

Responses to Public Comments and Peer Reviews

Phase III: Cyfluthrin 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



Tessa L. Fojut, Ph.D.
and
Ronald S. Tjeerdema, Ph.D.

Department of Environmental Toxicology
University of California, Davis

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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
AF	Assessment Factor
CDFG	California Department of Fish and Game
CVRWQCB	Central Valley Regional Water Quality Control Board
DOC	Dissolved organic carbon
DOM	Dissolved organic matter
DPR	California Department of Pesticide Regulation
EC _x	The chemical concentration that has an effect on x% 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
SPME	Solid-phase microextraction
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 cyfluthrin is one.

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

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 – Karen Cain, Bayer Crop Science

COMMENT 1-1: Data Collection and Selection

In any data analysis project the collection, review, and selection of relevant information is critical to the process. Many times errors or flaws or bias in an analysis can be traced to how the input data was selected and used. Often, data selection plays a more critical role than the analysis scheme chosen. It is clear that the authors have done a thorough job in collecting the available aquatic toxicity information for cyfluthrin. Based on the extensive review scheme used, it is also clear that data quality is recognized as an important factor. However, we are concerned that while the data collection process was extensive, and review highly structured, the process has not necessarily led to the use of highest quality and most relevant studies and information.

BCS believes that the authors have identified most of the parameters necessary to judge the quality of studies for criteria derivation, but application of these parameters via a strict scoring scheme is misguided. The data evaluation process must be conducted in the context of the needs of the overall analysis. For example, a study with poor control performance can be rated as RR, if the other parameters are acceptable and properly documented. However, most acute toxicity test guidelines consider a study invalid if a minimum control performance is not met. Some parameters, such as control performance, are “make or break”; either the study is within accepted norms and acceptable, or is not and therefore cannot be used. Also, the importance of some parameters or review criteria is dependent on the chemical being evaluated, such as metals and hardness. One would not want to use a study with a metal, without knowing the hardness. But, for organic chemicals, hardness is generally not considered a factor that has a strong influence on toxicity.

Response To Comment (RTC) 1-1: 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 1-2: The availability, or lack thereof, of other studies can also influence whether a study should be included in the derivation process and how that study is used. One good example is that the authors’ have prioritized (*and BCS agrees*) flow-through studies over static, where both exist for a species. Looking at a different case, but on the same theme, does it make sense to exclude a study with a “new” species, just because the study was performed with a formulation? BCS agrees with the authors

that studies conducted with technical grade active agreement should be prioritized over formulation studies, but do not think they should always be excluded. In cases where a study using a “non-preferred” design is available, an evaluation needs to be carried out whether more is gained or lost by including the study in the analysis. So, if inclusion of a formulation or other non-preferred study adds significant new information, like an additional test species it should be included in the analysis.

RTC 1-2: The use of formulations for toxicity testing with <80% pure active ingredient are excluded from use in criteria derivation because use of a formulation tests the toxicity of a mixture of chemicals and the observed toxicity effects cannot be directly linked to the presence and concentration of the chemical of interest. Toxicity tests used for criteria derivation should clearly exhibit a dose-response that is proportional to the concentration of the chemical of interest. Chemical mixtures are addressed separately, after criteria have been derived with single-species laboratory toxicity tests with high purity chemicals.

COMMENT 1-3: The authors combine results of studies with cyfluthrin which is a racemic mix of four isomers (I-25%; II-18%; III-35%; IV-22%) and beta-cyfluthrin which is a refined mixture of isomers containing a higher portion of the two most active isomers (II-35%; IV-62%). This is inappropriate, since the two isomer mixture are not equally active: beta-cyfluthrin is approximately twice as active as cyfluthrin. This impacts the derivation of endpoints for a number of species, for example with the Bluegill sunfish, where the study of Gagliano (1994) is with cyfluthrin, while the study of Bowers (1994) is with beta-cyfluthrin. Taking the geometric mean of these two studies is inappropriate since the results reflect the different isomer composition and closely match the expected difference in toxicity. Typically environmental monitoring programs measure the sum of all four cyfluthrin isomers, therefore, it is most appropriate to base a criteria on the cyfluthrin toxicity data. In reviewing toxicity studies with cyfluthrin it is important that the methods make it clear what isomer mixture is used in the study since it will have a significant impact on the study results. For all the registrant sponsored studies it is clear what isomer mix was used, but some of the literature studies cited it is not and should be checked.

RTC 1-3: We agree that data for racemic cyfluthrin should not be combined with data for beta-cyfluthrin. The Bowers (1994) study, and several other studies that were done with beta-cyfluthrin (Forbis 1988; Machado 1994a, b; Surprenant 1991a, b), have been removed from the data set. All other studies have been re-checked to ensure that they use racemic cyfluthrin and not beta-cyfluthrin or any other purified isomer.

COMMENT 1-4: Finally , it must noted that many of the studies referenced are neither cited in text, listed in Tables 3 to 9, or in the toxicity data

summary sheets in the appendix, for example: Brander, *et al.* (2009), Froelich *et al.* (1984) or Maul *et al.* (2008a). We request references not relevant to the derivation of criteria for cyfluthrin be removed, and that any studies considered in the evaluation always have a corresponding toxicity data summary sheet. Some of the non-cited studies do appear to be relevant to criteria derivations, so recalculation may be necessary. Inclusion of these “extra studies” makes a fair evaluation of the document difficult. As a matter of transparency, it would be useful if the actual values assigned in the scoring for each parameter were included.

RTC 1-4: The references have been re-checked and all single-species studies that were evaluated are included in the data summary sheets in the appendix, and any other types of studies evaluated for the report are cited in the text and listed in the bibliography, and any that are not used in the criteria report have been removed from the bibliography. Brander *et al.* (2009) has been added to the report, while Froelich *et al.* (1984) and Maul *et al.* (2008) have been removed from the bibliography.

COMMENT 1-5: Bioavailability

The authors make an accurate summary in section 9.0 of the available information on the factors that impact pyrethroid bioavailability in aquatic systems. A number of the studies cited are very relevant to the question, although they have missed some (e.g. Maul *et al.* 2008a; Ortego and Benson, 1992). Clearly the authors recognize the importance of organic matter in impacting pyrethroid bioavailability. Therefore it is surprising that, despite the available information, the authors reject modifying the cyfluthrin criteria by the organic matter or carbon content. They cite some of uncertainties associated with the available studies and implementation of a water quality correction into the criteria as reason for not making any adjustments. However, ignoring a known and accepted factor that strongly influences pyrethroid bioavailability and toxicity results in criteria that are less applicable and relevant to the real world. Binding of pyrethroids to particulate matter or dissolved organic matter greatly reduces their bioavailability to aquatic organisms. It is the freely dissolved pyrethroids that are bioavailable and toxic; the bound fraction does not significantly contribute to toxicity. 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 of the total pyrethroid may be bioavailable. Comparing a criterion derived on concentrations of freely dissolved cyfluthrin, to a total concentration is not appropriate. For an accurate assessment the bioavailability of cyfluthrin must be taken into account both in generating a criterion and in applying to environmental samples. Freely dissolved cyfluthrin can be measured directly using solid phase microextraction (or other techniques), or estimated using an equilibrium partitioning model. There is no technically valid reason not to include an adjustment factor.

