

## **Prevailing Comments on the Draft Policy for Toxicity Assessment and Control**

### **1. Commenters expressed concern with the use of the Test of Significant Toxicity, claiming that it will result in unsubstantiated determinations of toxicity.**

State Water Board staff (staff) received numerous comment letters that were critical of the Test of Significant Toxicity (TST) method, claiming that the stated false positive rate of five percent is, in actuality, much higher. Further, these commenters believe that the false positives associated with the TST will result in unwarranted toxicity reduction evaluations (TRE) and violations, as well as incorrect impairment determinations in water bodies throughout the state.

#### **Response**

The false positive rate is explicitly defined in the TST and has been validated in numerous analyses, including peer-reviewed simulations. In addition, the State Water Board has completed an additional “Test Drive” of the method using actual data provided by California dischargers. These studies demonstrate that the false positive rate is no greater than five percent overall, and often much less for most test methods using the TST. Commenters appear to be mistakenly referencing sporadic TST analyses that, despite having effect levels below the regulatory management decisions (RMD) of 25 percent for chronic or 20 percent for acute, failed the TST analysis. Such occurrences arise when a statistically significant difference between the sample and control is of a magnitude sufficient to declare the sample toxic. Such results are not false positives. In addition, as demonstrated by the TST Test Drive, the percentage of toxicity tests that produce such a result are minimal, as are the probabilities of unwarranted TREs and violations.

Regarding impairment determinations, section 3.6 of the *Water Quality Control Policy for Developing California’s Clean Water Act (CWA) Section 303(d) List* leaves the choice of analytical techniques used in listing decisions to the discretion of Water Board staff. The draft Policy for Toxicity Assessment and Control (draft Policy) would not, in any way, override this provision.

#### **Conclusion**

Approaches to effluent limit expression will be examined in order to address toxicity tests that sporadically result in a “fail,” despite meeting the RMDs established in the TST (see “Numeric Effluent Limits” in the “Alternatives to Select Provisions of the Draft Policy for Toxicity Assessment and Control” document).

### **2. Provisions for storm water and channelized dischargers were found to be confusing by some commenters.**

Commenters thought the sections of the draft Policy addressing storm water and channelized dischargers (Sections B and C respectively) lacked clarity, citing compliance ambiguity and cross-references to wastewater remediation measures in particular. Some commenters were also under the impression that storm water and channelized dischargers would be required to comply with numeric effluent limitations under the draft Policy.

## Response

The provisions proposed for storm water and channelized dischargers only require the implementation of a monitoring program—not compliance with numeric effluent limitations. Staff recognizes the difficulty in applying numeric limitations to these discharger categories. However, incorporating language explicitly precluding the State and Regional Water Boards from applying effluent limitations when feasible would be shortsighted and unnecessarily prohibitive.

## Conclusion

Given the multiple comment letters expressing confusion about the proposed provisions for storm water and channelized dischargers, staff will revise Sections B and C of the draft Policy for clarity (see “Storm Water and Channelized Discharger Provisions” in the “Alternatives to Select Provisions of the Draft Policy for Toxicity Assessment and Control” document).

### **3. Commenters worry that small, disadvantaged communities will be disproportionately impacted by the costs associated with the implementation of the draft Policy.**

Several commenters were concerned that the proposed monitoring provisions may prove to be an economic burden to small municipalities and the publicly owned treatment works (POTW) serving them.

## Response

While the draft Policy’s single-concentration toxicity test requirement will reduce per-test unit costs for many dischargers, POTWs serving small, disadvantaged communities may see an increase in monitoring frequency and, in turn, an increase in laboratory costs. Staff acknowledges that small, disadvantaged communities are special cases and may need accommodation.

## Conclusion

Staff will address small, disadvantaged communities in the draft Policy (see “Economic Impact on Small, Disadvantaged Communities” in the “Alternatives to Select Provisions of the Draft Policy for Toxicity Assessment and Control” document).

