

Responses to Public Comments and Peer Reviews

Phase III: Lambda-cyhalothrin Criteria Derivation Report

using the

Phase II: Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life in the Sacramento and San Joaquin River Basins



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Responses to Comments

Terms, Abbreviations, Acronyms, and Initialisms Used in this Report

Term	Definition
ACR	Acute to Chronic Ratio- used to estimate concentration that will protect against chronic toxicity
CDFG	California Department of Fish and Game
CVRWQCB	Central Valley Regional Water Quality Control Board
DPR	California Department of Pesticide Regulation
EC _x	The chemical concentration that has an effect on <i>x</i> % of the test population.
K _{oc}	Organic Carbon Partition Coefficient
LC ₅₀	The chemical concentration that is lethal to 50 % of the test population.
LOEC	Lowest Observed Effect Level- lowest concentration tested that has some effect on the test population
MATC	Maximum Allowable Toxicant Concentration -geometric mean of LOEC and NOEC
NOEC	No Observed Effect Level- highest concentration tested that has no effect on the test population
SSD	Species Sensitivity Distribution- Statistical probability distribution of toxicity data
UC Davis	University of California, Davis
US EPA	U.S. Environmental Protection Agency
Water Quality Objective (WQO)	The limits of water quality constituents or characteristics that are established for the reasonable protection of beneficial uses of water or the prevention of nuisance within a specific area.

1.0 Introduction

This document presents the responses to public comments and peer reviews received on a technical report prepared by the University of California at Davis, Environmental Toxicology Department, under contract (#05-100-150-0) to the Regional Water Quality Control Board, Central Valley Region (Regional Board). This report represents one of six the end product reports of the third phase of a three-phase project to evaluate, develop and apply a method to derive pesticide water quality criteria for the protection of aquatic life.

The first phase of the project was to review and evaluate existing water quality criteria derivation methodologies to determine if there was an existing available method that met the Regional Board's stated project goals. The review indicated that there is no single method that meets all of the Regional Boards requirements. Therefore, the second phase of the project was to develop a new method that could meet the project requirements. The Phase II report details this new methodology and its application to chlorpyrifos. The third phase of the project was to apply the criteria derivation method to six additional pesticides, of which lambda-cyhalothrin is one.

The lambda-cyhalothrin criteria report was submitted to peer review, conducted by experts from academia and sister agencies, including the Department of Pesticide Regulation and the Department of Fish and Game.

These technical reports may be considered by the Regional Board during the development of the Central Valley Pesticide Basin Plan Amendment or other Board actions. However, the reports do not represent Board Policy and are not regulations. The reports are intended to generate numeric water quality criteria for the protection of aquatic life. However, these should not be construed as water quality objectives. Criteria and guidelines do not have the force and effect of regulation, nor are they themselves water quality objectives.

2.0 Response to Comment to Public Comments

2.1. Comment Letter 1 – Jeffrey M. Giddings, Compliance Services International (CSI); Kevin S. Henry, Syngenta Crop Protection, Inc.

COMMENT 1-1: Criteria Derivation for Lambda-Cyhalothrin

CSI examined the data selected by UCD for derivation of the acute and chronic criteria for lambda-cyhalothrin and found it to be generally consistent with the data compiled by the Pyrethroid Working Group, of which Syngenta is a member.

Response To Comment (RTC) 1-1: Comment acknowledged.

COMMENT 1-2: CSI also confirmed UCD's calculation of the 5th percentile (HC5) of the Species Sensitivity Distribution (SSD) using the Burr Type III distribution and the BurliOZ software. However, CSI questions the selection of the Burr Type III distribution over the more commonly used log-normal or log-logistic distributions, as implemented in the ETX program. The ETX program is an appropriate tool for describing an SSD; it has the advantages of being well-tested, standardized, and widely accepted throughout the world. Using ETX and the same acute toxicity dataset, CSI calculated an HC5 value for lambda-cyhalothrin of 3.251 ng/L, compared with the HC5 of 2.432 ng/L from BurliOZ. The Acute Criterion corresponding to the ETX acute value is 2 ng/L, compared with 1 ng/L as derived by UCD. The Chronic Criterion (1 ng/L) is unaffected by the choice of SSD models.

RTC 1-2: The Burr Type III distribution was thoroughly tested in Chapter 2 of the methodology (section 2-3.1.1, TenBrook *et al.* 2009). The Burr Type III demonstrated an equivalent or better fit for ten of twelve pesticide data sets compared to the log-normal distribution. For the two pesticide data sets that the log-normal distribution resulted in a better fit, the goodness of fit is only slightly better for the log-normal distribution than for the Burr Type III distribution. The Burr Type III distribution provided an equivalent or better fit than the log-normal distribution in most cases, and therefore was recommended for use in the UC-Davis methodology. The Burr Type III distribution approximates the log-normal and log-triangular distributions, and includes the log-logistic distribution as a special case (section 2-3.1.6, TenBrook *et al.* 2009).

COMMENT 1-3: Data collection

The goal of data collection is stated as “to find virtually all available physical-chemical and ecotoxicity data for a given pesticide” (TenBrook *et al.* 2009, Section 3-2.1). “Only data for freshwater species that are members of families with reproducing populations in North America will be used for criteria derivation, but all data should be collected as it may be used for supporting information or for derivation of an acute-to-chronic ratio (ACR).” This restriction is unnecessary, because toxicity test species are surrogates for all species, and there is no indication that species from North American families are better surrogates than species from families that do not occur in North America.

RTC 1-3: The choice to consider geographic distribution at the family level, rather than the species level - as is done in current USEPA methodologies (USEPA 1985, 2003) - is based on work by the USEPA showing that interspecies toxicity correlations work well at the family level (Asfaw *et al.* 2003).

COMMENT 1-4: TenBrook *et al.* (2009, Section 3-2.1) note that “data from agencies [i.e., GLP studies submitted to agencies by registrants] can make up most of the high quality toxicity studies available, especially for compounds with limited data. “ We agree with this generalization. The deficiencies of academic studies published in the open literature are generally of two kinds: use of non-standard test protocols, and failure to report data critical to evaluation of study acceptability. This issue is further discussed in Section 3.2 below.

RTC 1-4: Comment acknowledged.

COMMENT 1-5: TenBrook *et al.* (2009, Section 3-2.1.1.2) state, “For derivation of chronic criteria or acute-to-chronic ratios, obtain maximum acceptable toxicant concentrations (MATCs). Chronic data expressed as EC_x values (from regression analysis), may be used for criteria derivation only if studies are available to show what level of *x* is appropriate to represent a no-effect level.” However, use of the MATC does not address the question of determining an appropriate value of *x*; the MATC is based on determinations of statistical significance, regardless of biological significance or magnitude of effect. An MATC can be associated with a wide range of EC_x values depending on the nature of the measurement endpoint and the variability of the measurements. We believe it is better to establish (as a matter of policy grounded in science) a tolerable level of effect for a particular species and endpoint, and use concentration- effect models (e.g., regression analysis) to estimate the concentration corresponding to that level of effect, i.e., the EC_x.

RTC 1-5: The UCD methodology recognizes the limitations of hypothesis test data, and chronic data expressed as results of hypothesis tests are evaluated to

ensure that the reported toxicity values are reasonable estimates of no-effect levels (section 2.1.2, TenBrook *et al.* 2009). Because the goal of the method is to prevent detrimental effects to organisms, an EC₅₀ is not a valid toxicity value for use in derivation of a chronic criterion because a 50% reduction compared to the control cannot be considered “no effect.” If a study were available that demonstrated what level of x represented a no-effect level, then an EC_x toxicity value could be used in chronic criterion calculation (section 2-2.1.2, TenBrook *et al.* 2009). No chronic studies were identified for lambda-cyhalothrin that reported EC_x toxicity data and indicated a level of x that could be a reasonable estimate of a no-effect level.

COMMENT 1-6: Data evaluation

The UCD methodology calls for an evaluation of the data for relevance first, and for reliability only if the relevance score is 70 or greater. This tiered approach makes data selection more efficient, because a relevance evaluation can usually be done very quickly and no further time needs to be invested in evaluating the reliability of an irrelevant study. For relevant studies, the recommended process is to extract information to data sheets, and use the results to evaluate reliability according to the rating systems shown in Tables 3.7 and 3.8 of TenBrook *et al.* (2009). While the data extraction process (using the forms provided) can be cumbersome, it is objective and reasonably complete, and does provide a good basis for evaluating data reliability and documenting the evaluation.

RTC 1-6: Comment acknowledged.

COMMENT 1-7: Two categories of reliability criteria are used: Documentation and Acceptability. Many criteria in the two groups are related. For example, failure to report dissolved oxygen concentrations results in loss of 4 points for Documentation, and inability to confirm that dissolved oxygen concentrations were acceptable results in loss of 6 points for Acceptability. Thus, a peer-reviewed open-literature publication that fails to report dissolved oxygen concentrations has already lost 10 points (out of 200) in its Reliability score. Failure to report pH, hardness, alkalinity, and conductivity results in loss of 16 more points. These water quality variables are needed only to confirm that the test was run under acceptable conditions – they generally do not affect the outcome of the test – yet their omission from a publication results in a substantially reduced reliability rating.

Similar reporting deficiencies (not uncommon in journal articles, where words are often at a premium) can result in a useful toxicity test receiving a rating of “Less Reliable.” In contrast, because of the data reporting requirements for regulatory studies and the requirements of Good Laboratory Practices, studies submitted by registrants are nearly always “Reliable.”

An unavoidable consequence of the reliability evaluation is that standard studies, many of which test species that are known to be highly sensitive to pesticides (e.g., daphnids, mysid shrimp, amphipods, and salmonid fish), are more likely to be included in criteria derivation than studies on non-standard species. The use of sensitive species in standard toxicity tests confers additional conservatism on the derived criteria.

RTC 1-7: It is true that the acceptable lambda-cyhalothrin data set contains many more toxicity values from registrant-submitted studies than from peer-reviewed open literature studies, but there does not seem to be a lack of diversity in this data set. There are 20 different species represented in the acute data set with varying sensitivities (LC50s in Table 3 range 0.0023 – 3.3 µg/L). Unfortunately this is not the case for the chronic data set, where acceptable toxicity values are only available for two species. Very few GLP or peer-reviewed studies were identified that investigated chronic toxicity of lambda-cyhalothrin, and the data set was not limited because studies were rated with low reliability scores. Only five chronic studies were identified, and all rated RR, except the two that used saltwater species.