RTC 1-5: The bioavailability section of the final cyfluthrin criteria report has been revised to emphasize that the dissolved fraction of cyfluthrin is recommended for criteria 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 1-6: Mesocosms, Microcosms, and Field Studies

In section 13 of the report the ecosystem level studies available to the authors are summarized. These complex higher tier studies are not used in the criteria derivation process other than indicate that the derived chronic criterion is well below any of levels examined in the studies. What the ecosystem studies actually indicated is that at concentrations greater than approximately two orders of magnitude above the proposed chronic criterion, no ecological significant effects, or at most slight and transient effects can be expected. The microcosm/microcosm findings suggest that adequate protection could be achieved with a drastically higher criterion than proposed in this report.

RTC 1-6: Very few of these studies applied or measured concentrations near the derived cyfluthrin criteria, most tested concentrations were far above the derived criteria. All of these studies did observe adverse effects due to cyfluthrin applications, especially on aquatic macroinvertebrates. It is not possible to assess if effects would have occurred at lower cyfluthrin concentrations, but the derived chronic criterion of 0.05 ng/L is well below the measured cyfluthrin concentrations reported in these studies, and therefore should be protective of the organisms found in these studies. The ecosystem-level studies summarized in the report cannot be used for upward adjustment of the criteria, because only single-species laboratory data have indicated that the derived concentrations will be protective.

COMMENT 1-7: Methodology used for Cyfluthrin Criteria Derivation

The review of the data available to the authors led them to the conclusion that there was insufficient data from enough different taxa for them to use species sensitivity distribution (SSD) approach, so they applied an assessment factor to the lowest available acute toxicity value. As discussed further in following sections, if the study of Rodriguez *et al.* (2007) had been including in the evaluation, then a sufficient number of species would be available to use the SSD method. Justification for the assessment factor should be given in the criteria document due to its importance in deriving the criteria. It is our understanding that the assessment factor was taken from Tenbrook *et al.* (2009) and relies heavily on data where most of the compounds are organochlorine insecticides. The role of the assessment factor is to compensate for uncertainty in a small data set where it is unclear about relative sensitivity of untested species. But in the case of cyfluthrin, and the other pyrethroids, it is well

documented that amphipods, isopods, and similar taxa are the most sensitive species. Evidence comes both from single species testing, but also the ecosystem studies mentioned above.

RTC 1-7: The authors of the Rodriguez *et al.* (2007) study were contacted and enough additional information has been gathered about that study that it now rates as RR and can be used for criteria derivation. The authors were contacted several times in attempts to obtain enough information about how the experiments were conducted to check that it was an acceptable test, and the final information needed was obtained after the draft cyfluthrin criteria report was released. The acute criterion calculation section of the final report has been revised and the acute criterion is now calculated using a log-logistic SSD.

COMMENT 1-8: Applying a large safety factor to lowest LC50 in the cyfluthrin data set, which is *Hyalella* and therefore one of the most sensitive species just results in criteria that are overly conservative and unrealistic. While one can argue that the criterion is protective, being overly conservative or protective can result in unintended consequences. If one compares the draft acute criteria recently released by the same authors for two other pyrethroids, one would get the impression that cyfluthrin is 5 to 20 times more toxic to aquatic organisms than the other pyrethroids. An unbiased review of the available information does not support the assertion that cyfluthrin is up to 20x more toxic to aquatic organism than other pyrethroids.

RTC 1-8: The acute criterion has been re-calculated in the final report using a SSD instead of an assessment factor. The criteria in the final report (0.3 and 0.05 ng/L) are lower than the criteria calculated for other pyrethroids using the UC-Davis methodology, but the cyfluthrin data set indicates that setting the criteria higher would not be protective of sensitive species that are present in aquatic ecosystems, such as *Hyalella azteca*.

COMMENT 1-9: Considering the available information, the limited acceptance of the methods used, along with the unresolved errors in the document, BCS request that this document be withdrawn until more information is available or a more robust method are available. USEPA currently has a project underway that is examining the methods to derive benchmarks for pesticides. We assert that it would be better to wait for the output of this effort, rather than to apply methodology that may not be considered in the near future, the most appropriate for the derivation of water quality criteria for pesticides.

RTC 1-9: The water quality criteria derived using the UC-Davis methodology are documents that are available for environmental managers and regulators to use, or not use, as they see fit.

COMMENT 1-10: Page 3

Was the BCF of 4231 listed in the report actually calculated in Yang *et al.* (2007) as cited, or calculated by this report's authors? It does not appear to have been reported in Yang *et al.* (2007). It should be noted that it is misleading to report a BCF value unless steady state has been clearly demonstrated. Yang *et al.* (2007) conducted bioaccumulation experiments at 200 ppt for 24 hrs, which is above the LC50 of 160 ppt used in this report for *D. magna* after 48 hrs. While the water used does influence the bioavailability, the bioaccumulation work of Yang et al was likely done at lethal levels, putting this value into question.

It should be noted that the BCF report by Laskowski is a recalculation of Carlisle and Rooney dataset. Also, a mean values was not given in the original report. A more robust evaluation of the study has been conducted since it was originally conducted generating a BCF estimate of 459.

RTC 1-10: The BCF value cited from Yang *et al.* (2007) was not given in the original report, but was calculated from the data given in the study. The values have been removed from the report because they were conducted at potentially lethal concentrations, as noted in the comment. The BCF cited from Laskowski has been updated to note that it was originally from the Carlisle and Roney (1984).

COMMENT 1-11: Page 4

Lambda-cyhalothrin is referenced. The authors should confirm that all the data in the report is for cyfluthrin.

RTC 1-11: Lambda-cyhalothrin was referenced in error; this error has been corrected in the final report.

COMMENT 1-12: Page 4-5

The authors note that "Approximately 53 original studies..." , which this reviewer has not been able to confirm. Approximately 42 data summary sheets are in the appendix. Proper documentation of the studies reviewed and used in this study is critical in making a fair evaluation of the work. We request that the evaluation of the other studies be provided, and time be allowed for review, prior to finalizing this report.

