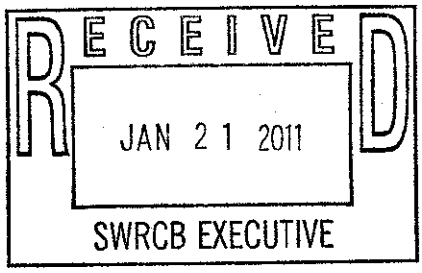
WPHA
Western Plant Health Association

January 21, 2011



Ms. Jeanine Townsend
Clerk to the Board
State Water Resources Control Board
1001 I Street
Sacramento, CA 95814

Re: Policy for Toxicity Assessment and Control

Dear Ms. Townsend:

The Western Plant Health Association (WPHA) appreciates the opportunity to comment upon the State Water Board's (Board) proposed Policy for Toxicity Assessment and Control (TAC). WPHA represents the interests of fertilizer and crop protection manufacturers, distributors, agricultural biotechnology providers, and agricultural retailers in California, Arizona, and Hawaii.

WPHA is opposed to the adoption of TAC objectives for general application to ambient waters in California. In particular, we are opposed to the use of the proposed null hypothesis where all water quality is presumed toxic until sufficiently demonstrated that the water is non-toxic. This approach inappropriately shifts the burden to dischargers for proving that the ambient water and discharges to the receiving water are not toxic versus proving that agricultural discharges are causing toxicity in the receiving water.

WPHA believes that the Board's use of the null hypothesis relative to the proposed control strategy is not appropriate. The chronic toxicity objective is expressed as a null hypothesis and a regulatory management decision of 0.75 for chronic toxicity methods, where a 0.25 effect level (or more) at the instream waste concentration (IWC) demonstrates an unacceptable level of chronic toxicity. The acute toxicity objective is expressed as a null hypothesis and a regulatory management decision of 0.80 for acute toxicity methods, where a 0.20 effect level (or more) at the IWC demonstrates an unacceptable level of acute toxicity. To illustrate the difficulties and the flaws in the proposed policy, WPHA has amended this comment letter (attachment A) with a more detailed statistical review document.

WPHA finds the use of the "most sensitive test species" for identification and confirmation would also inappropriately require agricultural dischargers to conduct reasonable potential analyses for chronic TAC in order to confirm or identify the most sensitive test species for routine monitoring. Reasonable potential analyses apply specifically to NPDES permitted discharges and are primarily a function of federal regulatory requirements. Agricultural discharges are specifically exempt from NPDES permit requirements and associated federal regulatory requirements. Thus, it is inappropriate to use this policy to apply such analyses to agricultural discharges.

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WPHA believes the requirement for Test of Significant Toxicity (TST) method as proposed will lead to a significant number of false positive test results (i.e., incorrectly identifying non-toxic samples as toxic). WPHA believes this is significant considering the fact that such toxicity test results will burden the agricultural communities with many different compliance requirements. Successive toxicity finding or results for irrigated agricultural entities in the Central Valley will require additional toxicity identification evaluations (TIE) and possibly a revised farm management plan.

WPHA believes the minimum chronic testing requirement as proposed, the Draft TAC policy, would require irrigated agriculture or "channelized dischargers" to conduct at least four chronic TAC tests per year. Such chronic toxicity testing is not currently required by the Central Valley Regional Water Quality Control Board (CVRWQCB) in the irrigated agricultural waiver program because it is not an appropriate measurement for agriculture. Because agricultural discharges tend to be more episodic, acute toxicity testing is more appropriate.

Currently the CVRWQCB works with each agricultural coalition to determine the appropriate frequency for toxicity monitoring in each coalition area. It is inappropriate for the Board to generically dictate the type and frequency of monitoring without consideration of any watershed specific information. Additionally, the Draft TAC Policy would either provide regional boards the discretion to require, or would require agricultural dischargers to submit Toxicity Reduction Evaluations (TRE) work plans for approval and implementation. The TRE process departs significantly from the accepted process provided for in the Central Valley agricultural waiver programs. Currently, the agricultural coalitions are generally required to perform TIEs if there is a 50% or greater difference in test organism mortality as compared to the laboratory control in an ambient sample. Depending on the results of the TIE, the Executive Officer from the Central Valley may require a specific agricultural coalition to prepare an agricultural management plan for the constituent or constituents of concern, if determined necessary and appropriate.

