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Public Comment
Toxicity Provisions
Deadline: 12/21/18 by 12 noon

December 21, 2018

Ms. Jeanine Townsend
Clerk to the Board
State Water Resources Control Board
P. O. Box 100
Sacramento, CA 95812-2000



Re: Proposed Establishment of the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California; and Toxicity Provisions; Notice of Opportunity for Public Comment

Dear Ms. Townsend:

The American Petroleum Institute (API) represents over 625 companies involved in all aspects of the oil and natural gas industry (exploration, production, refining, marketing and transportation). API appreciates the opportunity to comment on the State Water Resources Control Board's proposed Establishment of the Water Quality Control Plan for Inland Surface Waters, Enclosed Bays, and Estuaries of California; and Toxicity Provisions (hereafter Proposed Rule). API member companies own and operate facilities in the State of California that discharge effluents subject to National Pollutant Discharge Elimination System (NPDES) permits, as such are affected by the State's Proposed Rule.

API objects to the imposition of the test of significant toxicity (TST) method on state policy and incorporation into state-administered NPDES permits. The State has neither specified its authority nor provided any justification for mandating exclusive use of the TST, which has not been promulgated as an approved method in the Code of Federal Regulations (CFR) at 40 CFR 136, over procedures already promulgated, commonly used, and well accepted. The State has failed to show that use of promulgated alternatives poses any risk or compromise to human health and the environment. API urges the State to drop its proposed TST mandate and allow other alternatives to be flexibly used in its stead.

API's technical concerns with the TST are detailed as follows:

- API supports the use of point estimates (EC25, IC25) of effect from a full range of effluent dilutions in a whole effluent toxicity (WET) assay as the primary determinant of compliance with WET permit requirements.
 - API believes WET testing is best used to monitor WET and correct observations of toxicity without the imposition of numeric limits, particularly pass/fail limits based on comparison to a laboratory control.

- Point estimates are recommended by the Environmental Protection Agency (EPA) scientists who generated the WET method guidance promulgated at 40 CFR 136 as the determinant of effect.
- The use of a full effluent dilution series (5 dilutions plus a control) allows inspection of the concentration-response relationship to determine if it represents toxicity, accounting for the inherent variability of the tests.
- Paired comparison hypothesis testing, whether conducted using the no observed effect concentration (NOEC) or TST approach, is constrained by the concentrations or dilution ratio tested, restricting the effect level to one of the tested concentrations. The NOEC and lowest observed effect concentration (LOEC) may represent effect concentrations near 25%, or any other effect level, depending on the tested dilutions and the response of the organisms. The TST, using only one effluent dilution, effectively establishes that specific tested dilution as either the NOEC or the LOEC.
- API is concerned that the use of the TST predisposes toward false positive findings.
 - The use of a single compliance concentration to compare to control performance assumes a classic concentration-response, in spite of the fact that EPA has shown that anomalous responses frequently occur.
 - EPA's recommendation to increase the number of tested replicates only partly, if at all, normalizes the response of the test organisms to the effluent, while at the same time potentially providing an even narrower control response against which to test for effects, increasing the likelihood of failure. Ultimately, increasing replication does not decrease the variability of the response data.
- The assumption an effluent is toxic for the purpose of statistical sensitivity, and the consequential high false positive rate for the TST, carry potentially severe consequences for permittees, the vast majority of whom are in fact very unlikely to be discharging toxicity on a routine, ongoing, or long-term basis.
 - Exceeding permit WET limits is a violation with potential penalties and fines, notwithstanding the vanishingly small likelihood of any impact to human health and the environment.
 - Violations of all kinds affect the permittees' public image; for this and other reasons, the assumption of guilt until proven otherwise is an unfair and undemocratic stance.
 - Test failures cause operations to devote significant additional resources to address the violation immediately upon failure of a test – though “toxicity” often is not apparent upon an immediate retest – only to sporadically arise as an issue again due to either actual toxicity, laboratory performance, or statistical causes. Distinguishing among these three causes is subject to interpretation and may vary from one test instance to another.
 - Progression to a TRE, and incorporating a TIE, is also costly and risky, particularly for very complex effluents such as petroleum refinery effluents; the increased rate of false positive TST results is likely to result in increased TIE efforts.
 - Following sample receipt, the chronic toxicity testing program takes about three weeks plus an additional week to prepare and send the monitoring report to the client. According to the draft Water Quality Control Plan, for non-stormwater

