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VIA E-MAIL AND U.S. MAIL

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**Re: Request for Denial of the California State Water Resources Control Board's
November 25, 2020 Request for Review and Approval of a One Effluent
Concentration Alternative Test Procedure for Whole Effluent Toxicity Testing**

Dear Ms. Johnson and Mr. Walker:

On behalf of the Southern California Alliance of Publicly Owned Treatment Works ("SCAP"), I am writing to submit written comments and a formal request that the U.S. Environmental Protection Agency ("USEPA") deny the California State Water Resources Control Board's ("State Water Board") November 25, 2020 request for review and approval of a one effluent concentration compared to one control ("one-concentration") alternative test procedure ("ATP") for whole effluent toxicity ("WET") testing pursuant to 40 Code of Federal Regulations ("CFR") Part 136.5 (the "State Water Board's ATP Request").¹

In 2014, the State Water Board requested USEPA Region IX to approve the use of one-concentration with the Test of Significant Toxicity ("TST") through a separate ATP request. On March 17, 2014, USEPA approved the request. SCAP challenged USEPA's approval of the ATP before the U.S. District Court for the Eastern District of California. Before a ruling on the merits, USEPA withdrew the prior ATP in 2015. However, for similar reasons outlined below, USEPA's approval of the State Water Board's ATP Request would violate federal law and exceed USEPA's authority. Therefore, SCAP respectfully requests that USEPA disapprove of the State Water Board's November 25, 2020 ATP request.

¹ A copy of the State Water Board's ATP Request is available here:

https://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/atp_request_letter.pdf (last accessed Dec. 28, 2020).

I. Legal Background

A. The Clean Water Act's Discharge Permitting Scheme

As you know, the Clean Water Act (“CWA”) created a system for permitting wastewater discharges through the National Pollutant Discharge Elimination System (“NPDES”) program. 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 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).)

Within the NPDES program, freshwater and marine acute and chronic whole effluent 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. “Whole effluent toxicity” or “WET” is a term used to describe the aggregate toxic effect of an aqueous sample (*e.g.*, whole effluent wastewater discharge) as measured by a laboratory organism’s response upon exposure to the sample, including lethality or death, impaired growth, or reduced reproduction. WET tests are designed to replicate the total effect and environmental exposure of aquatic life to toxic pollutants in an effluent without initially requiring the identification of the specific pollutants. Since WET is not a pollutant, more in-depth analyses, known as Toxicity Identification Evaluations (“TIEs”) and Toxicity Reduction Evaluations (“TREs”) are done if toxicity is detected in order to determine what pollutant or pollutants are likely causing the toxicity effect.

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)(italics added).)

USEPA regulations at 40 C.F.R. Part 136 prescribe the specific test procedures and methods that must be used for the analysis of pollutants in all 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; *see also* 40 C.F.R. §122.44(i)(iv) (monitoring to be done according to test procedures approved under 40 C.F.R. Part 136).)

B. Alternative Test Procedures

Under limited circumstances and subject to specific regulatory requirements, a person may request to use an ATP 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.)

Under 40 C.F.R. section 136.4, a person seeking approval of an ATP for nationwide use must submit its application to the National Alternate Test Procedure Program Coordinator at USEPA Headquarters in Washington, D.C. for approval. If approved, USEPA will propose to amend 40 C.F.R. section 136.3 to include the ATP as an approved analytical method through notice and comment rulemaking. The ATP is not approved for nationwide use unless and until the ATP is approved by publication in a final rule in the Federal Register. (40 C.F.R. §136.4(c).)

Under 40 C.F.R. section 136.5, a person seeking approval of an ATP for limited use must submit its application to the Regional Alternate Test Procedure Coordinator or permitting authority for approval. (40 C.F.R. §136.5(a).) When the request for the use of an ATP concerns use in a State with a delegated NPDES permit program approved pursuant to section 402 of the CWA, such as California, the following is required: “[T]he requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator or permitting authority with a recommendation for or against approval.” (40 C.F.R. §136.5(b).) All applications for a limited use ATP must contain five (5) specific items. (40 C.F.R. §136.5(c).) If approved by the Regional ATP Coordinator, “the approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator or permitting authority, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region.” (40 C.F.R. §136.5(d).)