COMMENT 1-8: Acute Criterion derivation using SSD

The UCD methodology (TenBrook *et al.* 2009) requires data for at least 5 species representing at least the following 5 groups: the family Salmonidae (e.g. rainbow trout), a warm water fish (e.g. bluegill sunfish, fathead minnow), a planktonic crustacean – at least one from the family Daphniidae (e.g. *Daphnia magna*, *Ceriodaphnia dubia*), a benthic crustacean (e.g., *Hyalella azteca*, *Gammarus pulex*), and an aquatic insect (e.g., *Cloeon dipterum*). UCD's acute dataset for lambda-cyhalothrin, with 20 species, fulfilled all five categories.

RTC 1-8: Comment acknowledged.

COMMENT 1-9: TenBrook *et al.* (2009) provide detailed statistical guidance for SSD analysis, but recommend using the BurrliOZ program (CSIRO 2001) or the ETX program (Van Vlaardingen *et al.* 2004) to derive the Acute Criterion. These programs are among the many tools and methods available for estimating the 5th percentile of the SSD. ETX has the advantages of being user-friendly, reliable, standardized, and widely accepted throughout the world.

RTC 1-9: Comment acknowledged.

COMMENT 1-10: Chronic Criterion derivation

Deriving a Chronic Criterion using the SSD approach requires MATC values for at least five species from the same categories as the acute

criterion. Reasons for using ECx values rather than MATCs were presented above (Section 3.1).

RTC 1-10: See RTC 1-5.

COMMENT 1-11: If chronic data are insufficient for an SSD approach, an ACR approach is used (TenBrook *et al.* 2009, Section 3-4.2). At first, TenBrook *et al.* (2009, Section 3-4.2.1) seem to require that the acute and chronic data used to calculate an ACR must come from the same study in the same dilution water, but then this requirement is relaxed to allow a different study in the same laboratory under identical conditions, or even in a different laboratory – in other words, only the dilution water must be the same. The rationale for this requirement is unclear, since toxicity values are not presumed to be strongly affected by the source of laboratory dilution water.

RTC 1-11: The requirement to use the same dilution water in acute and chronic studies to calculate an ACR for a given species is based on guidance from the US EPA methods (1985, 2003).

COMMENT 1-12: ACRs are required for three species, including a fish and an invertebrate. If there are insufficient data, a default ACR of 12.4 is used for one or more of these species. The default ACR (TenBrook *et al.* 2009, Section 3-4.2.3) is the 80th percentile value derived from ACRs for 8 insecticides (chlordane, chlorpyrifos, diazinon, dieldrin, endosulfan, endrin, lindane, and parathion). TenBrook *et al.* (2009) do not explain why these insecticides should be considered representative of pesticides from different chemical groups, or why the 80th percentile should be used as the basis for a default ACR. Because ACRs for three species were available for lambda-cyhalothrin, the default ACR was not used in this case.

RTC 1-12: The calculation of the default ACR is explained in more detail in section 2-3.2.5.3 of the methodology (TenBrook *et al.* 2009). The procedure outlined in the Great Lakes criteria derivation methodology (USEPA 2003) was used to calculate the default ACR for the UCD methodology. The default ACR in the Great Lakes methodology was calculated for a wide array of chemicals using all available ACRs from USEPA criteria documents (Host *et al.* 1995). The pesticide ACRs used to calculate the default ACR for the UCD methodology include all of the pesticide ACRs in the Great Lakes methodology data set, an updated diazinon ACR (Siepmann & Finlayson 2000), and an updated chlorpyrifos ACR (Chapter 4, TenBrook *et al.* 2009). The ACRs for these eight pesticides have been derived from carefully reviewed studies (criteria documents). There are currently no other multi-species pesticide ACRs to include to be more representative of all pesticide classes. When ACRs are available for

more pesticides, it is recommended that the default ACR be re-calculated to be more representative of all classes of pesticides.

The procedure for deriving this factor was based on an extensive report by Host et al. (1995) in which they described both empirical and theoretical methods for derivation of factors using data sets for all kinds of chemicals. The 80th percentile was calculated in that report; however the decision to use it was from the Great Lakes Initiative (USEPA 2003).

COMMENT 1-13: Bioavailability of Lambda-Cyhalothrin

The draft criteria report summarizes evidence that pyrethroids bound to particulate matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. Bound pyrethroids become bioavailable only when they desorb from particles or dissociate from dissolved organic matter. The UCD report notes the possibility that pyrethroids can be taken up from ingested particles, citing the findings of Mayer *et al.* (2001) as evidence that hydrophobic compounds can be desorbed by digestive juices. The cited study involved uptake of benzo(a)pyrene and zinc by 18 species of benthic marine invertebrates, including 10 species of worms, 5 species of echinoderms, 2 species of mollusks, and a sea anemone. The relevance of these findings to uptake of pyrethroids by sensitive freshwater taxa (such as insects and crustaceans) is unclear. There is no evidence for uptake of pyrethroids by this route, and the UCD report in fact summarizes the evidence to the contrary.

TenBrook *et al.* (2009, Section 3-5.1) state that when a pesticide has only a single bioavailable phase (sorbed to solids, associated with dissolved organic matter, or freely dissolved in water), it is appropriate to evaluate compliance with water quality standards based on concentrations in the bioavailable phase alone. This is the case for lambda-cyhalothrin and other pyrethroids, of which only the freely dissolved phase is bioavailable. Pyrethroid concentrations in the freely dissolved phase can be measured using techniques such as solid-phase microextraction (SPME), or calculated based on partitioning coefficients (Equation 3.6, TenBrook *et al.* 2009). The equilibrium partitioning model requires input values for dissolved and particulate organic carbon (OC); UCD considers these values to be site-specific properties that are “laborious” to measure. CSI disagrees: measurement of dissolved and particulate organic carbon and total suspended solids is not particularly difficult (compared to analysis of lambda-cyhalothrin, for example) and is useful for calculation of freely dissolved lipophilic chemicals. The US EPA uses equilibrium partitioning models to estimate freely dissolved concentrations of pyrethroids in sediment pore water, based on measured or default values for dissolved and particulate organic carbon concentrations (e.g., USEPA 2005).

In laboratory toxicity tests using low-particulate, low-OC water as the exposure medium, pyrethroids are much more bioavailable than in water with natural levels of particulates and OC. Because aquatic toxicity test guidelines require the use of water containing minimal amounts of particulate matter and dissolved organic carbon, bioavailability is not a significant factor under standard test conditions. In ambient water, however, analysis of total pyrethroid is liable to overestimate the bioavailable concentration by at least an order of magnitude. For these reasons, we believe that evaluation of water quality compliance for pyrethroids should be based on measured or calculated concentrations of freely dissolved pyrethroid, consistent with the recommendations of TenBrook *et al.* (2009, Section 3-5.1). We therefore do not concur with UCD's recommendation that criteria compliance be based on whole-water lambda-cyhalothrin concentrations, without consideration of bioavailability. UCD concedes that use of whole-water concentrations is likely to be overprotective, but accepts such overprotection as "compensating for the use of nominal concentrations and unknown effects of dietary exposure." Since the bioavailable fraction may be on the order of a few percent or less of the whole-water lambda-cyhalothrin concentration, the overprotection that would be incurred by basing compliance on whole-water concentrations greatly outweighs the potential underprotection (a factor of 2 or 3 at most) caused by use of nominal concentrations. UCD suggests that this recommendation should be revised when more toxicity data based on measured concentrations are available. We note that measured concentrations are already available for 10 of the 20 relevant and reliable studies in the final database.

RTC 1-13: The bioavailability section of the final lambda-cyhalothrin criteria report has been revised to recommend the use of the dissolved fraction of lambda-cyhalothrin for compliance. While use of the dissolved fraction is preferred for criteria compliance, whole water measurements may also be used for compliance at the discretion of the environmental manager.

COMMENT 1-14: Mesocosm and Microcosm Data

UCD identified and rated 11 mesocosm and microcosm studies, but only presented results for 8, including 5 rated relevant and reliable and 3 rated less relevant and reliable (Fojut and Tjeerdema 2010, Table 10). The rating forms were not presented. UCD characterized the studies as primarily representing riverine environments, but in fact only 2 of the 8 (both rated less reliable) involved flowing water.

RTC 1-14: The references for the ecosystem-level studies rated N have been added to this section in the report. This section has also been revised so that the studies are not summarized as primarily representing riverine environments.

COMMENT 1-15: An important study not cited in the UCD report was the GLP guideline study by Hill et al. (1994a,b). In this study, large outdoor ponds were treated with 12 simulated spray drift events at weekly intervals and 6 simulated runoff events at two-week intervals, using three treatment rates. The lowest spray treatment rate corresponded to a nominal concentration of 1.7 ng/L (from each of the 12 applications), and the lowest runoff treatment rate corresponded to a nominal concentration of 5 ng/L; the other treatment rates were 10 and 100 times greater than the lowest rate. Results were similar to those obtained by Farmer et al. (1995), with minor and transient effects on invertebrates at the low and medium treatment rates. No adverse effects on fish were observed in any of the treatments.

RTC 1-15: The Hill *et al.* (1994b) study was obtained and is included in the final criteria report. The Hill *et al.* (1994a) study was not obtained in time for inclusion in the final report, but it seems that they may have reported similar data in both reports.

COMMENT 1-16: The mesocosm and microcosm studies summarized by UCD, as well as the study by Hill et al. (1994a,b), indicate that multiple exposures to concentrations much greater than the proposed acute and chronic criteria have no effect, or at most a slight and transient effect, on a variety of aquatic ecosystems. UCD interprets these findings as confirmation that the proposed criteria are sufficiently protective. In fact, the mesocosm/microcosm findings suggest that adequate protection could be achieved with higher criteria.

RTC 1-16: Several of the mesocosm and microcosm studies evaluated in the criteria report indicate effects at low levels (1-2 ng/L), as do the Hill (1994a, b) studies cited in comment 1-15. These concentrations are very close to the derived criteria (1 and 0.5 ng/L), and indicate that the derived criteria are not overly protective, but are in fact very close to true ecosystem no-effect levels, and may in fact be underprotective. The criteria were not adjusted downward based on these studies because the studies that demonstrated adverse effects near the criterion either did not calculate a toxicity value (e.g., NOEC, EC_x), with which to compare to the criteria, or did not measure concentrations of lambda-cyhalothrin.

COMMENT 1-17: The UCD methodology for deriving numeric water quality criteria (TenBrook *et al.* 2009) is generally sound, though some details of the data selection process could be improved. The SSD approach requires data for more species than are typically represented by available guideline studies, and data for additional species generally must be found in non-guideline studies in the open literature. Though data evaluation criteria appropriately favor well-documented GLP guideline studies over non-

guideline studies in the open literature, too-stringent criteria will reject useful data and may limit the applicability of the SSD approach.

RTC 1-17: See RTC 1-7.

COMMENT 1-18: For derivation of Chronic Criteria, ECx values are preferable to MATCs. An MATC simply reflects a determination of statistical significance, regardless of biological significance or magnitude of effect. An ECx represents a specific magnitude of effect. Appropriate values of x have not yet been agreed upon, but they should be selected with biological significance in mind.