### **4. Commenters suggest revising compliance provisions so that a single toxicity test resulting in a “fail” would not be construed as a permit limit violation.**

A number of commenters are concerned that a violation incurred from an initial sample failure may result in negative publicity and citizen lawsuits.

## **Response**

Staff agrees that the resources of both the State Water Board and stakeholders are better focused on significant toxicity, rather than transient, low level toxicity detections.

## **Conclusion**

Staff will revise the draft Policy to focus effluent limitation expression on significant toxicity (see “Numeric Effluent Limits” in the “Alternatives to Select Provisions of the Draft Policy for Toxicity Assessment and Control” document).

### **5. Commenters claim that the economic analysis for the draft Policy does not satisfy the requirements of California Water Code Section 13241.**

A number of commenters feel that the economic analysis developed for the draft Policy is inadequate and does not comply with California Water Code (CWC) Section 13241. Some comment letters cited a lack of costs associated with TRE actions and specific price estimates for storm water, channelized discharger, and acute toxicity monitoring, while others claimed that the entire report was obsolete because it was based on a prior version of the draft Policy.

## **Response**

CWC section 13241 does not require a cost-benefit analysis of a proposed standard. Rather, the CWC only requires the Water Boards to consider economics when establishing water quality objectives. Staff fulfilled this requirement by working with a consultant (Science Applications International Corporation) to prepare a detailed estimate of the costs associated with the draft Policy. This economic analysis indicates that routine monitoring costs are expected to decrease under the draft Policy for many dischargers. Most of the comments asserting the contrary failed to acknowledge the reduction in per test costs and built upon incorrect assumptions regarding the false positive rate of the TST method (see response to comment 1).

As TREs are site-specific studies tailored to individual dischargers, any such cost estimates would be purely speculative. However, due to the concerns expressed by numerous commenters regarding this issue, staff will revise the economic analysis to include price ranges of previous TRE undertakings from various dischargers.

Given the draft Policy’s discretionary approach to acute toxicity limitations, coinciding cost estimates were not included. Any cost increases resulting from such monitoring represent unit costs that can be estimated by using the toxicity test price tables included in Exhibits B-11 through B-14 of the economic analysis. While these tables can also be used to estimate unit costs for storm water and channelized dischargers, staff will specifically address these discharger categories in the forthcoming version of the economic analysis.

Additionally, the economic analysis will be revised to reflect the most up-to-date version of the draft Policy. Nonetheless, it should be noted that the current economic analysis remains relevant to the present draft Policy despite the fact that it was developed using an earlier version of it. The primary difference between the two drafts is the means by which chronic and acute toxicity effluent limitations would be

assigned to dischargers. This deviation proved irrelevant, however, as chronic toxicity test methods remained the focal point of the economic analysis.

## **Conclusion**

Staff will amend the economic analysis to include cost estimates for TREs, as well as storm water and channelized discharger monitoring programs. In addition, the economic analysis will be revised to reflect the most up-to-date version of the draft Policy.

### **6. Several commenters suggest replacing the proposed numeric objectives and effluent limitations with narrative objectives and numeric triggers.**

Many commenters believe numeric objectives and effluent limitations are inappropriate for toxicity, claiming that the test methods are subject to significant variability and are ultimately poor indicators of in-stream impacts. In addition, some commenters are concerned that the proposed numeric objectives are more stringent than required by federal law, suggesting the adoption of narrative objectives with numeric permit triggers instead.

## **Response**

The need for the proposed numeric objectives and effluent limitations is two-fold. The State Water Board directed staff to consider numeric objectives and amend the narrative toxicity control provisions in the *Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California* (SIP) as needed. Staff concluded that the compliance-driven approach of numeric effluent limitations would provide the most efficient and ultimately successful means of regulating toxic discharges. Regardless of the imposition of numeric triggers, narrative objectives represent an oversight-driven approach to water quality regulation that would obligate the Water Boards to manage any remediation measures that may be necessary. Such an approach would further deplete the state's limited resources.

