RISK SCIENCES

21 January 2011

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State Water Resources Control Board
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Sacramento, CA 95814

RE: Comment Letter - Policy for Toxicity Assessment and Control

Over the last 20 years, Risk Sciences has worked closely with numerous dischargers in California and, in particular, have assisted them as they implemented the whole effluent toxicity testing requirements specified in NPDES permits. That experience leads us to conclude that the state's current approach, using a narrative receiving water limitation and a step-wise procedure for investigating and reducing toxicity, works exceptionally well and has all but eliminated whole effluent toxicity from the municipal effluents discharged to inland waters of Southern California.[1]

The State Water Resources Control Board's (SWRCB) proposed Policy for Toxicity Assessment and Control represents a significant change in state regulation; one that is not justified given the enormous success demonstrated by current WET implementation strategy. It appears that the primary reason given in support of the new policy is that more stringent requirements are needed to ensure dischargers do everything possible to eliminate toxicity. However, absolutely no evidence has been offered to suggest that this is not already happening.

Every permittee with toxicity monitoring requirements in their permits acts with great diligence to identify and reduce toxicity in their effluent. The greatest impediment to total success is not a lack of effort on their part but, rather, the ephemeral nature of toxicity itself and the inherent variability of the tools we use to measure this phenomenon. The overall incidence of WET test failure is now so low that we have great difficulty distinguishing true toxicity caused by chemical pollutants from the inevitable and unavoidable failures built into the test methods. EPA acknowledges that at least 5% of all toxicity tests will fail for reasons utterly unrelated to the actual effluent quality. This is the natural consequence of using live biological organisms as the primary measurement instrument.

[1] Hunt, J., B. Markiewiez & M. Pranger. State Water Resources Control Board. Summary of Toxicity in California Waters: 2001-2009. November, 2010.

We are deeply concerned that the proposed policy will hinder rather than aid the effort to minimize aquatic toxicity in California. The state's current approach emphasizes the need to take action rather than assign blame. And, while there may be a theoretical risk that some dischargers might exploit this system to delay treatment upgrades, no evidence has been provided in support of this new regulatory shift to suggest any sort of bad-faith is actually occurring in practice. And, even if it were true, the new policy would punish the vast majority of honest and conscientious permittees for the sins of a few bad actors by electing to use a "bigger hammer" to indiscriminately pound all dischargers into compliance.

The proposed policy would be, by far, the most stringent and punitive ever adopted by any state in the nation. Yet, there is no evidence to suggest that such an approach is needed to remedy some heretofore unaddressed problem in California. On the contrary, it is our sincere belief that the proposed policy would greatly undermine the state's current successful program by forcing dischargers to expend considerable resources to defend themselves against false permit violations. Specifically, the proposed policy has the following deficiencies:

1) The proposed TST method reverses the legal presumption of innocence by establishing a null hypothesis (H_0) that all effluent samples are toxic and will significantly reduce survival, growth and reproduction among aquatic organisms *until proven otherwise*. This represents a significant change from the state's current approach to toxicity testing which relies on a null hypothesis that all effluent samples are non-toxic until proven otherwise. It is contrary to the official EPA methods identified at 40 CFR Part 136 and the entire past history of toxicity testing performed in California.

   Because failure to comply with the Clean Water Act carries severe civil and criminal penalties, the state bears the burden to prove that violations have occurred. The TST procedure illegally shifts this burden to the discharger and obligates the permittee to "prove the negative." As a result, the proposed policy violates constitutional due process protections.

   The staff report for the proposed policy analogizes the TST procedure to the "bioequivalence methods" used by the Food and Drug Administration (FDA). However, FDA uses the bioequivalence techniques to evaluate the safety and efficacy of chemical compounds to determine whether various new drugs can be sold in the United States. FDA does not subject manufacturing companies to civil and criminal enforcement based on a bioequivalence method.

   Neither the SWRCB nor the U.S. Environmental Protection Agency (EPA) have statutory authority to establish a new legal presumption that a permitted discharge is violating water quality standards even if that assumption is rebuttable, or worse, incorrect.. Nor has the SWRCB shown that the same level of environmental protection cannot be achieved by less intrusive means including continued reliance on the statistical methods already authorized under 40 CFR Part 136.