Pursuant to USEPA guidance related to ATPs, the “limited use” ATP approach can apply to applications for single discharger, single laboratory facility uses (i.e., Tier 1), or multi-discharger, multi-laboratory facility uses (i.e., Tier 2 and Tier 3). All but a single lab, single discharger ATP (i.e., Tier 1) must go through rulemaking. For broader application Tier 2 and 3 new methods, “EPA will begin the rulemaking process.” (*See Guide to Method Flexibility and Approval of EPA Water Methods*, USEPA Office of Water (Dec. 1996 Draft) at pp. 80-82.)

In May of 2012, USEPA expanded the reach of limited use ATPs when it promulgated a rule that modified 40 C.F.R. section 136.5 to ostensibly allow the Regional ATP Coordinator or permitting authority, at his or her discretion, to grant approval of a limited use ATP to all dischargers or facilities specified in an approval letter. (*See Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; Final Rule*, 77 Fed. Reg. 29,758 (May 18, 2012)(“2012 Rule Modification”).) The 2012 Rule Modification was not challenged at the time because members of the public were unaware that the new rule would be used to apply “limited use” ATPs beyond single discharger, single laboratory facility uses to an *entire state* and to all discharges and permits issued within that state with no notice and comment rulemaking as required by the Administrative Procedure Act (“APA”).

USEPA has issued protocols detailing the information needed to evaluate ATP applications for potential approval. However, by its own admission, USEPA does not currently have a protocol for approving ATPs for WET testing. (*See Guide to Method Flexibility and Approval of EPA Water Methods*, USEPA Office of Water (Dec. 1996 Draft) at p. 93 (“EPA is developing a protocol for approval of new and modified (alternate) WET methods....”); *see also*

<http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm> (last accessed 12/23/2020) (stating “**Note:** EPA does not have an ATP review protocol for toxicity testing under EPA’s Whole Effluent Toxicity (WET) program.”).)

Under 40 C.F.R. section 136.6, a person may make limited minor modifications to an approved testing method included in 40 C.F.R. Part 136.3 without prior USEPA approval, including for example, changing purge volumes and automating manual methods. However, changes to the determinative step, the quality control, or significant chemistry of the method, are outside the scope of modifications authorized by section 136.6. Additionally, the Method Modification approach under section 136.6 applies only to CWA chemical methods and cannot be used for “Method-Defined Analytes.” Specifically, USEPA regulations prohibit modifications of WET methods. (40 C.F.R. §136.6(b)(3)(“Restrictions. An analyst may not modify an approved Clean Water Act analytical method for a method-defined analyte.”)(emphasis added).) Whole effluent toxicity methods are *not chemical methods* and USEPA has previously declared that WET is a Method-Defined Analyte. (See 67 Fed. Reg. 69,965 (“toxicity is inherently defined by the measurement system (a ‘method-defined analyte’) and toxicity cannot be independently measured apart from a toxicity test.”).)

C. Approved WET Test Methods and the Test for Significant Toxicity

In November of 2002, USEPA promulgated through a formal rulemaking process short-term chronic WET test methods for use in monitoring compliance with NPDES permit limitations in accordance with 40 C.F.R. Part 136. (See *Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule*, 67 Fed. Reg. 69,952 (Nov. 19, 2002) (the “2002 Methods”).) These methods specifically include the No-Observed-Effect-Concentration (“NOEC”) and the 25% Inhibition Concentration (“IC25”). The 2002 Methods are USEPA’s promulgated WET methods that, where the rule allows hypothesis testing, specifies a null hypothesis that presumes an effluent sample is non-toxic, and requires testing to determine compliance with an NPDES effluent limitation consisting of a control group and a minimum of **five** effluent concentrations in order to evaluate the validity of the dose-response relationship. (See 2002 Methods, 67 Fed. Reg. 69,962-63.) The 2002 Methods do not mention the TST or provide that the one-concentration TST may be used as an approved method. In addition, the USEPA in the 2002 Methods specifically “recommends the use of point estimation techniques over hypothesis testing approaches for calculating endpoints for effluent toxicity testing.” (*Id.* at 69,958.)