RTC 1-18: See RTC 1-5.

COMMENT 1-19: Pyrethroids bound to particulate matter or associated with dissolved organic matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. In laboratory toxicity tests using water with minimal particulate or dissolved organic matter, nearly all the pyrethroid is bioavailable. In natural water, only a small fraction – a few percent or less – of the total pyrethroid may be bioavailable. Compliance with lambda-cyhalothrin water quality standards should therefore be based on concentrations of freely dissolved lambda-cyhalothrin, not total lambda-cyhalothrin. Freely dissolved lambda-cyhalothrin can be measured directly using solid phase microextraction (SPME), or estimated using an equilibrium partitioning model such as the one presented by Tenbrook *et al.* (2009).

RTC 1-19: See RTC 1-13.

COMMENT 1-20: The mesocosm and microcosm studies summarized by UCD, as well as others that were not included in this document, indicate that multiple exposures to concentrations much greater than the proposed acute and chronic criteria have no effect, or at most a slight and transient effect, on a variety of aquatic ecosystems. UCD interprets these findings as confirmation that the proposed criteria are sufficiently protective. In fact, the mesocosm/microcosm findings suggest that adequate protection could be achieved with higher criteria.

RTC 1-20: See RTC 1-16.

2.2. Comment Letter 2 – Kelye McKinney, City of Roseville; Michael Bryan, Ph.D., Brant Jorgenson, and Ben Giudice, M.S., Robertson-Bryan, Inc.

COMMENT 2-1: The City does not accept the assumption of dose additivity. Compliance with criteria should not be based on simplifying assumptions of concentration addition as the principals of concentration addition do not necessarily hold true under all possible environmental mixture scenarios. Assumptions of dose additivity are unsuitable for regulatory purposes in this case and as such allowance for dose additivity should be omitted.

RTC 2-1: The mixtures section has been revised, and the concentration addition method of calculating toxicity of mixtures of pyrethroids is no longer recommended. There are several studies in the literature that indicate that pyrethroids may demonstrate slight antagonism in mixtures (Barata *et al.* 2006, Brander *et al.* 2009), and therefore, additivity is no longer assumed for pyrethroids.

COMMENT 2-2: The City disagrees that pyrethroid compliance should be measured against whole water analysis. Scientific evidence points to freely dissolved pyrethroid as the bioavailable fraction. Compliance should be measured against that portion of a pyrethroid that is known to be toxic. The draft lambda-cyhalothrin criteria report should be revised in a manner that allows for either direct measurement of the bioavailable fraction or allow for some compensating factor accounting for particulate matter and dissolved organic matter effects.

RTC 2-2: See RTC 1-13.

COMMENT 2-3: The capabilities of commercial laboratories in achieving low enough reporting limits is very troubling to the City. Similar to the standardization of minimum mandatory reporting limits in the State Implementation Plan (SIP), the City requests similar effort of standardization for these pesticides. Without such standardization, monitoring and compliance efforts can produce data of limited to no value, and likely at considerable economic expense to the regulated community.

RTC 2-3: The derivation of water quality criteria do not take into account reporting limits of commercial laboratories or other economic feasibility issues. These considerations are taken into account when setting water quality objectives, while water quality criteria are derived with only the objective of the protection of aquatic life.

COMMENT 2-4: When considering the plausible future use of these draft criteria, as quantitative interpretations of existing Basin Plan narrative toxicity objectives, the City is troubled by the seeming lack of critical quality assurance review. The rounding error in the lambda-cyhalothrin report represents the second draft criteria report to include an arithmetic-related error (the first being a derivation methodology error in the bifenthrin report), and the cyfluthrin report includes an error in the description of the final criteria statement. Acute criteria should be expressed as one-hour averages and chronic criteria should be expressed as four-day averages, not the inverse. These errors unfortunately call into question the accuracy of all work pertaining to the derivation - namely the compilation, review and screening of studies for which the toxicity values are selected. The City requests a thorough outside review of all the derivation reports.

RTC 2-4: Each of the criteria reports is subject to a peer review process and public comment process. These processes were undertaken simultaneously, instead of subsequently, to save time and to meet the deadline of the contract. All errors found in the draft reports by reviewers are corrected in the final versions of the criteria reports.

COMMENT 2-5: The acute criterion for lambda-cyhalothrin is based on a species distribution approach and results in a supportable criterion compared to that derived from an assessment factor approach.

RTC 2-5: Comment acknowledged.

COMMENT 2-6: The ACR derived for lambda-cyhalothrin is based on a dataset that does not contain the most sensitive species *H. azteca* or its taxon. Therefore, there is no way to determine whether the derived value of the ACR is appropriate for application to the acute value.

RTC 2-6: The goal of an ACR is to extrapolate from acute to chronic toxicity, and it is not required to have ACR toxicity data for every species in order to apply an ACR (sections 2-3.2.5 and 3-4.2, TenBrook *et al.* 2009, USEPA 1985). The acute SSD represents toxicity data for 20 species, and the fit of the SSD is not completely determined by the lowest toxicity value. The log-triangular distribution, used in the USEPA (1985) method, weights the sensitive end of the distribution much more heavily than does the Burr Type III distribution.

COMMENT 2-7: For all derived criteria, the assumption of dose additivity between pesticides of similar mode of toxicity is assumed. Caution is advised in applying concentration addition principals to compliance measurements. Dose additivity is not settled science, and its accuracy as a model predictor is sensitive to many variable factors. Where science is not settled, compliance should not be based on simplifying assumptions.

RTC 2-7: See RTC 2-1.

COMMENT 2-8: The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including lambda-cyhalothrin and cyfluthrin, is the fraction that is bioavailable. Compliance should be based on measurements that most accurately predict toxicity. Either compliance should be determined using analytical procedures measuring the dissolved fraction, or compliance should be determined using total recoverable methods but adjusted for pyrethroid sorption to particulate matter and dissolved organic matter.

RTC 2-8: See RTC 1-13.

COMMENT 2-9: Achieving commercially available analytical reporting limits below the pyrethroid criterion utilizing EPA approved methods is currently lacking or limited. Maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.

RTC 2-9: See RTC 2-3.

COMMENT 2-10: The rounding error contained in chronic criterion for lambda-cyhalothrin should be corrected.

RTC 2-10: The rounding error has been corrected in the final report.

2.3. Comment Letter 3 –Lenwood Hall, University of Maryland

COMMENT 3-1: The authors are to be commended for striving to use a very thorough process for reviewing the scientific credibility of each lambda-cyhalothrin toxicity study used for criteria development. The use of scientifically valid toxicity data is the foundation of credible criteria. However, I am concerned because the current review process is cumbersome and somewhat flawed which could result in invalid studies being accepted for criteria development or valid studies being rejected. The current data review process described in TenBrook et al. (2009) requires the completion of 4 forms if the relevance score in Table 3.6 is ≥ 70 . I would suggest initially prioritizing the critical elements of each study that **must** be acceptable before conducting any further study evaluation. Critical elements of a study that must be acceptable before evaluating any other components of the study are: (1) Is the current document under review the primary (original) source of the data (don't use data summaries

from a secondary source)?; (2) Is the control endpoint (survival, growth, or reproduction) acceptable based on peer-reviewed guidelines?; (3) Was the duration of exposure reported?; (4) Were adverse effects evaluated using exposures to a single pesticide?; (5) Were effects reported for relevant endpoints (e.g., survival, growth or reproduction)?; (6) Was more than one dose/concentration used in a toxicity test?; (7) Was the test species reported?; (8) Was the chemical form (% active ingredient) of the test material reported?; and (9) Was a dose response evident? In the current data review process, a study with unacceptable control survival receives a 7.5 point reduction (see Table 3.6 in TenBrook *et al.* 2009) but can still be rated acceptable for criteria development. This is a clear case where an invalid study could be used for criteria development. Conversely, it seems unreasonable and highly restrictive in the grading process, described in TenBrook *et al.* 2009, to deduct points for the following study elements if control response is acceptable: (1) tolerance ranges for various water quality parameters (e.g., hardness, alkalinity, conductivity, and pH – a maximum of 7 points could be deducted); (2) dilution water information (2 point deduction) and (3) information on prior contaminant exposure to test organisms that is rarely mentioned in a document (4 point deduction). For example, in many cases tolerance ranges for water quality parameters such as hardness, alkalinity, conductivity, and pH are simply unknown for a test species. In summary, I am concerned that both valid toxicity studies could be graded as unacceptable, and that studies of questionable scientific merit could be graded as acceptable using the current data review process.

RTC 3-1: The data evaluation process of the methodology has been thoroughly reviewed by both peer review and public comment processes, but may be revised in the future.

COMMENT 3-2: In order to develop the chronic criterion, Acute to Chronic Ratios (ACRs) were developed for 3 species (2 freshwater and 1 saltwater species in Table 8) using the corresponding acute LC50 values and the MATCs (chronic values). The MATC (maximum acceptable toxic concentration) is the geometric mean of the No-Observed-Effect-Concentration (NOEC) and the Lowest-Observed-Effect-Concentration (LOEC). These MATC, NOEC, and LOEC values have a high degree of uncertainty because they are determined by the range of test concentrations (dilution series) and the sample size used in the toxicity test. For example, one of the tested concentrations will be the NOEC and if different test concentrations are used the NOEC will change. The peer reviewed literature has a number papers that discuss the uncertainty associated with using NOEC, LOEC and MATC values in the regulatory process because these values have no statistical confidence (Newman, 2010; Crane *et al.*, 2010; among others). In cases where a suboptimal design is used, higher NOEC and LOEC values may be reported due to

low statistical power and high error variance. In contrast, when a superior study design is used, lower NOEC and LOEC values could be reported. Due to the uncertainty associated with the use of MATC, NOEC and LOEC values it is recommended that EC50s, EC25s or EC20s should be used to represent chronic values.

RTC 3-2: See RTC 1-5.

COMMENT 3-3: The microcosm and mesocosm studies presented in Table 10, where 5 of these studies were rated as reliable, are not used to their full potential in the criteria derivation process. Community level NOEC values from these studies are merely used as confirmation that the criteria are low enough and sufficiently protective. For example, a study graded as reliable (Schroer *et al.*, 2004) reported a community level NOEC of 10 ng/L while other investigators (Van Wijngaarden *et al.*, 2006; Roessink *et al.*, 2005) have reported significantly higher community level NOECs (the lowest was < 10,000 ng/L) from reliable studies. The weight of the microcosm/mesocosm data in total suggests that the proposed acute and chronic lambda-cyhalothrin criteria (1 ng/L) are highly over protective of resident biota and should be reconsidered to account for the “**reasonable protection of designated uses**” as stated in the Porter Cologne Act. Note that the legal standard for protection of beneficial uses, such as warm or cold freshwater habitat, by State and Regional Boards in California is “**reasonable protection**” not “**full protection**” (See *United States v. State Water Resources Control Board* (1986) 182 Cal. App.3d82, 121-122) so there is some flexibility in establishing criteria as 100% protection of all individual species all the time is not required.

