

Responses to Public Comments and Peer Reviews

Phase III: Cypermethrin 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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Table of Contents

1.0	Introduction	1
2.0	Response to Comment to Public Comments	2
2.1.	Comment Letter 1 – Jeffrey M. Giddings & Jeffrey Wirtz, Compliance Services International on behalf of FMC	2
2.2.	Comment Letter 2 – Christopher Davis, FMC Corporation.....	15
2.3.	Comment Letter 3 – Kelye McKinney, City of Roseville; Michael Bryan, Brant Jorgenson, and Ben Giudice, Robertson-Bryant, Inc.....	16
2.4.	Comment Letter 4 – Debbie Webster, Central Valley Clean Water Association.....	28
2.5.	Comment Letter 5 – Linda Dorn, Sacramento Regional County Sanitation District.....	31
3.0	Response to Comment to Peer Reviews	37
3.1.	Peer Review 1 – John P. Knezovich, Lawrence Livermore National Laboratory.....	37
3.2.	Peer Review 2 – Stella McMillan, California Department of Fish and Game.....	45
3.3.	Peer Review 3 - Xin Deng, California Department of Pesticide Regulation.....	45
4.0	References	48

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 eight 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 eight additional pesticides, of which permethrin is one.

The permethrin criteria report was submitted to peer review, conducted by experts from academia and sister agencies, including the Department of Fish and Game and 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 – Jeffrey M. Giddings, Ph.D. & Jeffrey Wirtz, Compliance Services International (CSI) on behalf of FMC

COMMENT 1-1: 2. Derivation of Acute Criterion

UCD's draft Acute Criterion is based on data for 14 freshwater species, presented in Table 3 of their report. Toxicity values for several of these species require correction, as discussed below. Relevant and reliable data are also available for other species, and these affect the calculated acute value and the Acute Criterion. The aquatic toxicity data used by UCD and those proposed by CSI are summarized in Table 1. Evaluation forms for studies rated by CSI are presented in Appendix A.

Response To Comment (RTC) 1-1: Each of the points in comment 1-1 are addressed in more detail in below responses (RTC 1-2 through RTC 1-13).

COMMENT 1-2: 2. Derivation of Acute Criterion

2.1 Baetis rhodani

UCD did not identify any *B. rhodani* studies to rate before calculating the Acute Criterion for cypermethrin. However, a 96-h LC50 of 0.0123 µg/L is available for a flow-through study (Edwards *et al.* 1980a) rated "Relevant and Reliable" (RR) by CSI. The 96-h LC50 of 0.0123 µg/L should be used in the calculation of the Acute Criterion for cypermethrin.

2.2 Cloeon dipterum

UCD derived the Acute Criterion using the *C. dipterum* 24-h LC50 of 0.6 µg/L (Stephenson 1982; the primary source is Stephenson 1980a). Results are also available from one other study rated RR. The additional 96-h LC50 value is 0.02 µg/L (Stephenson 1980b). The latter study is preferred, because it used flow-through exposure and because of the 96-h exposure duration. Therefore, the 96-h LC50 of 0.02 µg/L is the appropriate value to use for this species in deriving an Acute Criterion for cypermethrin.

RTC 1-2: The Edwards *et al.* (1980a) and Stephenson (1980a, b) studies are not publicly available and are not listed in either the EPA database or the California Department of Pesticide Regulation database. The reference given in the CSI comments did not list an identification number for either agency, which I would need to request the data if they were held by either agency. If these studies have not been submitted to a regulatory agency, then they cannot be obtained by the public. We have requested that FMC submit these studies to a public agency, but at this time these studies are not available from any public agency.

COMMENT 1-3: 2. Derivation of Acute Criterion

2.3 Corixa punctata

UCD used the 24-h EC50 of 0.7 µg/L for *C. punctata*, from Stephenson 1982. The primary source for this study (Stephenson 1980a) reports a 24-h LC50 of >5 µg/L. The LC50 is more appropriate than the EC50 for derivation of the Acute Criterion.

RTC 1-3: The EC50 was used instead of LC50 because toxicity values reported as greater than or less than cannot be used for criteria derivation. The effect tested to determine the EC50 was immobility, which is an acceptable endpoint related to survival.

COMMENT 1-4: 2. Derivation of Acute Criterion

2.4 Cyprinus carpio

UCD did not use a *C. carpio* LC50 to calculate the Acute Criterion for cypermethrin. The two *C. carpio* tests evaluated by UCD (Aydin *et al.* 2005; Stephenson 1982) were rated “Less Relevant, Reliable” (LR) and “Less Relevant, Less Reliable” (LL), respectively, and CSI agrees with those ratings. However, a third *C. carpio* test by Hill (1981) was not evaluated by UCD and was rated RR by CSI. The *C. carpio* LC50 of 1.6 µg/L from Hill (1981) should be used in deriving the Acute Criterion for cypermethrin.

RTC 1-4: As stated in RTC 1-2, the study referred to (*C. carpio* test, Hill 1981) could not be requested from a public agency and therefore is not available for use in the criteria report.

COMMENT 1-5: 2. Derivation of Acute Criterion

2.5 Daphnia magna

UCD derived the Acute Criterion using the *D. magna* 48-h LC50 of 0.147 µg/L (geometric mean of results from Ward and Boeri [1991a] and Wheat and Evans [1994]). Results are also available from three other studies that CSI rated RR. The additional 48-h EC50 values for immobilization range from 0.21 µg/L (Rufli 1989) to 1.25 µg/L (Edwards *et al.* 1980b). However, among all the studies, only Wheat and Evans (1994) used flow-through exposure. Therefore, the LC50 of 0.162 µg/L (Wheat and Evans 1994) is the most appropriate value to use for this species in deriving an Acute Criterion for cypermethrin.

RTC 1-5: The Ward and Boeri (1991a) LC50 will continue to be included in the *Daphnia magna* SMAV because it is a reliable toxicity value, and there is no cause to exclude it according to the data reduction procedure of the UCD methodology (section 3-2.4). The Ward and Boeri (1991a) LC50 was from a static renewal test calculated using measured concentrations, while the Wheat & Evans (1994) LC50 was from a flow-through test using nominal concentrations. Data from flow-through tests using measured concentrations are preferred (part

11, section 3-2.4), but Wheat & Evans (1994) used nominal concentrations, so there it does not cause exclusion of the Ward & Boeri (1991a) study.

The Rufli (1989) and Edwards et al. (1980b) studies could not be requested from a public agency and therefore are not available for use in the criteria report.

COMMENT 1-6: 2. Derivation of Acute Criterion

2.6 Gammarus pulex

The 24-h LC50 for *G. pulex* is shown as 0.1 µg/L in the publication by Stephenson (1982; the primary source is Stephenson 1980a). However, a 96-h LC50 of 0.009 µg/L is available for a flow-through study (Stephenson 1980b) rated RR by CSI. The 96-h LC50 of 0.009 µg/L should be used in the calculation of the Acute Criterion for cypermethrin because (a) it is from a flow-through study, and (b) the exposure duration is 96 h.

RTC 1-6: As stated in RTC 1-2, the other *G. pulex* test (Stephenson 1980b) could not be requested from a public agency and therefore is not available for use in the criteria report.

COMMENT 1-7: 2. Derivation of Acute Criterion

2.7 Gyrinus natator

UCD used the 24-h EC50 of 0.07 µg/L for *G. natator*, from Stephenson (1982). The primary source for this study (Stephenson 1980a) reports a 24-h LC50 of >5 µg/L. The LC50 is more appropriate than the EC50 for derivation of the Acute Criterion.

RTC 1-7: The EC50 was used instead of LC50 because toxicity values reported as greater than or less than cannot be used for criteria derivation. The effect tested to determine the EC50 was immobility, which is an acceptable endpoint related to survival.

COMMENT 1-8: 2. Derivation of Acute Criterion

2.8 Hyalella azteca

UCD presents LC50 data from two studies with *H. azteca*, including three tests by Weston and Jackson (2009) and one by Hamer (1997). UCD's analysis used the geometric mean of the LC50 values from the four tests (0.0027 µg/L). If the two studies (rather than the four individual tests) were weighted equally in the analysis, the species geometric mean would be 0.0030 µg/L. We believe this value, with the two studies receiving equal weight, should be used in the calculation of Acute Criterion, though we acknowledge that the small difference in this case is unlikely to affect the result.

RTC 1-8: We followed guidance in the UCD methodology by keeping the three toxicity values from Weston & Jackson (2009) separate until they are all combined using the geometric mean to determine the SMAV. This guidance

appears in the last paragraph of section 3-2.2.2 (Ecotoxicity data) of the UCD methodology:

If a study has results from multiple tests with the same species report each value as an individual test by the same author. These toxicity values will be combined when data is reduced.

COMMENT 1-9: 2. Derivation of Acute Criterion

2.9 Lepomis macrochirus

UCD did not identify any *L. macrochirus* studies to rate before calculating the Acute Criterion for cypermethrin. A relevant and reliable study (Hill 1980a) reported a 96-h LC50 of 1.78 µg/L. This LC50 should be used in the calculation of the Acute Criterion for cypermethrin.

RTC 1-9: As stated in RTC 1-2, the *L. macrochirus* test (Hill 1980a) could not be requested from a public agency and therefore is not available for use in the criteria report.

COMMENT 1-10: 2. Derivation of Acute Criterion

2.10 Oncorhynchus mykiss

UCD used the 96-h LC50 of 0.90 reported by Vaishnav and Yurk (1990) for *O. mykiss*. Two other relevant and reliable flow-through studies (Davies *et al.* 1994; Hill 1980b) reported 96-h LC50 values of 1.47 and 0.92 µg/L, respectively. Davies *et al.* 1994 was rated LR by UCD since it did not state if a standard method was followed and because the control response was not described. However, sufficient detail is provided in the report to conclude that the methods followed were equivalent to standard methods. Therefore, it should have been rated RR and used in the Species Mean Acute Value (SMAV) determination for *O. mykiss*. The Hill 1980b study was not evaluated by UCD; it was rated RR by CSI. The geometric mean of all three tests, 1.07 µg/L, should be used in the calculation of the Acute Criterion.

RTC 1-10: The Davies *et al.* (1994) study will continue to be rated LR because a study must state which standard method they follow in order to receive points for this parameter, so this rating of this parameter will not change. As stated in RTC 1-2, the study referred to (*O. mykiss* test, Hill 1980b) could not be requested from a public agency and therefore is not available for use in the criteria report. At this time, the *Oncorhynchus mykiss* SMAV will continue to be 0.90 µg/L.

COMMENT 1-11: 2. Derivation of Acute Criterion

2.11 Orconectes sp.

UCD did not identify any *Orconectes sp.* studies to rate before calculating the Acute Criterion for cypermethrin. A relevant and reliable study (Jaber 1981a) reported a 96-h LC50 of 0.068 µg/L. This LC50 should be used in the calculation of the Acute Criterion for cypermethrin.

2.12 *Pimephales promelas*

UCD indicated that no acute toxicity data were found for *P. promelas*. Two relevant and reliable studies (Balog 1989a,b) reported 96-h LC50 values of 0.84 µg/L and 1.28 µg/L, respectively. The geometric mean of these two values (1.04 µg/L) should be used in the calculation of the Acute Criterion.

