FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

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"USEPA" or "Defendants"), to challenge and invalidate USEPA's use of documents, unpromulgated "rules," and actions that violated the Administrative Procedure Act ("APA"), 5 U.S.C. §553(b), (c) and §701 *et seq.*, and violated regulations implementing the Federal Water Pollution Control Act (commonly known as the "Clean Water Act" or "CWA"), 33 U.S.C. §1251 *et seq.*, and allege as follows:

I. INTRODUCTION

- 1. Under the APA, USEPA has no legal authority to utilize, impose, or mandate "rules" that have not been properly promulgated by notice and comment rulemaking. In the context of whole effluent toxicity ("WET") testing under the Clean Water Act, testing methodologies cannot be used or required until properly promulgated by USEPA and incorporated into federal regulations at 40 Code of Federal Regulations ("C.F.R.") Part 136 (referred to herein as "Part 136").
- 2. Plaintiffs are trade associations with member agencies that own and operate wastewater treatment plants and water reclamation plants, often called Publicly Owned Treatment Works ("POTWs"), which are designed to collect and treat municipal and industrial wastewater. Many of Plaintiffs' members operate pursuant to National Pollutant Discharge Elimination System ("NPDES") permits under the Clean Water Act issued by States, including California's State Water Resources Control Board or Regional Water Quality Control Boards under a delegated federal program, or by USEPA if discharges are to federal waters (e.g., ocean outside state boundaries, tribal lands). Many of these NPDES permits include WET testing and compliance provisions.
- 3. USEPA has failed to comply with the law and exceeded its statutory authority in using, requiring the use, or allowing the use of unpromulgated statistical and other toxicity testing procedures, including the Test of Significant Toxicity ("TST"), in modified permitting and compliance provisions in relation to WET requirements in NPDES permits. Because of these illegal actions, Plaintiffs' members are now currently or will be imminently subjected to the unjustifiably onerous impacts of the TST. These impacts include higher costs and increased enforcement jeopardy due to an increased frequency of "false positive" test results (namely,

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erroneous test results indicating toxicity is present when in fact no toxicity is present). These impacts go beyond the effects of any single permit. USEPA's actions, if unchecked threaten to affect all subsequent NPDES permits and to spread nationwide. This lawsuit is a substantive challenge to these actions by USEPA.

- 4. USEPA's failures to comply with the law, as set forth herein, demonstrate a pattern and practice, as well as constitute final agency actions subject to judicial review under the APA. Examples of USEPA's final agency actions include, but are not limited to the following: June 15, 2012 joint issuance of the Orange County Sanitation District NPDES Permit with the Regional Water Quality Control Board, Santa Ana Region; June 18, 2015 issuance of an NPDES Permit to Table Mountain Rancheria Wastewater Treatment Plant; February 2, 2017 issuance of an NPDES Permit to Hyperion Treatment Plant; March 6, 2015 issuance of an NPDES Permit Fact Sheet required under 40 C.F.R. §§ 124.8 and 124.56 to the Guam Waterworks Authority; May 7, 2015 issuance of an NPDES Permit Quality Review to the State of Hawaii on March 18, 2015; and May 7, 2015 email instructions to the California Water Board. All of these actions require the use of the TST and all constitute final agency actions "by which rights or obligations have been determined, or from which legal consequences will flow." (United States Army Corps of Engineers v. Hawkes Co., Inc., 136 S. Ct. 1807, 1813 (2016) (citing Bennett v. Spear, 520 U.S. 154, 117 (1997)).) All of these final agency actions relied upon unpromulgated guidance documents issued in 2010 regarding a new statistical method and related procedures for use in WET testing called the TST ("TST Guidance") as rules in contravention of USEPA's statutory authority. Upon information and belief, USEPA has continued to issue NPDES Permits and instructions to state permitting authorities requiring the use of the unpromulgated TST Guidance, the issuance of which also constituted final agency action.
- 5. In this case, Plaintiffs seek a declaration that, in using, allowing the use, or requiring the use of unpromulgated "rules," including the TST, in NPDES permit monitoring and compliance requirements, USEPA has acted contrary to the mandates of the APA and the regulations implementing the CWA and exceeded its statutory authority by issuing, utilizing and encouraging the use of unpromulgated "rules." As a result, USEPA's actions are unlawful and

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void. (28 U.S.C. §2201; Fed. R. Civ. P. 57.) Plaintiffs further seek preliminary and permanent injunctive relief to forestall further injury to Plaintiffs' members and others from the unjustifiably onerous impacts of the TST. (28 U.S.C. §2202; Fed. R. Civ. P. 65.)

II. JURISDICTION AND VENUE

- 6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 because this case arises under the "laws . . . of the United States." This Court is authorized to award declaratory relief pursuant to 28 U.S.C. §2201 and injunctive relief pursuant to 28 U.S.C. §2202. This Court has the statutory power to review the USEPA's agency actions at issue pursuant to 5 U.S.C. §§ 702, 704, and 706.
- Plaintiffs' challenges to USEPA's agency actions pursuant to provisions of the APA, 5 U.S.C. §§701-706. The APA "creates a comprehensive remedial scheme for those allegedly harmed by agency action." (*Navajo Nation v. United States Dep't of Interior*, 819 F.3d 1084, 1090 (9th Cir. 2016) (citing 5 U.S.C. §§ 701-706).) "Section 702 of the APA waives sovereign immunity for suits alleging wrongful agency action or inaction." (*Id.* (citing 5 U.S.C. § 702).) "Section 704 of the APA provides a right to judicial review of any 'final agency action for which there is no other adequate remedy in a court."" (*Id.* (citing 5 U.S.C. § 704).) Section 706 of the APA grants courts the power to invalidate agency actions that are, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," and "without observance of procedure required by law." 5 U.S.C. § 704. Accordingly, Plaintiffs' challenge to USEPA's actions lies properly in this Court. (*See* 5 U.S.C. §§ 702, 704, 706; *Navajo Nation*, *supra.*)
- 8. Plaintiffs have standing to bring this suit on behalf of its members because at least one of Plaintiffs' members would have standing to sue in its own right; the interests these trade associations seek to protect are germane to their organizations' purpose; and neither the claims asserted nor the relief requested requires an individual member to participate in this suit. (*See Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 507 (D.C. Cir. 2010).)