RTC 3-3: As described in the methodology (section 2-2.1.4, TenBrook *et al.* 2009), ecosystem data is not used to derive water quality criteria because they have poor repeatability, reproducibility, and ecological realism, whereas criteria derived using single-species data are protective of ecosystems in many cases. The methodology recommends that these ecosystem-level studies may only be used for downward adjustment of criteria if they indicate that the derived criteria are not protective of test organisms in ecosystem-level studies (section 2-2.1.4, TenBrook *et al.* 2009). Upward adjustment is not recommended because single-species data have indicated a protective concentration, and raising the criterion may cause toxicity to sensitive species.

The Porter-Cologne Act refers to water quality objectives, not water quality criteria. We define water quality criteria as values derived solely considering the protection of aquatic life. Water quality criteria do not have the force and effect of regulation, nor are they themselves water quality objectives.

Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 3-4: The basis for using 1-h (acute criterion) and 4-d (chronic criterion) averaging periods for allowable exposure duration for pesticides such as lambda-cyhalothrin in the Central Valley is not appropriate. These two averaging periods were likely selected because they are used by USEPA in their criteria development method (Stephen et al., 1985). It is important to remember that the USEPA water quality criteria development approach initiated in the mid 1980s was primarily developed for POINT SOURCE discharges where constituents such as ammonia are measured at frequent intervals (hourly or daily). However, for pesticides hourly measurements are rare for monitoring efforts in California. Even daily measurements for four consecutive days would be an exception and not the rule for pesticide monitoring studies in the Central Valley. Pesticide data collected from monitoring studies in the Central Valley and obtained from California's Department of Pesticide Regulation should be reviewed to determine the most common frequency of pesticide measurements (i.e., once a month for a year) and these data could be used to select the most appropriate averaging periods for both acute and chronic criteria. Further highlighting the issue of appropriate exposure selection is the fact that acute aquatic toxicity test durations typically range from 2 to 10 days, while chronic studies can be 21 days in duration or longer. Longer-term chronic averaging criteria of greater than 4 d would thus more appropriately fit common standards for chronic toxicity testing and risk assessment.

RTC 3-4: The averaging periods of the UC-Davis methodology were selected based on literature reviews of pesticide data (TenBrook & Tjeerdema 2006; section 2-3.3.1, TenBrook *et al.* 2009). Derivation of water quality criteria does not account for economic feasibility of monitoring; the averaging periods were determined solely based on what duration was long enough such that toxicity might occur due to an exceedance, but short enough that the effects of concentration fluctuations on the average concentration are minimized (section 2-3.3, TenBrook *et al.* 2009).

COMMENT 3-5: In setting an allowable frequency of exceedance of the acute and chronic criterion, the key question is how much time is needed for organisms at various levels of organization to recover from brief pulse exposures to contaminants. The proposed criteria method recommends an allowable frequency of exceedance of once in three years. This is the same frequency of exceedance used by the USEPA in their criteria method (Stephen et al., 1985). TenBrook et al. 2009 in their criteria development document have stated that the 3-year frequency of

exceedance was supported by minimal data. The receptor group (most sensitive biological assemblage) for any given pesticide should be considered when establishing the acceptable frequency of exceedance for a specific type of pesticide. For example, the receptor group for lambda-cyhalothrin consists of various benthic macroinvertebrates (amphipods - *Hyalella*, insects, isopods etc.). The most sensitive species to lambda-cyhalothrin is the amphipod *Hyalella azteca*. The life cycle of *Hyalella* is approximately 1 to 1.5 months (egg to egg carrying female) depending on water temperature. Therefore, a once in three years exceedance is overprotective for a species such as *Hyalella* that can recover fairly quickly in the environment. In contrast, for species with long life cycles (greater than 5 years) such as various fish, a once in three year exceedance may be appropriate. For lambda-cyhalothrin there should be some flexibility for the frequency of exceedance component of the new criteria that would allow the use of life histories for appropriate receptor species in order to determine the most appropriate frequency of exceedance. The authors should also explore the use of the binomial approach for determining the number of pesticide exceedances needed before a violation occurs. The California State Board uses the binomial approach for listing and delisting impaired water bodies in the State based on exceedances of both toxicants (i.e. pesticides) and conventional pollutants (i.e., pH, dissolved oxygen) (SWRCB, 2004). The binomial approach has statistical underpinnings that allows the determination of error rates associated with impairment declarations and a process to limit error rates.

RTC 3-5: When the three-year frequency component was first proposed by the USEPA (1985), there was minimal data to support it, but the literature review in the methodology (section 2-3.4.1, TenBrook *et al.* 2009) demonstrates that there is now ample data to support this frequency. The three-year frequency of exceedance was chosen to allow for full recovery from effects of an excursion above either acute or chronic criteria for all species, including those with long life-cycles (section 2-3.4.2, TenBrook *et al.* 2009).

COMMENT 3-6: In the Bioavailability Section, it is stated as a general statement of fact that water column concentrations of pyrethroids have been reported to cause toxicity in surface waters of California's Central Valley. However, there are no references to support this point. Furthermore specific data (references) are needed to document reports of potentially toxic water column concentrations of lambda-cyhalothrin in the environment since this is the focus of this criteria document.

RTC 3-6: Several citations regarding surface water contamination have been added to the bioavailability section, including Phillips *et al.* (2007), Weston *et al.* (2009), and Weston and Lydy (2010).

COMMENT 3-7: Page 4, Ecotoxicity data, line 1 – It is stated that 65 lambda-cyhalothrin toxicity studies were identified and reviewed. Does this mean that data are available for 65 different species?

RTC 3-7: We identified 65 studies with lambda-cyhalothrin toxicity data, some studies contained data for multiple species, or multiple tests. Each toxicity value reported in a study is listed separately in the data tables (Tables 4-9).

COMMENT 3-8: Page 5, parag 2, lines 5 and 6 – It is not clear how studies rated less relevant-less reliable (LL) or less relevant-reliable (LR) were useful for this criteria development exercise since these studies were judged as unacceptable for criteria development.

RTC 3-8: Clarification on the use of supplemental data (studies rated RL, LR, or LL) in criteria adjustment has been added to the sensitive species section 12. Section 3-6.0 of the methodology, titled “Check criteria against ecotoxicity data,” describes how the criteria are evaluated to ensure they are protective to: 1) particularly sensitive species, 2) ecosystems, and 3) threatened and endangered species (TenBrook *et al.* 2009). Supplemental data are used to evaluate the criteria, particularly for sensitive species, as described in section 3-6.1 of the methodology, because there may be particularly sensitive species in the supplemental data set that are not well-represented in the acceptable data set (studies rated RR), from which the criteria are calculated. It is stated in this section (3-6.1): if the calculated criterion is higher than toxicity values reported for particularly sensitive species, then the criterion may require downward adjustment (TenBrook *et al.* 2009). The criteria would never be adjusted upward because the various percentiles are calculated to provide a range of robust and more conservative values, and increasing the criterion above the calculated percentiles could potentially be underprotective of sensitive species.

COMMENT 3-9: Page 6, top 3 lines – The final criterion was reported to one significant digit. Does the TenBrook *et al.* 2009 methods document address the issue of significant digits in criteria development?

RTC 3-9: Section 3-3.2.6, titled “Calculate criterion from 5th percentile value,” of the methodology describes how the number of significant digits in the final criterion are rounded (TenBrook *et al.* 2009). The criterion is not expressed with more significant digits than are in the original toxicity data, which often only have one significant digit. The significant digits of the final criteria are rounded to be consistent with the known variability in the calculated criteria. For example, if the median estimate is used for criterion calculation the last digit that is relatively variable in comparison to the 95% confidence limit is the last significant digit.

COMMENT 3-10: Page 6, Figure 2 – For the range of values on the x axis (In acute value, ug/l) in Figure 2, the last range on the far right lists a

range of -0.62 – 1.2. Is this the correct range? It would seem that the – 1.2 value is incorrect.

RTC 3-10: The value is correctly reported in Figure 2 as 1.2. It is not a negative value, there is a dash in front of it that indicates the range is from -0.62 to +1.2.

COMMENT 3-11: Page 7, Figure 3 – Table 3 lists a total of 20 acute values used in the SSD; however, I only count 19 dots in this distribution. There are two values of 0.16 that perhaps overlap and may account for this but I just want to be sure that a value was not omitted.

RTC 3-11: The two values at 0.16 µg/L overlap, and therefore both are not visible in the graph.

COMMENT 3-12: Page 8, Chronic Criterion – Both the acute and chronic values are equal (1 ng/L). This suggests that the criteria derivation process may be flawed or lambda-cyhalothrin is a fast acting toxicant where only acute exposures are relevant (i.e., chronic exposures do not increase toxicity). Can the authors provide any insight on this?

RTC 3-12: In the draft report, the chronic criterion was incorrectly rounded to 1 ng/L, and in the final report it is correctly reported as 0.5 ng/L. Chronic toxicity of lambda-cyhalothrin has been demonstrated to occur at concentrations below those causing acute toxicity for several organisms (*Daphnia magna*, *Pimephales promelas*, *Cyprinodon variegatus*), which can be seen in the acute-to-chronic ratio data (Table 8).

COMMENT 3-13: Page 11, parag 4 – I am not sure what to make of this Barata et al., 2006 paper (which I have not read) that suggests slight antagonism between lambda-cyhalothrin and deltamethrin since additivity of pyrethroids is generally assumed when assessing ecological risk of multiple pyrethroids (particularly for sediment). Antagonism is not uncommon with stressors with the same mode of action as they may not have identical affinity for binding of the same sites. If antagonism is the true response of multiple mixtures of pyrethroids we may need to reevaluate how we assess ecological risk of pyrethroids.

RTC 3-13: The mixtures section has been revised, and the concentration addition method of calculating toxicity of mixtures of pyrethroids is no longer recommended. There are several studies in the literature that indicate that pyrethroids may demonstrate slight antagonism in mixtures (Barata *et al.* 2006, Brander *et al.* 2009), and therefore, additivity is no longer assumed for pyrethroids.

COMMENT 3-14: Page 12, sensitive species, line 6 – Why are the data in Table 9 rated as LR and LL (see above comment) used for validation in

this process if these data were judged to be unacceptable for criteria development?

RTC 3-14: See RTC 3-8.

COMMENT 3-15: Page 13, parag 2 – It is stated that ‘*Gammarus* species were examined in several studies and it was found that they were particularly sensitive to lambda-cyhalothrin’. Please provide the effect concentrations (EC50s, NOECs etc.) that were used to support the statement that *Gammarus* were particularly sensitive to lambda-cyhalothrin.