RTC 1-12: The 53 studies referred to includes all ecotoxicity studies examined for the report, in the following categories: single-species (all summaries are available in the appendix), multi-species ecosystem-level, mixtures, bioaccumulation, wildlife, and water quality effects.

COMMENT 1-13: Page 5

Text indicates six SMAV were used, yet Figure 2 shows seven. Please clarify.

RTC 1-13: There are actually seven SMAVs in the acceptable acute data set of the draft report; the number six was given in error. There are eight SMAVs in the final acute data set of the final cyfluthrin report.

COMMENT 1-14: Page 6

A more detailed rationale of why a specific assessment factor was chosen would be helpful. Is knowledge about the relative sensitivity of the available species used in assigning an assessment factor? How is it justified to say that final acute value is the 5th percentile when all that has been done is divide the lowest toxicity value by an AF? There appears to be insufficient information available to support assigning a percentile to the final criterion.

RTC 1-14: The cyfluthrin criteria were re-calculated in the final report, and the acute criterion was calculated with a SSD; the AF approach is no longer used and as such, is not discussed in the final criteria report.

The assessment factor procedure is described in the methodology (sections 2-3.2 and 3-3.3, TenBrook *et al.* 2009). The number of taxa available in the data set that fulfill the taxa requirements for use of a SSD determines the magnitude of the AF. The draft cyfluthrin data set fulfilled four of the five taxa requirements, and therefore the AF of 5.1 was applied to the lowest SMAV in the data set. The AFs were derived by randomly sampling eleven pesticide data sets and calculating factors that would yield the median 5th percentile value of the entire data set. The goal of the AF procedure is to apply an AF that gives a reasonable estimate of the median 5th percentile value, even though a SSD is not appropriate to fit to the data set.

COMMENT 1-15: Page 7

The statement that pyrethroids have been found to cause toxicity in surface water should be fully referenced, or the statement deleted. Amweg *et al.* (2005) does not appear to be the appropriate reference. Equilibrium partitioning theory in general supports the statement at the end of the first paragraph under bioavailability. Please clarify statement “They also measured the organic carbon (OC) content of the DOM and did not find a direct correlation, indicating that not only the OC content,...” attributed to Yang *et al.* (2007). It seems at best an oversimplification of the work described by Yang *et al.* (2007).

RTC 1-15: More relevant citations have been added that report surface water contamination due to pyrethroids (Phillips *et al.* 2007, Weston *et al.* 2009, Weston and Lydy 2010).

The sentence describing the Yang *et al.* (2007) work now reads “They did not find a direct correlation between the dissolved organic carbon (DOC) content of

the DOM and uptake or toxicity, indicating that the quantity of DOC did not directly correlate with sorption, and that the quality, or characteristics, of the DOC and also affected uptake.” The work of Yang *et al.* (2007) emphasizes that sorption of pyrethroids, quantified by partition coefficients (K_{DOC}), varied with the different DOM tested, and could not be predicted by the DOC content of the DOM. This indicates that sorption is not solely dependent on the quantity of DOC, but also the quality of the DOC. This data demonstrates the need for using site-specific information for calculation of dissolved fraction of cyfluthrin from whole water concentrations, including site-specific partition coefficients (K_{OC} , K_{DOC}).

COMMENT 1-16: Page 8

Hyalella is not a true “benthic” organism and is not expected to be found in close proximity to pore water. It is epibenthic and a detritivore and tends to be associated with leaf packs or other decaying plant material at the surface of the bottom sediment. Maul *et al.* (2008a) demonstrated that toxicity of pyrethroid was reduced when *Hyalella* was exposed in the presence of its natural substrate, leaf material.

RTC 1-16: *Hyalella azteca* is accepted as benthic crustacean by the USEPA methodology, as well as the UC-Davis methodology. We recommend that only the dissolved fraction of cyfluthrin be used for criteria compliance, which should compensate for the presence of natural sorbents, such as leaf litter.

COMMENT 1-17: Page 9

A site specific partition coefficient are not necessarily to apply the model propose y needed. While there clearly is variability in K_{OC} estimates, more uncertainty is introduced into the process by ignoring bioavailability, rather than trying to address it. The authors have failed to fully quantify the uncertainty in the process.

RTC 1-17: We recommend the use of the dissolved fraction of cyfluthrin for criteria compliance

COMMENT 1-18: Page 10

Most aquatic toxicologists would consider LC50 values of 0.62 ppb and 0.46 ppb within normal experimental variation. Based on the information cited it does not appear the PBO has a significant impact on the toxicity of cyfluthrin to *Daphnia*.

RTC 1-18: The interaction coefficient for *Daphnia magna* was calculated to be 1.35, which indicates relatively little synergism. Brander *et al.* (2009) observed *Hyalella azteca* LC₅₀ values decreased by a factor of 2 when a nonlethal concentration of PBO was mixed with cyfluthrin. Many studies have reported synergism between pyrethroids and PBO, but few have been studies with

aqueous exposures, so a multispecies interaction coefficient cannot be calculated.

COMMENT 1-19: Page 11

Would it be more meaningful to compare the proposed criteria to the results of mesocosm, microcosm and field studies, which are true ecosystems studies, instead of the laboratory database used to derive the value? It is a circular argument to confirm the validity of the water quality criteria with the same data used to derive them.

The results from a single species in laboratory studies are given more credence than ecosystem studies dealing with tens, if not hundreds of species in deriving a WQC. Using the mesocosm data to only confirm the criterion is underutilizing the available information.

RTC 1-19: The derived criteria are compared to the results of mesocosm, microcosm, and field studies in section 13 of the cyfluthrin criteria report. The derived criteria are also compared to data in the single-species data sets, including those data excluded from criteria calculation, because it is possible for toxicity values in the data set to fall below the 5th percentile estimate, which could be cause for adjustment of the criteria.

Multi-species ecosystem-level studies are not used directly in criteria calculation because they are not typically tests that are reproducible; they typically do not test replicates, test few concentrations, and rarely report toxicity values (e.g., NOEC, LOEC, EC_x). These types of studies can be used for criteria adjustment if there is multispecies evidence that indicates the criteria are underprotective. They are not used for upward adjustment of criteria because high-quality single-species data from reproducible tests have indicated that increasing the criteria may cause toxicity to sensitive species (section 2-2.1.4, TenBrook *et al.* 2009).

COMMENT 1-20: Page 13

See comment on bioaccumulation on page 3

RTC 1-20: See RTC 1-10.

