November 25, 2020

Audrey L. Johnson  
Quality Assurance Office  
U.S. Environmental Protection Agency, Region 9  
75 Hawthorne Street  
San Francisco, CA 94105

Dear Ms. Johnson:

REQUEST FOR REVIEW AND APPROVAL OF A ONE EFFLUENT CONCENTRATION ALTERNATIVE TEST PROCEDURE FOR WHOLE EFFLUENT TOXICITY TESTING

The California State Water Resources Control Board (State Water Board) hereby applies for United States Environmental Protection Agency (U.S. EPA) Region IX review and approval of a limited-use alternative test procedure (ATP) for the use of one-effluent concentration when conducting whole effluent toxicity (WET) testing pursuant to 40 Code of Federal Regulations part 136.5 (Aug. 28, 2017), referred to hereafter as “Part 136.5”. This application is specific only to conducting acute or chronic whole effluent toxicity tests when using the Test of Significant Toxicity (TST) statistical approach (U.S. EPA 2010) for analyzing the data. This request is being sought for all dischargers or facilities in the State of California and their associated laboratories.

Proposed Establishment of the Toxicity Provisions

The State Water Board has developed Toxicity Provisions that, if approved, will establish numeric acute aquatic toxicity and numeric chronic aquatic toxicity water quality objectives for all inland surface waters, enclosed bays, and estuaries in California with aquatic life beneficial uses as well as establish a program of implementation that includes numeric effluent limitations for non-stormwater NPDES dischargers in California. The Toxicity Provisions specify the chronic and acute aquatic toxicity test methods to be used to assess whether the ambient waters meet the numeric water quality objectives or whether discharger effluent complies with applicable permit terms.
The Toxicity Provisions would require the TST statistical approach be used to assess compliance with numeric effluent limitations and numeric water quality objectives. Under the current project schedule, the State Water Board plans to consider adoption of the Toxicity Provisions in December of 2020. If adopted by the State Board, the Toxicity Provisions would be submitted to California Office of Administrative Law and the U.S. EPA for review and approval.

This ATP application is made independent of the outcome of the adoption process of the Toxicity Provisions, and subsequent U.S. EPA approval process. Some California permits already require the TST statistical approach to analyze WET data for compliance with applicable NPDES permit terms. If the Toxicity Provisions are approved, certain additional non-storm water and storm water NPDES dischargers would be required to use the TST upon the next permit issuance, reissuance, renewal, or reopening (to address toxicity requirements) after the effective date of the Toxicity Provisions. The TST approach is a statistical option that U.S. EPA has added to the current recommended statistical approaches. California requiring the use of the TST approach does not alter promulgated requirements of the test method, such as specified biological and laboratory procedures (see sections below for a description of U.S. EPA Method Update Rule and U.S. EPA’s response). As has been affirmed by U.S. EPA, the TST statistical approach can be used with current U.S.EPA methods that require testing multiple concentrations of effluent. This ATP would provide significant cost savings for those existing permittees.

Procedures for an ATP Application within California [Part 136.5(a) & (b)]

Part 136.5 defines who can request an ATP. Under Part 136.5 (b), “[a]ny person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.” Under Part 136.5 (b), the requester “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 with a recommendation for or against approval.” The requestor is the State Water Board. The State Water Board, along with the Regional Water Boards, has responsibility for generation and issuance of National Pollutant Discharge Elimination System (NPDES) permits within California, and for oversight of the NPDES Quality Assurance Program Plan implementation. The State Water Board Quality Assurance Officer has been granted authority by the Executive Director to submit the limited use ATP application to U.S. EPA Region 9.

Name and Address of Applicant [Part 136.5(c)(1)]

Andrew Hamilton
Quality Assurance Officer
California State Water Resources Control Board
1001 I Street
Sacramento, California 95814
Existing and Pending Permits [Part 136.5(c)(1)]

This ATP request is being sought for all dischargers or facilities (Attachment 1. Current Non-Storm Water NPDES Permits; Attachment 2. Current Storm Water NPDES Permits) and their associated laboratories (Attachment 3. ELAP Accredited WET Laboratories) in the State of California. This request also extends to California dischargers or facilities included in the attached lists, that may have a new, reissued, renewed, or reopened NPDES permit not listed in the attachment.

