inclusion into the promulgated regulations for use nationwide.

21 **B. The Toxicity Provisions' Unauthorized Null Hypothesis Deems All**  
22 **Water "Toxic."**

23 50. Current law presumes that a water sample (either from a river/creek/bay  
24 or from a discharge) is *not toxic* until proven to be toxic as set forth in the  
25 promulgated methods. The approved Toxicity Provisions flip that presumption on its  
26 head. Under the Toxicity Provisions, all tested water in reservoirs, bays, and rivers,  
27 and from all wastewater, recycled, and storm water discharges to receiving waters  
28 will be initially *presumed to be toxic*. This is 180 degrees opposite of the USEPA

1 rule requirements, and contrary to law. The current “objective of aquatic toxicity tests  
2 with effluents or pure compounds is to estimate the ‘safe’ or ‘no effect’ concentration  
3 of these substances, which is defined as the concentration which will permit normal  
4 propagation of fish and other aquatic life in the receiving waters.” *See* USEPA, 2002  
5 Methods at Section 2.1.1 and 9 .1.1.

6 51. Flipping the hypothesis also flips the error percentage. The 2002  
7 Methods determined a 5% alpha error rate (non-toxic water declared toxic), but did  
8 not specifically define a potentially higher beta error rate (toxic water not declared  
9 toxic), but this rate has been recognized to be “up to 20%.”<sup>2</sup> Under the Toxicity  
10 Provisions, the beta error rate of up to 20% flips to become the alpha error rate, which  
11 creates more potential liability for dischargers (from false “Failures”). This “guilty  
12 until proven innocent” approach, and statistical guarantee to be in violation up to 20%  
13 percent of the time (if not more depending on test species used), when it is undeniable  
14 that proving a negative is difficult if not impossible, should not have been approved  
15 by USEPA. This would be the equivalent of deeming everyone to be a criminal until  
16 proven otherwise. No United States law authorizes such a presumption, particularly  
17 under a strict liability statute such as the CWA that ascribes civil and criminal  
18 penalties and even potentially jail time for violations that at least one fifth of the time  
19 could be wrong. This equates to giving ten men pregnancy tests and 2 of the tests  
20 claim the men are pregnant.

21 **C. The Toxicity Provisions Allow Unauthorized “Pass/Fail” Hypothesis**  
22 **Endpoint.**

23 52. As shown in Table IA copied above, USEPA rules for hypothesis testing  
24 prescribe specific test endpoints (e.g., NOEC/LOEC). 40 C.F.R. § 136.3; 2002  
25

26 <sup>2</sup> *Edison Electric v. EPA*, 391 F.3d 1267, 1272 (D.C. Cir. 2004). In a legal challenge  
27 to the 2002 Methods, the court found that “[t]he ratified WET tests are not without  
28 their flaws”<sup>4</sup> and cautioned that “[e]ven by EPA’s calculations, WET tests will be  
wrong some of the time.”

1 Methods at section 9.3.1.1 (“When hypothesis tests are used to analyze toxicity test  
 2 data, it is not possible to express precision in terms of a commonly used statistic. The  
 3 results of the test are given in terms of two endpoints, the No-Observed- Effect  
 4 Concentration (NOEC) and the Lowest-Observed-Effect Concentration (LOEC).”) The Toxicity Provisions include a *new* test endpoint of **Pass/Fail** despite USEPA  
 5 discouraging the use of pass/fail. The 2002 Methods incorporated into 40 C.F.R. Part  
 6 136 state the following (emphasis in original):  
 7

8           2.2.3 Use of pass/fail tests consisting of a single effluent concentration  
 9 (e.g., the receiving water concentration or RWC) and a control is **not**  
 10 **recommended.**

11           53. Because Pass/Fail is not an authorized test endpoint, USEPA had no  
 12 authority to approve the Toxicity Provisions water quality standards that use a  
 13 Pass/Fail test endpoint, or approve use of Pass/Fail as an effluent limitation to  
 14 implement those standards. In fact, USEPA’s 2002 Methods express concern  
 15 that “single concentration, pass/fail, toxicity tests do not provide sufficient  
 16 concentration-response information on effluent toxicity to determine  
 17 compliance. It is the Agency’s policy that all effluent toxicity tests include a  
 18 minimum of five effluent concentrations and a control.” *See* USEPA, Whole  
 19 Effluent Toxicity: Guidelines Establishing Test Procedures for the Analysis of  
 20 Pollutants - Supplementary Information Document (SID) at pg. 28 (Oct. 2, 1995).