RTC 3-15: Lauridsen and Friberg (2005) examined macroinvertebrate drift in outdoor experimental channels with *Gammarus pulex*. Catastrophic drift was observed during the one-hour pulse exposure and 2-3 h post-exposure. *G. pulex* was significantly affected at 0.001 µg/L (nominal). Rasmussen *et al.* (2008) demonstrated that *Gammarus pulex* exposed to 10.65 ng/L lambda-cyhalothrin (nominal) drifted significantly less than controls ($p < 0.0001$). Farmer *et al.* (1995) sprayed pond mesocosms with two levels of lambda-cyhalothrin; at the lower level *Gammarus* spp. abundance was significantly reduced compared to controls, and in the higher treatment they were completely eliminated, with no indication of recovery 3 months later. Lambda-cyhalothrin was measured in the water column 1 hr after application and was determined to be 2 ng/L in the lower treatment and 59 ng/L in the higher treatment.

COMMENT 3-16: Page 16, Assumptions, Limitations, and Uncertainties, parag 2, last sentence – The authors express concern over the lack of chronic data for *Hyalella*, the most sensitive species to lambda-cyhalothrin in the data set. However, this should not be a concern because the 1 ng/L (acute and chronic criteria value) is below the acute *Hyalella* LC50 value of 2.3 ng/L and the criteria derivation process supports the finding that chronic exposures do not increase lambda-cyhalothrin toxicity.

RTC 3-16: The chronic criterion is now 0.5 ng/L, and data for other species indicates that chronic effects do occur at lower levels than levels at which acute effects are observed.

2.4. Comment Letter 4 – Renee Pinel, Western Plant Health Association

COMMENT 4-1: The UCD methodology for deriving numeric water quality criteria (TenBrook *et al.* 2009) is generally sound, though could be improved though the use of an species sensitivity distribution approach.

RTC 4-1: A species sensitivity distribution was used to derive the acute criterion.

COMMENT 4-2: For derivation of Chronic Criteria, ECx values are preferable to MATCs. An MATC simply reflects a determination of statistical significance, regardless of biological significance or magnitude of effect. This issue has been well documented in the peer-reviewed literature. An ECx represents a specific magnitude of effect, and can include confidence intervals. Appropriate values of x have not yet been agreed upon, but they should be selected with appropriate biological significance in mind.

RTC 4-2: See RTC 1-5.

COMMENT 4-3: Pyrethroids bound to particulate matter or associated with dissolved organic matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. In laboratory toxicity tests using water with minimal particulate or dissolved organic matter, nearly all the pyrethroid is bioavailable. In ambient water, only a small fraction – a few percent or less – of the total pyrethroid may be bioavailable. Compliance with lambda-cyhalothrin water quality standards should therefore be based on concentrations of freely dissolved lambda-cyhalothrin, not total lambda-cyhalothrin. Freely dissolved lambda-cyhalothrin can be measured directly using solid phase microextraction (SPME), or estimated using an equilibrium partitioning model such as the one presented by Tenbrook et al. (2009).

RTC 4-3: See RTC 1-13.

COMMENT 4-4: The mesocosm and microcosm studies summarized by Fojut and Tjeerdema, as well as others that were not included in this document, indicate that multiple exposures to concentrations much greater than the proposed acute and chronic criteria have no effect, or at most a slight and transient effect, on a variety of aquatic ecosystems. As an example, a community level NOEC of 10 ng/L would suggest that a proposed acute and chronic criterion (1 ng/L) is highly overprotective and should be reconsidered. Fojut and Tjeerdema cite these findings as confirmation that the proposed criteria are sufficiently protective. In fact, the mesocosm/microcosm findings suggest that adequate protection could be achieved with much higher water quality criteria.

RTC 4-4: Effects were observed on *Gammarus* spp. in ecosystems at concentrations of lambda-cyhalothrin as low as 1 ng/L and 2 ng/L (Lauridsen and Friberg 2005, Farmer et al. 1995). See RTC 3-15 and the ecosystem section of the final report for more information on these exposures. The ecosystem-level studies do not indicate that adequate protection of these species could be achieved at higher levels than the derived criteria.

COMMENT 4-5: WPHA is concerned that the current data review process used to select lambda-cyhalothrin toxicity data for criteria development is flawed because critical study elements (i.e., acceptable control response) were not initially evaluated and deemed acceptable before a more detailed assessment of various study components. The current data review process could result in invalid studies being accepted for criteria development or valid studies being rejected.

RTC 4-5: The data evaluation process of the methodology has been thoroughly reviewed by both peer review and public comment processes, but may be revised in the future.

COMMENT 4-6: We request that the UCD authors of this Method clearly define the proposed numeric criteria which do not have a "detrimental physiological responses" in aquatic life, and how this was defined.

RTC 4-6: Detrimental physiological responses are measured in toxicity tests that test for effects on survival, growth or reproduction. A dose-response relationship must be observed for the effects, and the responses of exposed organisms are always compared to those of control organisms. The goal of numeric criteria is to derive concentrations at which organisms in the environment will not experience adverse effects on their survival, growth, or reproduction, using toxicity data.

COMMENT 4-7: Despite the rigorous review process to screen toxicity data described in the draft WQC document, it is stated that studies that were determined to be unacceptable for criteria development (LL or LR rated studies) are still used in this process. How can unacceptable studies provide any value to this process?

RTC 4-7: See RTC 3-8.

COMMENT 4-8: WPHA is concerned because this report states that water column concentrations of pyrethroids (e.g. lambda-cyhalothrin) have been reported to cause toxicity in surface waters of California without providing references to support this statement. Specific references are needed to document the presence of potentially toxic concentrations of lambda-cyhalothrin in the environment.

RTC 4-8: See RTC 3-6.

COMMENT 4-9: The allowable frequency of exceedance (once in three years) for this lambda-cyhalothrin criteria is not supported by the receptor group (invertebrates such as *Hyaella*) for this pesticide. The life cycle for lambda-sensitive species such *Hyaella* is short (generally 1 to 1.5 months). Therefore, populations can recover fairly quickly, and a once-in-

three-year exceedance is highly overprotective. The frequency of exceedance component of the criteria should have some flexibility to account for the life history of the receptor group.

RTC 4-9: See RTC 3-5.

2.5. Comment Letter 5 – Jason Loft, Sacramento Regional County Sanitation District

COMMENT 5-1: SRCSD is concerned with the Regional Board's proposed use of the draft criteria to interpret narrative water quality objectives. The specific concern is the Regional Board's potential use of the criteria to set water quality based effluent limitations in NPDES permits, as it will create liability for SRCSD. Considering the liability associated with complying with such effluent limitations, the Regional Board should take care in using only criteria that are well-developed and well-founded. , As indicated in our comments below, the draft criteria for lambda-cyhalothrin are most likely overly-protective, thereby creating unnecessary liability for wastewater dischargers. Effluent limitation violations may subject dischargers to the Regional Board's discretionary administrative civil liability authority, mandatory minimum penalties, or to third party lawsuits brought under the CWA's citizen suit enforcement provisions. (See 33 U.S.C. 5 505.)

RTC 5-1: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 5-2: SRCSD is concerned with the use of the draft criteria to interpret narrative objectives as it creates de facto water quality objectives that have not been adopted in accordance with the law. Under Porter-Cologne Water Quality Control Act (Porter-Cologne), the Regional Board is required to regulate water quality in a manner that attains the highest level of water quality which is reasonable, considering all demands being made and to be made on those waters. (See Wat. Code, § 13000.) Further, water quality objectives are supposed to be established to ensure reasonable protection of beneficial uses, considering a number of different factors. The factors that must be considered include: past, present and probable future beneficial uses; environmental characteristics of the hydrographic unit under consideration, including the quality of water; water quality conditions that could reasonably be achieved through the coordinated control of all factors which affect water quality in the area; economic considerations; the need for developing housing; and the need to develop and use recycled water. (Wat. Code, § 1324 1 .)

RTC 5-2: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 5-3: Also, the Regional Board is required to adopt a program of implementation for achieving water quality objectives at the time of adoption. (See Wat. Code, § 13242.) In other words, when adopting water quality objectives, the Regional Board must determine if the objective is necessary to provide for reasonable protection of the beneficial uses, and the Regional Board must balance all of the competing demands on the water and consider the economic implications associated with adoption of water quality objectives. SRCSD respectfully requests that the Regional Board refrain from using the draft criteria for lambda-cyhalothrin until the criteria are properly adopted as water quality objectives pursuant to all requirements in Poster-Cologne and the following technical issues are addressed.

RTC 5-3: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 5-4: As confirmed by UCD, the main problems with lambda-cyhalothrin criteria development are the lack of good toxicity data. Because the necessary toxicity studies are insufficient to use standard EPA methodology to develop the criteria, the draft criteria were developed based on unique criteria derivation techniques. Minimal acute toxicity data were used to develop an acute criterion of 1 ng/L. A factor of 2 was applied to the 5th percentile LC50 to achieve this draft acute criterion because of the sparse data set, including the few taxa in the species-sensitivity distribution.

RTC 5-4: The data set is only missing one taxon for the use of the USEPA (1985) methodology, as demonstrated in section 18 of the criteria report. There were no species in the data set that were neither a Chordate or an Arthropod to fulfill the missing taxon. Typically this taxon would be fulfilled with data for a mollusk, but mollusks are very insensitive to pyrethroids, and as such, few are tested, and toxicity values may not be calculable if no effects are observed near the solubility of the compound. The USEPA (1985) methodology was used to calculate criteria for lambda-cyhalothrin in section 18 of the criteria report because the missing taxon is likely very insensitive, and would have little effect on the fit of the distribution to the data set. The acute toxicity data set contained 20 toxicity values, much more than the minimum of five values required by the UC-Davis methodology, or the minimum of eight values required by the USEPA (1985) methodology.

A factor of 2 was applied to the median 5th percentile acute value to derive the acute criterion, but not because of the number of toxicity values in the acute data set. The factor of 2 is applied to the acute value because the LC₅₀ toxicity values indicate a 50% effect level, and the goal is to set the criterion at a no-effect level (section 2-3.1.6, TenBrook *et al.* 2009). A concentration of ½ of the LC₅₀ is accepted as a good approximation of a no-effect concentration (section 2-3.1.2 TenBrook *et al.* 2009). The USEPA (1985) criteria derivation methodology also applies a factor of 2 to the final acute value (see section 20 of the final criteria report).