Description of the Requested ATP Parameter [Part 136.5(c)(2)]

When conducting Whole Effluent Toxicity testing, this ATP request is to allow for the testing of only a single effluent test concentration and the control, when the statistical approach required for permit compliance or study design only compares results from those two treatments.

Justification for using the ATP [Part 136.5(c)(3)]

The TST (a form of a statistical t-test) is a statistical approach which U.S. EPA has identified (U.S. EPA 2010) as an option for use when analyzing WET data. In Appendix H (U.S. EPA 2002b) U.S. EPA recommends a t-test when only testing one concentration of concern: “To statistically compare a control with one concentration, such as 100 percent effluent or the instream waste concentration, a t-test is the recommended analysis.”

The TST statistical approach determines whether an organism’s response to a single concentration (for NPDES permits, referred to as the instream waste concentration or IWC) demonstrates a statistically significant difference from the response to control water.

The result of the TST statistical analysis is either a pass (not toxic) or a fail (toxic). Data from the other concentrations currently required to be conducted under WET test methods in part 136.3 are not used in this analysis nor in determining whether the test organism response in the IWC and the control differ by a statistically significant amount. Therefore, testing multiple concentrations of effluent as a dilution series is an unnecessary cost and use of time and materials.

Currently, there are multiple approved NPDES permits in California requiring the TST statistical approach to determine compliance. Five of the nine regional water quality control boards (Regional Water Boards) have issued individual NPDES permits requiring the use of the TST statistical approach in analyzing WET data for compliance with effluent limitations or to determine whether additional monitoring or a toxicity reduction evaluation is required.

Regional Water Boards requiring the use of the TST:
1. North Coast Regional Water Quality Control Board
2. Central Coast Regional Water Quality Control Board
3. Los Angeles Regional Water Quality Control Board
4. Colorado River Regional Water Quality Control Board
5. San Diego Regional Water Quality Control Board

The State Water Board has required the use of the TST statistical approach in other NPDES permits. The State Water Board has included provisions requiring the use of the TST approach in the California Department of Transportation general permit for storm water discharges (Order No. 2012-0011-DWQ).

In addition, the U.S. EPA has issued NPDES permits requiring the TST as the statistical approach. Examples of NPDES permits issued to Tribes in California that require use of the TST:

- Jamul Indian Village; Hollywood Casino WWTP; Jamul, CA - NPDES Permit No. CA0084284
- Tish Non-Community WWTP, Loleta, CA - NPDES Permit No. CA0084282
- Santa Ynez Band of Chumash Indians WWTP, Santa Ynez, CA - NPDES Permit No. CA0050008

**Precedent for a State-Wide Limited Use ATP [Part 136.5(c)(3)]**

There is a precedent for this application and approval of a state-wide limited use alternative test procedure for the use of one effluent concentration and a control. In 1986 (prior to the current ATP application language defining “limited-use” and “nationwide use” ATPs), the North Carolina Department of Natural Resources requested approval of an alternative test procedure to test one effluent concentration and a control when using the t-test. After review of North Carolina’s request and submittal, U.S. EPA Region 3 approved North Carolina’s statewide test procedure utilizing the alternative test condition. This was limited to the state of North Carolina, and not the entire U.S.EPA Region 3.

From U.S. EPA’s letter to North Carolina Department of Natural Resources 12-17-1986:

“We encourage the use of the Ceriodaphnia Pass/Fail Mini-Chronic Bioassay Procedure as a routine requirement in State-issued NPDES permits.”

U.S. EPA reaffirmed the approval of North Carolina’s use of the alternate test procedure for one effluent concentration in their response to comments regarding the August 17, 2015 Permit Quality Review (U.S. EPA 2015b): “The EPA acknowledges its prior approval for North Carolina’s Alternate WET test procedures . . . .”