21           54. Because of the general unreliability and inaccuracy of these  
 22 biological tests, and the amplifying effects on the false Failure error rate  
 23 imposed by the TST method, strictly construed “Pass/Fail” water quality  
 24 standards for toxicity are inappropriate, infeasible to consistently attain or  
 25 comply with, and should not have been approved by USEPA.

26 **D. The Toxicity Provisions’ Unauthorized Statistical Approach.**

27           55. Instead of using one of Part 136’s four specified hypothesis testing  
 28 statistics, the Toxicity Provisions use the TST statistical approach, which as discussed

1 above was *not* included or incorporated by reference in USEPA’s Part 136 test  
2 methods. Relying upon the one highlighted sentence in the USEPA 2002 Methods set  
3 forth below, and ignoring the other context in the same paragraph, USEPA’s approval  
4 letter attempts to justify use of an unpromulgated statistical approach. The entire  
5 section of the 2002 Methods states the following (highlighting and underlining  
6 added):

7 9.4.1.2 The statistical methods recommended in this manual are  
8 not the only possible methods of statistical analysis. Many other  
9 methods have been proposed and considered. Certainly there are other  
10 reasonable and defensible methods of statistical analysis for this kind  
11 of toxicity data. Among alternative hypothesis tests some, like  
12 Williams’ Test, require additional assumptions, while others, like the  
13 bootstrap methods, require computer-intensive computations.  
14 Alternative point estimation approaches most probably would require  
15 the services of a statistician to determine the appropriateness of the  
16 model (goodness of fit), higher order linear or nonlinear models,  
17 confidence intervals for estimates generated by inverse regression,  
18 etc. In addition, point estimation or regression approaches would  
19 require the specification by biologists or toxicologists of some low  
20 level of adverse effect that would be deemed acceptable or safe. The  
21 statistical methods contained in this manual have been chosen because  
22 they are (1) applicable to most of the different toxicity test data sets  
23 for which they are recommended, (2) powerful statistical tests, (3)  
24 hopefully “easily” understood by nonstatisticians, and (4) amenable  
25 to use without a computer, if necessary.

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

1 9.5.1. The recommended statistical analysis of most data from chronic  
2 toxicity tests with aquatic organisms follows a decision process  
3 illustrated in the flowchart in Figure 2. An initial decision is made to  
4 use point estimation techniques (the Probit Analysis, the Spearman-  
5 Karber Method, the Trimmed Spearman-Karber Method, the  
6 Graphical Method, or Linear Interpolation Method) and/or to use  
7 hypothesis testing (Dunnett's Test, the t test with the Bonferroni  
8 adjustment, Steel's Many-one Rank Test, or the Wilcoxon Rank Sum  
9 Test with the Bonferroni adjustment). **NOTE: For the NPDES**  
10 **Permit Program, the point estimation techniques are the**  
11 **preferred statistical methods in calculating end points for effluent**  
12 **toxicity tests.** If hypothesis testing is chosen, subsequent decisions  
13 are made on the appropriate procedure for a given set of data,  
14 depending on the results of the tests of assumptions, as illustrated in  
15 the flowchart. A specific flow chart is included in the analysis section  
16 for each test.

17 57. Neither the text of the 2002 Methods, nor the related flowchart allow  
18 for the TST approach to be used in lieu of the promulgated statistical or point  
19 estimate approaches. The Toxicity Provisions also contradict the June 18, 2010  
20 USEPA Headquarters memo accompanying the TST Implementation Document,  
21 from James Hanlon, the Director of the USEPA Office of Wastewater Management,  
22 which stated: "The TST approach does not preclude the use of existing  
23 recommendations for assessing WET data provided in EPA's 1991 Water Quality-  
24 based Technical Support Document (TSD) which remain valid for use by EPA  
25 Regions and the States." The TST method was to be used for *additional* information,  
26 not a replacement to be used for water quality standards creation or for compliance  
27 determination purposes.