COMMENT 1-21: Page 14

As one of the limitations the authors should note that the acute criterion, which in turn the chronic is based on, relies on a sole publication (Weston & Jackson, 2009), whose focus was not on derivation of a pyrethroid LC50 *Hyalella* value, but instead TIE methods. It is a comparative study, and in context of the hypotheses they were examining, it is a good study. However, it was not designed to generate a standard or benchmark LC50 value for *Hyalella*. Test concentrations were not maintained or measured throughout the study, and are in fact only an estimate, based on measurements at single test levels. In this study, the measurements were

highly variable, with initial concentration ranging from 64 -189% of nominal, and the 48 hr concentration ranging from <12 -72% of nominal.

The methods used to measure the toxicity of pyrethroids to aquatic organisms do matter as can be seen in the current database. For example, the LC50 Bluegill under flow-through conditions with measured values is 0.998 ppb (Gagliano, 1994), while under static conditions with nominal concentrations the value is 1.5 ppb (Bowers, 1994). This pattern can be seen with other species.

RTC 1-21: The assumptions, limitations, uncertainties section of the report (section 17) has been revised to list the lack of acute data from flow-through tests calculated with measured concentrations as an important limitation in the data set.

COMMENT 1-22: Page 15
Typo? - heath instead of health?

RTC 1-22: This typographical error has been corrected in the final cyfluthrin report.

COMMENT 1-23: Page 27, table 3
Not all the values listed from Yang *et al.* (2007) are correct. The 0.0093 value is incorrect by a factor of 10. All values should be checked and geometric mean and the criteria recalculated. QC procedures for this report are not documented. Standard methods call for *Daphnia* to be tested for 48hrs, so it is unclear why the Yang work has been given preference over Wheelock *et al.* (2004).

RTC 1-23: The Yang *et al.* (2007) values have been checked and the 0.0093 value is now correctly reported as 0.093 in Table 3. The Wheelock *et al.* (2004) study has also been added back to the data set used for criteria derivation, and the *Ceriodaphnia dubia* SMAV has been recalculated to be 0.155 µg/L instead of 0.110 µg/L.

COMMENT 1-24: Page 28, table 3
With respect to Weston & Jackson (2009) work: With the limited measurements made, the authors did as well as possible to estimate, but these methods are well below standard. It is surprising the study scored so well considering that no standard method exists for water column tests with *Hyalella* and the limitation of the reported analytical measurements. The desire to include *Hyalella* in the criteria derivation data set is understood, however we question whether this study was conducted close enough to current standards and that it should be relied on as the value that drives the derivation of the criterion.

It should be noted that Brander *et al.* (2009), one of the studies not used, also reports a *Hyalella* LC50 for cyfluthrin, although the reliability of this study is unclear.

RTC 1-24: The reliability scoring for the Weston & Jackson (2009) study is available in the data summary sheet in Appendix B of the final criteria report. The Brander *et al.* (2009) study has been added to the data set, but they use a 10-d acute test, which is not a valid exposure duration for acute studies (section 3-2.1.1.1, TenBrook *et al.* 2009).

COMMENT 1-25: Page 28

Suprenant (1991) is a study with beta-cyfluthrin, and therefore should not be combine with studies with cyfluthrin. There is a clear difference in toxicity attributable to isomer composition. All available fish studies do not seem to have been utilized. Therefore the geometric mean for trout needs to be recalculated.

RTC 1-25: The Surprenant (1991) study has been removed from the data set because it is a test with beta-cyfluthrin and the rainbow trout SMAV was recalculated.

COMMENT 1-26: Page 29, Table 4

Rejecting studies because they are not the most sensitive endpoint for the species is wrong, and adds an unnecessary bias to the process. When multiple valid studies exist for a species, the geometric mean should be taken, not just the lowest value. The exclusion Wheelock *et al.* (2004) with *Ceriodaphnia* is a good example of this bias.

RTC 1-26: The data reduction steps are clearly described in section 3-2.6 of the methodology (TenBrook *et al.* 2009). Data are reduced to one value per species so that there is not undue weight or bias given to any one species. Toxicity values for a given endpoint are combined for a given species; data that examine different endpoints cannot be combined. The most sensitive endpoint related to survival, growth, or reproduction is used to represent the species in the final data set because the goal is to protect each species from detrimental effects. The *Ceriodaphnia dubia* value from Wheelock *et al.* (2004) has been added back to the final acute data set.

COMMENT 1-27: Page 31, Table 5

It is difficult to understand why Rodriguez *et al.* (2007) was excluded from the analysis, compared to the studies that were included. It would provide the missing insect species, allow for an SSD based estimate to be derived.

RTC 1-27: There were a lot of study details that were not reported in the original Rodriguez *et al.* (2007) article, and some study parameters were not acceptable (e.g., carrier solvent concentration, dilution factor between tested

concentrations), which led to a low reliability score for this study. After additional correspondence with the authors, we have been able to obtain enough information about this study to determine that the reliability is high enough to use in a SSD.

COMMENT 1-28: Page 38, Table 11

It is unclear how the trout LC50 value of 0.1192 ppb? was derived. While ICE was not run by this reviewer, the predicted LC50 values are surprising considering the input values.

RTC 1-28: The ICE predictions for various trout have been removed from the report. When the predictions were run on a newer version of the program (v. 2), the program indicated the input value of 0.1192 µg/L (Rainbow trout SMAV, Table 3) was below the modal minimum requirement, so the predictions for other trout species were not used.

COMMENT 1-29: All

Units should be included in all tables.

RTC 1-29: Units have been added to Tables 8 and 11.

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 validity of the cyfluthrin acute criterion, derived utilizing an assessment factor applied to the most sensitive freshwater species *Hyaletta azteca*. Use of the assessment factor provides for unnecessary extrapolation and results in an overprotective numeric criterion. In this case, use of an assessment factor for cyfluthrin is not scientifically defensible and results in aquatic life criteria unsuitable for regulatory purposes.

RTC 2-1: The acute criterion has been re-calculated in the final criteria report using a SSD because data that fulfilled the missing taxon was obtained. Regardless, the assessment factor procedure for criteria derivation has been thoroughly reviewed by both peer review and public comment processes and is a valid procedure for criteria derivation.

COMMENT 2-2: The City does not accept the validity of the cyfluthrin chronic criterion. The acute-to-chronic ratio derived is of dubious scientific applicability to the acute criterion. The use of this acute-to-chronic ratio, combined with the assessment factor used to derive the acute criterion,

results in an overprotective chronic criterion for cyfluthrin that is unsuitable for regulatory purposes.

RTC 2-2: The acute-to-chronic ratio procedure for calculation of chronic criteria has been thoroughly reviewed by both peer review and public comment processes and is a valid procedure for criteria derivation. This procedure is also used by the USEPA (1985) method for criteria derivation.