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9. Venue is proper in this Court under 28 U.S.C. §1391(e) because this action is against an agency of the United States, and CVCWA maintains its principal place of business in this judicial district.

III. PARTIES

- 10. SCAP 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. SCAP 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 or state agencies veer from the requirements set forth in laws and regulations. SCAP has several members that have NPDES permits containing TST-based requirements.
- 11. 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.
- 12. NACWA is a non-profit industry trade association representing the interests of POTWs and storm water agencies of all sizes across the nation, including 32 utilities in California. Founded in 1970, NACWA is the nation's recognized leader in regulatory, legislative, and legal advocacy on the full spectrum of clean water issues, and is involved in all facets of water quality protection and advocates for its members before all branches of the federal government. NACWA often participates in litigation where, as here, federal or state agencies veer from the requirements set forth in laws and regulations. NACWA has several members that have NPDES permits containing TST-based requirements.
- 13. BACWA is a joint-powers agency created by the California Government Code.

 BACWA is comprised of the five largest wastewater treatment agencies in the San Francisco Bay

 Area and associate members that provide technical expertise and financial support to

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municipalities and special districts providing sanitary sewer services to more than 6.5 million
people. BACWA participates in litigation where, as here, topics of import to the BACWA
membership are raised.

- 14. At the very least, SCAP and NACWA have standing in this matter. (*See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).) Most of SCAP's members are currently operating under NPDES permits that are or will be subject to permitting and compliance requirements that include TST. Many of these SCAP members are also members of NACWA. CVCWA's and BACWA's members are concerned that USEPA's unlawful actions to use, mandate, implement, promote, encourage, and authorize the use by delegated States of unpromulgated "rules" will increase the costs of compliance and the likelihood of false findings of non-compliance for its members if TST requirements are placed in their members' permits. This result can be avoided by a finding in Plaintiffs' favor. The standing of at least one organization assures that this matter is justiciable, because only the presence of one party with standing is required. (*See Director, Office of Workers' Compensation Programs v. Perini North River Associates*, 459 U.S. 297, 303–305 (1983).)
- 15. 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.
- 16. Defendant Alexis Strauss is the Acting Regional Administrator of USEPA Region IX of the USEPA and is generally responsible for administering USEPA Region IX in accordance with the Clean Water Act and other applicable laws. Ms. Strauss is sued in her official capacity.
- 17. Doe Defendants 1 to 10 are responsible in some manner for the events herein referred to, and caused injuries proximately thereby to Plaintiffs as alleged herein. The names of the individual Doe defendants are at this time unknown. Plaintiffs will insert the true names and capacities of the fictitiously named defendants when ascertained. Plaintiffs are informed and believe that, at all times herein mentioned, each Doe defendant was an agent of Defendant

USEPA and, in taking the actions hereinafter alleged, was acting within the scope of their authority as an agent and with the permission and consent of USEPA.

IV. FACTUAL AND LEGAL BACKGROUND

A. Overview of the Statutory Scheme

- 18. The CWA created a system for permitting wastewater discharges through the NPDES program. Under CWA sections 301 and 402, facilities that discharge pollutants from any point source into waters of the United States are required to obtain an NPDES permit. Effluent limitations serve as the primary mechanism in NPDES permits for controlling discharges of pollutants from point sources to receiving waters. Water quality standards are used as the basis for deriving the specific effluent limitations in NPDES permits. (40 C.F.R. §122.44(d).)
- 19. USEPA is required to review and to approve or disapprove state-adopted water quality standards under the CWA. Under CWA section 303(c), a "revised or new water quality standard shall consist of the <u>designated uses</u> of the navigable waters involved and the <u>water quality criteria</u> for such waters based upon such uses." (33 U.S.C. §1313(c)(2)(A) (emphasis added).) Generally, "designated uses" are the types of activities for which the water can be employed (e.g., recreation, agriculture), and "water quality criteria" are the numeric or narrative water quality levels necessary to support the water's designated uses. Numeric water quality criteria are expressed as specific concentrations of individual pollutants (e.g., no more than 5 mg/l pollutant X). Narrative water quality criteria (e.g., no toxics in toxic amounts) are the catch-alls of water quality regulation, and are narrative statements describing a desired water quality goal. Currently, in California, the water quality standards for chronic toxicity are narrative in form.
- 20. Since at least 2001, California's Ocean Plan has set water quality objectives based on chronic toxicity units ("TUc") and has specified that TUc shall be used for critical lifestage toxicity tests using Part 136 methods. (See 2015 Ocean Plan at 78-79.) Even though the TST guidance was available in 2012 and 2015 when the Ocean Plan was amended, the Ocean Plan clearly requires that, where chronic toxicity effluent limitations must be included, those limitations must be based on TUc, which is calculated based upon the NOEL, and not on a

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Pass/Fail basis as used with the TST. Use of the TST contradicts the promulgated toxicity requirements of the Ocean Plan.