RTC 1-11: As stated in RTC 1-2, the studies referred to (Balog 1989a, b, Jaber 1981a) could not be requested from a public agency and therefore are not available for use in the criteria report.

COMMENT 1-12: 2. Derivation of Acute Criterion

2.13 *Pseudaphritis urvillii*

UCD did not use the 96-h LC50 of 2.19 µg/L available for *P. urvillii* (Davies *et al.* 1994) since they rated it LL. This study was rated poorly since it did not state if a standard method was followed, did not provide a control response, and had a low reliability score. However, sufficient detail is provided in the report to conclude that the methods followed were equivalent to standard methods and that the reliability score should be 77, not 71. Therefore, it should have been rated RR and used in the calculation of the Acute Criterion.

RTC 1-12: We have revised the data summary sheet for this study. A study must state which standard method they follow in order to receive points for this parameter, so this rating of this parameter will not change. Other parameters were rated erroneously in the draft report and have been revised in the final report (Table 3.7: conductivity; Table 3.8: control response, prior contamination, conductivity). The carrier solvent concentration is now reported in the data summary sheet, but it is too high to be acceptable. For these reasons, this study is still rated as LL and is not used in criteria calculation.

COMMENT 1-13: 2. Derivation of Acute Criterion

2.14 Calculation of Acute Criterion

The UCD report stated that the ETX 1.3 software program (Aldenberg 1993) was used to fit the data set to a log-logistic distribution. UCD reported a median HC5 of 0.0126904 µg/L. Using an updated version of the same software (ETX 2.0, Van Vlaardingen *et al.* 2004) and the data shown in UCD's Table 3, CSI obtained a median HC5 value of 0.0130427 µg/L, quite close to UCD's result. UCD's result corresponds to an Acute Criterion (HC5 divided by 2, reported with one significant digit) of 6 ng/L. The result obtained by CSI, though only slightly greater than UCD's, would correspond to an Acute Criterion of 7 ng/L.

As discussed above, CSI proposes additions or corrections to UCD's toxicity values for *B. rhodani*, *C. dipterum*, *C. punctata*, *C. carpio*, *D. magna*, *G. pulex*, *G. natator*, *H. azteca*, *L. macrochirus*, *O. mykiss*,

Orconectes sp, *P. promelas*, and *P. urvillii*. These proposed changes are summarized in Table 1. With these revisions, the median HC5 is calculated as 0.007021 µg/L (0.001427-0020919 µg/L). The revised Acute Criterion is 4 ng/L.

Conclusion on Acute Criterion

- UCD's draft Acute Criterion for cypermethrin was 6 ng/L. Using the same data and an updated version of the same software, CSI obtained an Acute Criterion of 7 ng/L.
- CSI proposes additions and corrections to the dataset used for derivation of the Acute Criterion. Based on the revised dataset, the Acute Criterion for cypermethrin is 4 ng/L.

RTC 1-13: We used the ETX 1.3 program because it is capable of fitting a log-logistic distribution to the data, while the newer ETX 2.0 program is only capable of fitting a log-normal distribution to data. This is likely why CSI obtained a different acute value with the UCD dataset – the result CSI reports is for a log-normal distribution instead of a log-logistic distribution. The UCD methodology specifies fitting a log-logistic distribution in section 3-3.2.2.

CSI reported several toxicity values that UCD did not review, but at this time these studies are not held by public agencies, and UCD is not able to obtain them for use in the criteria report. CSI also disputed the ratings of several studies, which are discussed in detail in the above responses. While the ratings of the Davies et al. (1994) study were revised, the final ratings did not change, so the final acute dataset remains identical to that reported in the draft report.

COMMENT 1-14: 3. Derivation of Chronic Criterion

UCD's draft cypermethrin criteria report discussed chronic toxicity data for *D. magna* and *P. promelas* (Table 1). For *D. magna* UCD used the 21-d Maximum Acceptable Toxicant Concentration (MATC) of 0.0000063 µg/L from a study by Kim *et al.* (2008). While the study is rated RR, this MATC is highly suspect; it is more than 1000 times lower than the lowest chronic endpoint reported for any pyrethroid (a NOEC of 0.00095 µg/L for *D. magna* and bifenthrin; Surprenant and Yarko 1985). Two other available chronic *D. magna* studies were not included in UCD's dataset: Edwards *et al.* (1981) and Garforth (1982). CSI evaluated these studies using the UCD methodology and rated both of them Relevant and Reliable. Edwards *et al.* (1981) reported two separate *D. magna* tests that provided 21-d MATC values of 0.013 and 0.009 µg/L, respectively. The 21-d MATC for Garforth (1982) was 0.17 µg/L. Of the three available *D. magna* studies that are relevant and reliable, only the Edwards *et al.* (1981) studies used flow-through exposures with measured concentrations. Therefore, the geometric mean of the two Edwards *et al.* (1981) 21-d MATC values (0.01 µg/L) should be used as the *D. magna* Species Mean Chronic Value (SMCV).

RTC 1-14: We agree that the Kim et al. (2008) *D. magna* value is suspect, and therefore we are extremely interested in obtaining the chronic *D. magna* studies that CSI refers to: Edwards et al. (1981) and Garforth (1982). As stated in RTC 1-2, these studies cannot currently be requested from a public agency and therefore are not available for use in the criteria report.

COMMENT 1-15: 3. Derivation of Chronic Criterion

Relevant and reliable chronic toxicity data were also available for *P. promelas*. UCD used 30-d and 60-d MATC values of 0.11 µg/L from Tapp et al. (1988) to derive a SMCV of 0.11 µg/L for *P. promelas*. (Table 6 of the draft criteria report indicates that UCD calculated the geometric mean of these two endpoints. Calculating the geometric mean of 30-d and 60-d endpoints from a single study is not appropriate, and not consistent with the UCD methodology [TenBrook et al. 2009]. However, since the endpoints were identical, this had no impact on the criterion derivation.) One other flow-through study was available (Jaber 1981b) and rated relevant and reliable by CSI. The 30-d MATC for survival from the Jaber (1981b) study was 0.21 µg/L. The geometric mean of the *P. promelas* MATC values from the two studies is 0.15 µg/L.

RTC 1-15: We agree that it was not appropriate to calculate the geometric mean of the 30-d and 60-d endpoints for *P. promelas*. The final chronic dataset (Table 6) has been revised, and the 30-d MATC for *P. promelas* has been moved to the table of acceptable reduced chronic data (Table 7), although, as noted by CSI, this revision does not change the SMCV. As stated in RTC 1-2, the Jaber (1981b) study cannot currently be requested from a public agency and therefore is not available for use in the criteria report.

COMMENT 1-16: 3. Derivation of Chronic Criterion

Derivation of a chronic criterion using the SSD approach would have required, in addition to the species listed above, data on chronic toxicity to the family Salmonidae, a benthic crustacean, and an aquatic insect. Because chronic toxicity data for these groups were not available, UCD applied an Acute-to-Chronic Ratio (ACR) approach instead (TenBrook et al. 2009).

To derive a Chronic Criterion using the ACR approach, ACRs are required for three species, including a fish and an invertebrate. The UCD methodology is unclear about the requirements for ACR calculation. At first, the methodology states 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 dilution water.

RTC 1-16: We appreciate your comments about the ACR calculation guidance in the UCD methodology. The guidance on ACR calculation was taken directly from the USEPA (1985) methodology, including the requirement that the acute and chronic tests must be performed in the same dilution water (section VI.-I., p. 40-41, USEPA 1985).

It is possible that these guidelines will be revised in the future, but at this time the chronic cypermethrin criterion will be calculated according to the current UCD method. We agree that it is preferable to use ACRs based on measured data over default ACRs, but it is important that toxicity tests should be matched because there are intra-species and inter-laboratory variations between tests that could significantly affect the calculation of an acute to chronic ratio. If the UCD methodology is revised in the future, clearer guidance on which studies are appropriate to pair for ACR calculation will be added. While dilution water properties such as hardness and alkalinity may not have a strong effect on the toxicity of pyrethroids, parameters such as salinity and dissolved organic carbon could have significant effects.

COMMENT 1-17: 3. Derivation of Chronic Criterion

According to UCD, for *D. magna*, only the study by Kim *et al.* (2008) could be paired with an appropriate acute datum and satisfy the invertebrate data requirement for calculation of an ACR based on measured data. The resulting SMACR that UCD used was 949. As discussed above, a more reliable MATC for *D. magna* is available, which when paired with the *D. magna* SMAV (0.162 µg/L) gives an ACR of 16.2.

RTC 1-17: The derivation of the chronic criterion has been revised, and the *D. magna* ACR from the Kim *et al.* (2008) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate ACRs. This interpretation excludes the Kim *et al.* (2008) study because the acute test was rated RL. As discussed in RTC 1-5 and RTC 1-14, we do not have access to the chronic *D. magna* study that CSI refers to, and the *D. magna* SMAV in the draft report was calculated correctly according to the UCD methodology. In the final criteria report, there is no SMACR for *D. magna* because there is no longer an acceptable chronic toxicity value.

COMMENT 1-18: 3. Derivation of Chronic Criterion

UCD calculated an ACR for *O. mykiss* based on data from a 10-d study by Davies *et al.* (1994). The acute study (rated LR by UCD but rated RR by CSI, as discussed in Section 2.10) resulted in a 96-h LC50 of 1.47 µg/L. The chronic results presented by Davies *et al.* (1994) consisted of 10-d responses of plasma glucose, brain acetylcholinesterase (AChE), and liver

glutathione-S-transferase (GST). Dose-response trends were inconsistent (not monotonic) for glucose and brain AChE; neither of these endpoints was significantly affected at the highest concentration tested. For GST, the NOEC was 0.49 µg/L and the LOEC was 0.87 µg/L, corresponding to an MATC of 0.65 µg/L. UCD cited an MATC of 0.65 µg/L but listed the endpoint as mortality (Table 9 of the draft criteria report). Actually, none of the endpoints from this study qualify as chronic endpoints under the UCD methodology: the 10-d test involved neither full life-cycle exposure, partial life-cycle exposure, nor early life-stage exposure, and none of the endpoints represented survival, growth, or reproductive effects (TenBrook *et al.* 2009, Section 3-2.1.1). Thus, the ACR generated by UCD for *O. mykiss* is not reliable.

RTC 1-18: The derivation of the chronic criterion has been revised, and the *O. mykiss* ACR from the Davies *et al.* (1994) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate ACRs. This interpretation excludes the Davies *et al.* (1994) study because the neither the acute nor chronic tests were rated RR by UCD. We have revised our data sheets and the data tables containing these toxicity values to reflect our revised ratings of these tests. We agree that the chronic endpoints cited in the study are not appropriate and have corrected the error in the draft report stating the chronic endpoint as mortality.