2) Use of the TST procedure is not authorized under federal law. The Clean Water Act, and related federal regulations require permittees to demonstrate compliance using standardized test procedures approved pursuant to 40 CFR Part 136 when such methods are available. U.S. EPA promulgated such methods for evaluating chronic and acute toxicity in October, 2002. All of the approved statistical procedures for analyzing toxicity test data are described, in detail, in EPA's official method manuals and related guidance. No deviation from these methods is allowed unless approved, in advance, by U.S. EPA.

The TST procedure is not among the approved methods identified in 40 CFR Part 136. As such, it cannot be used in lieu of standard methods to demonstrate compliance with effluent limitations for toxicity in a NPDES permit. Consequently, the SWRCB's proposed WET policy is not in conformance with law.

EPA acknowledges that WET is a "method-defined parameter" that cannot be calibrated or corroborated by independent means. Therefore, the specific statistical procedure used to analyze test data is as much a part of the method as the laboratory protocols used to generate the data. That is why EPA's method manuals include detailed flowcharts to identify the specific statistical method that must be used for each foreseeable data condition. EPA has long maintained that any deviation from the statistical techniques identified in the official manuals constitutes a change to the method that must be approved as an Alternate Test Protocol pursuant to 40 CFR Part 136.5[2]. California's adoption of the TST procedure must be considered a change in the WET test method itself particularly because the new statistical technique produces results which are inconsistent with and contrary to the conclusions reported using the existing authorized procedures.

3) U.S.EPA lacks authority to authorize use of the TST procedure in lieu of the statistical techniques previously enacted under 40 CFR Part 136. Such a deviation requires formal agency action to approve an Alternate Test Protocol as described in 40 CFR Part 136.5. To date, EPA has not taken such action. EPA failed to provide adequate public notice of their intent to develop or allow use of any new WET methods. Nor has EPA provide any opportunity for public comment on the proposed TST procedure. The documents EPA recently published describing the TST method were not noticed as official agency guidance. And, it does not appear that the Agency prepared the required Quality Assurance Project Plan (QAPP) before performing computer simulation studies to assess the general validity of the TST method. Thus, EPA has failed to meet the minimum legal requirements to authorize an Alternate Test Protocol and the SWRCB may not mandate use of the unapproved TST procedure to assess compliance with WET limits in an NPDES permit.

[2] See, for example, EPA's disapproval of South Carolina's statistical procedure for calculating "Percent Effect" or EPA's recent disapproval of Texas' statistical procedure using a 99% confidence interval (Dec. 2, 2010).

In addition, federal law requires permittees to certify that all data reported pursuant to monitoring conditions in an NPDES permit are "...true, accurate and complete." U.S. EPA has published guidance memoranda stating that, by attesting to the accuracy of WET test data, permittees are certifying that the data was collected in accordance with the standard method specified in 40 CFR Part 136. If the SWRCB elects to require use of the TST procedure, dischargers will no longer be able to certify the results are "accurate" in accordance with 40 CFR 122.22(d). This will severely compromise the state's ability to rely on TST data in any future enforcement proceeding.

4) The TST method does not comply with federal or state law requiring scientific peer review. Although U.S. EPA asserts that an external peer review was performed, there is no evidence in the record to support this claim. It appears that the only peer-review was performed by staff assigned to EPA's regional offices or by contractors working under EPA's supervision to help develop the TST method. This is not in accordance with recent revisions to U.S. EPA's official peer review policy.[3] Nor does it comply with the federal Data Quality Act of 2000 [P.L. 106-398] requiring impartial scientific peer review. The "Charge to Peer Reviewers," "Peer Review Comments" and "EPA's Response to Peer Reviewers" have not been made publically available.