B. WET Testing

- 21. Within the NPDES program, freshwater and marine acute and chronic toxicity tests are used in conjunction with other chemical analyses to evaluate and assess the compliance of wastewater discharges and surface waters with water quality standards under the CWA.
- 22. WET (i.e., Whole Effluent Toxicity) describes the aggregate toxic effect of an aqueous sample (e.g., effluent from wastewater discharge) as measured by laboratory organisms' responses upon exposure to the sample, including premature death, impaired growth, or reduced reproduction. WET is thus defined by the measured effects on organisms. Because toxicity is inherently defined by the measurement system employed, toxicity is referred to as a "methoddefined analyte." (67 Fed. Reg. 69,965.)
- 23. In WET testing, the final result is not based on a single measurement, but is the product of a series of replicated measurements on a range of at least five effluent concentrations compared to a control sample, when testing final effluent. This contrasts with chemical methods, which generally rely on a single instrument measurement.
- 24. The contrast with chemical measurements does not stop there. Chemical measurements have tremendous amounts of quality control/quality assurance ("QA/QC") procedures such as matrix spikes, matrix spike duplicates, known reference samples, etc. WET has no accuracy component, which is why the promulgated methods in Part 136 require five effluent treatments to provide more certainty in WET test results, which are not provided by the QA/QC common to chemical measurements.
- 25. The series of replicated measurements produced through WET testing can be assessed through a number of distinct statistical procedures specified in 40 C.F.R. Part 136. The outcome of a statistical procedure is called the "endpoint," which under the promulgated test methods in Part 136 can include one of the following, although no specific one of these endpoints included in the approved list are mandated:

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a.	The No Observed Effect Concentration ("NOEC") or the No Observed
	Effect Level ("NOEL"), both of which refer to the highest concentration of
	a toxicant that causes no observable effects in the exposed organisms;

- b. The 25% Inhibition Concentration ("IC25"), which is the concentration of a toxicant that causes a 25% inhibition in growth or reproduction in the exposed organisms; and
- c. The 50% Lethal Concentration ("LC50"), which is the concentration of a toxicant that causes death in 50% of the exposed organisms).

An endpoint of "Pass/Fail" is not authorized under the promulgated methods.

- 26. The endpoints of NOEC/NOEL, IC25, and LC50 are all expressed as percent of the effluent, while an endpoint of Pass/Fail is "unitless" (i.e., not expressed as a percent or in terms of units). Because WET is a method-defined analyte, the statistical procedures used and the endpoint reported are important as different procedures often create different results. In other words, one statistical procedure may produce a result of "toxic," while another may produce the result of "non-toxic" on the exact same tested effluent.
- 27. WET tests are surrogates, designed to replicate the total effect and environmental exposure of aquatic life to toxic pollutants in water without initially requiring the identification of the specific pollutants. Because WET testing does not identify the specific pollutant(s), more indepth analyses, known as Toxicity Identification Evaluations ("TIEs") and Toxicity Reduction Evaluations ("TREs") are often performed if toxicity is initially indicated in order to determine what pollutant(s) may be causing the toxicity effect.

C. The WET Regulatory Scheme

- 28. Section 304(h) of the CWA requires USEPA to "promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section [401 of the CWA] or permit application pursuant to section [402 of the CWA]." (33 U.S.C. §1314(h); 33 U.S.C. §§1341, 1342.)
- 29. USEPA regulations at 40 C.F.R. Part 136 prescribe the specific methods and reporting units for each parameter tested that must be used for the analysis of pollutants in all

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applications and reports submitted under the NPDES program under section 402 of the CWA, as well as State certifications pursuant to section 401 of the CWA. (40 C.F.R. §§136.1(a), 136.3.) Under EPA rules, NPDES permit compliance monitoring must be done according to test procedures approved under 40 C.F.R. Part 136. (*See accord* 40 C.F.R. §122.41(j)(4) and §122.44(i)(iv).)

- 30. In November of 2002, USEPA promulgated through a formal notice and comment rulemaking process acute and short-term chronic WET test methods and procedures, for use in monitoring compliance with NPDES permit limitations in accordance with 40 C.F.R. Part 136. (*See* USEPA Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule, 67 Fed. Reg. 69,952 (Nov. 19, 2002).) This regulation and the documents incorporated by reference are herein referred to as the "2002 Rule." The 2002 Rule specifies the parameter to be measured and the required units for determining the acute and chronic toxicity for freshwater and saline water. The 2002 Rule constituted the universe of USEPA's promulgated WET methods and procedures. (*See* 2002 Rule, 67 Fed. Reg. 69,972.)
- 31. The 2002 Rule does not mention or authorize the TST statistical procedure. In addition, the 2002 Rule, among other things, also does not mention or authorize an alternative hypothesis presuming the water tested is toxic. The 2002 Rule does not authorize and actually discourages the use of single sample "Pass/Fail" test results as is prescribed with the use of the TST. In fact, the 2002 Rule states that the "[u]se of pass/fail tests consisting of a single effluent concentration (e.g., the receiving water concentration or RWC) and a control is not recommended." The 2002 Rule does not authorize Pass/Fail endpoints, or unitless expressions of toxicity. The 2002 Rule does not authorize a statistical method that relies only on the information from two tested concentrations instead of a minimum of six concentrations of effluent and control groups when testing final effluent. Plaintiffs challenge what is herein called "the TST," which includes each of these unauthorized WET test and compliance related requirements. Because the 2002 Rule does not authorize use of the TST or methods or procedures related to the TST, the TST and its related procedures may not be used to set permit limits or determine compliance with

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NPDES permit requirements. If USEPA desires to use these alternative methods, then those alternatives should be formally promulgated.

- 32. In adopting the 2002 Rule, USEPA specifically considered allowing alternative statistical procedures, but chose not to do so, explaining that, "EPA has not included such alternative statistical methods in today's modifications to WET test methods. EPA believes that the statistical methods currently recommended in the WET methods [NOEC, IC25, LC50] are appropriate." (67 Fed. Reg. 69,964 (emphasis added).) The 2002 Rule acknowledged that other techniques do exist and that the statistical methods adopted into 40 C.F.R. Part 136 are not the only possible methods. However, the 2002 Rule concludes that, "[t]he recommended statistical methods described in the method manual were selected because they are (1) applicable to most of the different toxicity test data sets for which they are recommended, (2) powerful statistical tests, (3) hopefully "easily" understood by nonstatisticians, and (4) amenable to use without a computer, if necessary." (*Id.* (emphasis added)) Thus, the 2002 Rule clearly stated that a reasoned analysis and decision had been made to only include and approve use of certain statistical procedures. Significantly, the TST was not among them.
- 33. To validate the performance of the test methods included in the 2002 Rule, USEPA relied on an Interlaboratory Variability Study and established a false positive error rate for each WET test method. The Interlaboratory Variability Study did not include the TST statistical procedure, and the USEPA has not conducted a study to determine the false positive error rate of the TST statistical procedure.