COMMENT 1-19: 3. Derivation of Chronic Criterion

UCD also calculated an ACR for *Acartia tonsa* based on studies by Barata *et al.* (2002). Both the acute and chronic portions of this study were rated as LL by UCD, with a low reliability score. To calculate the ACR, UCD selected a 5-d LC50 for adults (although nauplii were much more sensitive) and a 5-d MATC for adult survival (or perhaps a 2-d MATC for egg survival – the two MATC values were identical). The reasons for those selections are not presented, and different selections would have resulted in quite different ACRs; indeed, had the lowest LC50 (a 4-d LC50 for nauplii) been used, the ACR would have been less than 1. Furthermore, 2-d and 5-d MATC values do not meet the definition of chronic toxicity data presented by TenBrook *et al.* (2009): they do not “take into account the number of young produced” and the exposure durations are too short. Thus, the ACR generated by UCD for *A. tonsa* is not reliable.

RTC 1-19: The derivation of the chronic criterion has been revised, and the *A. tonsa* ACR from the Barata *et al.* (2002) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate ACRs, unless a saltwater species is being used, such as *Acartia tonsa*, in which case the tests would have to be rated LR. This interpretation excludes the Barata *et al.* (2002) study because the neither the acute nor chronic tests were rated LR by

UCD. We agree that the 2-d and 5-d LC50s are not appropriate chronic tests and these toxicity values have been removed from the supplemental chronic dataset (Table 9).

COMMENT 1-20: 3. Derivation of Chronic Criterion

Because UCD was unaware of the existing acute data for *P. promelas*, they were unable to develop an ACR for this species. As discussed above, there were two similar relevant and reliable LC50s: 0.84 µg/L (Balog 1989a) and 1.28 µg/L (Balog 1989b), with a geometric mean of 1.04 µg/L. There were also two similar and reliable MATCs: 0.11 µg/L (Tapp *et al.* 1988) and 0.21 µg/L (Jaber 1981b), with a geometric mean of 0.15 µg/L. The consistency of both acute and chronic endpoints supports their validity for deriving an ACR of 6.9.

Reliable acute and chronic data are also available for *Americamysis bahia*. There are two similar reliable LC50 values: 0.005 µg/L (Ward *et al.* 1992) and 0.0049 (Ward and Boeri 1991b), with a geometric mean of 0.005 µg/L. There is also a reliable MATC of 0.00124 µg/L (Wheat 1993). These results support an ACR of 4.0 for *A. bahia*.

Since the *D. magna* ACR was much larger than the other two ACRs of 2.11 for *A. tonsa* (Barata *et al.* 2002) and 2.26 for *O. mykiss* (Davies *et al.* 1994), UCD also calculated an example chronic criterion without using the *D. magna* ACR. In this example, the final ACR was calculated as the geometric mean of the remaining two ACRs (Barata *et al.* 2002; Davies *et al.* 1994) and one default ACR of 12.4¹, which resulted in an example final ACR of 3.90.

However, as discussed, none of the ACRs used by UCD is valid. Appropriate ACRs for cypermethrin are summarized in Table 2. As discussed in Section 2.14, the acute toxicity value (HC5) derived based on CSI's revised dataset is 0.007021 µg/L. The ACR for the species with SMAV nearest the acute value (*A. bahia*) is 4.0. Applying the ACR of 4.0, the Chronic Criterion is 0.0018 µg/L, or 2 ng/L.

RTC 1-20: We agree that the three ACRs used in the draft report are not appropriate and they are not used in the chronic criterion calculation in the final report. The two ACRs that CSI has calculated for *Pimephales promelas* and *Americamysis bahia* cannot be used by UCD because we do not currently have access to the studies they are based on (Balog 1989a, b, Jaber 1981b, Ward and Boeri 1991b, Ward *et al.* 1992, Wheat 1993). As stated in RTC 1-2, these studies cannot currently be requested from a public agency and therefore are not available for use in the criteria report.

COMMENT 1-21: 4. Bioavailability of Cypermethrin

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.

“As a counterpoint” to the evidence relating cypermethrin toxicity to the freely dissolved fraction, the draft criteria report notes (p. 9) that “equilibrium partitioning would suggest that as organisms take up cypermethrin, more cypermethrin will desorb from particles, so the fraction absorbed to solids is likely not completely unavailable.” This is not a logical inference. In the equilibrium partitioning model, the flux of cypermethrin between phases (freely dissolved, associated with dissolved organic matter, and sorbed to particulate organic matter) is such that concentrations in each phase are constant – fluxes into each phase (e.g., desorption from particles as an input to the freely dissolved phase) are balanced by fluxes in the opposite direction (e.g., sorption of freely dissolved cypermethrin to particles). The fact that cypermethrin molecules can move from one phase to the other does not “counter” the evidence that cypermethrin molecules are bioavailable only when freely dissolved.

RTC 1-21: The assumption of the equilibrium partitioning model is that the system is at equilibrium, and at equilibrium, we agree that the fluxes between phases would be constant. The paragraph regarding equilibrium partitioning theory has been revised in the final criteria report to reflect this. Because it is unlikely that environmental ecosystems are at equilibrium, and it has been shown that pyrethroids have a long equilibration time (~30-d, Bondarenko et al. 2006), continued desorption, and the associated toxicity, could persist over long time periods. This concept has been described as the “bioaccessible” fraction (Semple et al. 2004, You et al. 2011), the fraction of a chemical that will rapidly desorb from particles, and has been linked to biological effects.

COMMENT 1-22: 4. Bioavailability of Cypermethrin

The draft criteria 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.

RTC 1-22: There are very few studies available in the literature regarding dietary exposure of pyrethroids, or any hydrophobic organic compounds, but lack of

information does not imply that toxicity due to pyrethroid ingestion does not occur. While the Mayer et al. (2001) study does not use insects or crustaceans, it demonstrates that hydrophobic compounds can be taken up from ingested particles. Pyrethroids are hydrophobic organic compounds with log K_{ow} s ranging from 4-7, similar to benzo(a)pyrene (log K_{ow} = 6.13, Schwarzenbach et al. 2003), which is used in the Mayer et al. (2001) study. The Palmquist et al. (2008) study, also cited in this section of the report, clearly demonstrated toxicity to three aquatic insects due to ingestion of a pyrethroid, including mortality and reduced growth and egg production.

COMMENT 1-23: 4. Bioavailability of Cypermethrin

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 cypermethrin 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, presented as Equation 1 in the draft criteria document for cypermethrin). UCD notes that Equation 1 should not be used unless site-specific data are available for all the terms in the equation. These terms include SS, the concentration of suspended solids in the water, and f_{oc} , the fraction of organic carbon in the suspended sediment. While f_{oc} of suspended sediment is not usually measured directly, the term $[SS]/f_{oc}$ in Equation 1 is equivalent to the concentration of particulate organic carbon (POC), which can be readily determined as the difference between total organic carbon (TOC) and dissolved organic carbon (DOC). Thus, the site-specific data needed for Equation 1 are the total concentration of cypermethrin in water, the concentration of DOC, and the concentration of POC. Values for the other terms in Equation 1, K_{OC} and K_{DOC} , are available in the literature. The suggestion by TenBrook *et al.* (2009) that site-specific K_{OC} and K_{DOC} values must be available is unreasonable: it would prevent all use of the model, because such data are virtually non-existent for any chemical.

RTC 1-23: It is stated clearly in the UCD methodology that regulators have the conservative option to determine compliance based on whole water pesticide concentration, even if there is evidence that some phases are not bioavailable (Section 2-4.1, TenBrook *et al.* 2009). While we recommend using the concentration of cypermethrin in freely dissolved phase for compliance determination, we stand by the statement that regulators can also use whole water concentrations because techniques to measure freely dissolved concentrations (e.g., SPME) are not yet included in standardized testing

methods. We recommend using site-specific K_{OC} and K_{DOC} values to estimate the dissolved concentration using partition coefficients because these values can vary by several orders of magnitude (Bondarenko et al. 2007, Laskowski 2002, Muir et al. 1994). Depending on which partition coefficients are used, predicted dissolved concentrations can also vary by an order of magnitude.

COMMENT 1-24: 5. Conclusions

The data selected by UCD for derivation of the Acute Criterion for cypermethrin overlooked several Relevant and Reliable studies. Inclusion of these studies resulted in a recalculated Acute Criterion of 4 ng/L. (UCD's recommended Acute Criterion was 6 ng/L.)

RTC 1-24: Please see RTC 1-2 through RTC 1-13. At this time the studies that CSI cites that were not included in the acute datasets are not available to UCD, so the UCD acute dataset (Table 3) has not been revised from the draft report, and the initial acute criterion calculation remains to be 6 ng/L, but the adjusted acute criterion of 1 ng/L is the final acute criterion.

COMMENT 1-25: 5. Conclusions

Due to limited data available on chronic toxicity, an ACR approach was used to derive the Chronic Criterion for cypermethrin. The ACRs calculated by UCD were based on several unreliable endpoints. Using acceptable acute and chronic toxicity data, CSI calculated ACRs for 3 species ranging from 4.0 to 16.2. Based on the ACR for the species closest to the acute value, the recalculated Chronic Criterion is 2 ng/L. (UCD's proposed Chronic Criterion was 0.01 ng/L.)

RTC 1-25: We agree that the ACRs proposed in the draft report were unreliable and they have been removed from the final report. The ACRs calculated by CSI were based on studies that are not available to UCD, and therefore could not be used by UCD. Instead, the default ACR was used to calculate the final chronic criterion in the final criteria report. The final chronic criterion for cypermethrin is 0.2 ng/L.

COMMENT 1-26: 5. Conclusions

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. For consistency with the underlying data, compliance with cypermethrin water quality standards should therefore be based on concentrations of freely dissolved cypermethrin, not total cypermethrin. Freely dissolved cypermethrin can be measured directly

using SPME, or estimated using an equilibrium partitioning model such as the one presented by TenBrook *et al.* (2009).

RTC 1-26: Please see RTC 1-23.

2.2 Comment Letter 2 – Christopher Davis, FMC Corporation

COMMENT 2-1: FMC Corporation appreciates the opportunity to submit comments on the draft criteria for cypermethrin and permethrin, as developed by the University of California, Davis' using its *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 Chlorpyrifos Criteria* (UCD Pesticide Criteria Methodology). Technical comments on both draft documents were submitted under separate cover on May 18, 2011.

Further, FMC Corporation must convey its concerns with respect to the draft criteria in general and the Central Valley Regional Water Quality Control Board's (Regional Water Board) potential use of the criteria to interpret narrative objectives without first undertaking an appropriate Basin Plan amendment process. As you know, the state's Porter Cologne Water Quality Control Act (Porter-Cologne) requires the Regional Water Board to adopt water quality objectives for the protection of reasonable beneficial uses after considering a number of factors, including economics and attainability. (Wat. Code, § 13241.) The development of draft criteria through use of the UCD Pesticide Criteria Methodology does not equate to or comply with these requirements. Thus, the draft criteria developed through this process are not adopted water quality objectives, and should not be used for regulatory purposes until they are adopted as such through the Regional Water Board's statutory process.

RTC 2-1: 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 2-2: To the extent that the Regional Water Board decides to move forward with a Basin Plan amendment to consider adopting the draft criteria as water quality objectives, FMC Corporation and its representatives would like to be active participants in the Regional Water Board's process. Further, as part of the Basin Plan amendment process, FMC Corporation suggests that adopted water quality objectives for

cypermethrin and permethrin should be expressed as dissolved objectives and not total objectives as only the dissolved forms of these compounds are bioavailable.

