Attachment 2

Draft Policy for Toxicity Assessment and Control
Findings to be Addressed by Peer Reviewers

The statutory mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices. State Water Resources Control Board (State Water Board) staff requests that you make this determination for each of the following topics that constitute the scientific portion of the proposed standard.

1. **Inclusion of the Test of Significant Toxicity in the draft Policy for Toxicity Assessment and Control:** The U.S. Environmental Protection Agency (U.S. EPA) developed the Test of Significant Toxicity (TST) to address concerns regarding the use of the current hypothesis test method, the No Observed Effect Concentration (NOEC). Derived from the bioequivalence approach used by the Food and Drug Administration and countless researchers, this modified hypothesis test requires the use of only two dilutions: the in-stream waste concentration (IWC) and a laboratory control. Unlike the NOEC approach, the TST incorporates percent-based effect thresholds, (*b* values) that define unacceptable levels of chronic or acute toxicity in an IWC sample. In addition, the TST utilizes a restated null hypothesis that assumes toxicity, thereby placing the responsibility of proving otherwise on the discharger. Most importantly, however, the TST establishes a false negative error rate that is absent from the current NOEC approach (see the draft Staff Report and the *TST Implementation* document for additional information about the TST).

   Evaluate the conceptual soundness of the draft Policy for Toxicity Assessment and Control's (draft Policy) null hypothesis-based objectives, and the provision requiring applicable dischargers to use the TST for all toxicity data analyses. Consider the TST as a means of compliance determination for NPDES wastewater and point source WDR dischargers, as well as the analytical function it will serve for storm water and channelized dischargers.

2. **Use of effect level reporting in compliance determination:** The TST was designed in a manner that prevents an IWC sample from being incorrectly declared to be "toxic" no more than five percent of the time whenever the effect level of the test organisms is at or below 10 percent. As such, the sensitivity of a test's design or the influence of within-test variability can occasionally produce a result of "fail" (i.e. toxicity detection) when the effect level of the sample is above 10 percent, but below the regulatory management decisions (RMD) of 0.75 for chronic, and 0.80 for acute (i.e. an effect level of 0.25 for chronic, and 0.20 for acute). In most cases, these discrepancies can be mitigated by retesting with additional replicates (see the *TST Test Drive* for examples).

   To address this issue, State Water Board staff has included both maximum daily effluent limitations (MDEL) and average monthly effluent limitations (AMEL) in the revised draft Policy. The proposed MDELs are set at effect levels equivalent to double the RMDs for acute and chronic toxicity (0.40 and 0.50 respectively). Discharge samples that "fail" below an MDEL will be directed to conduct two additional toxicity tests in order to determine compliance with the AMEL. If either of these subsequent toxicity tests results in a "fail," the discharger will be in exceedance of the AMEL and required to implement an accelerated monitoring schedule.

Assess the effectiveness of these effluent limitations in reducing discrepancies that arise from toxicity detections below the RMDs. Determine whether or not the proposed AMEL is better suited to reduce these discrepancies than that of a monthly limitation set at the RMDs and measured by the average effect level of three toxicity tests.

3. **Comparative approaches to toxicity analyses:** As previously explained, State Water Board staff believes the TST to be an improvement over the hypothesis testing approach currently used for toxicity monitoring. Unlike the NOEC approach, the TST rewards laboratory precision, accounts for false negatives, and incorporates an effect threshold that clearly specifies the level of biological impact. Additionally, the two-concentration test design of the TST costs approximately 50 percent less than the five-concentration tests required by the NOEC.

   Staff also believes the TST to be more appropriate for the draft Policy than point estimate approaches such as the Spearman-Karber method or Probit. While point estimates offer some benefits over hypothesis testing, such as the ability to interpolate effect levels and utilize nonmonotonic data, staff feels that this statistical approach will introduce unnecessary complications to toxicity data analyses. For example, bias can be introduced through ill-fitting models and data smoothing techniques, while the Spearman-Karber, Trimmed Spearman-Karber, and Graphical methods are incapable of calculating endpoints below a 50% effect level (see the draft Staff Report for additional information).

   Assess the efficacy of the TST in light of the NOEC and point estimate approaches. Consider the benefits and drawbacks of the three approaches when applied to routine monitoring, accelerated monitoring, and Toxicity Reduction Evaluations (TRE).

4. **Utility of the proposed accelerated monitoring schedule:** The draft Policy proposes the implementation of an accelerated monitoring schedule for dischargers that exceed the chronic or acute effluent limitations. This schedule, adopted from U.S. EPA's *Toxicity Training Tool* guidebook, would consist of four, five-concentration toxicity tests, conducted at approximately two-week intervals, over an eight-week period (see the draft Staff Report for additional information). The use of five concentrations during accelerated monitoring serves to satisfy the federally-required test conditions that are incorporated by reference in 40 Code of Federal Regulations section 136.3. In addition, staff is of the opinion that multiple-concentration analyses can prove beneficial to dischargers that are required to conduct a TRE after an exceedance occurs during accelerated monitoring.

   Evaluate the appropriateness of this accelerated monitoring schedule. Consider its effectiveness in characterizing effluent magnitude and the individual probability of declaring a sample as a "fail" below the proposed effluent limitations.

5. **The big picture:** Reviewers are not limited to addressing only the specific topics presented above, and are asked to contemplate the following questions as well:

   a. In reading the draft Policy and Staff Report, are there any additional scientific topics that are part of the scientific basis of the proposed standard not described above? If so, please comment.

   b. Taken as a whole, is the scientific portion of the draft Policy based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed provisions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the draft Policy. At the same time, reviewers should also recognize that the State Water Board has a legal obligation to consider and respond to all feedback on the scientific portions of the draft Policy. Because of this obligation, reviewers are encouraged to focus feedback on the scientific topics that are relevant to the central regulatory elements being proposed.