D. USEPA's Unpromulgated TST Guidance

34. In 2010, USEPA issued the TST Guidance, which is comprised of guidance documents regarding a potential new statistical method for use in WET testing called the TST. (*See e.g.*, National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document, EPA 833-R-10-003 (June 2010); EPA Regions 8, 9, and 10 Toxicity Training Tool (January 2010).) The TST relies on an alternative hypothesis presuming toxicity and includes Pass/Fail endpoints not contained in or authorized by the promulgated 2002 Rule.

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Furthermore, the TST Guidance was not promulgated through notice-and-comment rulemaking
and the document even includes an explicit disclaimer confirming that the document is not "a
permit or a regulation itself." In fact, the TST Guidance further states:

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

- 35. In 2012, USEPA amended the 2002 Rule's WET test methods and procedures in its modifications to the Promulgated Guidelines Establishing Test Procedures for the Analysis of Pollutants under the Clean Water Act: Analysis and Sampling Procedures ("2012 Rule"). (77 Fed. Reg. 29758 (May 18, 2012); see 40 C.F.R. Part 136.) These amendments did <u>not</u> incorporate or authorize use of the TST, even though the TST approach had been available as guidance for nearly two years.
- 36. Despite the fact that the TST was unpromulgated and unauthorized by the 2012 Rule and 2002 Rule, on July 15, 2012, USEPA and the Regional Water Quality Control Board, Santa Ana Region, issued NPDES Permit No. CA0110604 to the Orange County Sanitation District, a SCAP and NACWA member. This NPDES Permit requires the use of the unpromulgated TST, and states "The reported results shall include: determination of 'Pass' or 'Fail' and 'Percent Effect' following the Test of Significant Toxicity hypothesis testing approach in *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document* (EPA 833-R-10-003, 2010) [the TST Guidance]."
- 37. In 2015, USEPA again proposed to modify the regulations in 40 C.F.R. Part 136. These proposed modifications included clarifications and corrections to the procedures for toxicity testing (*see* 80 Fed. Reg. 8956-9075 (February 19, 2015) accessible at http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-02841.pdf.) Significantly, the newly proposed rule failed to include the TST. (80 Fed. Reg. 8968-8969.) The Final Rule to modify the regulations in 40 C.F.R. Part 136 was posted by USEPA on its website on December 15, 2016, and is awaiting publication in the Federal Register. (See "2016 Final Rule," USEPA,

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Prepublication Version (Dec. 15, 2016), accessible at

https://www.epa.gov/sites/production/files/2016-12/documents/mur_final_prepub_12-15-

<u>2016.pdf</u>.) Although USEPA could have requested comment on and included the TST, the 2016 Final Rule also does include or authorize the TST.

E. USEPA's Use of an Alternative Test Procedure as an End-Run around Rulemaking

- 38. Under limited circumstances and subject to specific regulatory requirements, a person may request an Alternative Test Procedure ("ATP") authorizing the use of test methods and procedures not previously approved and formally promulgated by USEPA. (40 C.F.R. §136.3(a).) The ATP process was designed to "encourage organizations external to EPA to develop and submit for approval new analytical methods." (*See Guide to Method Flexibility and Approval of EPA Water Methods*, USEPA Office of Water (Dec. 1996) at p. 77.) USEPA regulations at sections 136.4 and 136.5 describe the specific procedures and requirements for obtaining USEPA review and approval of ATPs. (40 C.F.R. §§136.4, 136.5.)
- 39. USEPA Region IX had been urging the State of California to utilize the TST in NPDES permits and its pending Toxicity Policy for many years. Regulated dischargers objected to the use of the TST over concerns regarding high false positive error rates and most importantly because the TST is not a formally promulgated and publicly vetted rule.
- 40. On February 12, 2014, to overcome concerns over the lack of a promulgated rule, the California State Water Resources Control Board requested USEPA Region IX approval to use USEPA's own TST statistical method in conjunction with a test design incorporating only two samples (effluent and control) rather than the minimum of six required for effluent testing under the 2002 Rule. A little more than a month later, on March 17, 2014, USEPA Region IX approved a statewide, limited use ATP allowing the use of the TST with just two concentrations (effluent sample and control) under 40 C.F.R. Part 136.5. Further, USEPA applied this ATP to non-ocean and ocean waters, even though application to ocean waters was not requested by the State Water Board in its ATP request, and was inconsistent with the terms of the promulgated Ocean Plan.
- 41. After USEPA approved the ATP for California in 2014, NPDES permits began to be issued using the TST based on the modified test design approved in ATP. Plaintiffs

challenged USEPA's approval of the ATP in this court (see *SCAP v. USEPA*, Case No. 2:14-cv-01513-MCE-DB), but before a ruling was issued, USEPA withdrew that ATP on or about February 11, 2015. Therefore, currently, no valid ATP for WET testing using the TST or two concentration design exists or is approved in California.