RTC 2-2: We recommend using the concentration of cypermethrin in freely dissolved phase for compliance determination, but regulators may also choose to use whole water concentrations because techniques to measure freely dissolved concentrations (e.g., SPME) are not yet included in standardized testing methods. It is stated clearly in the UCD methodology that regulators have the conservative option to determine compliance based on whole water pesticide concentration, even if there is evidence that some phases are not bioavailable (Section 2-4.1, TenBrook et al. 2009).

2.3 Comment Letter 3 – Kelye McKinney, City of Roseville; Michael Bryan, Ph.D., Brant Jorgenson, and Ben Giudice, M.S., Robertson-Bryan, Inc.

COMMENT 3-1: The City does not accept the validity of the cypermethrin chronic criterion, particularly the use of the *Daphnia magna* ACR of 949. The draft criteria for cypermethrin appears to misinterpret guidance provided in the methodology. Furthermore, guidance provided in the methodology does not appear to address the specific issues related to cypermethrin and the use and reduction of available empirical data. Related, it is the City's position that the Kim *et. al.* 2008 study on which the ACR of 949 is derived should be excluded from use in derivation of the chronic criteria. The subject study was excluded from derivation of the acute criterion, and no justification is provided as to why the study would be acceptable for derivation of the chronic criterion. Furthermore, authors of the study state that they followed OECD guidance, however OECD test acceptability criteria were not achieved and OECD test methodology were not followed. Given the lack of clear guidance in the criteria derivation methodology, the apparent misinterpretation of guidance, and the use of a study that should have been excluded from the data set, the City requests that the chronic criterion be re-calculated. Because issues related to the derivation of the chronic criteria are several-fold, the City requests that the cypermethrin criteria document be suitably revised to address our concerns related to interpretation of the methodology and the use of Kim *et. al.* 2008 *Daphnia magna* study, and resubmitted in draft form for public comment. The City requests this additional opportunity for comment because the City believes the methodology, as presently written, does not provide clear guidance and will ultimately require subtle interpretation, on which the City desires the opportunity to review and provide new comment.

RTC 3-1: The chronic criterion has been revised and the Kim et al. (2008) study is no longer used in the chronic criterion derivation. The interpretation of which studies are acceptable to use in calculating acute-to-chronic ratios (ACRs) has been revised. The authors of the cypermethrin draft criteria report interpreted that studies that were rated RR, RL, LR, or LL could be used in ACRs, but upon further consultation with other co-authors of the UCD methodology, we reached consensus that the original intent of the ACR guidance was that only RR data should be used in calculating ACRs.

The cypermethrin criteria report will not be available for another round of public comments because the budget did not allow for multiple comment periods. The approach taken in the final report follows the approach used for ACR calculations in other criteria reports and additional review and comments would not likely yield additional changes in the criteria document at this time.

COMMENT 3-2: 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, the report should specifically recommend against inclusion of dose-additivity assumptions for compliance determination purposes.

RTC 3-2: As discussed in the mixtures section of the report, all studies of pyrethroid mixtures predicted joint toxicity of the compounds using the concentration addition model within a factor of 2, which shows that this model predicts joint pyrethroid toxicity well.

COMMENT 3-3: The City disagrees that whole water analysis is valid for criteria compliance. 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 criteria reports should be revised in a manner that retains the scientifically-based recommendation for compliance determinations based on either direct measurement of the bioavailable fraction or allowing for some compensating factor accounting for particulate matter and dissolved organic matter, but should remove statements regarding the validity of whole water measurement for compliance, which are not supported.

RTC 3-3: It is stated clearly in the UCD methodology that regulators have the conservative option to determine compliance based on whole water pesticide concentration, even if there is evidence that some phases are not bioavailable (Section 2-4.1, TenBrook et al. 2009). While we recommend using the concentration of cypermethrin in freely dissolved phase for compliance determination, regulators may also choose to use whole water concentrations,

because techniques to measure freely dissolved concentrations (e.g., SPME) are not yet included in standardized testing methods.

COMMENT 3-4: The limited capability 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 3-4: 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 the only objective in deriving water quality criteria is the protection of aquatic life.

COMMENT 3-5: 3.1.2 Cypermethrin

In the case of cypermethrin, three ACRs could be calculated, and were 2.11 (*Acartia tonsa*), 2.26 (*Oncorhynchus mykiss*), and 949 (*Daphnia magna*). The authors state the following:

“There was not a clear trend of SMACRs increasing or decreasing as the SMAVs increased, but the ACRs are not all within a factor of 10. In this case, it is recommended that only the SMACRs for species with SMAVs within a factor of 10 of the acute 5th percentile value should be used for the final multi-species ACR (section 3-4.2.1, parts 1-2 TenBrook et al. 2009a), which for cypermethrin is the only SMACR for *Daphnia magna* of 949” (Fojut et al., 2011b).

The portions of the methodology which are referenced read as follows:

“1) If the SMACR seems to increase or decrease as the SMAVs increase, calculate the ACR as the geometric mean of the ACRs for species whose SMAVs are close to the acute criterion (this includes species whose SMACRs are within a factor of 10 of the SMACR of the species whose SMAV is nearest the 5th percentile value);

2) If no major trend is apparent and the ACRs for all species are within a factor of ten, calculate the ACR as the geometric mean of all of the SMACRs” (Section 3-4.2.1, parts 1-2, TenBrook et al. 2009).

There are numerous issues, both in the methodology and in the draft criterion document, that need to be resolved before accurate interpretation and calculation of an ACR can be made. The following issues have been identified:

1. None of the conditions specified in parts 1, 2, or 3 of section 3-4.2.1 of the methodology are applicable to the cypermethrin scenario. Part 1 only applies when the SMACR seems to increase or decrease as the SMAVs increase, which the authors state is not the case. Part 2 only applies when there is *both* no major trend, *and* when all SMACRs are within a factor of 10, which is not applicable to the cypermethrin case. Part 3 only applies if the most appropriate SMACRs are less than 2, which is not the case for cypermethrin. Finally, the methodology states that if the requirements in bullets 1, 2, and 3 are not met, the ACR should be calculated using the default ACR of 12.4, per section 3-4.2.2. This last method appears to be the path most consistent with the methodology, although the use of a default ACR is dubious to begin with (see discussion on permethrin above), especially when cypermethrin ACRs for *Acartia tonsa* and *Oncorhynchus mykiss* exist.

RTC 3-5: Upon consultation with other co-authors of the UCD methodology, we have reached a consensus on how the ACR guidance should be interpreted with regards to these issues. First, the ACRs have been revised to only include RR toxicity values. It is likely that there was no trend within the ACRs in the draft criteria report because they were not based on the most reliable data. None of the ACRs proposed in the draft criteria report are used in the final criteria report because each one contained a toxicity value that was not rated RR, or LR in the case for saltwater species. If the UCD methodology is revised in the future, guidance will be added regarding how to proceed if the ACRs vary by more than a factor of 10 and there is no increasing or decreasing trend in an ACR dataset based on highly rated data. The ACR guidance in the methodology was adopted because if there is no increasing or decreasing trend then it is likely that there is an unreliable or erroneous ACR within the dataset, which was the case for the ACRs proposed in the draft criteria report.

COMMENT 3-6: 3.1.2 Cypermethrin

The authors of the cypermethrin document appear to have attempted to follow Part 1, even though there was no trend apparent. However there are two issues that arise from doing so.

- Part 1 of the methodology appears to have an internal inconsistency. First, it states that the geometric mean of the ACRs for species whose SMAVs are close to the *acute criterion* is to be used. The parenthetical phrase that follows appears to define what “close” means, that is, species whose SMACRs are within a factor of 10 of the SMACR of the species whose SMAV is nearest the 5th *percentile value*. The acute criterion and the 5th percentile value differ by an imposed factor of 2, and in this case, the species whose SMAV is nearest the acute criterion (*Daphnia magna*) is not the same as the species whose SMAV is nearest the 5th percentile value (*Acartia tonsa*). If the parenthetical phrase is not meant to

define what “close” means, then close remains undefined, and the issue remains that ACRs of species whose SMAV is close to the acute criterion are different than the ACRs within a factor of 10 of the species whose SMAV is nearest the 5th percentile value (see also number 3, below).

- The authors misinterpret the language in Part 1. The authors’ state that the methodology indicates that the ACR should be calculated based on the ACRs of species whose SMAVs are within a factor of 10 of the acute 5th percentile value. The methodology does not indicate this. Rather, the methodology appears to indicate that the ACR should be calculated based on those SMACRs which are within a factor of 10 of the SMACR for the species whose SMAV is nearest the acute 5th percentile value (as noted above). However, even if the authors are correctly interpreting the methodology, which does not appear to be the case, they then have incorrectly applied the methodology to the cypermethrin scenario, as described below.

RTC 3-6: We agree that there is an inconsistency in the method in section 3-4.2.1, part 1. The guidance in part 1 of section 3-4.2.1 of the UCD methodology was supposed to be taken directly from the Water Quality Guidance for the Great Lakes System (USEPA 2003), which states in section VI.K.1., “If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR [final acute-to-chronic ratio] shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the final *acute value*.” The acute value is whichever percentile is chosen for use in the acute criterion calculation, and should not be restricted to the 5th percentile, as currently indicated in the method. For future implementation of section 3-4.2.1 part 1, we will calculate the ACR as the geometric mean of the ACRs for species whose SMAVs are close the acute value, which will include species whose SMACRs are within a factor of 10 of the SMACR of the species whose SMAV is nearest the acute value (whichever percentile is chosen for use in the acute criterion calculation).

We agree that the following wording in the draft report is not an accurate interpretation of the methodology: “In this case, it is recommended that only the SMACRs for species with SMAVs within a factor of 10 of the acute 5th percentile values should be used for the final multi-species ACR.” This language has been removed from the final criteria report because the ACR calculation no longer uses any experimental ACR.

COMMENT 3-7: 3.1.2 Cypermethrin

3. The authors appear to have misapplied their interpretation of the methodology that “only the SMACRs for species with SMAVs within a factor of 10 of the acute 5th percentile value should be used for the final multi-species ACR” (Fojut *et al.*, 2011b). Although it is never specified in either the methodology or in the draft criteria derivation document whether

the acute 5th percentile value refers to the median (50% confidence limit) or the 95% confidence limit 5th percentile value, we assume it refers to the median 5th percentile value (0.0126904 µg/L), since this is the value used previously in the acute criterion derivation and used with the ACR in the initial calculation of the draft chronic criterion. If this is so, the authors appear to have erroneously determined that the SMAV for *Daphnia magna* was within a factor of 10 of the acute 5th percentile value, and simultaneously determined that the SMAV for *Acartia tonsa* was not. Table 1 shows the MATC, SMAV, ACR, and the factor between the calculated ACR and the acute median 5th percentile value, for reference. The SMAV for *Daphnia magna* is a factor of 21.2 lower than the acute 5th percentile value, while the SMAV for *Acartia tonsa* is a factor of 8.52 greater than the acute 5th percentile value. According to the authors interpretation of the methodology and recommendation cited above, the ACR thus should have been calculated as simply the ACR for *Acartia tonsa*, or 2.11. If the parenthetical expression of part 1 of section 3-4.2.1 is then added to this interpretation, the final ACR should actually be the geometric mean of the ACR for *Acartia tonsa* and for *Oncorhynchus mykiss* (since this ACR is within a factor of 10 of the ACR for *Acartia tonsa*), which would have resulted in an ACR of 2.18. Either way, the impact on the initial calculation of the chronic criterion is substantial. Instead of 0.01 ng/L, the chronic criterion would be calculated as 6 ng/L, equivalent to the draft acute criterion.