There is no evidence in the record to indicate that SWRCB staff reviewed EPA's peer review documents to determine if the materials were adequate to meet the specific peer review requirements specified under California law. In addition, staff's assertion that state peer review is unnecessary in light of EPA's previous peer review efforts is inconsistent with staff's previous position on this matter. Recently, Gerald Bowes of the SWRCB's staff informed Regional Board staff in Region 8 that a separate state-initiated scientific peer review is required to support adoption of new water quality objectives for pathogen indicator bacteria. Furthermore, Regional 8 staff was told that they may not rely on EPA's peer review process to meet this state independent obligation even if the Regional Board intends to enact EPA's 304(a) criteria for bacteria without revision. If so, then it is not clear how the SWRCB can mandate the use of an unapproved WET test method without first conducting the scientific peer review required by state law.

[3] U.S. EPA. Addendum to the Peer Review Handbook, 3rd Ed. Appearance of a Lack of Impartiality in External Peer Reviews. December, 2009.

5) The TST method is inconsistent with federal court decisions restricting the use of test data in enforcement proceedings. In Amoco Oil Co. v. EPA [501 F.2d 722 (D.C. Cir. 1974)] the U.S. Court of Appeals found that analytical variability is inevitable in all test measures and that such variability does not necessarily invalidate the method. However, the Court also declared such variability precludes federal and state authorities from initiating enforcement actions when the laboratory results fall within the known error band of the test. Under the current WET test methods, an effluent sample must continue to be presumed non-toxic when analytical variability makes it impossible to conclude, with adequate statistical confidence, that the test sample is toxic.

However, under the proposed TST method, the same level of analytical variability will now mean that there is insufficient statistical confidence to reject the null hypothesis and the effluent will continue to be presumed "toxic." Thus, if the TST procedure is adopted, results that fall within the known error band of the test can be used to demonstrate that that a permit violation has occurred in a manner contrary to the court's ruling in Amoco.

6) Test results prepared using the TST procedure cannot be submitted as evidence in an enforcement proceeding because it fails to meet well-established judicial criteria for scientific validity [see Daubert v. Merrell Dow Pharmaceuticals, Inc. 43 F.3d 1311 (9th Cir. 1995)]. In particular, the TST method has not yet achieved general acceptance by the relevant scientific community because EPA published the procedure only six months ago and did not solicit any public comment on the technical merits of the method.

In addition, the TST procedure has not been subjected to empirical testing, using known non-toxic samples, to establish the potential error rate. The TST method frequently produces conclusions regarding the presence or absence of toxicity that are opposite those reported using the existing, lawfully adopted test procedures. U.S. EPA states that the TST procedure will incorrectly identify benign effluents as "toxic" approximately 5% of the time. However, independent re-analyses of EPA's test data from non-toxic blank samples shows the true error rate is actually three times higher than that (e.g. 15% of all non-toxic samples will be misclassified as toxic). Unlike the WET test methods currently authorized under 40 CFR Part 136, U.S. EPA did not perform the requisite interlaboratory studies to demonstrate acceptable precision for the TST procedure. Consequently, as a matter of law, the TST technique lacks sufficient scientific certainty to allow it to be admitted as evidence in any state or federal enforcement proceeding. Nor can the SWRCB compel permittees to certify such test results on the monthly Discharge Monitoring Reports as would otherwise be required under 40 CFR Part 122.22(d).

7) The proposed toxicity control policy is unconstitutionally void for vagueness because it does not provide permittees with adequate notice as to what specific behaviors are prohibited or what specific actions are required. Historically, the regulating authority has had the obligation to determine the safe and unsafe level of various pollutants. These levels were then used to specify numeric effluent limits in the NPDES permits. Thus, the discharger knew exactly what concentrations of various pollutants were allowed or disallowed. The TST procedure does not follow this model.

The proposed toxicity test method simply enjoins permittees from discharging harmful stuff. But, there is no way to know in advance what chemicals, at what levels, are harmful. By the time the information becomes available at the conclusion of a WET test many days later, the "violation" has already occurred and there is nothing the permittee can do to avoid the infraction. SWRCB's own staff report states that all large wastewater treatment plants have "reasonable potential" to cause toxicity precisely because the influent is comprised of a wide-range of unpredictable chemical combinations over which the discharger has no control. Thus, the SWRCB's proposed toxicity policy establishes an inequitable and unfair mandate on the regulated community.