COMMENT 5-5: The suggested chronic criterion (1 ng/L) was derived using the paired acute-to-chronic (ACR) toxicity data from three species, yielding a low ACR of 4.73. The chronic value is documented as being somewhat conservative. It is a factor of 2.6 below the lowest acceptable chronic toxicity value in the dataset (waterborne exposure) and one to two orders of magnitude below any of the estimated NOEC values based on bioaccumulation to wildlife or humans (oral exposure route). The resulting draft criteria (1 ng/L for acute and chronic) create a number of problematic analytical issues for SRCSD. Both criteria are below or at the reporting limits and detection limits for most, if not all, labs (in clean matrix such as deionized water). Although not recognized in the draft criteria document, analytical quantitation limits have an impact on the ability of SRCSD achieving compliance with effluent limitations and receiving water limits derived from the draft criteria. Moreover, the ability to detect concentrations below one ppt (less than one ng/L) in a complex matrix such as effluent is even more challenging than detecting these low concentrations in a clean matrix. In fact, because of the challenges, detections below one ppt have yet to be demonstrated. Currently, one ppt detection limits are the goal of California organizations evaluating pyrethroids (i.e., DPR, TriTAC, and the Pyrethroid Working Group (PWG)).

RTC 5-5: Analytical issues are not considered in the derivation of water quality criteria; criteria are derived solely to be protective of aquatic life. Analytical and other economic issues are considered when setting water quality objectives.

COMMENT 5-6: Further, the lack of a standard EPA methodology for analyzing pyrethroids may also pose a problem for pyrethroid analyses. For example, the academic lab of Dr. Mike Lydy (University of Southern Illinois) claims one of the lowest reporting limits (3 ng/L) for pyrethroids, yet it is still 3 times higher than the suggested chronic criterion in the draft criteria. Questions have been raised about the possibility of interferences or false positive identifications without confirmation by other methods. To achieve such low reporting limits, Dr. Lydy must perform multiple clean-up steps that are not available or commonly performed by commercial labs, and samples are concentrated 20,000 times (1,000x is normal). These

extreme steps have an unknown effect on analytical precision and accuracy.

RTC 5-6: See RTC 5-5.

COMMENT 5-7: The draft criteria were based on limited data and the authors recommend that the criteria be based on measurements in whole water, even though the literature suggests strong and highly variable interactions with suspended particulates and lambda-cyhalothrin concentrations in the dissolved phase. As a result, the authors recognize that the suggested criteria are likely to be overprotective and that the criteria should be revised when more, and appropriate, toxicity data become available. Several factors that reduce the toxicity of lambda-cyhalothrin were determined to be important for understanding the bioavailable fraction, and should be included in site specific lambda-cyhalothrin criteria.

RTC 5-7: The bioavailability section of the criteria report has been revised to recommend that the dissolved fraction of lambda-cyhalothrin is used for criteria compliance.

COMMENT 5-8: Dietary exposures produced higher NOEC values (reduced toxicity) than a direct, topical exposure route, and were one to two orders of magnitude higher than the chronic exposure criterion. This could be due lambda-cyhalothrin stuck to organic matter in contaminated food is not bioavailable. Nevertheless, the authors concluded that while dietary exposure is important in estimating true toxicity of lambda-cyhalothrin, it was not possible to incorporate dietary exposure into the criteria derivations.

RTC 5-8: I am not familiar with any dietary NOEC values for pyrethroids for aquatic organisms.

COMMENT 5-9: Suspended solids and sediments in the tests greatly reduced toxicity and data indicate that toxicity is from the freely-dissolved fraction. The authors concluded that bioavailability has to be estimated based on dissolved phase measurements or from calculations and that detailed site-specific data on suspended sediments and organic fractions is essential for estimating lambda-cyhalothrin toxicity in natural waters. However, this site-specific requirement for water quality factors affecting toxicity is not considered by adopting fixed values for acute and chronic criteria.

RTC 5-9: Toxicity is based on the dissolved fraction of lambda-cyhalothrin, and the toxicity of the dissolved fraction to organisms will not change with suspended solids or DOC concentrations. Measuring the suspended solids, DOC, and other

site-specific parameters is a way of calculating the concentration of the dissolved fraction of lambda-cyhalothrin, which can then be compared to the fixed criteria values.

COMMENT 5-10: Turbidity, TSS, DOC, and chlorophyll-a (another measure of particulate organic matter) are recognized as factors that reduce the bioavailability and toxicity of lambda-cyhalothrin in surface water. In fact, the best way to determine compliance with criteria would be to measure the dissolved phase (bioavailable) concentration. However, it is concluded that these known factors cannot be used in the application of criteria because they are not available for multiple-species and would not meet the criteria for toxicity data. The number of species-test combinations this document assumes is required to develop criteria that include a model parameter for particulate matter and/or DOC should not be the sole basis for excluding this important variable. Draft criteria should be developed with and without these modeled factors, based on available data, so that the CVRWQCB and regulated community may evaluate the options and determine the best possible criteria to meet all objectives. Alternatively, this information should be added to Section 17: Assumptions, Limitations, and Uncertainties.

RTC 5-10: The bioavailability section of the report has been revised to recommend the use of the dissolved fraction of lambda-cyhalothrin for criteria compliance.

COMMENT 5-11: Temperature is an important factor in determining pyrethroid toxicity and should be included in a model for determining the lambda-cyhalothrin criteria. Pyrethroid toxicity increases at lower temperatures when enzymes break down these chemicals more slowly.

RTC 5-11: Unfortunately, there is limited data on the effects of temperature on toxicity using aquatic exposures with aquatic species, making it infeasible to quantify the relationship between the toxicity of bifenthrin and temperature for water quality criteria at this time (section 3-5.3, TenBrook *et al.* 2009a).

COMMENT 5-12: The draft criteria should include the sediment organic carbon to water partitioning coefficient (K_{oc}), which is of interest for the fraction sorbed to sediments, and in addition to the K_{ow} , accounts for the partitioning to sediments and suspended solids.

RTC 5-12: K_{oc} and K_{ow} values for lambda-cyhalothrin are given in the criteria report in section 3.

COMMENT 5-13: It would be helpful understanding the degradation of lambda-cyhalothrin in sediments by including half-life for degradation rates in sediments in Table 2. This is relevant since much of the surface water

pyrethroid will partition to sediments due to the high Kow (7.0 at 20 degrees C), and be degraded there.

RTC 5-13: We did not include information on lambda-cyhalothrin degradation in sediments because criteria compliance is only based on water column measurements, and degradation in sediments does not directly affect these measurements.

COMMENT 5-14: Figure 3 shows one interpretation of acute toxicity data for lambda-cyhalothrin (the Burr III type), but the regression is extrapolated over an order of magnitude less than the lowest data point. There is great uncertainty when extrapolating beyond the ranges of data. It would be very helpful to add confidence intervals onto Figure 3 to more accurately describe these extrapolations.

RTC 5-14: The acute median 5th percentile value estimated by the distribution is actually slightly higher than the lowest toxicity value in the data set (0.00243 vs. 0.0023 µg/L). The lower 95% confidence limit of the 5th percentile estimate has been added to the graph.

COMMENT 5-15: The regression estimate for concentrations below 0.01 ug/L (10 ppb) may not accurately describe these data, which appear to have a dose response that drops more steeply than the Burr III-type regression estimate depicts (Figure 3). Alternative regression models, such as those used by the USEPA method for estimating the 5th percentile, should be evaluated and the one that best fits the data should be recommended for use. The USEPA method recognizes that results for insensitive species have little relevance on estimating criteria to protect sensitive species, has the added advantages of making fewer assumptions about the underlying distribution, and thus avoids potential problems of multimodality and outliers. Either changing the curve shape or limiting the data to the most sensitive species without assumptions about distribution of the data would probably raise the 5th percentile LC50 value to more closely approximate the available data.

RTC 5-15: The log-triangular distribution, which is used by the USEPA (1985), was also fit to the acute data set, as presented in section 18 of the criteria report. This distribution resulted in a 5th percentile value of 0.001845 µg/L, which yields an acute criterion of 0.92 ng/L, according to the USEPA (1985) methodology. This acute criterion is almost equivalent to the criterion derived using the UC-Davis methodology.

COMMENT 5-16: The statement that "...equilibrium partitioning would suggest that as organisms take up lambda-cyhalothrin, more lambda-cyhalothrin will desorb from particles, so the fraction absorbed to solids is likely not completely unavailable." [page 91 is misleading. If the dissolved

and particulate bound fractions of lambda-cyhalothrin are in a steady state, then the surface water concentrations would remain constant for reasons stated in the draft criteria. Because dissolved concentrations would be constant there is added confidence that they indicate the true bioavailable fraction, even though the bound fraction may decrease to maintain equilibrium. It is suggested that this sentence is removed from the document.

RTC 5-16: We agree that the dissolved concentration of lambda-cyhalothrin would remain constant if the system had reached a steady state, even though lambda-cyhalothrin could continue to desorb. A sentence of clarifying this point has been added to this section in the final report.

COMMENT 5-17: Estimated acute toxicity values for species similar to local, listed species of fish yielded toxicity values of several orders of magnitude higher than the suggested chronic criterion. Therefore, these criteria are overly protective of fish.

RTC 5-17: The goal of aquatic life criteria is to protect all species in an ecosystem, not just fish.

COMMENT 5-18: In general, the selected chronic criterion and supportive information were either lacking or overprotective. Further supportive data were inconclusive or unavailable on the effects of pesticide mixtures, temperature effects for freshwater organisms, and the effects on the most sensitive species, Epibenthic invertebrates (e.g., *H. azteca*) are the most sensitive model species for toxicity tests with pyrethroids but chronic tests with this sensitive species were lacking.

RTC 5-18: We agree that chronic data are lacking for lambda-cyhalothrin.

COMMENT 5-19: Because of the lack of confidence in the chronic criterion, and over-protectiveness of the proposed value SRCSD cannot support their use by the Regional Board until there is a better understanding of fate and transport, chronic toxicity, and affects of dissolved solids and suspended particles that can be accounted for in an empirical model. Therefore, SRCSD requests that the Regional Board refrain from using the draft criteria for lambda-cyhalothrin until more research is completed and the criteria are properly adopted as water quality objectives.

RTC 5-19: Because the chronic criterion is calculated with an ACR, the uncertainty cannot be calculated. The fate and transport of lambda-cyhalothrin is outside the scope of water quality criteria derivation. The effects of dissolved solids and suspended particles can be accounted for in an empirical model, which is recommended for use in the Bioavailability section of the final criteria

report. Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

3.0 Response to Comment to Peer Reviews

3.1. Peer Review 1 – John P. Knezovich, Ph.D., UC-Davis, Lawrence Livermore National Laboratory

REVIEW 1-1: *Overview*

Freshwater criteria for Lambda-cyhalothrin (L-cyhalothrin) defined in this draft report was derived using methodology recently developed by Tenbrook *et al.* (2009)¹. The methodology considers relevance of the endpoints and quality of the data in derivation of the criteria. This methodology was motivated by the California Regional Water Quality Control Board's desire to employ rigorous methods to develop criteria for protection of the Sacramento and San Joaquin River Watershed.