F. USEPA Continues to Require the Use of the Unpromulgated TST

- 42. Despite withdrawing the ATP, USEPA has continued to use, require the use, and approved of the use of the TST as a statistical procedure for toxicity tests, testing just two concentrations, under a null hypothesis not included in the 2002 Methods, 2012 Rule, or 2016 Final Rule, and prescribing a Pass/Fail endpoint for analyzing WET test results and determining compliance with NPDES permit requirements based upon the TST Guidance in excess of its statutory and regulatory authority, Upon information and belief, USEPA continues to do so.
- 43. On or about March 6, 2015, less than one month after withdrawing the ATP, USEPA issued a NPDES Permit and accompanying Fact Sheet pursuant to 40 C.F.R. §§ 124.8 and 124.56 for the Guam Waterworks Authority, which states that "EPA is requiring the recently developed Test of Significant Toxicity ('TST') statistical approach in assessing whole effluent toxicity ('WET'). The previous permit required WET testing with the traditional hypothesis testing approach outlined in EPA's TSD." (Emphasis added.) This "Fact Sheet" also states that "[t]he permit includes new WET requirements based on EPA's 2010 Test of Significant Toxicity," referring to the TST Guidance, and that "[t]he new method is based on comparing the mean response of the test organism in the control and at the instream waste concentration." The "Fact Sheet" communicates to Guam Waterworks Authority that the use of the TST was a "requirement," using the TST Guidance as the vehicle for implementing an unpromulgated rule.
- 44. On or about June 18, 2015, USEPA issued NPDES Permit No. 0084280 for Table Mountain Rancheria Wastewater Treatment Plant, located in California's Central Valley. This NPDES Permit requires the use of the unpromulgated TST, and states "This discharge is subject to a determination of 'Pass' or 'Fail' from a single-effluent concentration chronic toxicity test at the IWC (for statistical flowchart and procedures, see *National Pollutant Discharge Elimination*

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System	t Test of Sign	nificant Toxic	ity Implementa	tion Document,	Appendix A,	Figure A-1	[the TST
Guida	nce])."						

- 45. On or about February 2, 2017, USEPA issued NPDES Permit No. CA0109991for Hyperion Treatment Plant. This NPDES Permit requires the use of the unpromulgated TST in contravention of the requirements of the Ocean Plan, and states "This discharge is subject to a determination of 'Pass' or 'Fail' from a single-effluent concentration chronic toxicity test at the IWC (for statistical flowchart and procedures, see National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document, Appendix A, Figure A-1 [the TST] Guidance])."
- 46. USEPA issued these NPDES Permits and allowed many other permits to be adopted, many held by SCAP and NACWA members, requiring the use of the unpromulgated TST based upon the TST Guidance, even though the use of the TST was contrary to law and federal regulations, inter alia, the APA, 40 C.F.R. Part 136, 40 C.F.R. §122.41(j) and §122.44(i), and the Ocean Plan.
- 47. Upon information and belief, USEPA has continued to issue and allow the issuance of NPDES Permits requiring the use of the unpromulgated TST based upon the TST Guidance.
- 48. USEPA has also informed state permitting authorities that the use of the unpromulgated TST set forth in the TST Guidance is a "requirement" in their permits that involve WET testing, even though the use of the TST was contrary to law and federal regulations.
- 49. For example, on or about March 18, 2015, USEPA issued the NPDES Permit Quality Review, State of Hawaii, which provides that "[t]he State [referring to Hawaii] has made significant improvements in permit quality over the last few years as permit practices have changed from . . . requiring only monitoring requirements in some cases for chronic toxicity, to including chronic toxicity limits based on the Test of Significant Toxicity, or TST." The NPDES Permit Quality Review also refers to the use of the TST as a "requirement."
- 50. Also on March 18, 2015, the Regional Water Quality Control Board, San Diego Region, revised the Water Discharge Requirements for Continental Maritime of San Diego in

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Order R9-2015-0009 to require the use of the unpromulgated TST, stating that "[t]hese final
effluent limitations will be implemented using current USEPA guidance in National Pollutant
Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-
R-10-003, June/2010) [the TST Guidance] and EPA Regions 8, 9, and 10 Toxicity Training Tool
(January 2010)," and that "[t]he discharge is subject to determination of 'Pass' or 'Fail' from a
chronic toxicity test using the Test of Significant Toxicity (TST) statistical t-test approach
described in National Pollutant Discharge Elimination System Test of Significant Toxicity
Implementation Document (EPA 833-R-10-003, 2010) [the TST Guidance]." The Regional Water
Quality Control Board, San Diego Region, sent these Water Discharge Requirements to USEPA
the same day it adopted them, and upon information and belief, required the use of the
unpromulgated TST because it believed that the use of the TST was required by USEPA. USEPA
did not object to this permit even though it was "outside the guidelines and requirements" of the
Clean Water Act. (33 U.S.C. §1342(d)(2).)

- on or about April 9, 2015, after the ATP used to justify the previous permit was withdrawn by USEPA, the Regional Water Quality Control Board, Los Angeles Region, revised the NPDES permit for the Joint Outfall System, Order R4-2015-0070, for the San Jose Creek Water Reclamation Plant, to continue to require the use of the unpromulgated TST, now directly relying upon "current USEPA guidance in *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, June/2010)* [the TST Guidance] and EPA Regions 8, 9, and 10 Toxicity Training Tool (January 2010)." This permit also required that "[t]he discharge is subject to determination of 'Pass' or 'Fail' from a chronic toxicity test using the Test of Significant Toxicity (TST) statistical t-test approach described in *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, 2010)* [the TST Guidance]." Upon information and belief, the Regional Water Quality Control Board, Los Angeles Region, required the use of the unpromulgated TST because it believed that the use of the TST was required by USEPA.
- 52. On or about May 7, 2015, Becky Mitschele of USEPA informed Cassandra Owens of the State Water Board via email that "[a]ll NPDES effluent compliance monitoring for chronic

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toxicity shall be reported using the 100% effluent concentration and negative control, expressed
in units of USEPA's TST statistical approach (pass or fail, % effect). The TST hypothesis (Ho) is
statistically analyzed using only the permit-specified in-stream waste concentration and a
negative control." In this document, USEPA is informing the State Water Board that the use of
the unpromulgated TST is a "requirement" for "[a]ll NPDES effluent compliance monitoring for
chronic toxicity."