Numeric objectives and effluent limitations are an appropriate means of controlling chronic and acute toxicity, as evidenced by a U.S. Court of Appeals decision upholding the validity of toxicity test methods against a variety of constitutional, statutory, and administrative law challenges. In *Edison Electric Institute et al. v. EPA*, 391 F.3d 1267 (D.C. Cir. 2004), the Court found that:

- U.S. EPA reasonably validated the standardized testing procedures, including their precision and bias, as well as their high rates of successful completion.
- The methods did not produce unacceptably variable results.
- The method procedures (i.e. replication and comparison to controls) adequately compensated for the inability to determine a method detection limit.
- The results produced with the methods were representative of receiving water toxicity, including receiving waters of the arid West.

Furthermore, claims that the draft Policy is more stringent than federal law is incorrect, as the CWA authorizes the use of both narrative and numeric effluent limitations to achieve strict compliance with water quality standards (see *City of*

*Burbank v. State Water Resources Control Bd.* (2005) 35 Cal.4th 613, and State Water Board Order No. WQ 2006-0012 (*Boeing*)). Regardless of this fact, CWA Section 301(b)(1)(C) grants states the authority to impose effluent limitations that are more rigorous than those established in the CWA itself, in order to meet water quality standards.

## **Conclusion**

The adoption of numeric objectives and effluent limitations are appropriate for controlling chronic and acute toxicity.

### **7. Commenters questioned the sufficiency of relying on U.S. EPA's peer review process.**

Several commenters questioned the validity of the peer review conducted for the TST method, as well as staff's assertion that additional peer review was not necessary for the inclusion of the method in the draft Policy.

## **Response**

As required by Health and Safety Code, Section 57004(d), State Water Board staff is obligated to submit the "scientific findings, conclusions, and assumptions" of a proposed standard. However, as the State Water Board's Administrative Procedures Manual, Section 8 III.D. explains, "Peer review is not needed for source documents that have been previously peer reviewed by a recognized expert or body of experts."

The bioequivalence approach the TST method is based upon was first peer-reviewed by Erickson and MacDonald in 1995. Moreover, the TST was externally peer reviewed in accordance with U.S. EPA's Peer Review Policy during its development and, in addition, was reviewed by three anonymous evaluators prior to its publication in the internationally recognized *Environmental Toxicology and Chemistry* journal.

As noted in Section VI of the staff report, staff has determined that the scientific aspects of the Policy are based on source material that has already been peer reviewed. The proposed Amendment is itself just a new application of earlier, adequately peer-reviewed work products, specifically, U.S. EPA's TST. The proposed Policy does not depart from the scientific approach of the TST. Therefore, the proposed policy has met the requirements of Health and Safety Code 57004.

## **Conclusion**

The draft Policy and Staff Report comply with the peer review requirements of Health and Safety Code, Section 57004(d), and Section 8 III.D. of the Administrative Procedures Manual. No further peer review is planned.

**8. Commenters assert that the U.S. EPA is required to adopt the TST through a formal rule-making process before the State Water Board can adopt it in a statewide policy.**

Several commenters claim that the draft Policy represents “underground rulemaking” because the TST guidance document was neither released for public comment by U.S. EPA nor adopted in the Code of Federal Regulations.

**Response**

The TST approach is merely a statistical approach to analyze valid toxicity test data and does not alter U.S. EPA’s toxicity test methods as set forth in 40 CFR, part 136. Therefore, an amendment to 40 CFR is not required. U.S. EPA has stated that the TST guidance document is not a substitute for the CWA, National Pollutant Discharge Elimination System (NPDES) permits, or regulations applicable to permits or toxicity testing and does not impose any legally binding requirements on U.S. EPA, states, permittees, or laboratories conducting toxicity tests.

Section 303(c) of the CWA and 40 CFR, part 131 provide the basis for the Water Quality Standards Program under which states adopt water quality criteria (denoted as “objectives,” in California), with sufficient coverage of parameters and adequate stringency. In so doing, states may directly adopt or modify criteria that U.S. EPA publishes under CWA section 304(a), or use other scientifically defensible methods. Where 304(a) criteria are not available, as with chronic and acute toxicity, the CWA enables states to adopt criteria based on biological monitoring or assessment methods (CWA section 303(c)(2)(B), 40 CFR 122.44(d)).