**Economic Discussion [Part 136.5(c)(3)]**
WET testing is an important tool for water quality assessment because it provides a comprehensive assessment of the effects of known toxicants, unknown toxicants, and the synergistic effects of multiple toxicants in water. WET testing is a less expensive alternative for assessing suitable water quality than analyzing for all potential toxicants in a surface water or effluent.

When the permit or study requires using the TST statistical approach, only the results from the control and instream waste concentration (IWC) treatments are used to determine whether the effluent or test sample is toxic.

The current U.S. EPA WET test requirements for testing five effluent concentrations plus a control generates data that are not analyzed nor necessary for determining whether the effluent is toxic at the IWC. The effort in collecting the additional volume of sample, shipping, handling, creating the dilution series, growing and feeding the organisms, and counting the results add unnecessary expense. This requested ATP reduces the resources and cost of the toxicity test method when compared to testing five effluent concentrations and a control as currently required by WET test methods.

The State Water Resources Control Board conducted a survey of a subset of California laboratories for costs associated with each WET test per species for conducting both five effluent concentrations and one effluent concentration (Attachment 4. Summary of Aquatic Toxicity Test Costs). In all cases where data were available, there were significant cost savings when conducting the one effluent concentration test design compared to the five effluent concentration test design. For example, for the Ceriodaphnia dubia chronic test, potential savings ranged from $141 to $692, with an average savings of $243 per test. This estimate does not take into account the costs associated with collecting, handling and shipping samples for a five effluent concentration test design. Additional cost savings are expected from a reduction in the volume of samples collected, handled and shipped when conducting the one effluent concentration test design compared to the five effluent concentration test design.

In addition to quantifiable cost savings there is an additional economy achieved. Certain WET test species are difficult to rear, and sometimes are in short supply for laboratories. This eliminates the waste of those species by not testing the four additional concentrations and the corresponding replicates.

**History of Prior ATP Approval and Withdrawal by U.S. EPA [Part 136.5(c)(3)]**

California previously submitted an alternative test procedure application described as a two-concentration test design (one effluent concentration and a control-effluent concentration of zero percent) and received approval from U.S. EPA, which U.S. EPA later withdrew. It is relevant to review the history of this process in the context of the review of the current application.
In a letter dated February 12, 2014, the State Water Board Quality Assurance Officer, Renee Spears, submitted an ATP request to U.S. EPA Region 9 for the statewide use of a two-concentration toxicity test design when using the TST statistical approach. This two-concentration test design was composed of a single effluent concentration and a control concentration (effluent concentration of zero percent).

U.S. EPA approved the ATP request on March 17, 2014. In June 2014, the approval was challenged in court on procedural grounds under the Administrative Procedures Act by the Southern California Alliance of Publicly Owned Treatment Works (SCAP) and the Central Valley Clean Water Association (CVCWA). The U.S. EPA withdrew the approval and notified the State Water Board in a memo dated February 11, 2015 (U.S. EPA 2015a).

The three reasons for withdrawal, as described in the February 11, 2015 memo, are clearly identified as procedural errors in the ATP submittal at the state level, as well as the U.S. EPA’s approval and procedural processes. It is important to note that U.S. EPA’s withdrawal of its approval of the ATP was not based on the scientific soundness of the two-concentration test design, or the TST statistical approach.

The withdrawal letter also stated that there was a proposed rulemaking to change the language in the ATP regulations at 40 Code of Federal Regulations part 136. The changes were promulgated by U.S. EPA on August 28, 2017. Part 136.5 now includes the following paragraph:

“136.5 (d) Approval for limited use. (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. 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, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.”

The State Water Board is requesting this limited use ATP in accordance with the application process indicated in 40 Code of Federal Regulations part 136.5.