RTC 3-7: As stated in RTC 2-6, we agree that section 3-4.2.1 of the methodology was misinterpreted by the authors in the draft criteria report with regard to the cypermethrin chronic criterion calculation. In the final criteria report, the cypermethrin chronic criterion is calculated using the default ACR of 12.4 because all of the SMACRs proposed in the draft criteria report are now found to be unreliable because they were not based on toxicity values rated RR (or LR for saltwater species). We agree that *Acartia tonsa* actually had the SMAV nearest to the acute value of 0.0126904 µg/L, and that the SMACRs of *A. tonsa* and *O. mykiss* should have been used instead of the *D. magna* SMACR if those SMACRs were reliable.

COMMENT 3-8: 3.1.2 Cypermethrin

The authors later adjust the acute criterion, using instead the 1st percentile, 50% confidence limit value to re-calculate the acute criterion, in order to protect sensitive species since the initially determined acute criterion was higher than the SMAV for some species in the data set. The resulting acute criterion is 1 ng/L (Fojut *et al.*, 2011b). Using the calculated ACR of 2.11 or 2.18 with the 1st percentile, 50% confidence limit value results in an adjusted chronic criterion of 1 ng/L, equivalent to the adjusted acute criterion. However, the methodology does not address selection of appropriate ACRs based on use of the 1st percentile, 50% confidence limit value. When compared to this value (0.0025723 µg/L), the only species

with a SMAV within a factor of 10 is *Daphnia magna*, which if used in place of the 5th percentile acute value, would result in an ACR of 949, and an adjusted chronic criterion of 0.003 ng/L. This approach, however, is technically inconsistent with the methodology. Furthermore, *Daphnia magna* is not very acutely sensitive (LC₅₀ of 147 ng/L), but apparently very chronically sensitive to cypermethrin, resulting in a very large ACR. Applying this ACR to an acute value driven largely by data for *Hyalella azteca*, which is very acutely sensitive, results in a criterion that is very likely overprotective.

RTC 3-8: In the UCD methodology, section 3-4.2.1 (part 1) refers to choosing SMACRs based on the species whose SMAV is nearest the 5th percentile value, but when we go back to the Great Lakes methodology (USEPA 2003), from which the ACR guidance was taken, we see that the guidance is to use the geometric mean of the SMACRs for species whose SMAVs are close the final acute value, not specifically the 5th percentile value (see RTC 2-6). The 5th percentile value is erroneously referenced in the UCD methodology, instead of the broader “final acute value,” likely because the 5th percentile is the value that is recommended to begin with, and is the most common to use as the acute value. However, as discussed by the co-authors of the methodology, the intention of the UCD methodology was to follow the guidance in the Great Lakes methodology (USEPA 2003) for use of ACRs. The Great Lakes methodology (USEPA 2003) refers to the final acute value, which in the UCD methodology may be any of the estimates from the acute species sensitivity distribution, or the acute value derived using an assessment factor. If the UCD methodology is revised in the future, the errors and inconsistencies in the ACR section will be revised and clarified. We sincerely appreciate your diligence in reviewing these sections so that we may continue to improve the UCD methodology and our use and interpretation of it.

COMMENT 3-9: 3.1.2 Cypermethrin

In summary, it appears that if the methodology is to be applied as written, the final ACR should be the default of 12.4, which would result in an adjusted chronic criterion of 0.2 ng/L. However, if the authors’ interpretation of the methodology takes precedence over a literal reading of the methodology, the final ACR should be 2.11 and the adjusted chronic criterion should be 1 ng/L, equivalent to the acute criterion. The only chronic value below either of these criteria is the MATC of 0.00063 ng/L for *Daphnia magna*, which, as the authors state, was calculated based on nominal concentrations, and thus the criterion should not be adjusted downward (TenBrook *et al.*, 2009).

RTC 3-9: In the final criteria report, the default ACR is used, because with our current interpretation (see RTC 2-5) none of the proposed SMACRs in the draft criteria report are acceptable. Using the default ACR of 12.4 and the acute

median 5th percentile value the chronic criterion is 1 ng/L, but this is adjusted downward later in the criteria report based on data for sensitive species.

COMMENT 3-10: 3.1.2 Cypermethrin

As a final note, the study on which the *Daphnia magna* ACR was derived (Kim *et al.*, 2008) was excluded from the list of studies used in the derivation of the acute criterion. This exclusion appears appropriate, but subsequent use of the study, particularly the acute value determined in the study, in the derivation of the ACR and chronic criterion is questionable. The methodology requires an “appropriate acceptable acute value” to pair with an acceptable MATC value to calculate an ACR (TenBrook *et al.*, 2009). Use of the word “acceptable” implies that the data are from the data set rated “RR”, and not those excluded because of deficiencies in the testing or reporting. The authors should reconsider use of the Kim *et al.* 2008 study entirely or provide more explicit reasoning for its inclusion in the ACR and chronic criterion derivation, despite its exclusion in the acute criterion derivation. Additionally, the ACR for *Daphnia magna* is highly sensitive to the MATC, which in this case was calculated from the geometric mean of the no observable effect concentration (NOEC) and the lowest observable effect concentration (LOEC). In the subject study, the concentration intervals used are based on a factor of 10. The Organization for Economic Cooperation and Development (OECD) guidelines recommend the intervals to be no greater than a factor of 3.2, since larger intervals can introduce significant bias in the calculation of the MATC (OECD 1998). Furthermore, the mean control response (number of young per female) of the Kim *et al.* 2008 study did not meet OECD test acceptability criteria. For the less than 24 hour old neonates, the mean number of living young should be equal to or greater than 60; mean number of living young in the Kim *et al.* 2008 study was less than 20. It is possible that a different clone of organism was used than that specified in the OECD guidance, but no evidence is provided in the Kim *et al.* 2008 study to suggest that this low control response is indeed acceptable.

RTC 3-10: As stated in RTC 3-6, the *Daphnia magna* ACR from the Kim *et al.* (2008) study is no longer used in criteria calculation. Also, additional points have been taken off the Kim *et al.* (2008) tests for inappropriate dilution factor (please see Appendix B1), because we agree that the dilution factor of 10 is too large according to test guidelines. The chronic control response was originally rated as acceptable because in the Kim *et al.* (2008) study, the caption for Figure 2 states that Fig. 2b shows the “brood size per female,” indicating that the total young produced by a female would be the brood size multiplied by the number of broods, which would be 90 for the <24 hr old neonate controls (18*5=90), which is acceptable. But the information displayed is not clear because the y-axis on Fig. 2b is labeled as “number of young per female (individuals),” so it is not clear what the plot is displaying. Because it is not clear if the control result is

acceptable or not, points have been taken off for this parameter in the final report.

COMMENT 3-11: 3.1.2 Cypermethrin

It is recommended that the authors revisit the methodology and/or the cypermethrin chronic criterion derivation, and subsequently re-release a draft report for public comment. Overall, this issue appears too complex to allow a final revision not subject to peer scrutiny and public comment.

RTC 3-11: The chronic criterion derivation has been revised, and the direction in the methodology for this calculation has been clarified. The cypermethrin criteria report will not be available for another round of public comments because the budget did not allow for multiple comment periods. The approach taken in the final report follows the approach used for ACR calculations in other criteria reports and additional review and comments would not likely yield additional changes in the criteria document at this time.

COMMENT 3-12: 3.2 Assumed Dose-Effect Additivity

Environmental toxicologists recognize the importance of considering toxicant mixtures when evaluating and predicting toxicity to an organism. It is a held theory that toxicants of similar mode of action can act additively on an organism. Through such simplifying models of concentration addition, the effect of dose additivity can be predicted.

In past reports, the authors made definitive statements regarding the use of dose-additivity in compliance determination, i.e., “The additivity of pyrethroid mixture toxicity has not been clearly defined in the literature, and in fact, antagonism has been observed, thus the concentration addition method is not recommended for use when multiple pyrethroids are found in a sample.” (Fojut et al, 2010). In the permethrin and cypermethrin reports, although definitive statements regarding the interaction of PBO with pyrethroids and, more generally, non-additive chemicals, are made, no definitive statement is made regarding dose-additivity of pyrethroids for compliance determination. The authors do state that results of Trimble et al., 2009 indicate “...that in general, pyrethroid mixture toxicity is additive.” (Fojut *et al.*, 2011a; Fojut *et al.*, 2011b). The authors rely on the same set of literature in discussing dose-additivity of pyrethroids in the permethrin and cypermethrin draft reports as they did in the final reports for bifenthrin, lambda-cyhalothrin, and cyfluthrin, and so it is unclear why no definitive statement is made. In absence of such a recommendation, the indication is that the body of evidence supports use of dose-additivity in compliance determination, which is not the case.

Indeed, in investigations conducted by Trimble et al. (2009) on additivity in binary mixtures of Type I and Type II pyrethroids, although concentration

addition models predicted experimental results well, as would be hypothesized, in some cases so did independent action models. Furthermore, actual toxicity often deviated substantially from predicted toxicity at low toxicant concentration, well below expected LC₅₀ values (i.e., in the range of the derived acute criterion). There is enough inherent uncertainty in the use and applicability of concentration addition models, be they toxic unit or relative potency factor approaches, that compliance determination should not be based on assumed additivity. The reports should be revised to clearly state that dose-additivity is not recommended for the purposes of compliance determinations.

RTC 3-12: The recommendations regarding mixture toxicity of pyrethroids have changed in the permethrin and cypermethrin reports compared to the previous pyrethroid criteria reports because when we look at the whole body of evidence for all of the pyrethroids, it appears that the concentration addition model is able to predict observed toxicity of mixtures within a factor of 2. As we gathered more information on this topic it became clear that using the concentration addition model is reasonable for pyrethroids. Studies that reported a degree of antagonism when multiple pyrethroids were present reported very slight antagonism, and the observed toxicity was still within a factor of 2 of that predicted using the concentration addition model (Brander et al. 2009).

COMMENT 3-13: 3.3 Bioavailability

The UCD criteria derivation methodology should be praised for including considerations of bioavailability. In Section 9 of the draft permethrin and cypermethrin criteria reports, the propensity of pyrethroid insecticides to sorb to particulate matter, sediments, and laboratory equipment is discussed. In this discussion several studies are mentioned providing evidence that pyrethroid toxicity in the water column is associated with the dissolved fraction, and that the freely dissolved fraction is the better predictor of toxicity. The reports state:

“[Studies] suggest that the freely dissolved fraction of permethrin/cypermethrin is the primary bioavailable phase, and that this concentration is the best indicator of toxicity, thus, it is recommended that the freely dissolved fraction of permethrin/cypermethrin be directly measured or calculated based on site specific information for compliance assessment. Whole water concentrations are also valid for criteria compliance assessment, and may be used at the discretion of environmental managers, although the bioavailable fraction may be overestimated with this method” (Fojut *et al.*, 2011a; Fojut *et al.*, 2011b).