The SWRCB's current approach to regulating whole effluent toxicity avoids this problem by requiring permittees to investigate, identify and remediate toxicity to the best of their ability. But, it does not obligate dischargers to achieve strict compliance with a numeric effluent limit where the cause of the failure is unknown. However, national experience gleaned from performing tens of thousands of such tests over the last 20 years also shows that WET tests can fail for any number of reasons unrelated to actual water quality. One study, published by the Water Environment Research Foundation (WERF) found that nearly 60% of all the statistical variation in *Ceriodaphnia dubia* reproduction data was due to factors other than the specific chemical concentrations in the effluent sample.[4] These factors are outside the control of the discharger and should not be allowed to influence the evidence used to determine whether a permit infraction has occurred.

This problem is made worse by the fact that the exact same effluent quality and exact same test results may be deemed evidence proving a sample is simultaneously toxic and non-toxic depending on which state the discharge occurs. While states retain some discretion to set water quality standards to reflect local conditions, that is not the case here. Reliance on the TST procedure will frequently produce a different conclusion than would be reported if one of the other statistical methods authorized by 40 CFR Part 136 were used.

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[4] Water Environment Research Foundation. Whole Effluent Toxicity Testing Methods: Accounting for Variance. 1999. Alexandria, VA. (See Table 3-1 on pg. 3-4).

Because toxicity is being regulated pursuant to federal statute and regulation, the intrinsic definition of the prohibited act cannot vary from jurisdiction to jurisdiction or it runs afoul of equal protection requirements. And, even if it were allowed, the specific distinctions must be identified in advance in order to provide adequate notice under law. Compliance cannot and should not depend on which statistical procedure is used to analyze the data where those procedures do not produce consistent results. Any enforcement action based on such an approach would be arbitrary, capricious and void for vagueness.

8) The administrative record supporting adoption of the proposed toxicity control policy does not comply with Section 13241 of the California Water Code or those sections of the California Environmental Quality Act (CEQA) that require the SWRCB to consider the reasonably foreseeable costs of compliance. Rather, the staff report claims that the causes and remedies of toxicity are too numerous and, thus, any such effort would be "purely speculative." First, such a claim strongly supports our previous objection that the policy is void for vagueness. In the same report, SWRCB staff acknowledges that wastewater influent is a complex amalgam of a vast number of chemicals in a nearly infinite number of concentrations and combinations. This, staff says, makes it impossible to draw any reasonable inferences about what it might cost to comply. However, the permittees would be expected to achieve strict compliance despite such vagaries. Either toxicity is predictable and preventable or it's not. The SWRCB cannot exempt themselves from the same sort of analysis they would impose on others by claiming such a requirement is unreasonable. Doing so would be arbitrary and capricious.

Second, Exhibit 4-3 in the staff report identifies numerous specific remedial actions for achieving compliance with toxicity limitations. Thus, it can hardly be "purely speculative" to estimate the statewide compliance costs that would be expected if such mechanisms are necessary to meet the proposed WET policy.

Third, routine WET testing has been performed in California for more than 20 years. Experience garnered from those previous tests has already shown that additional wastewater treatment may be necessary to prevent toxicity in the effluent. At a minimum, every major POTW without dilution will likely be required to build nitrification facilities to eliminate excess ammonia from the discharge. There is nothing speculative about this because years of WET testing have already revealed what ammonia levels must be achieved to pass the tests. The same is true for chlorine, diazinon, chlorpyrifos, and numerous other common household chemicals routinely discharged to the sewer system.

Wastewater treatment plants were not designed to treat these organic chemicals and must be re-built as a result. It is not credible claim that toxicity is uniquely different at every POTW; two decades of real-world data show considerable commonality to the cause of most WET test failures in municipal effluent. Ignoring this historical data is contrary to both the letter and intent of CEQA requirements.

Finally, if it is impossible to predict what remedial actions may be required to comply with the new WET policy, then it is unclear how the SWRCB staff was able to determine that there would be "No Impacts" when the CEQA Environmental Checklist was prepared. In light of the statements made in Exhibit 4-3, the historical record of plant improvements to eliminate toxicity from municipal effluents in Southern California, and the public comments submitted at the SWRCB workshop in November, 2010 there is no factual basis to support such a conclusion.