COMMENT 2-3: 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 2-3: 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 2-4: The recommendation in the cyfluthrin report that whole water analysis should be used in cases where total recoverable analysis achieves lower detection limits confuses the issue of analytical capability with that of toxicological relevancy. This recommendation should be removed from the cyfluthrin report and the report suitably revised to recommend that treatments or measurements of the dissolved fraction be the basis of compliance determinations.

RTC 2-4: See RTC 1-5.

COMMENT 2-5: 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 2-5: 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 2-6: 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 2-6: Each of the criteria reports is subject to a peer review process and public comment process. These processes were undertaken simultaneously, instead of concurrently, 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.

COMMENT 2-7: Overly conservative extrapolation through the use of an assessment factor (i.e., uncertainty factor) for cyfluthrin yields an acute criterion of questionable scientific validity. Context and scientific knowledge should be employed in evaluating the appropriateness of the utilized assessment factor. The assessment factor used not only was derived from a list of insecticides that does not include any pyrethroids, the assessment factor was applied to a *H. azteca* LC50 value. *Hyalella azteca* is known to be exceptionally sensitive to pyrethroid exposure; indeed, *H. azteca* pyrethroid sensitivity is rarely exceeded.

RTC 2-7: The acute criterion has been re-calculated in the final report using a SSD.

COMMENT 2-8: 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. The ACR derived for cyfluthrin has the same deficiency, but also relies on a dataset in which LC50s are ~2 orders of magnitude higher than the LC50 to which the ACR is applied. The resulting ACR is of questionable scientific validity, and this shortcoming is compounded by the assessment factor used to derive the acute criterion, as discussed above. The use of the derived ACR, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin.

RTC 2-8: See RTC 2-1 and RTC 2-2.

COMMENT 2-9: 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 2-9: See RTC 2-3.

COMMENT 2-10: 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 2-10: See RTC 1-5.

COMMENT 2-11: 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 2-11: See RTC 2-5.

COMMENT 2-12: The final criteria statement for cyfluthrin should accurately state acute and chronic averaging periods.

RTC 2-12: The averaging periods of the final criteria statement for cyfluthrin have been corrected in the final criteria report.

2.3. Comment Letter 3 –Debbie Webster, Central Valley Clean Water Association

COMMENT 3-1: CVCWA is concerned with the proposed draft Cyfluthrin criteria. Our comments mirror our concerns in our January 15, 2010 comment letter on the draft Bifenthrin criteria and with the draft Lambda-Cyhalothrin criteria. Our concerns include:

- The lack of good toxicity data;

RTC 3-1: We rated ten acute studies and three chronic studies as highly relevant and highly reliable. We agree that the lack of data was the most important limitation for cyfluthrin criteria calculation.

COMMENT 3-2: The lack of established and available analytical methods, and issues surrounding this such as:

- The absence of laboratories with analytical methods available to monitor down to the proposed acute and chronic levels in a clean matrix,
- Not having analytical methods that can monitor complex matrixes to detection levels,
- Unanswered questions about interferences and not having available methods to confirm interferences,
- The extreme level of concentration of the sample in order to measure for the constituent.
- Lack of a standard USEPA methodology for monitoring pyrethroids.

RTC 3-2: 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 3-3: The apparent recommendation to use the whole water concentration to assess compliance even though it is a poor indicator of toxicity because some problematic aspects of measuring the freely-dissolved fraction of Cyfluthrin;

RTC 3-3: See RTC 1-5.

COMMENT 3-4: The lack of consideration of site/sample specific requirements for water quality factors affecting toxicity in determining appropriate criteria for the waterbody;

RTC 3-4: Several site-specific parameters are considered in the cyfluthrin criteria report: reduced bioavailability caused by the presence of dissolved organic carbon or suspended solids, increased toxicity caused by lower temperatures, and the presence of pesticide or chemical mixtures in the environment. Unfortunately, there is not enough data to account for temperature-related or non-additive mixture effects. The effects of dissolved organic carbon and suspended solids are accounted for by use of the equilibrium partitioning model for criteria compliance, or the measurement of the dissolved fraction of cyfluthrin.

COMMENT 3-5: The likelihood that the proposed criteria are overprotective, especially the extremely conservative chronic criteria.

RTC 3-5: The acute criterion was re-calculated in the final report using a SSD instead of an assessment factor to be 0.3 ng/L, and the chronic criterion was re-calculated to be 0.05 ng/L. The cyfluthrin data set indicated that setting the criteria higher would not be protective of sensitive species that are present in aquatic ecosystems, such as *Hyaella azteca*.

COMMENT 3-6: The need for a better understanding of fate and transport, chronic toxicity, and affects of dissolved solids and suspended particles.

RTC 3-6: The fate and transport of cyfluthrin are outside the scope of water quality criteria derivation. We agree that the biggest limitation of the cyfluthrin data set is chronic toxicity data, but the UC-Davis methodology provides procedures for calculation of chronic criteria with limited data sets that mirror the guidance in the USEPA (1985) methodology. The effects of dissolved solids and suspended particles are discussed in the bioavailability section of the report, and can be quantified by use of the equilibrium partitioning model, or measurement of the dissolved fraction of cyfluthrin.

COMMENT 3-7: CVCWA continues to be concerned with the Central Valley Water Board's proposed use of the *draft criteria* to interpret narrative water quality objectives and potential use of the criteria to set water quality based effluent limitations in NPDES permits, as it will create liability for POTWs in the Central Valley. Considering the liability associated with complying with such effluent limitations, the Central Valley Water Board should take care in using only criteria that are well-developed and well-founded.

Moreover, we continue to be concerned with the use of the draft criteria to interpret narrative objectives because 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 Central Valley Water 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.) Porter-Cologne requires that water quality objectives be established to ensure *reasonable* protection of beneficial uses, considering a number of different factors and requires the Regional Water Board 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 Central Valley Water Board must determine if the objective is necessary to provide for *reasonable* protection of the beneficial uses, and the Central Valley Water Board must balance all of the competing demands on the water and consider the economic implications associated with adoption of water quality objectives.

In general, CVCWA is opposed to the Central Valley Water Board's use of any draft criteria in this manner. Thus, CVCWA respectfully requests that the Central Valley Water Board refrain from using the *draft criteria* for cyfluthrin at least until the criteria are properly adopted as water quality objectives pursuant to all requirements in Porter-Cologne.

RTC 3-7: 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.