The statement that “whole water concentrations are also valid for criteria compliance” is troubling. After extensive discussion of the scientific reasoning behind the author’s recommendation of using the freely

dissolved fraction for compliance, there is no support or discussion for the assertion that whole water concentrations are valid for this purpose. The recommendation that compliance determinations be based on the freely dissolved fraction reflects scientific understanding of pyrethroid bioavailability in the environment, and there is no clear basis, scientific or otherwise, for the authors' assertion that whole-water concentrations are valid for compliance determination. In light of the current scientific understanding of pyrethroid bioavailability, any total recoverable measurement unadjusted to account for the fraction that is not bioavailable represents a knowingly biased measurement and should not be used for compliance determination.

RTC 3-13: It is stated clearly in the UCD methodology that regulators have the conservative option to determine compliance based on whole water pesticide concentration, even if there is evidence that some phases are not bioavailable (Section 2-4.1, TenBrook et al. 2009). While we recommend using the concentration of permethrin in freely dissolved phase for compliance determination, regulators may also use whole water concentrations because using techniques to measure freely dissolved concentrations (e.g., SPME) are not yet included in standardized testing methods.

COMMENT 3-14: 3.4 Analytical Concerns

For compliance testing purposes through National Pollutant Discharge Elimination System (NPDES) permits, EPA approved methodologies must be used. Existing analytical methods for the measurement of semi-volatile organic pollutants such as pyrethroid insecticides are limited in the capability of achieving the draft criteria values derived for permethrin and cypermethrin. Only the most diligent commercial laboratories can achieve reporting limits near the draft chronic permethrin and acute cypermethrin criteria using these analytical methods and employing good laboratory practices and standard quality assurance. No methods exist for the detection and quantification of cypermethrin near the draft chronic cypermethrin criterion, and indeed, such capabilities will likely not be seen for many years to come. There is limited commercial analytical capacity in California, and at present most laboratories could only assure reporting limits several times greater than the draft acute and chronic criteria. This limits the utility of criteria altogether, and potentially returns the regulated community to a position of providing the Regional Water Board with analytical results containing varied reporting limits. When using such criteria, maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.

RTC 3-14: Please see RTC 3-4.

COMMENT 3-15: 4 Summary of Review Findings

1. The draft acute criteria for permethrin and cypermethrin are based on a species distribution approach and result in supportable criteria.

RTC 3-15: Comment acknowledged.

COMMENT 3-16: 4 Summary of Review Findings

3. Regarding cypermethrin, there are several inconsistencies and/or errors in the methodology, in the authors' interpretation of the methodology, and in the application of that interpretation that result in an unsupported ACR and, therefore, and unsupported chronic criterion. Instead of the draft chronic criterion of 0.003 ng/L, if the methodology were applied as written, the cypermethrin adjusted chronic criterion should be 0.2 ng/L. However, if the authors' interpretation of the methodology takes precedence over a literal reading of the methodology, the adjusted chronic criterion should be 1 ng/L. Furthermore, the authors use a study in the derivation of the chronic criterion which was previously excluded from the derivation of acute criterion, thus introducing a methodological inconsistency. It is recommended that the authors revisit the methodology and/or the cypermethrin chronic criterion derivation, and subsequently re-release a draft report for public comment. The issue appears too complex and substantial (in terms of its effect on the proposed criterion) to allow a final revision not subject to peer scrutiny and public comment.

RTC 3-16: Please see RTC 2-5 through RTC 2-10. The final chronic criterion in the final criteria report is calculated with the default ACR of 12.4 and the acute median 1st percentile value (after downward adjustment based on data for sensitive species), to yield a chronic criterion of 0.2 ng/L. The cypermethrin criteria report will not be available for another round of public comments because the budget did not allow for multiple comment periods. The approach taken in the final report follows the approach used for ACR calculations in other criteria reports and additional review and comments would not likely yield additional changes in the criteria document at this time.

COMMENT 3-17: 4 Summary of Review Findings

4. For all draft criteria, it is not clear whether the assumption of dose additivity between pyrethroids of similar mode of toxicity is assumed for compliance determination. 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 and thus not always good. Where science is not settled, compliance should not be based on simplifying assumptions.

RTC 3-17: Please see RTC 3-12.

COMMENT 3-18: 4 Summary of Review Findings

5. The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including permethrin and cypermethrin, is a far better predictor of the bioavailable fraction than is total recoverable measurements. Therefore, compliance determinations 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. There is no scientific support for using whole-water concentrations for compliance determinations.

RTC 3-18: Please see RTC 3-13.

COMMENT 3-19: 4 Summary of Review Findings

6. Achieving commercially available analytical reporting limits below the draft criteria 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 3-19: Please see RTC 3-4.

2.4. Comment Letter 4 –Debbie Webster, Central Valley Clean Water Association

COMMENT 4-1: CVCWA continues to be concerned with the Regional Water Board's proposed use of *Draft Criteria* to interpret narrative water quality objectives and potential use of the criteria to set water quality based effluent limitations in NPDES permits, thereby creating liability for Central Valley POTWs. Considering the liability associated with such effluent limitations, the Regional Water Board should take care to use only criteria that are well-developed and well-founded.

RTC 4-1: 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 4-2: The chronic criterion is problematic for a number of reasons, particularly the lack of available reliable data and the acute to chronic ratio (ACR) used for its calculation. Within the *Draft Criteria*, the authors note that the sparse chronic toxicity data set was a major limitation, with three of the five taxa requirements not met (including salmonid, benthic crustacean, and insect). In the absence of an adequate

chronic toxicity data set, the authors relied on an ACR to derive the chronic criterion. The authors also noted a major concern with this approach, which depended largely on the very high species mean acute to chronic ratio (SMACR) for *Daphnia magna* that was determined in a study by Kim *et al.* (2008). The ACR determined for *Daphnia* in the Kim study was 949 – approximately two orders of magnitude higher than is typical for similar sensitive species. Other pyrethroid criteria reports have noted ratios between acute and chronic criteria ranging from 2 - 6.7, while the ratio between the acute and chronic criteria for cypermethrin was 333x due to the high *Daphnia* ACR from the Kim 2008 study. The authors noted that they were “suspicious of the extremely large cypermethrin SMACR for *Daphnia magna*, although there are no obvious faults in the study.” One potentially significant point of the Kim study not cited by the authors of the *Draft Criteria* was that the sublethal reproductive endpoints for the 21-day exposures were either not assessed or were not reported for the solvent controls. The Kim study states that there was no significant difference in mortality between solvent controls and negative controls, but does not report the results for sublethal endpoints in solvent controls. If there were significant reproductive effects in the solvent controls or if they were not conducted or assessed, all of the findings for the sublethal endpoints (including the LOECs and NOECs used to determine the ACR) would be invalid and unusable for criteria development. Therefore the results for the solvent controls must be evaluated before the 21-day exposure results can be used to calculate an ACR and chronic criterion.

RTC 4-2: The derivation of the chronic criterion has been revised, and the *D. magna* ACR from the Kim *et al.* (2008) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate ACRs. This interpretation excludes the Kim *et al.* (2008) study because the acute test was rated RL. We reviewed the study again and we agree that it is not clear if solvent controls were tested in the chronic tests, thus, reliability points were taken off for appropriate control, and the chronic study now rates as RL.

COMMENT 4-3: The findings of the Kim study that were not discussed or considered by the authors of the *Draft Criteria* also provide a number of additional insights into the limitations of the simplistic extrapolation-based ACR approach to developing chronic criteria. These limitations are shared by many chronic toxicity studies used in criteria development, but are particularly well illustrated by the Kim study.

- The chronic test used to develop the final ACR for *Daphnia* was a 21-day exposure with static renewal every 48 hours. This is completely unrealistic environmental exposure scenario that would never be expected to occur in the real world.

- The 21-day exposures and endpoints of the Kim study (brood size, time to first brood, number of broods) are used to develop criteria to be implemented as 4-day averages, even though those reproductive endpoints would not be affected by 4-day exposures at the same concentrations. The most environmentally relevant results from the 21-day static renewal exposures of the Kim study were that there were *no significant changes in population growth rates at much higher concentrations and even the highest concentration tested did not cause a population decrease*. These findings are much more environmentally relevant than the finding of a statistically significant effect on average brood size of an environmentally unrealistic exposure scenario. In spite of this, the authors ignored the population level context and chose to use a statistically significant *response* instead of a biologically significant *adverse effect* in their ACR calculation.
- In Kim's test of a more environmentally realistic exposure scenario (24 hour static exposure followed by a 20 day observation period), there were *no adverse effects at the highest concentration tested* (1.9 µg/L) on mortality, reproduction, brood size, or intrinsic population growth rate of *Daphnia* neonates. Kim noted that this finding was consistent with those of Christensen *et al.* [2005], who found that *Daphnia* exposed to environmentally relevant concentrations of cypermethrin recovered to their pre-exposure condition within 3 days after exposure.

RTC 4-3: As stated in RTC 3-6, the *Daphnia magna* ACR from the Kim *et al.* (2008) study is no longer used in criteria calculation.

There are many factors that cause variation between laboratory toxicity values and environmental toxicity, such as: interspecies and intraspecies variation, inter- and intralaboratory variation, mixture effects, temperature and water quality effects, variation in exposure durations, and use of various endpoints. In order to account for these types of variations between laboratory and environmental toxicity in a conservative manner, chronic tests of the longest exposure duration available are used for criterion calculation (section 3-2.4, TenBrook *et al.* 2009).

COMMENT 4-4: Because there are not adequate data to derive a chronic criterion directly, CVCWA recommends that the *Draft Criteria* refrain from setting a chronic criterion until additional studies are completed. Additionally, the available studies must be fully evaluated for their completeness and environmental relevance, and the results of the studies should not be used out of context, as is done in the *Draft Criteria*. The aberrant ACR based on environmentally irrelevant exposures in a single research study should not be used as the basis for a chronic criterion. The USEPA 1985 guidance for deriving numeric water quality criteria states that "It is not enough that a national criterion be the best estimate that can

be obtained using available data; it is equally important that a criterion be derived only if adequate appropriate data are available to provide reasonable confidence that it is a good estimate,” and that “If all required data are not available, usually a criterion should not be derived.” We believe this guidance is still good policy and should also be followed by the Regional Water Board.

RTC 4-4: While we would prefer to use more measured data for the chronic criterion calculation, the default ACR is used in the final criteria report. The default ACR is available when there is a lack of chronic data, such as for cypermethrin. A similar default ACR procedure is used by the EPA in the Water Quality Guidance for the Great Lakes System (USEPA 2003).

COMMENT 4-5: In addition, CVCWA is generally concerned with the Regional Water Board bypassing the USEPA process of deriving water quality criteria to create independent criteria that may be used to interpret narrative water quality objectives. The *Draft Criteria* should be thoroughly vetted through the public and regulatory process before they are made available for potential use by the Regional Water Board in NPDES permits. Considering the uncertainties associated with the *Draft Criteria*, it is ill-advised to utilize them at this stage. Thus, CVCWA respectfully requests that the Central Valley Water Board refrain from using the *Draft Criteria* for cypermethrin until the criteria are properly adopted as water quality objectives pursuant to all requirements in Porter-Cologne.