Response to review (RTR) 1-1: Comment acknowledged.

Review 1-2: *Basic information and physical-chemical data*

The report provides a comprehensive summary of the physical-chemical data for L-cyhalothrin. This data set indicates that this pesticide has high Kow, low volatility, high potential to bioaccumulate, high potential to sorb to sediments, and is persistent in aqueous environments (i.e., low rates of hydrolysis, photolysis, and biodegradation). Accordingly, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern, due to its persistence and high potential for bioaccumulation and food-web transfer.

RTR 1-2: Comment acknowledged.

Review 1-3: *Human and wildlife dietary values*

The FDA has not set action levels for L-cyhalothrin in fish tissue but has set a level for hog meat hogs at 0.1 mg/kg. Toxicity to mallard ducks is low, with an LC₅₀ (which should be reported as an LD₅₀) value for food of 3,948 mg/kg in 8-day old ducks. Another study, however, indicated no toxicity at an equivalent dose in food. It needs to be mentioned that this

¹ P. Tenbrook *et al.* (2009). *Methodology for derivation of pesticide water quality criteria for the protection of aquatic life in the Sacramento and San Joaquin River basins. Phase II: Methodology development and derivation of chloropyrifos criteria.* Report prepared for the Central Valley Regional Water Quality Control Board, Rancho Cordova, CA.

latter study was conducted with adult ducks. The reported NOEL of 30 mg/kg is deceptive as this is the highest dose that was tested (e.g., the NOEL could be significantly higher than this value). The authors correctly point out that a LOEL could not be determined for this reason.

RTR 1-3: This section of the report has been revised to clarify the age of the ducks and to emphasize that the NOEC is likely underestimated.

Review 1-4: *Ecotoxicity data and data reduction*

The authors evaluated approximately 65 published studies of L-cyhalothrin toxicity to develop the proposed criteria. Relevance was determined using the aforementioned methods¹ and only data for studies that were deemed acceptable were used in the criteria derivation. Adequate and reliable data was available for determining acute toxicity using animal studies and exclusion criteria appear to have been applied properly. Twenty acute, 3 chronic and 8 microcosm and ecosystem studies were used to support criteria development calculations. Four studies of effects on wildlife were reviewed for relevance to bioaccumulation.

Data was excluded using proper criteria ensuring analysis of properly conducted experiments and sensitive life stages.

RTR 1-4: Comment acknowledged.

Review 1-5: *Acute criterion calculation*

The acute criterion for L-cyhalothrin was calculated using methods defined by Tenbrook *et al.* (2009). Data for all five required taxa was available and a criterion of 1 ng/L was derived using acceptable calculations and rounding to significant digits.

RTR 1-5: Comment acknowledged.

Review 1-6: *Chronic criterion calculation*

The acute-to-chronic ratio (ACR) method was used to derive the chronic criterion using data for only two of the five required taxa. The chronic values for these two taxa (i.e., warm water fish and planktonic crustacean) were paired with acute data that included a saltwater species, which was appropriate for inclusion in this calculation according to the referenced method. However, the statement that “freshwater and saltwater ACRs have been shown to be comparable” does not appear to be supported by this data, as the saltwater ACR of 2.6 is substantially lower than the values for the freshwater species (i.e., 4.9 and 8.2). Accordingly, the inclusion of the saltwater ACR in this calculation requires a stronger justification.

RTR 1-6: ACRs for a given chemical can differ by more than an order of magnitude, as demonstrated by the ACRs calculated for diazinon of 2.3, 140,

and 106, in a related criteria report using the UC-Davis methodology (Palumbo *et al.* 2010). Similarly, the ACRs calculated for cyfluthrin (5.6, 18.9, 12.4) in the related UC-Davis criteria report (Fojut & Tjeerdema 2010), are all calculated for freshwater species, but differ by factors of 3.4, 2.2 and 1.5. The lambda-cyhalothrin ACRs for all species were within a factor of ten and there was not an increasing or decreasing trend in species mean ACR (SMACR) values with the species mean acute values; if either were the case, the SMACRs used calculate the final multispecies ACR would be restricted so that they were most representative of species near the 5th percentile value (step 1, section 3-4.2.1, TenBrook *et al.* 2009a). Saltwater ACRs have been used in many freshwater criteria derivations by the USEPA and other agencies, and have been demonstrated to be similar to freshwater ACRs (Siepmann & Finlayson 2000, USEPA 1980a, b, c, d, 2005).

Review 1-7: A final chronic criterion of 1 ng/L was calculated using the median 5th percentile value that was divided by the multi-species ACR. This calculation appears to have been performed correctly although the raw criterion value of 0.0005144 µg/L should be 0.0005142 µg/L, which are both rounded to the same value of 1 ng/L.

RTR 1-7: The chronic criterion value has been corrected, and is now rounded to 0.0005 µg/L.

Review 1-8: Bioavailability

Because L-cyhalothrin has a high K_{ow}, it will have a high affinity for dissolved organic and particulate phases in aquatic environments. The statement is made that toxicity is believed to occur primarily from the *portion* of the compound that is dissolved in the water. The phrasing of this sentence implies that a molecule of L-cyhalothrin can be partially dissolved. Instead, the authors should use the word *fraction* when distinguishing between soluble and sorbed phases. The conclusion that the dissolved phase of L-cyhalothrin is the primary bioavailable phase is consistent with data for compounds with similar physical/chemical characteristics.

RTR 1-8: The word portion has been changed to fraction in the final report.

Review 1-9: Many studies support the conclusion that sorption of L-cyhalothrin to organic phases that are present in aquatic environments reduces its bioavailability to aquatic organisms. This effect is consistent with the behavior of other compounds that have similarly high K_{ow}s. An evaluation of the work conducted by Smith and Lizotte (2007) concludes that the equations that they developed to account for L-cyhalothrin toxicity in the presence of binding agents (e.g., TSS, DOC) could be used to predict toxicity for the species that was used in these tests (*H. azteca*). The authors dismiss the use of this approach because it was only derived

for a single species. However, they should also point out that natural environments contain not one, but several sorbents, which renders this approach non-viable for natural waters.

RTR 1-9: We agree that bioavailability should not be assessed by equations that attempt to account for every type of sorbent present in natural aquatic environments; this has been clarified in the report. We recommend that bioavailability be assessed by measuring the dissolved fraction of lambda-cyhalothrin, as this approach accounts for any possible sorbent in the environment.

Review 1-10: The authors are correct in stating that it is not practical to recommend that the “freely-dissolved” phase of L-cyhalothrin be used for compliance purposes. Instead, isolation of the dissolved phase by solid-phase micro-extraction presents a practical approach for approximating the bioavailable phase of L-cyhalothrin. Determination of site-specific dissolved concentrations of L-cyhalothrin is not practical due to the need for accurate measurements of dissolved organic compounds and suspended solids, which require significant effort to acquire. The fact that these parameters can vary spatially and temporally further complicates such assessments and should be mentioned here.

Nominal (i.e., added concentrations) are likely to over-estimate exposure concentrations due to sorption of L-cyhalothrin to organic phases as well as container surfaces (this effect has the result of under-predicting toxicity). Accordingly, the authors recommend that criteria compliance be based on whole-water concentrations of L-cyhalothrin, as this will provide a conservative (i.e., over-protective) estimate of this compound’s availability. This is a prudent recommendation given uncertainties in reported exposure concentrations.

RTR 1-10: Comment acknowledged, although the bioavailability section has been revised to recommend that compliance should be based on the freely dissolved fraction of lambda-cyhalothrin, if such methods are available.

Review 1-11: *Mixtures*

Because L-cyhalothrin often occurs in the presence of other pyrethroid insecticides that have a similar mode of action, the toxic unit or relative potency factor approaches are appropriate to use. However, compounds that have dissimilar modes of action may exhibit additive, synergistic, or antagonistic effects in the presence of L-cyhalothrin. The conclusion that non-additive effects cannot be used for criteria compliance is appropriate due to the lack of a robust predictive model.

RTR 1-11: Comment acknowledged.

Review 1-12: Temperature, pH effects

An inverse relationship between pyrethroid toxicity and water temperature is well documented. This relationship is important as laboratory toxicity tests are often conducted at temperatures that are higher than those in natural ecosystems. Although sufficient data does not exist to enable accurate predictions of temperature-related toxicity due to L-cyhalothrin in aquatic ecosystems, this relationship should be considered in the derivation of safety factors as it is likely that criteria derived from laboratory studies conducted at relatively high temperatures will under-predict toxicity in many natural environments.

RTR 1-12: Additional safety factors are not recommended for the lambda-cyhalothrin criteria at this time to adjust for temperature related toxicity because there is inadequate aqueous exposure data to quantify this effect across species at this time. Environmental managers could choose to add an additional safety factor if it appeared that the criteria were not protective of aquatic life in a colder water body.

Review 1-13: Sensitive species

The calculated acute criterion of 1 ng/L is below all of the acute values on the data set. However, the lowest acute value of 2.3 ng/L (for *H. azteca*) is reported as an LC₅₀, which indicates that toxic effects will occur for this species at lower concentrations. This issue must be addressed. In addition, the MATC of 0.32 ng/L reported for *M. bahia* is dismissed because this is a saltwater species. Although fresh and saltwater species may have different sensitivities to L-cyhalothrin, no evidence is presented to specifically support this claim. As a result of these factors, a more rigorous evaluation of potential impacts of L-cyhalothrin on sensitive species is warranted.

RTR 1-13: It is generally accepted that a concentration of ½ of the LC₅₀ is an approximation of a no-effect level; the acute criterion of 1 ng/L is less than half of the *H. azteca* LC₅₀ of 2.3 ng/L, and therefore, the criterion will likely be protective of that species.

Mysid shrimp are very sensitive to pyrethroids; the lowest chronic toxicity values in the data sets for lambda-cyhalothrin, bifenthrin (Palumbo *et al.* 2010b), and cyfluthrin (Fojut *et al.* 2010) are for mysid shrimp. Solomon *et al.* (2001) performed a probabilistic risk assessment with pyrethroids, and initially combined saltwater and freshwater toxicity data. For compounds that had larger toxicity data sets, separate analyses were performed for freshwater and saltwater data. Differences were found especially for invertebrates, which suggested that the risk to freshwater and saltwater organisms should be assessed separately. This study provides evidence that the sensitivities of freshwater and saltwater species differ, and that adjustment of a freshwater criteria based on saltwater data is not justifiable for pyrethroids.