9) Under the proposed toxicity control policy all POTWs discharging more than 1 million gallons per day of municipal effluent will be presumed to have reasonable potential to cause or contribute to an excursion of the new toxicity objectives. This will be the case regardless of how well the permittee has performed in past toxicity tests and is contrary to long-standing policy and procedure used by federal and California authorities to determine reasonable potential. Moreover, to assume an effluent may be toxic in the face of clear historical data contradicting such claims is both arbitrary and capricious. 40 CFR 122.44(d) requires that the state provide clear findings of reasonable potential and evidence to support those findings when imposing a numeric effluent limit. The SWRCB may not sidestep these requirements by fiat declarations.

10) The proposed TST method will place most dischargers in danger of ex post facto violation of the Clean Water Act. State and federal law prohibit the discharge of toxics in toxic amounts. The proposed policy defines toxicity and mandates use of a specific statistical procedure to do the necessary calculations. Many tests that previously passed using the current statistical techniques will now fail when re-evaluated using the new TST procedure. Consequently, what was once deemed to be a compliant effluent may not be declared to be in violation of the narrative receiving water or effluent limitations found in nearly every NPDES permit issued in California. All one need do is reanalyze the existing data with EPA's new TST software. Nothing prevents such reanalyses from occurring because there is a 5-year statute of limitations for enforcing permit violations. Even if the SWRCB elected to exercise enforcement discretion, and forego retrospective toxicity audits, nothing precludes citizen suits from being filed pursuant to Section 505 of the Clean Water Act. This problem is created by the adoption of a new and different metric for calculating toxicity than was originally used to analyze the WET data. And, the problem is more likely to occur if the SWRCB and EPA continue to claim that applying a new statistical tool does not constitute a change in the method itself.

11) The proposed toxicity control policy would make each and every WET test failure a violation of the permit necessitating some sort of enforcement action under the Clean Water Act. This is contrary to EPA guidance and briefs, submitted to the Court during previous WET litigation, that strongly recommends *against* initiating enforcement actions for single WET test failures. In Edison Electric Institute, et al v. EPA, [U.S. Court of Appeals - D.C. Circuit. Case No. 96-1062 (December 10, 2004)] the court relied heavily on these assurances to uphold the general acceptability of WET testing for assessing permit compliance. By reversing the null hypothesis (thereby establishing a presumption of guilt) and adopting a new policy that each individual test failure constitutes a permit violation, California's new WET policy would nullify EPA's assurances and the rationale given by the Court in Edison.

The proposed toxicity objectives and related enforcement provisions reverse long-standing state and federal policy regarding WET implementation. This reversal occurs without explanation or evidence supporting the need for such extreme action. As such, any decision to enact the new policy would be arbitrary and capricious and should be entitled to no judicial deference.

12) Selection of a 25% effect threshold as the critical value in the TST procedure is arbitrary and capricious. The staff report states that using a 25% effect threshold is defensible because it is similar to the level used in other statistical procedures currently allowed under 40 CFR Part 136. However, elsewhere in the report, staff also stated that the existing statistical methods do not provide adequate environmental protection. Moreover, there is no evidence in the record to demonstrate the appropriateness of the 25% threshold even for the existing methods. On the contrary, numerous public comments have been submitted showing that no valid correlation exists between the proposed 25% effect level and the biological integrity of actual instream conditions.

In addition, the 25% effect threshold cannot be divorced from its statistical context. The current methods use a more sophisticated dose-response model to estimate the 25% effect level. The current methods also start with an initial presumption that the effluent is not toxic and set the burden of proof so as to demonstrate otherwise. Thus, there is virtually no risk that effect levels smaller than 25% will fail the test. However, that is not true for the TST. Analysis of several different data sets (both laboratory blanks and effluent samples) show that effect levels that fall between 18% and 24% will routinely fail the TST when the same samples would have passed EPA's existing IC-25 methodology.

Thus, assertion that a 25% effect threshold is appropriate, without including all of the other caveats that protect permittees against false conclusions, is a gross overgeneralization that lacks supporting evidence to justify such a conclusion. There is no scientific evidence cited in the record to demonstrate that the results of WET tests performed using the TST method are in any way related to actual instream conditions. This is because, to date, no field studies have been performed by EPA, the SWRCB, or any other reputable scientific organization using the proposed TST procedure. Any claim that the TST method "better protects beneficial uses" is simply an unfounded assertion.