Additionally, the State Water Board possesses the authority to apply U.S. EPA methodology to its permits (Wat. Code, §13160.). The adoption of the TST is being conducted pursuant to a public process that comports with the requirements of U.S. EPA and the California Office of Administrative Law (see Gov. Code, § 11353). As such, the State Water Board’s adoption of the draft Policy does not constitute an underground regulation (see Cal. Code Regs., tit. 1, § 250, subd. (a)).

**Conclusion**

State Water Board staff is certain that the TST and the draft Policy adhere to all applicable statutes and provisions.

**9. Some commenters claim that the assumption of toxicity, utilized by the TST method, is inappropriate.**

A number of comment letters charge that the reversed null hypothesis utilized by the TST (which assumes toxicity for a given sample) is tantamount to assigning guilt to dischargers until they can prove otherwise.

**Response**

The draft Policy does not relate to a criminal proceeding. CWC Section 13263(g) clearly states that all discharges of waste into waters of the state are privileges, not rights. As with all other forms of monitoring, it is appropriate to require the discharger to demonstrate that this privilege is exercised in a responsible way.

Moreover, the restated null hypothesis utilized by the TST effectively addresses false negatives and provides incentive to generate high quality toxicity data.

## **Conclusion**

The provisions requiring the use of the TST method will remain in the draft Policy.

### **10. Certain commenters desire greater flexibility in the draft Policy's compliance schedule provisions.**

Several comment letters express concern over the compliance schedule provisions proposed in the draft Policy. Citing the ten-year maximum established in the *Compliance Schedules in NPDES Permits Policy*, commenters feel that the two-year maximum for permittees not currently monitoring toxicity is too restrictive, and that a compliance schedule option should be extended to those dischargers presently monitoring toxicity as well.

## **Response**

The proposed compliance schedule is of appropriate length, given that chronic and acute toxicity test methods, established in 40 CFR, part 136.3 over a decade ago, are routinely carried out by laboratories throughout the state. Furthermore, there is no need to extend a compliance schedule option to those dischargers currently required to monitor toxicity as the draft Policy would merely require a change in data analysis methodology and possibly increase testing frequency, but would not affect the established test procedures in any way. If adopted, this change will be facilitated by the inclusion of the TST method in the Comprehensive Environmental Toxicity Information System (CETIS) program, and by the State Water Board's free TST Spreadsheet Tool, which can be downloaded here:

[http://www.swrcb.ca.gov/water\\_issues/programs/state\\_implementation\\_policy/tx\\_ass\\_cntrl.shtml](http://www.swrcb.ca.gov/water_issues/programs/state_implementation_policy/tx_ass_cntrl.shtml)

## **Conclusion**

The compliance schedule provisions will remain in the draft Policy.

### **11. Commenters question the applicability of chronic toxicity test methods to storm water discharges.**

Some commenters contend that the duration of chronic and acute toxicity tests overestimate the level of toxicity demonstrated by transient storm water discharges.

## **Response**

The span of an individual toxicity test, ranging from one hour to eight days for chronic methods, and 48 to 96 hours for acute, is the duration of the test exposure needed to elicit a biological response (e.g. reduced survival, growth, or fertilization). A transient storm event can, in fact, elicit such a toxicological response as demonstrated by Katznelson and Mumley 1997; Bailey et al. 2000; Fong et al. 2000; Larsen et al. 2000; and Larsen and List 2002. Composite samples, representative of the entire storm water discharge, are used to moderate the influence of transient toxicity spikes and limit the potential for overestimating toxicity from such variations. A growing preponderance of data, however, is showing that toxicity is commonly observed

during storm water runoff and that short-term pulse exposures can be more toxic than long-term, continuous exposures (Brent and Herricks 1998).

## **Conclusion**

Staff maintains that the toxicity test methods, established in 40 CFR, part 136.3, are appropriate for storm water dischargers.

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