Review 1-14: *Ecosystem and other studies*

The authors reviewed 5 studies of microcosm and ecosystem tests that had acceptable ratings. In each of these studies, toxicity was only reported for water concentrations that were higher than the proposed acute and chronic criteria. A study conducted by Lauridsen and Friberg (2005) reported toxic effects to *G. pulex* at a L-cyhalothrin concentration of 1 ng/L, which is equal to the proposed criteria. This study was presumably given a low reliability rating because only nominal values for L-cyhalothrin were reported. The authors state that the measured concentration may have been significantly lower than the nominal value, which is likely due to loss of L-cyhalothrin due to sorption. However, such a loss would serve to increase the apparent toxicity of L-cyhalothrin in this system. In other words, it would be toxic at a concentration lower than 1 ng/L. This study should not be dismissed without a more thorough examination of its implications.

RTR 1-14: The discussion of the Lauridsen and Friberg (2005) study has been revised to emphasize that toxicity to *Gammarus pulex* is likely demonstrated at concentrations below 1 ng/L. This study does indicate sublethal effects at a similar concentration to the chronic criterion, but will not be used to adjust the criterion because they do not report measured concentrations or a toxicity value (e.g., NOEC, LOEC, EC_x), both of which could be considered reliable evidence on which to base the criterion adjustment.

Review 1-15: *Threatened and endangered species*

Data on L-cyhalothrin toxicity is available for two threatened or endangered fish species (*O. mykiss* and *G. aculeatus*). Both of these species have toxicity values that are significantly higher than the proposed criteria. The EPA's interspecies correlation estimation method was used to estimate toxicity values for listed animals that are members of the same family or genus as organisms in the data set. These calculations produced values that were significantly higher than the proposed criteria.

Data for plants were not in the data set and specific conclusions could not be offered for these species. Overall, the proposed criteria would appear to be protective of threatened and endangered species.

RTR 1-15: Comment acknowledged.

Review 1-16: *Bioaccumulation*

L-cyhalothrin has a high K_{ow} and therefore a high potential to bioaccumulate in aquatic organisms. Reported bioconcentration factors are consistent with this K_{ow} and a bioaccumulation factor (BAF) approach was used to estimate the water concentration of L-cyhalothrin that would result in a lethal concentration in wildlife that would consume

contaminated fish. An LD₅₀ value was used for this calculation because a meaningful NOEL for mallards does not exist. The resulting formula is awkward because it uses a lethal concentration to calculate an NOEC. Nevertheless, using this approach, a water concentration of 176 ng/l would be required to produce a body burden of L-cyhalothrin in fish that would be lethal to 50% of a mallard population (i.e., not an NOEC). Although a true NOEL for mallards does not exist, a no-effect concentration based on the highest dose (i.e., 30 mg/kg) used by Beavers *et al.* (1990) would result in a water concentration of 1.3 ng/L, which is essentially equivalent to the proposed criteria. The true NOEC would therefore appear to lie between 1.3 and 176 ng/L. For the sake of completeness, this range for the “true” NOEC should be discussed in the final report.

RTR 1-16: A NOEC_{water} calculation with the mallard NOEL reported by Beavers *et al.* (1990) has been added to the Bioaccumulation section of the report to emphasize that the true no-effect level for mallard bioaccumulation lies somewhere in between 1.3 and 176 ng/L.

Review 1-17: Using tolerance levels for L-cyhalothrin in meat (i.e., 0.1 mg/kg) that would be protective of human health, an equivalent concentration in fish would require a water concentration of 18 ng/L. It should be mentioned that the water concentrations of L-cyhalothrin that would be required to cause concern for food-web transfer would likely result in acute toxicity to fish and aquatic invertebrates.

RTR 1-17: The NOEC_{water} level calculated in the bioaccumulation section would be likely to result in acute toxicity to many organisms, but the chronic criterion is well below both of them, and therefore the criterion should be protective of both toxicity and bioaccumulation.

COMMENT 1-18: *Harmonization with air and sediment criteria*

Sediment and air quality standards for L-cyhalothrin do not exist. Partitioning into the water column could serve as a proxy for sediment burdens.

RTR 1-18: Comment acknowledged.

COMMENT 1-19: *Assumptions, limitations, and uncertainties*

The authors correctly point out that the major source of uncertainty in this evaluation stems from the lack of viable L-cyhalothrin toxicity data for three of the five required taxa. The approaches used (i.e., ACR and Assessment Factor) were appropriate given this limitation. However, the lack of chronic data for *H. azteca* is cause for concern as this is the most sensitive species for acute effects. Coupled with the potential heightened sensitivity of this species at low water temperatures, it is possible that the

proposed chronic criterion would not be protective under all environmental conditions. Although the authors are correct to point out that an application of an additional safety factor has merit, there is little discussion of how such a factor could or should be derived. At minimum, a more thorough description of temperature effects derived from the Weston *et al.* (2008) study would be appropriate.

RTR 1-19: We agree that the lack of chronic *H. azteca* data is a major limitation of the chronic data set. If toxicity data from aqueous exposures for multiple species at multiple temperatures was available, then an equation could be derived to incorporate this effect into criteria compliance, as described in section 3-5.3 of the methodology. The Weston *et al.* (2008) study used sediment exposures, and therefore cannot be incorporated in to criteria compliance for water quality criteria. Environmental managers could choose to add an additional safety factor if it appeared that the criteria were not protective of aquatic life in a colder water body.

COMMENT 1-20: *Comparison to national standard methods*

EPA (1985) methods were also used to derive acute and chronic criteria for L-cyhalothrin. All required elements of the EPA method could not be met because data for organisms that are not chordates or arthropods is not in the data set. The authors used proper caveats and calculations in performing this analysis (i.e., they used 7 of the 8 requirements as did Cal Fish & Game).

RTR 1-20: Comment acknowledged.

COMMENT 1-21: The acute criterion proposed in this study is essentially the same as that derived by the EPA method (1 ng/L vs. 0.9 ng/L, respectively). The slight difference between these values appears to be due to the fact that the EPA method included data for studies that did not meet the quality requirements used in this study.

RTR 1-21: Actually, we calculated criteria using the EPA method using the exact same data set used to calculate the criteria by the UC-Davis methodology. The difference between the values is due to the use of different distributions to calculate the acute value.

COMMENT 1-22: The chronic criterion derived in this study (1.0 ng/L) is a factor of 2 higher than that derived using the EPA methodology (0.4 ng/L). Although both approaches yield acute values that are similar, the slight differences are inflated when the acute values are divided by the same ACR value of 4.73. This apparent difference is an artifact of the approach used for rounding. For example, if the final acute values of 2.43 ng/L and 1.84 ng/L are rounded prior to being divided by the safety factor, they yield the same number (i.e., 2 ng/L) and hence the same acute criterion (1.0

ng/L). Likewise, the rounded final acute values divided by the ACR yield the same chronic value of 0.4 ng/L. Because the rounding has such a profound effect on the final chronic value, the authors need to re-examine this approach and provide a strong rationale for the rounding method that they used.

RTR 1-22: The chronic criterion derived by the UC-Davis methodology was rounded incorrectly in the draft report; the chronic criterion is now reported as 0.5 ng/L in the final report. The chronic criteria calculated by the two methods are now very similar (0.4 vs. 0.5 ng/L).

COMMENT 1-23: *Final L-cyhalothrin criteria statement*

Based on the best available data, the acute criteria of 1 ng/L proposed in this report should be protective of aquatic species in the Sacramento and San Joaquin River basins. However, the chronic criteria needs to be re-evaluated and justified in light of calculation approaches that can result in the proposed value being high. This results from the relatively small differences in acute data that may be magnified due to mathematical rather than biological reasons. Both criteria should be re-evaluated as soon as additional data for sensitive species (acute and chronic) and temperature effects becomes available.

RTR 1-23: The chronic criterion has been revised in the final report to be 0.5 ng/L instead of 1 ng/L, because the criterion was incorrectly rounded in the draft report.

3.2. Peer Review 2 – Stella McMillan, Ph.D., California Department of Fish and Game

REVIEW 2-1: Your proposed acute and chronic criteria for lambda cyhalothrin are both 1 ng/L. The lowest available acute toxicity value is 2.3 ng/L for amphipod *Hyalella azteca*. Field studies have supported that amphipods are more sensitive to pyrethroids than are cladocerans. As the proposed acute criterion is less than half of the value for amphipods, it is likely to be adequately protective of sensitive organisms.

RTR 2-1: Comment acknowledged.

REVIEW 2-2: The chronic criterion was derived using acute-to-chronic ratios (ACRs) from two freshwater and one saltwater species. The final ACR value was 4.73. The acute median 5th percentile value of 2.432 ng/L was divided by the final ACR to give a chronic criterion of 0.5 ng/L, which was rounded up to 1 ng/L. This value is the approximate detection level of

lambda cyhalothrin. At this time, it appears that this is an appropriate chronic criterion.

RTR 2-2: Comment acknowledged, although the chronic criterion is now reported as 0.5 ng/L, instead of 1 ng/L, due to incorrect rounding in the draft report.

3.3. Peer Review 3 – Xin Deng, Ph.D., California Department of Pesticide Regulation

REVIEW 3-1: The lambda-cyhalothrin water quality criteria were derived by applying a methodology recently developed by the University of California, Davis. Explicitly following the data evaluation criteria of the methodology, the author(s) identified 20 acute and 3 chronic toxicity studies that were reliable and relevant for lambda-cyhalothrin criteria derivation from over 65 original studies. As acceptable acute toxicity data were available from more than eight taxa, the species sensitivity distribution method was chosen to derive the acute water quality criterion (TenBrook et al. 2009a), which yielded a recommended acute value of 1 ng/l. And as only two chronic toxicity values were acceptable, the chronic criterion was derived by applying the acute-to-chronic ratio method that produced a value of 1 ng/L (TenBrook et al. 2009a).

RTR 3-1: Comment acknowledged.

REVIEW 3-2: Limitations of the derived water criteria were from the chronic toxicity data set that is comprised of only two of the five required taxa, and lack of data from the most sensitive species *Hyaella azteca*. Following analyses on the existing toxicity data of sensitive species, threatened and endangered species, and ecosystem and other studies, it appears reasonable to conclude that there is no evidence shown that the derived acute and chronic criteria will be underprotective of aquatic organisms based on the current knowledge of lambda-cyhalothrin toxicity.

RTR 3-2: Comment acknowledged.

REVIEW 3-3: There is an error on the citation for the test type of a chronic study by Hamer et al. (1985b). The study was conducted in a 12 hours static water renewal condition, not in a flow-through condition. However, should this study be included in the acute-to-chronic ratio calculation, the error will not change the derived chronic water criterion. The author may check the source of a cited paper by Lauridsen and Friberg (2005). It was published in *Environmental Toxicology*, not *Environmental Toxicology and Chemistry*.

RTR 3-3: All of the above-mentioned errors have been corrected in the final criteria report.

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