The current approach in the Central Valley is appropriate as it first requires an identification of the toxicant in order to determine if it is in fact a chemical coming from agricultural discharges. Assuming that agriculture is the cause, the Central Valley Water Board then has the means to work with agricultural coalitions to prevent future discharges that may cause toxicity. The TRE process as applied to agriculture is inappropriate because it automatically assumes that the toxicity is caused by the "channelized dischargers" and then requires the dischargers to conduct a series of actions accordingly. This will result in excessive testing and management actions without benefitting the attainment of water quality objectives.

WPHA thanks you for your consideration of our comments, and looks forward to continuing to work with the Board staff. If you have any questions, please feel free to call upon me.

Sincerely,

Henry Buckwalter

Henry Buckwalter
Director, Environmental & Regulatory Affairs

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Amendment A.

The mere observation of an IWC means < 75% of the control mean is very inadequate grounds for declaring an effect. The power to detect an effect of a given size needs to be specified as well as specific statistical tests. The size of the sample on which it is based, the variability of the response across samples, and the statistical significance of the comparison are all critically important. The proposed method places a premium on one calculation without regard to sample size, sample-to-sample variability, power, or statistical significance. This is neither protective nor scientifically sound. The additional references cited provide some of the missing detail but do not alter the fact that a single observation is used to determine whether additional testing is required. This deficiency is partly addressed in section 6 Statistical Method, page 7, where Welsch's t-test is indicated, and Table 1, page 9, where different requirements are given on a per-species basis.

There is difficulty with the description of the test given in steps 4 and 5, page 8. The test statistic is given as

$$t = \frac{\bar{Y}_t - b \bullet \bar{Y}_c}{\sqrt{\frac{S_t^2}{n_t} + \frac{b^2 S_c^2}{n_c}}}$$

Where $\bar{Y}_c$ and $\bar{Y}_t$ are the mean responses in the control and IWC, respectively, and b is the specified proportion (0.75 for chronic tests and 0.8 for acute tests). This test statistic, t, will be positive if the response at the IWC exceeds 75% of the control mean, which means the sample passes according to the earlier cited text. However, the instructions are to compare the value t to the appropriate positive critical value in Table 2 and fail the test if t does not exceed the critical value. This test assumes the contaminant is toxic unless the data demonstrate otherwise, the opposite of most toxicity tests, where a compound is assumed non-toxic unless the data demonstrate otherwise. Depending on variability, this may not be reasonable for the applicant, as sample sizes to achieve sufficient power to demonstrate non-toxicity can be large. Two examples are provided below for Daphnia magna reproduction and Selenastrum growth where under typical conditions this approach will have adequate power under normal experimental design conditions but not under high variance scenarios that may be encountered in routine testing. Data are not available to determine whether the criteria in Table 1 are reasonable for most other species.

There is an error in the methodology for handling percent effects, such as survival. Step 1 on page 7 indicates that percent effect should be changed to proportion effect and then transformed by the arc-sine square-root transform before calculating the test statistic t shown above. While there is no disputing the value of such a transform, the formula for t is not correct for transformed data. This is because a 100b% effect in the response (percent or proportion survival) is not the same as a 100b% effect in the transformed response. Nor is there a simple fix. If the percent survival in the control is 100% and the number of observations per rep is 10, then the value of $\bar{Y}_c$ is 1.5708 - arcsin (square-root (1/40)) =1.5458. If the desired effect to find is 80%, such as for fathead survival, then 0.8* $\bar{Y}_c$ =1.237. But a back transform of 1.237 is 0.89, so the test compares the observed treatment effect to an 11% mortality rate, not a 20% rate, a much more severe

restriction. If the number of observations per rep is 20 instead of 10, then the maximum passing observed treatment mortality rate is 15%. If the number of observations per rep is 5 then only a 5% or lower observed mortality passes.

Furthermore, if the control survival is 90%, then a 20% reduction in the control survival is a survival rate of 72%. However, a 20% reduction in arc-sin square-root of 0.9 is 1.237 which back-transforms to 0.89, only 1% more mortality than in the control, so the formula is much more restrictive than the nominal value and it becomes almost impossible to pass. These calculations are refined below in the example for fathead survival.

The problem indicated for survival responses is a simple example of the broader problem of computing a p% effects concentration using a transformed response. There is no simple solution.

Power Calculation Example

Daphnia Reproduction (TYS21). For routine studies, Vrep ranges from 100 to 238 and the control mean ranges from 74 to 161. From Table 1, the appropriate chronic effect is 25% and the false negative rate is 20%. The critical value is dependent on the number of replicates, or more specifically, on the degrees of freedom of the t-test. Assuming homogeneous variances and common number, r, of reps in treatment and control, the formula for t is

$$t = \frac{\bar{y}_t - 0.75 * \bar{y}_c}{\sqrt{1.75 * \frac{Vrep}{r}}}$$

The following table was constructed using the mean value, 117.5, for the control mean, and three values, 100, 169, and 238 for the variance, representing the minimum, mean, and maximum observed variances.