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

“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.”

USEPA has had ample opportunity to approve the TST in its Part 136 regulations, including in its most recent 2019 proposed rulemaking (and in 2014), but has not done so. (*See U.S. v. Riverside Bayview Homes*, 474 U.S. 121, 137 (1985) (An action not to include modifications of which the entity was aware can be read as a presumption that the modifications were not intended to be included).) In fact, although USEPA recently proposed amendments to the Part 136 methods, including specific changes to the 2002 Methods, the TST was not included. (*See, e.g.*, Federal Register Notice, <https://www.federalregister.gov/documents/2019/10/22/2019-22437/clean-water-act-methods-update-rule-for-the-analysis-of-effluent> (Oct. 22, 2019).) Numerous amendments to Part 136 have occurred since 2010, and none have included the TST.

II. USEPA’s Approval of the State Water Board’s ATP Request Would Violate Federal Law and Impermissibly Exceed USEPA’s Authority

In light of the foregoing statutory and regulatory framework under the CWA, USEPA’s approval of the State Water Board’s ATP Request would violate federal law and impermissibly exceed USEPA’s authority. More specifically, such action by USEPA would be unlawful for the following main reasons:

- **Federal Law Prescribes Specific Test Method Requirements and Requires Promulgated Methods.** Section 304 of the CWA requires USEPA to develop *and publish* methods for establishing and measuring water quality criteria for toxic pollutants, including monitoring and assessment methods (33 U.S.C. §1314(a)(8)); to *promulgate* guidelines establishing test procedures for the analysis of pollutants (33 U.S.C. §1314(h)); and to *promulgate* guidelines establishing the procedural and other elements of a state water quality control program, including monitoring and reporting requirements (33 U.S.C. §1314(i)(A) and (B)). USEPA regulations at 40 C.F.R. Part 136 prescribe the specific test procedures and methods that must be used for the analysis of pollutants in all applications and reports submitted under the NPDES program under section 402 of the CWA. (40 C.F.R. §§136.1(a), 136.3; *see also* 40 C.F.R. §122.44(i)(iv) (monitoring to be done according to test procedures approved under 40 C.F.R. Part 136).) Analytical results obtained using a non-promulgated method cannot be used for NPDES compliance determination purposes until that method has been properly incorporated into 40 C.F.R. Part 136. (40 C.F.R. §122.44(i)(iv), §122.41(j)(4).) USEPA’s approval of the State Water Board’s ATP Request and use of the TST undermines and completely subverts these explicit requirements to not only use the currently approved test methods (*i.e.*, NOEC and IC25), but also USEPA’s requirement to develop and promulgate Part 136 test methods.

- **USEPA’s Approval of the State Water Board’s ATP Request would be Unlawful without an Approved ATP Protocol.** As noted above, USEPA has issued protocols detailing the information needed by USEPA to evaluate ATP applications for potential approval. Further, by its own frequent admission, USEPA does not have a protocol for approving ATPs for WET testing. Without an approved protocol for reviewing or approving WET ATPs under Sections 136.4 or 136.5, the State Water Board’s ATP Request cannot be validly approved.
- **USEPA’s Approval of the State Water Board’s ATP Request would be Unlawful Because the State is Not a Proper Requesting Party.** Section 136.5(a) states that “Any person may request the Regional Alternate Test Procedure (ATP) Coordinator or permitting authority to approve the use of an alternate test procedure in the Region.” (40 C.F.R. §136.5(a).) Because the person making the request must seek this action from either the Regional ATP Coordinator at USEPA, or the permitting authority, which in California consists of the State and Regional Water Boards, it would stand to reason that the person making the request was never meant to be either the USEPA, or the State Water Board as the permitting authority. This argument gains support by the further text of this regulation where, at Section 136.5(b), the rule requires that “the requestor shall first submit an application to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator or permitting authority with a recommendation for or against approval.” (40 C.F.R. §136.5(b)(emphasis added).) In this case, the permitting authority sent an ATP request to the Regional ATP Coordinator directly, bypassing required steps in the process. The mandated chain of events spelled out in the regulations never happened because no outside person beyond the USEPA or State Water Board made any request for this ATP.
- **Comparability Data Shows that the Proposed ATP Does Not Compare Favorably to the 2002 Methods.** Section 136.5(c)(5) requires the ATP requestor to “provide comparability data for the performance of the proposed alternate test procedure compared to the performance of the reference method.” The State’s ATP Request fails to provide any comparability data and just assumes that the ATP and the reference method “are inherently the same with the exclusion of the four dilution concentration treatments.” (ATP Request at p. 12.) The State Board’s ATP is inadequate to meet the regulatory requirements.