RTC 4-5: 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.

2.5. Comment Letter 5 – Linda Dorn, Sacramento Regional County Sanitation District

COMMENT 5-1: SRCSD has technical and regulatory concerns with the draft acute/chronic criteria. Our primary concern with the exceedingly overly protective draft criteria directly relates to our ability to maintain our excellent compliance record should the Central Valley Regional Water Quality Control Board (Regional Board) staff use these draft criteria to interpret narrative objectives in the Sacramento-San Joaquin Basin Plan. Additionally, SRCSD has technical concerns with how the draft acute/chronic criteria were derived. Following are SRCSD’s concerns regarding use of draft criteria to interpret narrative water quality objectives based on technical issues with the derivation of the draft criteria.

SRCSO 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 SRCSO. 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 above, the draft criteria for cypermethrin are 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 Clean Water Act's citizen suit enforcement provisions. (See 33 U.S.C. § 505.)

SRCSO 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.)

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. The draft cypermethrin criteria, like all other draft criteria, are in the process of rigorous review by peers and the public to ensure that the final criteria are well-developed and well-founded.

COMMENT 5-2: 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, § 13241.)

Also, the Regional Board is required to adopt a program of implementation for achieving water quality objectives at the time of adoption (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 cypermethrin until the criteria are properly adopted as water quality objectives pursuant to all requirements in Porter-Cologne.

RTC 5-2: Water quality criteria were derived only with regard to the protection of aquatic life and the UCD criteria report does not address how the criteria could be used or implemented.

COMMENT 5-3: As confirmed by UCD, the main problems with cypermethrin 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.

RTC 5-3: Comment acknowledged.

COMMENT 5-4: Draft chronic water quality criteria (WQC) derived for the Regional Board were typically calculated by dividing the median 5th percentile of the acute toxicity data by an acute-to-chronic ratio (ACR) developed from paired acute and chronic toxicity values in the dataset when a species sensitivity distribution was unavailable. In the case of cypermethrin, the median 1st percentile (50% confidence limit) of the acute toxicity data was divided by the ACR of 949. This ACR is significantly greater than ACR values developed for five other pyrethroids which ranged from 4.73 to 12.4 (default value). Thus, the criteria developed for cypermethrin is 10 times overly-protective than the ones developed for other pyrethroids. The draft WQC authors recognized this outlier when stating that the high ACR “*made us suspicious of the extremely large cypermethrin SMACR for Daphnia magna...*” The cypermethrin ACR of 949 is suspect for several reasons. The cypermethrin ACR for *Daphnia* is much greater than the ACRs for two other species, one copepod and one fish, were 2.1 and 2.3, respectively. It is also based on a single study (Kim et al. 2008) where there is uncertainty in the reported concentrations from this study that were based on nominal concentrations rather than measured values, the lack of reporting control data, and the failure to report the statistical methods upon which significant differences were based. Data presented by Kim et al. (2008) also show interrupted dose responses for several endpoints, which are an indication that the data should be interpreted with caution (USEPA 2000). The environmental relevance of the reproductive endpoint (young per female over 21 days for <24-hour neonates) for *Daphnia* is also questionable when Kim et al. (2008) noted that the population would not decrease at any of the tested concentrations (up to 200 ng/L) due to positive rates of intrinsic growth.

RTC 5-4: The chronic criterion has been revised in the final criteria report. The Kim et al. (2008) chronic test was reviewed and is now rated RL, and is not used in criteria calculation. The final chronic criterion was calculated with the default ACR of 12.4 and the acute median 1st percentile value to yield a chronic criterion of 0.2 ng/L. The chronic endpoint of young per female over 21 days fits the description of chronic toxicity data provided in the methodology (section 3-2.1.1.1), which includes any test that takes into account the number of young produced, regardless of exposure duration and encompassing full or partial life-cycle exposures. Kim et al. (2008) do note that there is a positive rate of intrinsic growth at all tested concentrations, but there is a decrease in the growth rate as the test concentration increases, indicating an adverse effect on the population.

COMMENT 5-5: Furthermore, it is not clear why the acute data from Kim et al. (2008) were determined to be unusable for calculating an acute toxicity criteria based on the lack of a control response description and low reliability score (Table 5) when one of these same acute data (0.0006 ug/L) was used in the calculation of the *Daphnia* ACR of 949 (Table 8).

RTC 5-5: The derivation of the chronic criterion has been revised, and the *D. magna* ACR from the Kim et al. (2008) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate SMACRs (contrary to the SMACRs proposed in the draft report). This interpretation excludes the Kim et al. (2008) study because the acute test was rated RL.

COMMENT 5-6: Given the highly conservative and uncertain nature of the draft cypermethrin chronic WQC, the usefulness of the chronic criteria is extremely questionable and should not be used for compliance purposes. SRCSD agrees that future criteria updates should be done as soon as additional information, such as enough data for a species sensitivity distribution or updated ACR for an aquatic invertebrate, becomes available that can reduce this uncertainty.

RTC 5-6: The final chronic criterion in the final criteria report is 0.2 ng/L, which is in the range of chronic criteria for other pyrethroids (0.05-2 ng/L). We agree that the criteria should be revised and updated as more data becomes available, particularly chronic data.

COMMENT 5-7: SRCSD support the authors' recommendation that "*the freely dissolved fraction of cypermethrin be directly measured or calculated based on site specific information for compliance assessment.*" This conclusion was based on multiple study findings "*that the freely dissolved concentration will be the most accurate predictor of toxicity and that bound cypermethrin was unavailable to the organisms that were studied.*" SRCSD does not find it scientifically defensible to use whole water concentrations for criteria compliance assessment and does not

agree with the recommendation to use whole water concentrations for criteria compliance assessment at the discretion of the environmental managers; however, total concentrations could be an indicator of where additional information is needed to determine if there is a potential risk to the aquatic community from cypermethrin.

RTC 5-7: It is stated clearly in the UCD methodology that regulators have the conservative option to determine compliance based on whole water pesticide concentration, even if there is evidence that some phases are not bioavailable (Section 2-4.1, TenBrook et al. 2009). While we recommend using the concentration of cypermethrin in freely dissolved phase for compliance determination, regulators may also use whole water concentrations because using techniques to measure freely dissolved concentrations (e.g., SPME) are not yet included in standardized testing methods.

COMMENT 5-8: Because of the lack of confidence in these draft WQC (based on chronic data without measured concentrations, lack of a species sensitivity distribution, based on whole water concentrations when the dissolved phase determines toxicity, fewer species data than recommended by both the EPA [1985] and TenBrook et al. [2009] methods), and over-protectiveness of the proposed values, SRCSD does not support their use by the Regional Board as a water quality objective (WQO) 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. The suggested WQC may be useful as risk screening values and concentrations above them could be evaluated further for possible environmental relevance, but the proposed water quality criteria are insufficiently supported to support the regulatory weight associated with WQO.

RTC 5-8: While there is uncertainty in the draft WQC, it does not preclude the use of WQC, but rather should inform regulators. The fate and transport of pyrethroids are relatively well-understood in that they are predominately determined by the fate and transport of particulate and dissolved solids. 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. We agree that more chronic toxicity data, particularly based on measured concentrations, would reduce the uncertainty in the chronic criterion.

COMMENT 5-9: On page 10, the text notes “*Bondarenko & Gan (2009) report a method detection limit of 2.0 ng/L for cypermethrin, which is below the acute criterion and identical to the chronic criterion, although method detection limits vary between laboratories.*” The statement is incorrect as the chronic criterion for cypermethrin was calculated at 0.003 ng/L, not 2.0 ng/L. Additionally, the acute criterion is 1.0 ng/L. Both of these are below

the referenced method detection limit of 2.0 ng/L. Please revise the text relative to the correct criteria developed for cypermethrin and indicate the implications of draft WQC below available detection limits, as discussed below.

RTC 5-9: We have corrected this error in the text in the final criteria report. This sentence now states: “Bondarenko & Gan (2009) report a method detection limit of 2.0 ng/L for cypermethrin, which is above both the acute and chronic criteria.” Analytical detection limits may create a problem for criteria compliance because it is possible that cypermethrin could be present in toxic amounts, yet be below the detection limit so that an excursion is not identified.

COMMENT 5-10: The resulting draft criteria (0.003 and 1 ng/L acute and chronic, respectively) create a number of problematic analytical issues. Both criteria are below reporting limits and detection limits for most, if not all, labs (in clean matrices such as deionized water). Although not recognized in the draft criteria document, analytical quantitation limits have an impact on the ability of dischargers to achieve compliance with effluent limitations and receiving water limits. 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]).

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 (Southern Illinois University) claims one of the lowest reporting limits (3 ng/L) for pyrethroids, yet it is still 1000 times higher than the suggested chronic criterion in the draft criteria. Questions have been raised about the possibility of interferences or false positive identification 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 in non-standard methods can have an unknown effect on analytical precision and accuracy.

RTC 5-10: 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 5-11: Authors of the draft criteria note that the dietary pathway for chronic exposure from cypermethrin may be an important exposure route but that it is not currently possible to incorporate this exposure route

into criteria compliance assessment. SRCSD agrees that future criteria updates should consider this pathway and be done as soon as additional information becomes available.

RTC 5-11: Comment acknowledged.

COMMENT 5-12: 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 effects 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 cypermethrin until more research is completed and the criteria are properly adopted as water quality objectives.

RTC 5-12: Please see RTC 5-5 for our response to the fate and transport, chronic toxicity, and effects of dissolved and suspended solids.

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*

The freshwater criteria for cypermethrin cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate 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 cypermethrin. This data set is straightforward and indicates that

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 chlorpyrifos criteria.* Report prepared for the Central Valley Regional Water Quality Control Board, Rancho Cordova, CA.

this pesticide has low solubility, high density, low volatility, and high ability to bioaccumulate and sorb to organic material. Cypermethrin is moderately persistent in aqueous environments but is susceptible to rapid hydrolysis at basic pH. Overall, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern.

RTR 1-2: Comment acknowledged.

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

The FDA has not set action levels for permethrin. Food tolerances for meat products should be reported in metric units (i.e., 50 µg/kg) and not ppm.

Avian mortality does not appear to be a concern for permethrin as the NOEC for mallard ducks is greater than 50 mg/kg. The last sentence in this section is poorly worded (i.e., "...it would be very unlikely to cause toxicity to birds ~~that~~ with significant food sources in water."). It appears that the intent of this statement is to indicate that cypermethrin concentrations in aquatic food items would not exceed 50 mg/kg. This conclusion is premature at this point in the report, as no data on cypermethrin concentrations in aquatic species has been presented.

RTR 1-3: The units of the food tolerances have been converted to metric units in the final criteria report.

The second half of the last sentence of this section has been removed, as this issue is addressed later in the report.

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

The authors evaluated 108 published studies of cypermethrin toxicity to develop the proposed criteria (why is the number of studies qualified as "approximate"?). Relevance was determined using the aforementioned criteria¹ and data for studies that were deemed acceptable were evaluated. Adequate and reliable data is available for determining acute toxicity using animal studies and exclusion criteria appear to have been properly applied.