2.4. Comment Letter 4 – Henry Buckwalter, Western Plant Health Association

COMMENT 4-1: The authors concluded that there was insufficient data for them to use species sensitivity distribution (SSD) approach, so they used an assessment factor (AF) approach. Justification for the AFs should be given in the criteria document due to its importance in deriving the criteria. The role of the AFs is to compensate for uncertainty in a small data set where it is unclear about relative sensitivity of untested species. However in the case of cyfluthrin, and the other pyrethroids, it is well documented that amphipods and similar taxa are the most sensitive species. Applying a large safety factor to lowest LC50 in the cyfluthrin data set, which is *Hyalella*, results in criteria that are overly conservative and unrealistic. If one compares the draft acute criteria recently released by the same authors for two other pyrethroids, one gets the impression that cyfluthrin is 5 to 20 times more toxic to aquatic organisms than the other pyrethroids. An unbiased review of the available information does not support the assertion that cyfluthrin is up to 20x more toxic than other pyrethroids.

RTC 4-1: The criteria have been re-calculated in the final report using a SSD instead of an AF because the missing taxa for use of a SSD could be fulfilled. The AF approach is no longer used, and as such, is not discussed in the final criteria report, but a full discussion of the use of AFs can be found in the methodology (sections 2-3.2 and 3-3.3, TenBrook *et al.* 2009). The criteria in the final report (0.3 and 0.05 ng/L) are lower than the criteria calculated for other pyrethroids using the UC-Davis methodology, but the cyfluthrin data set indicates that setting the criteria higher would not be protective of sensitive species that are present in aquatic ecosystems, such as *Hyalella azteca*.

COMMENT 4-2: 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 cyfluthrin water quality standards should therefore be based on concentrations of freely dissolved cyfluthrin, not total cyfluthrin. Freely dissolved cyfluthrin 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 4-2: See RTC 1-5.

COMMENT 4-3: The mesocosm and microcosm studies summarized by Fojut, Chang, and Tjeerdema, 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 the proposed chronic criterion (0.04 ng/L) is highly overprotective and should be reconsidered. Fojut, Chang 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 4-3: See RTC 1-6.

COMMENT 4-4: It is clear that the authors have done a thorough job in collecting the available aquatic toxicity information for cyfluthrin. Based on the extensive review scheme used, it is also clear that data quality is recognized as an important factor. However, we are concerned that while the data collection process was extensive, and review highly structured, the process has not necessarily led to the use of highest quality and most relevant studies and information.

RTC 4-4: The data evaluation process has been thoroughly reviewed by the peer review and public comment processes.

COMMENT 4-5: WPHA is concerned because this report states that water column concentrations of pyrethroids (e.g. cyfluthrin) 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 cyfluthrin in the environment.

RTC 4-5: Several citations have been added that report surface water contamination due to pyrethroids (Phillips *et al.* 2007, Weston *et al.* 2009, Weston and Lydy 2010).

COMMENT 4-6: The allowable frequency of exceedance (once in three years) for this cyfluthrin criteria is not supported by the receptor group (invertebrates such as *Hyaella*) for this pesticide. The life cycle for cyfluthrin-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 4-6: 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 4-7: Considering the available information, the limited acceptance of the methods used, along with the unresolved errors in the document, WPHA wonders whether this document should be withdrawn until more information is available or a more robust method are available. USEPA currently has a project underway that is examining the methods to derive benchmarks for pesticides. We assert that it would be better to wait for the output of this effort, rather than to apply methodology that may not be considered in the near future the most appropriate for the derivation of water quality criteria for pesticides.

RTC 4-7: The water quality criteria derived using the UC-Davis methodology are documents that are available for environmental managers and regulators to use, or not use, as they see fit.

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 cyfluthrin defined in this draft report was derived using methodology recently developed by Tenbrook *et al.* (2009)¹. The

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*

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 cyfluthrin. This data set indicates that this pesticide has high Kow, low volatility, high potential to bioaccumulate, high potential to sorb to sediments, and may persist in aqueous environments (i.e., hydrolysis is significant at high pH and photolysis is possible). Accordingly, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern, primarily due to its 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 cyfluthrin in fish tissue but has set a level for cattle and hog meat at 0.1 mg/kg and goat, horse and sheep meat at 0.05 mg/kg. The reason for this 2-fold difference in action levels is not clear and should be addressed.

Toxicity to mallard ducks is low, with an LC₅₀ (which should be reported as an LD₅₀) value for food >5,000 mg/kg in 16-day old ducks. An NOEC and NOEL of 250 mg/kg have been reported and were based on reproductive endpoints, which appear to be the more sensitive indicator of toxicity reported.

RTR 1-3: The USEPA determines food tolerances based on risk assessments, and no information was found that discussed why a lower tolerance was issued for cyfluthrin in some meats than others. We used the lower tolerance for bioaccumulation calculations to be conservative.

The dietary exposure value is reported as a LC₅₀, as done by the USEPA, because they are concentrations in feed, whereas the oral toxicity values are reported as LD₅₀s because they are tests that administer a pure chemical dose via oral intubation or oral gavage.

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

development and derivation of chlorpyrifos criteria. Report prepared for the Central Valley Regional Water Quality Control Board, Rancho Cordova, CA.

The authors evaluated approximately 53 published studies of cyfluthrin 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. Sixteen acute, 3 chronic and 5 microcosm and ecosystem studies were used to support criteria development calculations. Three 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 cyfluthrin was calculated using methods defined by Tenbrook *et al.* (2009). Data for four of the five required taxa was available (insect missing) and the Assessment Factor (AF) method was used to derive the acute criterion. A criterion of 0.2 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 three of the five required taxa. The chronic values for these taxa (i.e., salmonid, warm water fish and planktonic crustacean) were paired with appropriate acute data.

A final chronic criterion of 0.04 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.

RTR 1-6: Comment acknowledged.

Review 1-7: *Bioavailability*

Because cyfluthrin 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 cyfluthrin 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 cyfluthrin is the primary bioavailable phase is consistent with data for compounds with similar physical/chemical characteristics. Many studies support the

conclusion that sorption of cyfluthrin 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.

The authors are correct in stating that it is not practical to recommend that the “freely-dissolved” phase of cyfluthrin 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 cyfluthrin. Determination of site-specific dissolved concentrations of cyfluthrin 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.

The authors recommend that criteria compliance be based on whole-water concentrations of cyfluthrin, as this will provide a conservative (i.e., over-protective) estimate of this compound’s availability. This is a prudent recommendation given uncertainties in bioavailability and reported exposure concentrations.

RTR 1-7: The word portion has been changed to fraction in the final report. The bioavailability section has been revised to clarify that we recommend the use of the dissolved fraction of cyfluthrin for criteria compliance; environmental managers may also choose to use whole water concentrations for criteria compliance at their discretion.

Review 1-8: *Mixtures*

Because cyfluthrin 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 cyfluthrin. The conclusion that non-additive effects cannot be used for criteria compliance is appropriate due to the lack of a robust predictive model.

RTR 1-8: Comment acknowledged.