28 58. The 2010 USEPA guidance document, *National Pollutant Discharge  
Elimination System Test of Significant Toxicity Implementation Document*, EPA 833-  
R-10-003, introduced the TST protocol for analysis of chronic toxicity testing data.  
This guidance document made it clear in numerous places that the intent of the

1 guidance was to introduce a new method of analyzing data collected during a valid  
 2 WET analysis, not as water quality criteria guidance or for permitting (emphasis  
 3 added):

4 This document presents TST as a useful alternative data analysis approach  
 5 for valid WET test data that may be used **in addition to** the approaches  
 6 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.

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

10 59. Therefore, the Toxicity Provisions go beyond even the intent and scope  
 11 of the TST guidance, as well as lack consistency with federal law and regulations.

12 **E. Single Chronic Toxicity Tests Being Used for Water Quality Standards**

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

27 61. Instead of relying on multiple tests to prove persistent toxicity that could  
 28 realistically translate into potential instream impacts, the Toxicity Provisions set

1 water quality standards based on a single test result. Toxicity Provisions, 2021 Staff  
 2 Report at 61 (“Attainment of the water quality objective is demonstrated by  
 3 conducting toxicity testing, analyzing the data using the TST statistical approach,  
 4 and rejecting the null hypothesis.”) Since water quality standards can be and are  
 5 often incorporated into permits as receiving water limitations, a failure of the  
 6 toxicity test can be deemed an enforceable violation of the water quality standard,  
 7 even though that is discouraged by USEPA. 67 Fed. Reg. 69968. The Toxicity  
 8 Provisions’ Staff Report even acknowledges that “[a] statistically significant  
 9 difference may or may not be biologically significant.” Toxicity Provisions, 2021  
 10 Staff Report at p. 63. A water quality standard (and water-quality based effluent  
 11 limitations derived from such standards) set on a single chronic toxicity sample  
 12 result substantially increases the likelihood of violations for a false “Fail” result,  
 13 which is anticipated to occur statistically at least 5%-20% of the time, and with  
 14 certain test species such as *Ceriodaphnia dubia* may be much higher (>50%).<sup>3</sup>  
 15 Because USEPA did not follow its own guidelines and rules when approving the  
 16 Toxicity Provisions, USEPA’s approval should be invalidated.

## 17 V. PLAINTIFFS’ CLAIMS FOR RELIEF

### 18 FIRST CLAIM FOR RELIEF

#### 19 (Declaratory Relief Pursuant to 28 U.S.C. § 2201 and Federal Rule of Civil 20 Procedure 57 – Wrongful Approval of the Toxicity Provisions in Violation of 21 the Administrative Procedures Act)

22 62. Plaintiffs refer to and incorporate by this reference all allegations set  
 23 forth in paragraphs 1 through 61 above.

24 63. The APA authorizes the Court to hold unlawful and set aside final  
 25 USEPA actions that are “arbitrary, capricious, an abuse of discretion, or otherwise

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26 <sup>3</sup> The Toxicity Provisions recognize this problem and commissioned a study to  
 27 explore the issue, but instead of waiting for the results of the study, just deferred  
 28 compliance with some of the prescribed limits. However, the water quality standards  
 themselves were not paused and became effective on USEPA’s approval.

1 not in accordance with law.” 5 U.S.C. § 706(2)(A).

2 64. USEPA’s final agency action to approve the Toxicity Provisions was  
3 made without observance of legal requirements under the CWA and federal  
4 regulations as required under APA section 706(2)(D), and were not in accordance  
5 with law within the meaning of APA section 706(2)(A). Approval of water quality  
6 standards based upon the unpromulgated TST, and that require determining  
7 compliance by use of the unpromulgated TST were beyond USEPA’s statutory  
8 jurisdiction, authority or limitations, within the meaning of APA section 706(2)(C).

9 65. USEPA’s action approving the State Water Board’s water quality  
10 standards for whole effluent toxicity based on the unpromulgated TST is contrary to  
11 law and federal regulations, including, but not limited to the APA, the CWA and  
12 federal regulations such as 40 C.F.R. sections 131.5, 136.3, 136.4-136.6.