NPDES discharges greater than 5.0 MGD the chronic toxicity testing frequency would be increased from once per calendar quarter to once per calendar month. In most cases, this frequency would mean analytical testing results samples collected the previous month would not be available until another monthly sample is due to be collected. With this frequency of analysis, there would be no available time to collect extra samples to confirm an apparent non-compliant result or a potential false-positive result for that previous month. Large dischargers would have no opportunity to definitively demonstrate their final effluent is either in compliance or out of compliance with a chronic toxicity limit. This compliance uncertainty, potentially leading to unwarranted agency compliance actions or third-party lawsuits, is unreasonable. API recommends the frequency of chronic toxicity testing for large dischargers remain at quarterly.

- API advocates the elimination of the TST in the State's NPDES WET compliance programs.
 - If included in a state or tribal policy, the standard tests in promulgated EPA guidance should be adopted to avoid the assumption that dischargers are in violation (guilty) rather than innocent (in compliance).
 - EPA has designed the TST with the intent of having a 5% false failure error rate for individual tests. It would stand to reason that the actual false-failure (β) error rate would be significantly higher, given that the false-failure error rate built into the TST is a regulatory management decision conceived by EPA to identify no more than 5% of the tests with 10% mean effect or less as "toxic." This means that the 5% false-failure error rate only applies to tests with 10% mean effect or less. Therefore, a virtual gray zone occurs when the measured mean effect falls between 10% and 25%, creating a situation in which the false-positive error rate may be significantly higher than 5%, leaving the false-positive error rate largely contingent upon the within-test variability. Further, simulation analyses show that TST false failure error rates even at a mean effect $\leq 10\%$ are in fact much higher than the design false failure error rate.
 - Any inclusion of the TST must include the 10% negligible difference rate and 25% effect threshold detailed in the 2010 TST Implementation Guidance.
 - A hybrid program incorporating the promulgated statistical methods (point estimate and null hypothesis testing) and TST might be acceptable, provided TST is not the foremost arbiter of compliance.
- The State's proposed testing scheme is likely to result in an increase in the number of vertebrates (fish) used in testing – despite the commitment of many industrial permittees to decrease vertebrate testing.
 - Increased number of screening rounds for most-sensitive species
 - Requirement for annual acute fish screening and TST application to facilities already subject to high-frequency flow-through acute monitoring
 - Increased potential for accelerated testing and TIE using TST approach

API's concern with the TST is its presumption (null hypothesis) of non-compliance leading to unacceptably high rates of false positives, particularly as the coefficient of variation increases. The State's accusation that dischargers are not only tolerant of, but in pursuit of, poor data quality belies the countless hours expended by facility environmental staff and contract

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laboratories seeking improved predictability through better control performance and lower within-treatment variability. In fact, control performances within and between laboratories, including mean performance in concurrent control treatments in side-by-side tests, can easily vary by more than 10% - which is a test failure in the State's scheme. Predictable test outcomes are key to the success of costly and potentially lengthy TIE and TRE efforts, in addition to ongoing biomonitoring performance; thus, "poor quality" (i.e., variable) data are a problem for dischargers as well, but also highlight the issues related to trying to squeeze the square peg of WET testing into the round hole of compliance monitoring; the single-concentration instream wastewater concentration (IWC) vs. control carries that pressure one step further but without matching the certainty of a stand-alone permit limit - it is still based on relative performance, and still subject to the numerous known and unknown causes of variability in WET tests.

The State's "TST test drive" found equivalence between TST and NOEC in 95% of cases, and for the remaining 5% TST appropriately erred to the side of toxicity where warranted. This finding suggests EPA's promulgated statistical approaches at 40 CFR 136 are effective at identifying toxic effluents and do not need to be eliminated in favor of the TST.

For the reasons stated above, API urges the State to drop from its Proposed Rule the mandated use of the TST and allow other alternatives to be flexibly used its stead.

API appreciates the opportunity to provide these comments on the State's Proposed Rule. If you have any questions concerning API's comments, please contact me.

Sincerely,



Roger E. Claff
Senior Scientific Advisor, API

cc: A. Emmert, API
A. Miles, API