**U.S. EPA’s response to the State Water Board’s request for the two-concentration test method inclusion in the U.S. EPA Method Update Rule [Part 136.5(c)(3)]**

As part of the comment submittal process to the Method Update Rule Proposal (U.S. EPA 2016), the State Water Board requested U.S. EPA modify the WET requirements to allow for the use of the one effluent compared to a control procedure when using the TST. In response, U.S. EPA stated that the comment was outside the scope of the revision request. U.S. EPA provided the following direction in its response:
“However, the methods do not specify the statistical approach that must be used in analyzing the data generated from valid WET tests. Rather, as the commenter correctly notes, the EPA WET test methods provide only "recommended" statistical approaches and specifically state that approaches "other than those recommended may be appropriate . . . . This use of the TST would be fully consistent with the existing WET test methods and would not require the revision requested by the commenter. If, however, a person seeks to reduce the number of concentrations required to be tested when using the TST statistical approach, they could apply for an Alternative Test Procedure (ATP) (40 CFR 136.4; 136.5). Again, no ATP is required for the use of the TST, as long as the requirement to test five effluent concentrations is met. An ATP would be required only to reduce the required number of concentrations to be tested to the one effluent concentration plus a control used in the TST statistical approach.”

The current ATP submission to reduce the number of treatments to be tested to one effluent concentration and a control when using the TST statistical approach follows the direction provided by U.S. EPA’s response to the State Water Board comments to the Method Update Rule Proposal.

**Detailed Description of Proposed ATP [136.5(c)(4)]**

The proposed ATP is to use aquatic toxicity test methods approved in 40 CFR 136.3 and identified in Table 1 of this application with an alternative test condition. In all cases, the alternative test condition is to test only one effluent (IWC) concentration, and not to create and test the currently required four additional dilutions of the effluent. The requested use of one effluent concentration when conducting an NPDES required test applies to the species in Table 1 below that have determined acceptable maximum false positives (defined as beta when using the TST statistical approach) and false negatives rates (or alpha when using a TST statistical approach) (U.S. EPA 2010, State Water Board 2020). Table 1 describes the current test condition applicable to the species and the corresponding requested alternative test condition to test only one effluent concentration. All other current U.S. EPA approved test method requirements applicable to each species and found in the referenced manuals must be met, including Test Acceptability Criteria (TAC).

The Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms (U.S. EPA 2002a) includes *Hylella* spp. and *A. affinis* in a supplemental list of acute toxicity test species. The minimal testing requirements indicated in the method manual for these two species does not include testing with five concentrations of effluent. Therefore, the request for approval of the alternative test condition language for *Hylella* spp. and *A. affinis* is not included in this ATP application. It is the State Water Board’s position that the alternative test condition language included in Table 2 below for *Hylella* spp. and *A. affinis* could be required in the permit by the designated Permitting Authority for California. We are requesting U.S. EPA affirm this interpretation or indicate whether an ATP for *Hylella* spp. and *A.
affinis must be approved by U.S. EPA prior to the implementation of the one effluent test condition.

Toxicity test methods using West Coast-specific species are defined in the West Coast Marine Method Manual (U.S.EPA 1995). The West Coast Methods are not promulgated in 40 CFR 136.3, so the request for approval of the alternative test condition language for species in the West Coast Marine Method Manual is not included in this ATP application. It is the State Water Board’s position that the alternative test condition language included in Table 2 below for the West Coast Marine Methods could be required in the permit by the designated Permitting Authority for California. (Guidelines Establishing Test Procedures for the Analysis of Pollutants; Whole Effluent Toxicity Test Methods; Final Rule, 67 Fed. Reg. 69952, 69955 (Nov. 19, 2002). We are requesting U.S. EPA affirm this interpretation or indicate whether an ATP of the West Coast Methods must be approved by U.S. EPA prior to the implementation of the one effluent test condition.

Additionally, this ATP application is specific to approved aquatic toxicity test methods in 40 CFR 136.3 and identified in Table 1 of this application when testing effluent. For stormwater receiving water, ambient water, and effluent receiving water, the manuals state that five concentrations and a control are recommended but not required. Therefore, alternative test condition language for testing using stormwater receiving water, ambient water, and effluent receiving water is not included in this ATP application. We are requesting U.S. EPA affirm this interpretation or indicate whether an ATP must be approved by U.S. EPA prior to implementation of the one concentration test condition for stormwater receiving water, ambient water, and effluent receiving water.