- 53. On or about May 13, 2015, State Regional Water Quality Control Board, San Diego Region, issued an NPDES permit, Order No. R9-2015-0002, for the Padre Dam Municipal Water District, which requires the use of the unpromulgated TST method, and states that "[t]hese final effluent limitations will be implemented using . . . current USEPA guidance in *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document (EPA 833-R-10-003, June/2010)* [the TST Guidance] *and EPA Regions 8, 9, and 10 Toxicity Training Tool (January 2010)*." Upon information and belief, the Regional Water Quality Control Board, San Diego Region, required the use of the unpromulgated TST because it believed that the use of the TST was required by USEPA.
- 54. On or about May 21, 2015, USEPA emailed various individuals at the State Water Board to inform them that the ATP had been withdrawn three months earlier. In response, Charles Reed of the State Water Board emailed Elizabeth Sablad and Robyn Stuber of USEPA, and inquired as to the effect of the ATP withdrawal on California Ocean Plan-based NPDES permits. Ms. Sablad replied that "[d]espite the withdrawal of the ATP approval, the state is still able to use this new test evaluation method," referring to TST, "which is superior to methods previously used." Despite this determination that the TST is "superior," the TST was not included in the 2016 Final Rule.
- 55. Upon information and belief, state permitting authorities in California and elsewhere have issued additional NPDES Permits and have proposed policies mandating the use of the TST based upon the TST Guidance, and did so because they believed that the use of the TST was required by USEPA.
 - G. USEPA Has Issued Numerous Final Agency Actions Requiring the Use of the TST

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56. Final agency actions are subject to judicial review. Under the APA, an action is a
"final agency action" subject to judicial review if it "has the status of law or comparable legal
force or if immediate compliance is expected." Columbia Riverkeeper v. United States Coast
Guard, 761 F.3d 1084, 1095 (9th Cir. 2014) (internal quotation marks omitted); accord United
States Army Corps of Engineers v. Hawks Co., Inc., 136 S. Ct. 1807, 1813 (2016) (final agency
action marks "consummation of the agency's decisionmaking process" and is an action "by which
rights or obligations have been determined, or from which legal consequences will flow").
57. USEPA's first challenged final agency actions were the issuance of the TST
Guidance documents themselves in 2010, as set forth in Paragraph 34.

- 58. Although the June 2010 TST Guidance described itself as not imposing <u>any legally binding requirements on</u> "states, <u>NPDES permittees</u>, or laboratories conducting or using WET testing for permittees (or for states in evaluating ambient water quality)," USEPA has subsequently issued the following final agency actions transforming the TST Guidance into legally binding rules, including, but not limited to:
 - a. NPDES Permit No. CA0110604 for Orange County Sanitation District, requiring the use of the unpromulgated TST as set forth in Paragraph 35.
 - b. NPDES Permit Fact Sheet for Guam Waterworks Authority, dated March 6, 2015, "requiring" the use of the unpromulgated TST as set forth in Paragraph 43.
 - c. NPDES Permit No. 0084280 for Table Mountain Rancheria Wastewater Treatment Plant, dated June 18, 2015, requiring the use of the unpromulgated TST as set forth in Paragraph 44.
 - d. NPDES Permit No. CA0109991for Hyperion Treatment Plant, dated February 2,2017, requiring the use of the unpromulgated TST as set forth in Paragraph 45.
 - e. NPDES Permit Quality Review to the State of Hawaii, dated March 18, 2015, informing the State of Hawaii that permit "requirements" had "changed" to include the use of the unpromulgated TST as set forth in Paragraph 49.
 - f. Email from Becky Mitschele of USEPA to Cassandra Owens of the State Water Board dated May 7, 2015, informing Owens that "[a]ll NPDES effluent

Paragraph 52.

an injunction.

Each of these final agency actions communicate a decision that the TST is a legally valid option or requirement, that legal consequences flow based on the use of the TST, and that immediate compliance is expected. *See Hawks*, 136 S. Ct. at 1813; *Columbia Riverkeeper*, 761 F.3d at 1095. Upon information and belief, USEPA has continued to issue final agency actions requiring the use of the unpromulgated TST up through the present and will continue to do so in the absence of

compliance monitoring" must be done using the unpromulgated TST as set forth in

- 59. Generally, challenges to final agency actions have a six-year statute of limitations under the APA. (28 U.S.C. § 2401(a).) Plaintiffs' action is a substantive challenge to USEPA's use of the TST as a rule in excess of USEPA's statutory authority through the final agency actions as set forth in Paragraphs 57 and 58. USEPA withdrew the ATP in February 2015, at which point TST requirements in permits began to be justified on the TST Guidance documents directly, instead of on an approved, valid ATP. Several of the aforementioned final agency actions occurred from March through June of 2015, rendering those challenges clearly timely under the six-year statute of limitations contained in 28 U.S.C. section 2401(a). (See Wind River Corp. v. United States, 946 F.2d 710, 713-16 (9th Cir. 1991); Utu Utu Gwaitu Paiute Tribe of the Benton Paiute Reservation v. Dep't of Interior, 766 F. Supp. 842, 846-47 (E.D. Cal. 1991).)
- 60. The earliest this substantive action could have become ripe, concrete, and accrued was in July 2012, when USEPA and Orange County Sanitation District jointly issued an NPDES that, for the first time (that Plaintiffs are aware of) used the TST, even though this issuance was *before* the issuance of the ATP. With respect to the TST Guidance, Plaintiffs claims were not ripe until USEPA began requiring the TST as a rule based upon the TST Guidance, of which Plaintiffs had no notice until July 2012.¹