13 66. USEPA violated the Clean Water Act by unlawfully exceeding the  
14 review window of sixty (60) days for approval. 33 U.S.C. § 1313(c)(3). USEPA also  
15 failed to confirm that the state’s objectives met the requirements of the CWA and  
16 were “based on biological monitoring or assessment methods consistent with  
17 information published pursuant to section 1314(a)(8)” of the CWA. 33 U.S.C. §  
18 1313(c)(2)(B) and § 1313(c)(3).

19 67. USEPA violated federal regulations by approving water quality  
20 standards not based on sound scientific rationale (40 C.F.R. § 131.5(a)(2)), and  
21 contrary to the requirements contained in federal regulations at 40 C.F.R. Part 131  
22 and Part 136.

23 68. USEPA violated federal regulations under Part 131 by not determining  
24 that the Toxicity Provisions’ water quality standards were attainable or met all the  
25 requirements of state law. 40 C.F.R. § 131.2 (defining water quality standards as  
26 serving the purposes of the CWA “where attainable”); § 131.5(a)(6).

27 69. USEPA violated federal regulations by approving the use of the TST as  
28 an applicable water quality standard or sampling method modification not issued in

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1 a formal rulemaking or ATP in contravention of 40 C.F.R. Part 136 and USEPA  
2 guidance, including but not limited to Part 136.6 that restricts method modifications  
3 to chemical methods and prohibits modification of method-defined analytes, such as  
4 whole effluent toxicity.

5 70. USEPA’s interpretation of the requirements of 40 C.F.R. Part 131 and  
6 Part 136, and the 2002 Methods, as allowing the use of any statistical procedure  
7 instead of those specifically delineated in the 2002 Methods, was arbitrary and  
8 capricious.

9 71. USEPA approved the use of the TST as a part of water quality standards  
10 for WET without conformity to requirements for promulgation of test methods under  
11 CWA Section 304(h) and 40 C.F.R. Part 136.

12 72. USEPA’s action was arbitrary and capricious, violated federal  
13 regulations, and works great prejudice to the regulated community, including  
14 Plaintiffs’ members. USEPA violated the APA, the CWA, and regulations  
15 implementing CWA section 304(h), and thus acted in an arbitrary and capricious  
16 manner, abused its discretion, and acted in a manner not in accordance with law, as  
17 set forth herein.

18 73. The APA authorizes the Court to hold unlawful and set aside final  
19 USEPA actions taken without observance of procedure required by law. 5 U.S.C. §  
20 706(2)(D).

21 74. An actual and substantial controversy has arisen and presently exists  
22 between Plaintiffs and USEPA regarding the validity of USEPA’s May 1, 2023 water  
23 quality standards approval letter under federal law and regulations. USEPA’s actions  
24 as described herein are unlawful and therefore invalid. Plaintiffs are informed and  
25 believe that USEPA disputes these contentions.

26 75. Because Plaintiffs have no adequate remedy at law for USEPA’s  
27 actions, and Plaintiffs’ members and other similarly situated members of the  
28 regulated community will imminently incur substantial harm as the result of

1 USEPA’s wrongdoing, a declaration is necessary to clarify the parties’ obligations  
2 and to inform the public.

3 76. Plaintiffs seek an order pursuant to 28 U.S.C. section 2201 and Federal  
4 Rule of Civil Procedure 57, declaring the USEPA action of May 1, 2023, approving  
5 of the State Water Board’s toxicity water quality standards contained in the State’s  
6 Toxicity Provisions, void.

7 **SECOND CLAIM FOR RELIEF**  
8 **(Injunctive Relief Pursuant to 28 U.S.C. § 2202 and Federal Rule of Civil**  
9 **Procedure 65 – Preliminary and Permanent Injunctive Relief)**

10 77. Plaintiffs refer to and incorporates by this reference all allegations set  
11 forth in paragraphs 1 through 76 above.

12 78. Plaintiffs seek an order pursuant to 28 U.S.C. section 2202 and Federal  
13 Rule of Civil Procedure 65 to temporarily restrain and preliminarily and permanently  
14 enjoin the effectiveness of USEPA’s water quality standards approval letter of May  
15 1, 2023 and prevent USEPA from enforcing the portions of that letter that allow the  
16 use of the TST for water quality regulation, permitting, and compliance  
17 determination purposes.