The Environmental Laboratory Accreditation Program (ELAP) currently conducts inspections of laboratories that perform WET testing for California permit compliance. If this ATP is approved, ELAP will be informed of the ATP and will work with the State Water Board’s Division of Water Quality to ensure inspections and audits continue to be conducted for laboratories using the requested ATP.
Table 1. Summary of Existing and Requested Test Conditions

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<thead>
<tr>
<th>U.S. EPA Toxicity Test Method</th>
<th>Method Reference</th>
<th>Test Condition/Requested Alternative Test Condition</th>
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<tr>
<td>Chronic Freshwater Methods</td>
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<td>Requested Alternative Test Condition: Test concentrations: Effluents: 1 and a control (required minimum)</td>
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<td>Acute Freshwater Methods</td>
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<td><em>Ceriodaphnia dubia</em> (water flea); <em>Daphnia magna</em> (water flea); <em>Daphnia pulex</em> (water flea); <em>Pimephales promelas</em> (fathead minnow); <em>Onchorhyncus mykiss</em> (rainbow trout) <em>Salvelinus fontinalis</em> (brook trout); <em>Americamysis bahia</em> (mysid) Renamed from <em>Mysidopsis bahia</em></td>
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Table 2. Summary of Existing and Permitting Authority Specified Test Conditions

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<tr>
<td>U.S. EPA Toxicity Test Method</td>
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<td>Test Condition/Requested Alternative Test Condition</td>
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<tr>
<td>Acute Freshwater and Marine Methods</td>
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<tr>
<td><em>Hyalella spp.</em> (amphipod) Survival</td>
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<tr>
<td>Atherinops affinis (topsmelt) Survival</td>
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**Comparability data [136.5(c)(5)]**

Under this proposed ATP, besides the control and IWC (permitted effluent concentration of concern) the additional effluent dilutions do not need to be created and tested. All other test conditions and test acceptability criteria in the method manuals must be met for the applicable species. Since the WET ATP test method conditions and test acceptability criteria (TAC) for the control and permitted concentration of concern are exactly the same as the part 136.3 test method conditions and TAC, performance of the proposed alternate test procedure compared to the performance of the reference method are inherently the same with the exclusion of the additional four dilution concentration treatments.
Summary

The State Water Board requests that U.S. EPA approve the limited-use ATP for the use of one-effluent concentration when conducting whole effluent toxicity (WET) testing as described in this application. This request is being sought for all dischargers or facilities in the State of California and their associated laboratories. Approval of this ATP will reduce laboratory and permittee’s expenses when using the TST statistical approach for analyzing the data.

Thank you in advance for your review and consideration of the ATP request. Please do not hesitate to contact me with any questions regarding our application.

Sincerely,

(Greg Gearheart, Deputy Director, for Andrew Hamilton)
Andrew Hamilton, Quality Assurance Officer
Office of Information Management and Analysis

Attachments (4):
Attachment 1. Current Non-Storm Water NPDES Permits
Attachment 2. Current Storm Water NPDES Permits
Attachment 3. ELAP Accredited WET Laboratories
Attachment 4. Summary of Aquatic Toxicity Test Costs
cc:  (Sent via e-mail.)

Jonathan Bishop, Chief Deputy Director  
State Water Resources Control Board

Karen Mogus, Deputy Director  
Division of Water Quality  
State Water Resources Control Board

Greg Gearheart, Deputy Director  
Office of Information Management and Analysis  
State Water Resources Control Board

Rich Breuer, Environmental Program Manager  
Division of Water Quality  
State Water Resources Control Board

Zane Poulson, Senior Environmental Scientist  
Inland Planning Standards and Implementation Unit  
State Water Resources Control Board

References:


http://onlinelibrary.wiley.com/doi/10.1002/etc.2166/full


https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.4347
State Water Resources Control Board. 2011. Effluent, Stormwater, and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST).


https://www.govinfo.gov/content/pkg/USCOURTS-caDC-96-01062/pdf/USCOURTS-caDC-96-01062-0.pdf


https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NERL&dirEntryId=46584