Moreover, the one-concentration TST approach has been demonstrated to inaccurately identify non-toxic samples. When known “non-toxic” method blank data from USEPA’s Interlaboratory WET Variability Study is re-evaluated using the TST, the number of false indications of “toxicity” or “false failures” increases dramatically. Approximately 15% of all non-toxic samples would be declared “toxic” using the TST in the *Ceriodaphnia dubia* (water flea) reproduction tests – 4 times more than occurred when using either the NOEC or IC25 method. And, 8.3 % of all non-toxic samples were declared “toxic” using the TST to evaluate Fathead minnow growth. This is nearly double the rate of 4.2% at

which similar false indications of toxicity occurred when evaluating the same data with the traditional promulgated NOEC or IC25 methods (see table below).

Chronic Test Endpoint	TST	NOEC	IC25
<i>C. dubia</i> Reproduction	4 of 27 (14.8%)	1 of 27 (3.7%)	1 of 27 (3.7%)
<i>C. dubia</i> Survival	2 of 27 (7.4%)	0 of 27 (0%)	0 of 27 (0%)
Fathead minnow Growth	2 of 24 (8.3%)	1 of 24 (4.2%)	1 of 24 (4.2%)
Fathead minnow Survival	0 of 24 (0%)	0 of 24 (0%)	0 of 24 (0%)

The Southern California Coastal Water Research Project (“SCCWRP”) recently conducted a laboratory study where known non-toxic blank samples of water were tested. The results showed as high as a **50% false rate of toxicity** for the samples, where half showed up as “toxic” even though the samples were designed to be non-toxic. (See Schiff, Kenneth C., and Darrin Greenstein. “Stormwater Monitoring Coalition: Toxicity Testing Laboratory Guidance Document,” SCCWRP Technical Report 956 (2016).) False fail rates appear to be higher with TST, particularly related to water flea reproduction (see *Ceriodaphnia dubia* Short-term Chronic Reproduction Test: Understanding the Probability of Incorrect Determinations of Toxicity in Non-toxic Samples, prepared by Larry Walker Associates, Inc. (November 28, 2018).)

In a strict liability permit scheme, this extraordinarily high level of false indications of toxicity would place permit holders in a position of non-compliance where no wrongdoing had actually occurred and would subject permittees to hefty civil penalties, potential criminal penalties, and unnecessary citizen enforcement for discharges of “toxic water.” (Wat. Code, §§13385, 13387; 33 U.S.C. §§1319 and 1365.) In addition, a 2011 State Water Board toxicity study (*Toxicity in California Waters*, State Water Board (Oct. 2011), found at https://www.waterboards.ca.gov/water_issues/programs/swamp/docs/txcty_rpirt.pdf) recognized that the TST declared a sample “toxic” six percent (6%) more often than the promulgated methods. (*Id.* at p. 18.) The TST is clearly not comparable when the results differ 8% of the time. (*Id.*) This information demonstrates that the data is not comparable and the ATP should not be approved.