¹ Moreover, the statute of limitations on these claims was equitably tolled due to the related litigation concerning the ATP in Case No. 2:14-cv-01513-MCE-DB. (*See Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005) (statute of limitations may be equitably tolled where litigant establishes "(1) that he has been pursuing his rights diligently, and (2) some extraordinary circumstance stood in his way"); *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 770 (9th Cir. 1997) (holding that section 2401(a) statute of limitations was not jurisdictional and is subject to equitable

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61. In either case, this challenge is timely. USEPA "cannot avoid review by shifting
the bases of its actions until the statute of limitation on challenging the issuance of its regulatory
documents runs" and the USEPA's "actions can remain open to challenge on an 'as applied' basis
when regulations are used in new ways." (See Southern California Alliance of Publically Owned
Treatment Works v. EPA., No. 2:14-cv-01413-MCE-DB, 2016 WL 6135872, at *6 (E.D. Cal. Oct
21, 2016); accord Utu Utu Gwaitu, 766 F. Supp. at 846 (stating that if court accepted agency's
position that action accrued on substantive challenge at point regulation was published in federal
register that "agency could effectively shield its interpretation of [that] regulation from all judicial
scrutiny either by not enforcing it until after the statute of limitations has run or by reinterpreting
it after the statute has run").) Otherwise, an agency could sit on guidance until the statute ran to
shield itself from review.

62. With respect to the NPDES Permits issued by USEPA or the State set forth in Paragraphs 43-45, 50-51, and 53, Plaintiffs here do not challenge of the <u>issuance</u> of the NPDES Permits themselves, but instead challenge USEPA's actions to use or approve of the unpromulgated TST and its associated methods as requirements within those NPDES permits or to interpret compliance with those permits in excess of USEPA's statutory authority. The remedy Plaintiffs seek would rule USEPA's actions unlawful and the resultant TST requirements void as contrary to promulgated rules, methods, and procedures.

V. PLAINTIFFS' CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory Relief Pursuant to 28 U.S.C. §2201 and Federal Rule of Civil Procedure 57 – Wrongful Use or Approval of TST in Violation of the Administrative Procedures Act)

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

tolling). Plaintiffs believed that the Complaint in the related action was broad enough to cover a challenge to the TST Guidance. The Court, however, disagreed in its October 2016 order. *See SCAP v. USEPA.*, No. 2:14-cv-01413-MCE-DB, 2016 WL 6135872, at *6 (E.D. Cal. Oct. 21, 2016). Upon gaining client approval, Plaintiffs moved swiftly to prepare its initial complaint in this action, which was filed on December 19, 2016.

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- 64. The APA authorizes the Court to hold unlawful and set aside final USEPA actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (5 U.S.C. §706(2)(A).)
- 65. The APA also authorizes the Court to hold unlawful and set aside final USEPA actions that are "in excess of statutory . . . authority." (5 U.S.C. §706(2)(C).)
- 66. USEPA's use, implementation, mandate, encouragement, allowance, approval or authorization for States to use (i.e., "use or approval") the TST for use as a statistical procedure, with an alternative hypothesis and a Pass/Fail endpoint, using just two concentrations for analyzing WET test results or determining compliance with NPDES permit requirements, is contrary to law and federal regulations, inter alia, the APA, 40 C.F.R. Part 136, 40 C.F.R. §122.41(j) and §122.44(i), and the Ocean Plan.
- 67. USEPA violated federal regulations by use or approval of the use of the TST in the NPDES program in contravention of 40 C.F.R. Part 136 and the Ocean Plan.
- 68. Nothing in the CWA or its implementing regulations grants USEPA the authority for use or approval of the use of the non-promulgated TST with or without a Pass/Fail endpoint in place of other officially promulgated statistical and testing procedures, hypotheses, and endpoints in the NPDES program.
- 69. USEPA's use or approval of the use of the TST in NPDES permits failed to conform to the requirements for promulgation of test methods and procedures under CWA Section 304(h) and 40 C.F.R. Part 136.
- 70. USEPA's use or approval of the TST was arbitrary and capricious, violated federal regulations, and work to prejudice the regulated community, including Plaintiffs' members. USEPA violated the APA, federal regulations implementing CWA section 304(h), and the Ocean Plan, and thus acted in an arbitrary and capricious manner, abused its discretion, and acted in a manner not in accordance with law, as set forth herein.
- 71. The APA authorizes the Court to hold unlawful and set aside final USEPA actions that are without observance of procedure required by law. (5 U.S.C. §706(2)(D).)

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- 72. To the extent USEPA contends that the TST is authorized under the 2010 Guidance, then use of that guidance as a rule constitutes an unlawful regulation as applied because that guidance was contrary to the requirements of the APA.
- 73. USEPA has exceeded its statutory authority under CWA section 304(h) and 40 C.F.R. Part 136 in violation of the APA.
- 74. When an agency promulgates a rule, the APA requires that "[g]eneral notice of proposed rulemaking shall be published in the Federal Register" and that "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." (5 U.S.C. §553(b), (c).)
- 75. An actual and substantial controversy has arisen and presently exists between Plaintiffs and USEPA regarding the validity of USEPA's use and approval of the use of the TST and associated methods and procedures in violation of federal and state law and regulations. USEPA's actions as described herein are unlawful and therefore invalid. Plaintiffs are informed and believe that USEPA disputes these contentions.
- 76. Because Plaintiffs have no adequate remedy at law to challenge USEPA's actions, and Plaintiffs' members have incurred or will imminently incur substantial harm as the result of USEPA's wrongdoing, a declaration is necessary to clarify the parties' obligations and to inform the public.
- 77. Plaintiffs seek an order pursuant to 28 U.S.C. section 2201 and Federal Rule of Civil Procedure 57, declaring the USEPA's actions to use, implement, mandate, approve of, authorize, encourage, or allow the use of the TST in NPDES permits constitutes an unlawful underground regulation without promulgating the use of the TST as a rule, or under an approved ATP, and that all actions taken by the USEPA or by others in reliance upon USEPA regarding the TST in contravention of such procedures are void and shall have no legal force or effect. In addition, Plaintiffs seek an order that any test results based on the TST and associated methods and procedures as set forth in Paragraph 31 that were previously incorporated into NPDES ///

limitations or monitoring requirements based on the unpromulgated TST.