Table 3: Daphnia Magna Reproduction: Maximum Observed Effect to Pass

vrep	reps	maxeff	vrep	reps	maxeff	vrep	reps	maxeff
100	3	9	169	3	5	238	3	1
100	4	13	169	4	10	238	4	7
100	5	15	169	5	12	238	5	10
100	6	16	169	6	14	238	6	12
100	7	17	169	7	15	238	7	13
100	8	17	169	8	15	238	8	14
100	9	18	169	9	16	238	9	14
100	10	18	169	10	16	238	10	15

Thus, under the minimum variance scenario (VREP=100), the observed effect at IWC cannot exceed 9% of the control mean to pass if there are 3 reps per treatment and control. With 10 reps in each group, the observed effect at IWC cannot exceed 18%. Under the maximum variance scenario, if there are only 3 reps in each group, then any effect exceeding 1% at IWC will fail. Again under the maximum variance scenario, if there are 10 reps per group, then any observed effect exceeding 15% will fail.

Table 4: Selenastrum Growth: Maximum Observed Effect to Pass

cmean	vrep	reps	maxeff
1.2	0.0007	2	11
1.2	0.0007	3	21
1.2	0.0007	4	22
1.2	0.0007	5	22
1.2	0.0007	6	22
1.2	0.0007	7	23
1.2	0.0007	8	23
1.2	0.0007	9	23

cmean	vrep	reps	maxeff
1.2	0.003	3	16
1.2	0.003	4	18
1.2	0.003	5	19
1.2	0.003	6	20
1.2	0.003	7	20
1.2	0.003	8	21
1.2	0.003	9	21
1.2	0.003	10	21

cmean	vrep	reps	maxeff
1.2	0.007	3	12
1.2	0.007	4	15
1.2	0.007	5	17
1.2	0.007	6	18
1.2	0.007	7	18
1.2	0.007	8	19
1.2	0.007	9	19
1.2	0.007	10	19

For Selenastrum, 3 reps per group is typical, so that a maximum observed effect at the IWC that will pass is 12% under the high variance scenario and 21% under the minimum variance scenario. The variances and means are typical of routine testing.

Fathead Survival

Fathead survival was examined assuming 10% control mortality and otherwise following the guidelines of Table 2. Table 5 summarizes the power properties. The table shows only combinations of number of fish per group, number of reps per group, and maximum percent reduction from control mean will pass the criteria. Since there is no entry with 4 reps and sample size 10, it should be inferred that for such a design, the test will invariably fail. With 5 reps of size 10, the test will fail if the observed mortality in the IWC group exceeds that of the control by more than 4%. Since 4% of 40 is 1.6, this means that if more than one additional fish dies in the treatment group beyond what die in the control, the test will fail. This is a severe failure criterion. With 4 reps of 20 fish each, the maximum increase in mortality over the control is 7%. Since 7% of 40 is 2.8, this means if 3 or more fish die in the treatment group over the number of control mortalities, the test will fail. The stated failure criteria for percent effects appear too strict to be of practical importance and will trigger further testing routinely.

Table 5: Fathead Survival: Maximum Observed Effect to Pass

p0	pt	n	b	reps	maxeff
0.1	0.2	5	0.8	8	2
0.1	0.2	5	0.8	9	3
0.1	0.2	5	0.8	10	4
0.1	0.2	10	0.8	5	4
0.1	0.2	10	0.8	6	5
0.1	0.2	10	0.8	7	7
0.1	0.2	10	0.8	8	8
0.1	0.2	10	0.8	9	8
0.1	0.2	10	0.8	10	9
0.1	0.2	15	0.8	4	5
0.1	0.2	15	0.8	5	7
0.1	0.2	15	0.8	6	8

p0	pt	n	b	reps	maxeff
0.1	0.2	15	0.8	7	9
0.1	0.2	15	0.8	8	10
0.1	0.2	15	0.8	9	11
0.1	0.2	15	0.8	10	11
0.1	0.2	20	0.8	3	1
0.1	0.2	20	0.8	4	7
0.1	0.2	20	0.8	5	9
0.1	0.2	20	0.8	6	10
0.1	0.2	20	0.8	7	11
0.1	0.2	20	0.8	8	12
0.1	0.2	20	0.8	9	12
0.1	0.2	20	0.8	10	13