- **USEPA’s ATP is Unlawful Because a Non-Compliant Request was Made.** Among other things, all valid applications for a limited use ATP must contain the five specific items set forth in 40 C.F.R. Section 136.5(c)(1)-(5). The State Water Board’s ATP

Request failed to comply with these specific regulatory requirements. By way of example, the State Water Board must provide any particular discharge, permit, applicable ID number, or discharge serial number to which the ATP would apply. The intent of this regulation was to apply an ATP to a single or small number of discharges or laboratories to “provide increased flexibility to the regulated community and laboratories in their selection of analytical methods (test procedures) for use in Clean Water Act programs” (75 Fed. Reg. 58,024 (emphasis added)), not to have USEPA or a State prescribe a method for all discharges that never underwent a formal notice and comment rulemaking. Finally, as discussed in the previous bullet, the State Water Board failed to provide adequate “comparability data.” Because the State Water Board’s ATP Request failed to comply with these regulatory requirements, USEPA should deny the request.

- **The State Water Board’s ATP Request Represents an Unlawful Method Modification.** As explained above, under USEPA rules, a person may make limited minor modifications to an approved testing method included in 40 C.F.R. Part 136.6 without prior USEPA approval. (40 C.F.R. §136.6.) However, changes to the determinative step, the quality control, or significant chemistry of the method, are outside the scope of modifications authorized by section 136.6. Additionally, the Method Modification approach under section 136.6 applies only to CWA chemical methods and cannot be used for “Method-Defined Analytes.” Specifically, USEPA regulations prohibit modifications of WET methods. (40 C.F.R. §136.6(b)(3)(“Restrictions. An analyst may not modify an approved Clean Water Act analytical method for a method-defined analyte.”)(emphasis added).) Whole effluent toxicity methods are *not chemical methods* and USEPA has previously declared that WET is a Method-Defined Analyte. (See 67 Fed. Reg. 69,965 (“toxicity is inherently defined by the measurement system (a ‘method-defined analyte’) and toxicity cannot be independently measured apart from a toxicity test.”); see also *Edison Electric Institute v. EPA*, 391 F.3d 1267, 1270 (D.C. Cir. 2004) (“[U]nlike properties such as chemical concentration, toxicity is both measured and defined by the WET tests (i.e., it is a ‘method-defined analyte’).”.) Accordingly, USEPA’s approval of the State Water Board’s ATP Request would violate federal regulations by approving the one-concentration TST or as a method modification in contravention of Section 136.6 that restricts method modifications to chemical methods and prohibits modification of method-defined analytes, such as WET.
- **The State Water Board’s ATP Request Removes Procedural Safeguards ensured by the Judicially Approved 2002 Methods.** In a prior legal challenge to the 2002 Methods, a court found that “[t]he ratified WET tests are not without their flaws.” (*Edison Electric Institute v. EPA*, 391 F.3d 1267, 1274 (D.C. Cir. 2004).) However, the court upheld those methods because USEPA had provided adequate safeguards within those methods to protect against the concerns raised by the plaintiffs. One of these safeguards was the use of a multiple-concentration test to provide an adequate dose response. “EPA also offered an additional safeguard by designing the tests to give permittees the benefit of the doubt, limiting false positive rates to at most 5%, while allowing false negative rates up to 20%.” (*Id.* at 1272.) These safeguards have been removed from the State Water Board’s ATP Request for the one-concentration test, which merely compares an effluent

sample at 100% strength to a control blank. USEPA's potential action to approve the ATP request would thus remove these procedural safeguards without providing adequate public notice and comment.

For the foregoing reasons, SCAP urges USEPA to deny the State Water Board's ATP Request because such approval of the State Water Board's ATP Request would violate federal law and exceed USEPA's authority. EPA should only authorize WET tests that allow permittees to use a dose response curve to validate the results, thus avoiding excessive false indications of toxicity.

Please do not hesitate to contact me at mthorme@downeybrand.com to further discuss the State Water Board's ATP Request.

Respectfully submitted,

DOWNEY BRAND LLP



Melissa A. Thorme

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