SECOND CLAIM FOR RELIEF

permits are void and no enforcement actions can be taken for any previous violations of effluent

(Injunctive Relief Pursuant to 28 U.S.C. §2202 and Federal Rule of Civil Procedure 65 – Preliminary and Permanent Injunctive Relief)

- 78. Plaintiffs refer to and incorporate by this reference all allegations set forth in paragraphs 1 through 77 above.
- 79. Plaintiffs seek an order pursuant to 28 U.S.C. §2202 and Federal Rule of Civil Procedure 65 to enjoin the USEPA from using, implementing, mandating, or approving, allowing, encouraging, or authorizing the use of the unpromulgated TST and its associated methods and procedures for water quality regulation, permitting, and compliance determination purposes.
- 80. A substantial likelihood exists that Plaintiffs will succeed on the merits of the claims for the relief pled herein.
- 81. Plaintiffs' members will suffer or have already suffered irreparable injury in the absence of injunctive relief. Many of Plaintiffs' members operate POTWs pursuant to NPDES permits issued by delegated States, including California's State Water Resources Control Board and Regional Water Quality Control Boards, or by USEPA that include chronic toxicity testing and compliance provisions. If not enjoined from the use of the unpromulgated TST for testing and compliance purposes in all NPDES permits, many, if not all, of Plaintiffs' members as well as other dischargers in the affected States will be required to begin using and reporting WET testing results derived from an unpromulgated rule that adversely affects their compliance status.
- 82. Use of the TST will result in an increased cost to Plaintiffs' members in undertaking the additional replicate measurements necessary to reduce the likelihood of being found in violation; an increased frequency of false positives in toxicity testing and further unnecessary but significant costs in TIEs, TREs, and potentially facility upgrades; and, as a result, a higher incidence of alleged noncompliance with NPDES permits, potentially resulting in civil and even criminal liability. Injunctive relief is necessary given the fact that many of Plaintiffs' members have recently obtained or are in the process of obtaining new or revised NPDES permits from the State Water Board, Regional Water Quality Control Boards, or USEPA that include

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chronic toxicity testing and compliance provisions based on the unpromulgated TST and
associated methods and procedures. Furthermore, rulemaking without notice and comment
violates the APA, stifles public participation, and harms the Plaintiffs' members as well as the
public in general.

- 83. The threatened injuries outweigh any damage that an injunction may cause the Defendant since an injunction would merely maintain the status quo that existed prior to the recent use of TST in NPDES permits.
- 84. An order enjoining USEPA from the use or approval of the use of an unlawful rule is consistent with and serves the public interest.
- 85. Because Plaintiffs have no adequate remedy at law for the unjustified additional and substantial costs enumerated above, and because Plaintiffs' members have or will imminently incur substantial harm in the form of increased enforcement jeopardy as the result of USEPA's wrongdoing, preliminary and permanent injunctive relief is appropriate. Injunctive relief that maintains the status quo that existed prior to use of the TST until and after resolution of this adjudication of this matter is necessary in order to forestall irreparable injury to Plaintiffs and their members as demonstrated above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

- A. Declare that USEPA's use, implementation, mandate of the TST, or encouragement, allowance, approval or authorization for States to use the TST and associated requirements in the NPDES program was:
- 1. Made without observance of procedure required by law within the meaning of APA section 706(2)(D); or
 - 2. Not in accordance with APA section 706(2)(A); and
- 3. Beyond USEPA's statutory jurisdiction, authority or limitations, within the meaning of APA section 706(2)(C).
- B. Declare that the use and approval of USEPA's TST and associated methods and procedures and all actions taken by the USEPA or others in reliance upon USEPA's guidance

regarding the TST in contravention of promulgated rules, methods, and procedures are void and 1 2 shall have no legal force or effect unless and until promulgated as a rule. 3 C. Declare that any test results based on the TST and associated methods and 4 procedures, which was previously incorporated into NPDES permits, are void and no 5 enforcement actions can be taken for any previous violations of effluent limitations, permit 6 provisions, or monitoring requirements based on the unpromulgated TST. 7 D. Order that USEPA and its officers, employees, and agents, are enjoined from 8 using, mandating, or encouraging the use of the TST, or allowing, approving, or authorizing 9 States to use the TST, and are enjoined from the use of analytical results obtained through non-10 promulgated procedures and methods for NPDES toxicity compliance determination or other 11 Clean Water Act purposes unless and until those procedures and methods are properly and 12 formally promulgated as rules. 13 E. Award Plaintiffs reasonable attorneys' fees and costs incurred in the prosecution of 14 this action. F. Grant such other and further relief as this Court deems just and proper. 15 16 DATED: May 30, 2017 DOWNEY BRAND LLP 17 /s/ Melissa A. Thorme By: MELISSA A. THORME 18 Attorney for Plaintiffs, 19 SOUTHERN CALIFORNIA ALLIANCE OF PUBLICLY OWNED TREATMENT WORKS, 20 CENTRAL VALLEY CLEAN WATER ASSOCIATION, NATIONAL ASSOCIATION OF 21 CLEAN WATER AGENCIES, and BAY AREA CLEAN WATER AGENCIES 22 23 24 25 26 27 28 25 1483948.7

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CERTIFICATE OF SERVICE

I hereby certify that the above and foregoing FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF was served on May 30, 2017 via the Court's CM/ECF system to all registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent to those indicated as non-registered participants.

/s/ Marci Frazier

DOWNEY BRAND LLP

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