13) The proposed WET control policy arbitrarily denies a compliance schedule to any permittee who is already performing routine toxicity testing irrespective of the discharger's historical test performance. This is wholly unreasonable given the other statements in the staff report that municipal treatment plants receive a wide and unpredictable variety of chemicals from the sewage collection system. The treatment plant operators cannot predict the nature of these chemical pollutants or what effect, if any, will be shown by the toxicity test. Moreover, to the extent that the new toxicity objectives are intended to address pollutants not already subject to numeric effluent limits then, by definition, these are new requirements and the discharger is entitled to receive a compliance schedule to address the new obligation. This is entirely consistent with staff's claim that each toxicity event represents a unique set of circumstances that must be addressed on a case-by-case basis. To do otherwise would be "purely speculative." Therefore, it is unreasonable to prohibit use of compliance schedules under such circumstances.

14) The proposed toxicity control policy fails to make allowance for known sources of natural interference with the standard test procedure. Numerous studies have shown that the absence of key nutrients or minerals can cause test failure as easily as the presence of toxic pollutants. This phenomenon frequently occurs when groundwater and rainwater samples are submitted for toxicity testing. Such samples are usually "too clean" in that they lack the minimum concentration of chemicals needed to support freshwater organisms. Similar problems are also more common in the west where municipal demand is met using groundwater that is naturally elevated in hardness or alkalinity. All of these factors interfere with the normal conduct and interpretation of the test and may result in false and misleading conclusions about potential effluent toxicity.[5]

[5] U.S. EPA. "Clarifications Regarding Flexibility in 40 CFR Part 136 Whole Effluent Toxicity (WET) Test Methods" Memorandum from Tudor T. Davies, Director Office of Science and Technology to Water Management Division Directors, Regions I-X Environmental Services Division Directors, Regions I-X; April 10, 1996. See, also, U.S. EPA. Understanding and Accounting for Method Variability in Whole Effluent Toxicity Applications Under the NPDES Program. EPA-833-R-00-003 (June, 2000); p. D-7.

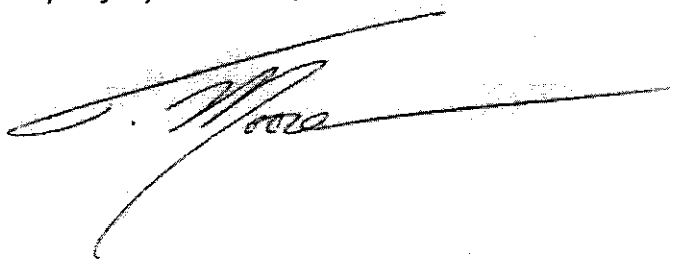
It is arbitrary and capricious to presume that all effluent samples are toxic and then require reliance on a test method to demonstrate otherwise when said method cannot reliably determine whether the adverse effects are the result of the presence of chemical pollutants, the absence of vital nutrients, or the natural ionic composition of local source waters.

15) Recent reports published by the SWRCB suggest that common agricultural and household pesticides are likely responsible for many of the WET test failures previously reported throughout California. Since all such pesticides were previously approved by the state's Department of Pesticide Regulation (DPR), it is unreasonable to make the wastewater treatment agencies responsible for any adverse consequences resulting from that authorization.

When DPR approves a pesticide for use in California, it must first certify that the chemical in question will not have a significant adverse effect on non-target organisms in the environment. To the extent that the SWRCB intends to rely on WET testing to support a contrary conclusion, the burden-of-proof must be on the state agencies to resolve the inconsistencies in their mutually-exclusive determinations before subjecting the regulated community to arbitrary violations of the Clean Water Act. It is an abuse of discretion to hold others responsible for the adverse consequences that naturally follow from the state's own failure to exercise proper oversight authority over the release of toxic chemicals in the environment.

For all of the reasons cited above, we strongly recommend that the SWRCB reject use of the TST method as the primary tool for assessing and controlling toxicity in California.

Respectfully submitted,



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