18 79. A substantial likelihood exists that Plaintiffs will succeed on the merits  
19 of the claims for the relief pled herein.

20 80. Plaintiffs’ members are likely to suffer or have already suffered  
21 irreparable injury in the absence of preliminary injunctive relief. Many of Plaintiffs’  
22 members operate POTWs pursuant to NPDES permits issued by the State Water  
23 Board, Regional Water Quality Control Boards, or USEPA that include chronic  
24 toxicity testing and compliance provisions. If the effectiveness of USEPA’s May 1,  
25 2023 letter is not enjoined, many, if not all, of Plaintiffs’ members as well as all  
26 dischargers throughout the state will be required to begin using and reporting results  
27 from an unpromulgated WET testing method that will likely adversely affect their  
28 compliance status. For example, in the Central Valley Region, several permits (for

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1 Mountain House and for the Municipal General Order covering numerous POTWs)  
2 are scheduled for adoption in June of 2023 that will modify the chronic toxicity  
3 requirements from narrative effluent limits with numeric triggers for further  
4 investigation to determine the cause of toxicity (since toxicity itself is not a pollutant),  
5 to new permit limits with more frequent monitoring requirements all based on the  
6 TST. All wastewater dischargers will eventually have their permits modified in the  
7 next five years to incorporate the new Toxicity Provisions' requirements. An  
8 injunction is needed to halt this process until a decision on the merits can be obtained.

9 81. Imposition of the TST as the mandatory WET testing method under the  
10 approved water quality standards will result in an harm to Plaintiffs' members,  
11 including increased costs to monitor more often. For example, some of Plaintiffs'  
12 members are only required to monitor annually, but under the new Toxicity  
13 Provisions, they will be required to monitor monthly instead to determine compliance  
14 with new Maximum Daily Effluent Limits ("MDELs") and Monthly Median Effluent  
15 Limitations ("MMELs") now required under the Toxicity Provisions, which for  
16 POTWs are contrary to federal regulations. 40 C.F.R. § 122.45(d)(2) (requiring  
17 "Average weekly and average monthly discharge limitations for POTWs). The  
18 Toxicity Provisions even recognized these increased obligations and costs. *See*  
19 Toxicity Provisions, 2021 Staff Report at p. 304 (Determining 9 of 13 dischargers  
20 analyzed would have an increase in laboratory resources and waste (of water and  
21 organisms), and 6 of these would have "significant changes in impacts.") In addition,  
22 in order to decrease the likelihood of a false indication of toxicity, many of Plaintiffs'  
23 members will undertake the additional replicate samples, which are necessary to  
24 reduce the statistical likelihood of being found in violation *even though the actual*  
25 *quality of the water does not change*. *See* Toxicity Provisions, 2021 Staff Report at  
26 p. 77 (addition of replicates would have resulted in these tests being declared non-  
27 toxic). Adding replicates obviously adds additional cost as well. *Id.* at p. 346.

28 82. With new water quality standards approved by USEPA, those standards

1 are then used to set water quality-based effluent limitations for industrial and POTW  
2 discharges, and to set receiving water limitations for storm water discharges by all  
3 municipalities, construction sites, and industrial discharges statewide. 33 U.S.C. §  
4 1342. These new water quality standards will also be used to determine whether  
5 waterbodies are in attainment or impaired for toxicity under CWA section 303(d),  
6 and whether Total Maximum Daily Loads (“TMDLs”) must be adopted to address  
7 these impairments. 33 U.S.C. § 1313(d)(4); Toxicity Provisions, 2021 Staff Report  
8 at 64 (“For the purposes of 305(b) assessments and 303(d) listing analyses and  
9 determining whether a water body exceeds the numeric water quality objective,  
10 statistical analysis of the water quality objectives would now be done using the TST  
11 approach.”) Thus, these water quality standards have immediate applicability,  
12 particularly for receiving water limitations that require compliance with “all  
13 applicable water quality standards” as these standards are now applicable. Once  
14 applicable, these standards can be enforced civilly or criminally by USEPA under  
15 Clean Water Act section 1319, and by the State Water Board and Regional Water  
16 Boards under the California Water Code. *See, e.g.*, 33 U.S.C. §§ 1319(b), (c) and (g);  
17 Cal. Water Code §§ 13350, 13385, 13387; *see also* Toxicity Provisions, 2021 Staff  
18 Report at p. 65 (“...it is possible that a discharger may be identified as exceeding the  
19 numeric toxicity receiving water limitation.”).