Review 1-9: *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 cyfluthrin 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 1-9: Additional safety factors are not recommended for the cyfluthrin 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 1-10: Sensitive species

The calculated acute criterion of 0.2 ng/L is below all of the acute values on the data set. However, the lowest acute value of 1.7 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. The proposed chronic criterion of 0.04 ng/L appears to be adequately protective of aquatic species.

RTR 1-10: The acute and chronic criteria have been re-calculated in the final report because additional RR data was added to the data set. The recommended acute and chronic criteria in the final cyfluthrin report are 0.3 and 0.05 ng/L, respectively. It is generally accepted that a concentration of ½ of the LC₅₀ is an approximation of a no-effect level; the acute criterion of 0.3 ng/L is less than half of the *H. azteca* LC₅₀ of 1.7 ng/L, and therefore, the criterion will likely be protective of that species.

Review 1-11: Ecosystem and other studies

The authors reviewed 4 studies of microcosm and ecosystem tests that had acceptable ratings. In addition, 1 study that was rated as less reliable was used in this assessment. In each of these studies, toxicity was only reported for water concentrations that were higher than the proposed acute and chronic criteria.

RTR 1-11: Comment acknowledged.

Review 1-12: Threatened and endangered species

Data on cyfluthrin toxicity is available for one threatened or endangered fish species (*O. mykiss*). Toxicity values reported for this species 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 1-12: Comment acknowledged.

Review 1-13: *Bioaccumulation*

Cyfluthrin 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 cyfluthrin that would result in a lethal concentration in wildlife that would consume contaminated fish. A NOEL value of 250 mg/kg for mallard ducks was used in this calculation. Because this was the highest dose tested, a higher NOEL is probable. Using this approach, a water concentration of at least 29 $\mu\text{g/l}$ would be required to produce a body burden of cyfluthrin in fish that would be below the toxic threshold for mallards. This result clearly indicates that toxicity to mallards via food web transfer is unlikely. The high likelihood that such a water concentration would be acutely lethal to prey species, including fish, should be mentioned.

Using the low tolerance levels for cyfluthrin in meat (i.e., 0.05 mg/kg) that would be protective of human health, an equivalent concentration in fish would require a water concentration of 6 ng/L. This value is also well above the proposed criteria. As noted above, it should be mentioned that this concentrations of cyfluthrin would likely result in acute toxicity to fish and aquatic invertebrates. In other words, food-web transfer would not be likely under such a condition.

RTR 1-13: The bioaccumulation section has been revised to note that food-web transfer would not be likely because the aqueous concentrations required for such transfers to occur are either above the aqueous solubility of cyfluthrin or would be likely to cause acute toxicity to aquatic invertebrates.

Review 1-14: *Harmonization with air and sediment criteria*

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

RTR 1-14: Comment acknowledged.

Review 1-15: *Assumptions, limitations, and uncertainties*

The authors correctly point out that the major source of uncertainty in this evaluation stems from the lack of viable cyfluthrin toxicity data for 1 of the 5 required taxa for the acute calculation and 2 of 5 taxa for the chronic calculation. The approaches used (i.e., ACR and Assessment Factor) were appropriate given this limitation. As for other pyrethroids, 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 1-15: We agree that the lack of data is the major limitation of both the acute and chronic data sets. 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.

Review 1-16: *Final cyfluthrin criteria statement*

Based on the best available data, the acute criteria of 0.2 ng/L proposed in this report should be protective of aquatic species in the Sacramento and San Joaquin River basins. The proposed chronic criterion of 0.04 ng/L would also appear to be adequately protective of aquatic life. Both criteria should be re-evaluated as soon as additional data for sensitive species (acute and chronic) and temperature effects becomes available.

RTR 1-16: Comment acknowledged.

Review 1-17: *Typographical errors*

Page 4, 3rd line from the bottom: “eleven” should be “eleven”

Page 16, line 6: “so an acute criterion” should be “so an acute criterion.”

RTR 1-17: The typographical errors mentioned above have been corrected in the final cyfluthrin report.

3.2. Peer Review 2 – Evan Gallagher, Ph.D., University of Washington

REVIEW 2-1: Physicochemical data. Presentation of physicochemical data for this compound is somewhat complicated by the fact that it consists of several stereoisomers. However, the authors present an appropriate summary of physicochemical information that takes into consideration these factors.

RTR 2-1: Comment acknowledged.

REVIEW 2-2: Information availability. Bioconcentration factors were only available for two species, including bluegill sunfish and Daphnia. Rather limited dietary information was available regarding humans and wildlife for those species with significant dietary sources in water. Specifically, there was some limited dietary information available for Mallard ducks only. These data gaps did not appear to significantly hamper the derivation of criteria for this compound relative to some other factors listed below.

RTR 2-2: Comment acknowledged.

REVIEW 2-3: Collectively, the authors identified and reviewed 53 studies. Where applicable, the report includes justification for the reduction of scientific data used to establish the water quality criteria. The data reduction approaches used in the criteria derivation document were described in the 2009 methodology. As with the other compounds reviewed in this series, a host of parameters were rated for data acceptability including, organism source and care, control description and response, chemical purity, concentrations tested, water quality conditions, and statistical methods. Single-species effects studies that were rated relevant (R) or less relevant (L) based upon the previous methodology of TenBrook *et al.* Ultimately, 16 acute toxicity studies collectively yielding 34 toxicity values, were judged reliable and relevant (RR) for criteria derivation, and 3 chronic toxicity studies were judged reliable and relevant (RR) for criteria derivation. Seven mesocosm, microcosm and ecosystem studies were identified and reviewed. Five of these studies were rated either relevant or less relevant and were used as supporting data in section 13. Collectively, these studies provided a smaller database to derive criteria values than available for some of the more commonly used agricultural compounds.

RTR 2-3: Comment acknowledged.

REVIEW 2-4: Comments on the acute and chronic criterion calculations. Because of the lack of available studies, there were not 5 acceptable acute toxicity values available to fulfill the five taxa requirements of the species sensitivity distribution (SSD) procedure described by Tenbrook *et al.* However, four of five taxa requirements were met, and the missing taxa was an insect. As a result of this data gap, the Assessment Factor (AF) procedure was used to calculate the acute criterion according to the methodology of TenBrook *et al.* This procedure resulted in an acute criterion of 0.2 ng/L.

RTR 2-4: The acute criterion has been re-calculated with a SSD because appropriate data was obtained for an insect species.

REVIEW 2-5: Similarly, chronic toxicity values were not available from 5 different families of aquatic organisms, and thus the acute-to-chronic ratio (ACR) method was used to calculate the chronic criterion. The lack of available toxicity studies is a source of uncertainty surrounding the ecological risk of this compound, especially given that for the chronic toxicity data set, there was no data for benthic organisms, considered sensitive species in these data sets (due to the potential for higher exposures associated with sediment contact). This is pointed out by the authors in their discussion.