20 83. Liability is not limited to agency enforcement as third party citizen suits  
21 are authorized under the Clean Water Act, subjecting Plaintiffs’ members to federal  
22 enforcement actions and liability for civil penalties, injunctive relief, and substantial  
23 attorneys’ fees. 33 U.S.C. § 1365. Given that the source of any toxicity is unknown  
24 until determined in a future TIE and TRE, such enforcement is problematic. Further,  
25 with the likely increased frequency of false indications of toxicity in WET testing  
26 using the TST, Plaintiffs’ members will, as a result, suffer from a higher incidence  
27 of alleged noncompliance with NPDES permits, even where the toxicity indicated is  
28 not real.

1           84. Immediate injunctive relief is necessary given the fact that many of  
 2 Plaintiffs' members are in the process of obtaining new or revised NPDES permits  
 3 from the State Water Board, Regional Water Quality Control Boards, or USEPA that  
 4 include chronic toxicity testing and compliance requirements based on the Toxicity  
 5 Provisions. These permits will soon be subject to use of the TST if USEPA is not  
 6 immediately enjoined from applicability of its May 1, 2023 letter. In addition, the  
 7 newly USEPA approved standards will now begin to be used to determine  
 8 impairments in receiving waters, which may result in more waters being listed as  
 9 impaired based on the TST that were not previously listed using the promulgated  
 10 methods. Furthermore, this USEPA essentially acts as a rulemaking approving the  
 11 use of an unpromulgated test method (that also is part and parcel of the water quality  
 12 criteria) without notice and comment, which violates the APA, stifles public  
 13 participation, and harms the Plaintiffs' members as well as the public in general.

14           85. The threatened injuries outweigh any damage that an injunction may  
 15 cause the Defendant since an injunction would merely maintain the status quo that  
 16 existed prior to the issuance of the USEPA's May 1, 2023 letter over the last two  
 17 decades.

18           86. An order enjoining USEPA from enforcing an unlawful mandate is  
 19 consistent with and serves the public interest.

20           87. Because Plaintiffs have no adequate remedy at law for USEPA's  
 21 actions, and because Plaintiffs' members have or will imminently incur substantial  
 22 harm as the result of USEPA's wrongdoing, a temporary restraining order, and  
 23 preliminary and permanent injunctive relief is appropriate. Preliminary injunctive  
 24 relief will maintain the status quo pending adjudication of this matter and is necessary  
 25 to forestall irreparable injury to Plaintiffs and their members as demonstrated above.

#### **PRAYER FOR RELIEF**

27 WHEREFORE, Plaintiffs pray for the following:

- 28           1. For a declaration that USEPA's issuance of the May 1, 2023 letter

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1 approving the water quality standards included in the State’s Toxicity Provisions and  
2 mandating the use of the TST violates the CWA, the APA, and/or federal regulations  
3 issued pursuant to the APA.

4 2. An order vacating and setting aside the USEPA’s May 1, 2023 water  
5 quality standards approval and implicit approval of the use of the unpromulgated TST  
6 because these actions were arbitrary, capricious, an abuse of discretion, or otherwise  
7 not in accordance with law, and without observance of the procedure required by law.

8 3. For an order for equitable relief, including a preliminary or permanent  
9 injunction, enjoining USEPA and its officers, employees, and agents from approving,  
10 imposing, implementing, or enforcing the use of the TST or the use of analytical  
11 results obtained by the TST for determining compliance with the CWA, including  
12 approval contained in the May 1, 2023 letter approving the toxicity water quality  
13 standards as applicable water quality standards under federal law based on the TST  
14 until and unless the USEPA complies with all of its obligations as required by law.

15 4. For attorneys’ fees.

16 5. For costs of suit.

17 6. For such other and further relief as this Court deems just and proper.

18 DATED: May 19, 2023

DOWNEY BRAND LLP  
By:



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