RTR 2-5: Comment acknowledged.

REVIEW 2-6: Comments concerning sensitive, threatened and endangered species. The authors discuss that several federally listed threatened or endangered species, including rainbow trout, may be relevant to these waters. The acute data set includes a SMAV for rainbow trout of 0.119 µg/L calculated from three studies rated RR. The chronic data set includes a SMAV for remote trout of 0.0133 µg/L calculated from two endpoints in one study rated RR. Both of these values in the data sets were included in the criteria calculations and are well above the recommended criteria. The authors used the USEPA interspecies correlation estimation (ICE) software to estimate toxicity values for the listed animals or plants represented in the acute data set by members of the same family or genus. This was accomplished for other endangered trout. There are no aquatic plants listed as state or federal endangered, threatened or rare species, so they were not considered in this analysis. Based on the available data and estimated values, there was not clear evidence that the calculated acute and chronic criteria would be underprotective of threatened and/or endangered species. This is highlighted by the fact that the chronic criterion of 0.04 ng/L was roughly a factor of >330 below the lowest acceptable chronic value (MATC) of 0.0133 µg/L for rainbow trout. With regards to sensitive species, the lowest acute value in the data sets rated RR, RL, LR, or LL was 1.7 ng/L for *Hyalella azteca*, and the derived acute criterion (0.2 ng/L) is well below all of the acute values in the available data sets, and thus assumed to be protective. Furthermore, the derived chronic criterion (0.04 ng/L) is likely to be protective given that the lowest chronic value (MATC) in the acceptable data sets was 0.27 ng/L for *Mysidopsis bahia* (Hoberg *et al.* 1986).

RTR 2-6: Comment acknowledged.

REVIEW 2-7: Water quality and temperature considerations. Increased toxicity of pyrethroids with decreasing temperature has been

reported, but it is unclear as to if these effects are real or due to interlaboratory variation. There is limited data of temperature effects on aquatic exposures, and it was not feasible to quantify the relationship between the toxicity of cyfluthrin and temperature for water quality criteria. Most importantly, it was not possible to quantitate the modulation of cyfluthrin toxicity at temperatures below 20 °C, which can occur in some streams in the California Central Valley. The authors propose that for colder water bodies, it may be appropriate to apply an additional safety factor to the cyfluthrin criteria in specific areas. This is a reasonable approach, although more information targeting the effect of temperature on sensitive aquatic species is certainly warranted to reduce the uncertainty surrounding criteria derivation. If future studies become available, it may be possible to incorporate temperature information, as well as data regarding pH or other water quality parameters, into criteria compliance.

RTR 2-7: Comment acknowledged.

REVIEW 2-8: Bioavailability. Bioavailability is another source of uncertainty regarding the derivation of criteria compliance for this compound. There is little information available on dietary exposures of pyrethroids to aquatic organisms, except in the case of aquatic insects. In general, the studies indicate that ingestion may be an important exposure route, but there's not enough information to incorporate ingestion exposures into criteria compliance assessment. Although pyrethroids are typically poorly soluble in water, these compounds are considered toxic to aquatic organisms, and toxicity to aquatic organisms from pyrethroid exposures has been reported in the Central Valley. The authors cite a report that suggests that pyrethroid toxicity in the Central Valley waters might be a result of dissolved, as opposed to particulate bound, compound (Amweg *et al.* 2005). If this is the case, then dissolved cyfluthrin concentrations may be the best predictor of toxicity. By contrast, the authors cite that equilibrium partitioning models suggest that bioaccumulation of cyfluthrin can lead to *in vivo* desorption and subsequent exposure. In essence, the bioavailability of this compound in aquatic systems appears to be very difficult to predict and has the potential to vary markedly among sites. The authors suggest a reasonable approach of using SPME-based studies in specific sites to address these issues. Ultimately, authors make the argument that due to these uncertainties, whole water concentrations should be used for cyfluthrin criteria compliance. This argument appears reasonable given the poor state of the science surrounding the bioavailability of cyfluthrin.

RTR 2-8: The bioavailability section has been revised to emphasize that the dissolved fraction of cyfluthrin is recommended for criteria compliance. It is up to the discretion of environmental managers to decide an appropriate analytical

method for measurement of the dissolved fraction, or to use the whole water concentration for criteria compliance.

REVIEW 2-9: Mixtures. Exposures to cyfluthrin has the potential to occur in the context of mixtures with other pyrethroids and chemical synergizers. One study indicated that the toxicity of cyfluthrin alone was less than that in the presence of piperonyl butoxide (PBO) a common additive and synergizer of pyrethroid toxicity. The study was conducted in *D. magna* and no other studies on aquatic organisms were identified that could provide a realistic and quantitative means to consider mixtures of cyfluthrin with other classes of pesticides. Because no multi-species interaction coefficients (K) were available to describe the synergism between cyfluthrin and PBO, it was not possible to account for this interaction in compliance determination. This data gap regarding mixture interactions is not specific to cyfluthrin.

RTR 2-9: Comment acknowledged.

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

REVIEW 3-1: The cyfluthrin 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 16 acute and 3 chronic toxicity studies that were reliable and relevant for cyfluthrin criteria derivation from 53 original studies. As acceptable acute toxicity data were only available from four taxa and dataset for insect was missing, the species sensitivity distribution method could not be applied to derive the acute water quality criterion (TenBrook et al. 2009a). Instead, the acute water quality criterion was calculated by using the Assessment Factor procedure which yielded a recommended acute value of 0.2 ng/L. And as only three chronic toxicity values were acceptable, the chronic criterion was derived by applying the acute-to-chronic ratio method that produced a value of 0.04 ng/L (TenBrook et al. 2009a).

RTR 3-1: Comment acknowledged.

REVIEW 3-2: Limitations of the derived water criteria were due to the lack of data from required taxa in both acute and chronic toxicity data sets, i.e., missing insect toxicity for the acute criterion derivation and *Hyaella azteca* toxicity for the chronic criterion. Because of the limitations, the national acute and chronic criteria for cyfluthrin can not be derived from the U.S. Environmental Protection Agency methodology. 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 cyfluthrin toxicity.

RTR 3-2: Comment acknowledged.

REVIEW 3-3: There were a couple of editorial errors that need to be corrected:

1. The first paragraph on page 4, "lambda-cyhalothrin" should be "cyfluthrin."
2. Units were missing on Tables 8 and 11. .

RTR 3-3: These two editorial errors have been corrected in the final cyfluthrin criteria report.

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