RTR 1-4: The number of studies is qualified with "approximate" because we include not only the single-species studies that appear in the appendices, but also studies on ecosystem-level effects, mixtures, water quality effects, bioavailability, and bioaccumulation and it is possible that some of the studies were double-counted because they are relevant in more than one section or were double-counted because some studies contained data from more than one type of test, although we tried not to do this.

Review 1-5: *Data reduction*

The rationale for the exclusion of chronic data presented in Table 7 requires clarification. The stated reasons for exclusion (i.e., less sensitive endpoint and less sensitive life-stage) do not appear to be appropriate for the test species (*Daphnia magna*), which was highly sensitive (as evidenced by the low LOECs) to cypermethrin in these tests. The fact that these tests were conducted as static renewals and not flow-throughs would appear to be a valid reason.

RTR 1-5: The stated reasons for exclusion of the *Daphnia magna* toxicity values were correct in the draft report, although this study is no longer rated RR in the final report after it was reviewed again. The reasons of less sensitive endpoint and less sensitive life-stage are in comparison to the one *D. magna* toxicity value reported in Table 6 (in the draft report, not in the final report). Some of the tests measured the endpoint brood/female, but the endpoint of young/female was more sensitive, and some the tests used neonates, which were more sensitive than juveniles.

Review 1-6: Acute criterion calculation

The acute criterion for cypermethrin was calculated using methods defined by TenBrook *et al.* (2009). The five taxa required for the species sensitivity distribution (SSD) were available and the species sensitivity distribution (SSD) method was used. The Burr Type III SSD method was used to derive the median 5th and 1st percentile values. However, a log-logistic distribution method was used in favor of the Burr III distribution as the former provided a satisfactory fit to the data. Calculations using both methods appear to have been performed correctly. An acute criterion of 6 ng/L was recommended using the log-logistic distribution and the median 5th percentile value and in accordance with TenBrook *et al.* (2009).

RTR 1-6: Comment acknowledged.

Review 1-7: Chronic criterion calculation

The acute-to-chronic ratio (ACR) method was used to derive the chronic criterion. The species mean ACRs span a range greater than two orders of magnitude (i.e., 2.11 – 949). The choice to use the SMACR for *Daphnia magna* (i.e., 949) was based on it being the only value within a factor of 10 of the acute 5th percentile. Because the data for *D. magna* was derived from a study that did not use measured concentrations of cypermethrin, this data is marginally reliable. The authors' correctly describe the issues with this study and are limited by the lack of other chronic data for daphnids.

Chronic criteria were calculated using both the recommended SMACR (949) and an "example" derived from the other two values (2.11 and 2.26) plus a default value of 12.4. As one would expect, these values result in significantly different criteria (0.01- and 3-ng/l). The authors recommend

the lower value based on application of the TenBrook *et al.* (2009) methodology. While this approach provides a conservative value for the chronic criterion, the weakness of the underlying data provides a cause for concern.

RTR 1-7: The derivation of the chronic criterion has been revised in the final criteria report. All of the SMACRs used in the draft report have all been excluded from use because the original intent of the methodology was to require that only toxicity values rated RR be used in calculating SMACRs. This interpretation was discussed with other co-authors of the methodology. Thus, the chronic criterion is calculated with the default ACR in the final criteria report.

Review 1-8: *Bioavailability*

Cypermethrin has a relatively high log K_{ow} value and therefore has a high tendency to sorb to dissolved and particulate organic materials. Due to their similar hydrophobicity, the bioavailability of cypermethrin is very similar to that of permethrin. The authors correctly point out that although ingestion of contaminated particles and food sources is likely an important route of exposure, it is not possible at this time to incorporate this pathway into criteria due to the lack of sufficient quantitative studies. Using the dissolved phase of cypermethrin to assess compliance is appropriate and will require site-specific data on water characteristics.

Isolation of the dissolved phase of cypermethrin by solid-phase micro-extraction presents a practical approach for approximating the bioavailable phase of this compound. Determination of site-specific dissolved concentrations of cypermethrin may not be practical, however, 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 cite the work of Bondarenko and Gan (2009), who reported a detection limit of 2.0 ng/L for cypermethrin. It is stated that this limit is below the acute criterion and is identical to the chronic criterion. However, the chronic criterion is 0.03 ng/L, which is well below the method limit of detection. The authors need to acknowledge this analytical shortfall and address its implications for criteria enforcement.

RTR 1-8: The following sentence has been added to the bioavailability section of the final report to address variation in dissolved and suspended solids:

Such physical-chemical properties can vary both spatially and temporally, further complicating measurement of these properties and subsequent assessment of bioavailability using site-specific partition coefficients.

The sentence citing the detection limit of Bondarenko & Gan (2009) has been revised and now states that the detection limit is above both the acute and chronic criteria. The following sentences have been added to this section discuss this analytical problem: “Li et al. (2009) report a method detection limit of 1.0 ng/L for cypermethrin using SPME, so lower detection levels may be possible as analytical techniques progress. Analytical detection limits may create a problem for criteria compliance because it is possible that cypermethrin could be present in toxic amounts, yet be below the detection limit so that an excursion is not identified.”

Review 1-9: *Mixtures*

Additive and synergistic toxicity effects in the presence of other pesticides have been reported for cypermethrin. Because a variety of potential interactions are possible, it is not practical to apply a quantitative model to predict toxicity at this time.

RTR 1-9: Comment acknowledged.

Review 1-10: *Temperature, pH effects*

An inverse relationship between pyrethroid toxicity and water temperature is well known. 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 cypermethrin 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.

Data presented in Table 2 indicates that cypermethrin undergoes rapid hydrolysis at high pH. This needs to be mentioned in this section and implications for reduced risk in natural water bodies should be discussed.

RTR 1-10: Additional safety factors are not recommended for the cypermethrin 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. The following sentences have been added to this section to address hydrolysis of cypermethrin at high pH levels: “While there are no studies about the effects of pH on cypermethrin toxicity, it is likely that there is reduced risk at high PH levels because the hydrolysis half-life of cypermethrin is < 2 days at pH 9 (Table 2).”

Review 1-11: *Sensitive species*

The derived acute criterion is reported here as 0.006 µg/L. It should be reported consistently as 6 ng/L. This criterion is higher than some reported acute toxicity values and may not be protective of all species. The authors acknowledge this and used the next lowest estimate from the species sensitivity distribution to drive an adjusted value of 1 ng/L based on the median 1st percentile value. While this is a conservative approach, it needs to be referenced (e.g., was it defined in the Tenbrook *et al.* methodology?). As presented, this approach seems somewhat arbitrary.

The development of the adjusted acute criterion causes a “trickle down” effect in the re-calculation of the chronic criterion, which has a new value of 0.003 ng/L. These calculations appear to have been performed correctly.

RTR 1-11: The guidance for downward adjustment of the criteria based on data for sensitive species is given in the methodology in section 3-6.1, which is cited in the first sentence of this section of the report. Guidance is given in the methodology that criteria should be adjusted downward if the criteria do not appear to be protective of sensitive species in the datasets rated RR, RL, LR, or LL.

Review 1-12: *Ecosystem and other studies*

The authors reviewed several studies that evaluated potential ecosystem impacts of cypermethrin in mesocosms and ecosystems. Impacts on invertebrates were only noted at concentrations of cypermethrin that exceeded the proposed acute and chronic criteria. No-observable effect levels were also higher than the proposed chronic criterion. The authors should note that many of these studies only reported nominal concentrations of cypermethrin and that actual dissolved concentrations were likely much lower than reported for these systems.

RTR 1-12: Several of the studies cited in this section did report measured concentrations, although they were whole water concentrations, not the freely dissolved concentration. The following sentence has been added to the last paragraph of the “Ecosystem and other studies” section: “It should be noted that nominal or whole water measured concentrations were reported in these studies, and that the truly dissolved concentrations were likely much lower, so it is not clear how close the truly dissolved concentrations were to the derived criteria.”

Review 1-13: *Threatened and endangered species*

Fish (*Oncorhynchus spp.*) that are listed as endangered in California are represented in the data set that was used to derive the acute criterion. Because fish in general, and these species specifically, are relatively insensitive to cypermethrin, the proposed acute and chronic criteria should be protective of these species.

Data for other threatened or endangered species, including plants, were not in the data set and appropriate surrogates were not available. Accordingly, specific conclusions could not be offered for these species. However, the mode of action of cypermethrin indicates that it should not be highly toxic to plant species.

RTR 1-13: Comment acknowledged.

Review 1-14: *Bioaccumulation*

Cypermethrin 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 cypermethrin that would result in a lethal concentration in wildlife that would consume contaminated fish. A definitive NOEC value for mallard ducks is not available and the single reported value of >50 mg/kg was used to calculate an aqueous NOEC. Using this approach, a water concentration of at least 6.0 µg/l would be required to produce a body burden of cypermethrin in fish that would be at 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, which exceeds the aqueous solubility of cypermethrin and would be acutely lethal to prey species, including fish, should be mentioned.

RTR 1-14: 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 above the aqueous solubility of cypermethrin.

Review 1-15: *Harmonization with air and sediment criteria*

Sediment and air quality standards for cypermethrin do not exist. However, because cypermethrin has a relatively high partition coefficient, dissolved concentrations may serve as a proxy for sediment burdens if K_{oc} values are available for a given site. This is consistent with the previous discussion of bioavailability.

RTR 1-15: Comment acknowledged.

Review 1-16: *Limitations, assumptions and uncertainties*

Although there was sufficient data to derive the acute criterion, it is not clear why there was a lack of fit of the Burr III SSD. The authors suggest that more data points would lead to a satisfactory fit, but lack a basis for this conclusion. It is likely that the general lack of data from flow-through tests and reliance on nominal concentrations are significant contributors to the lack of consistency in the toxicity tests.

In the third paragraph of this section, the authors state that “nominal concentrations and static tests can underestimate the true exposure...”. In fact, such factors will lead to an overestimation of exposure.

The chronic toxicity data set was limited by a lack of three of five required taxa and the lack of measured cypermethrin concentrations for key studies. The authors dealt with these shortcomings in a reasonable fashion; however, it does indicate that more and high quality data sets are required to develop more robust criteria.

The potential effect of lower temperatures on cypermethrin toxicity is potentially significant and should be considered in criterion development as more data becomes available.

RTR 1-16: The lack of fit of the Burr Type III SSD to the data set seemed to be related to the large spread between the lowest toxicity value (*Hyalella azteca* SMAV=0.0027 µg/L) and the next toxicity value, and the fit test is judging this low value to be an outlier (see fit test calculations in Appendix A). The *H. azteca* SMAV is very similar to those for other pyrethroids, and it based on two different studies, so it does not appear to be in error. It is true that if measured values were available for more species, the distribution would likely shift toward the lower end, and then the fit of the Burr Type III might pass the fit test.

The sentence stating the nominal concentrations underestimate the true exposure has been revised to state that the true exposure is overestimated.

Review 1-17: *Comparison to national standard methods*

EPA (1985) methods were also used to attempt to derive acute and chronic criteria for cypermethrin. The EPA method faces the same limitation encountered in this report, that is, lack of data for all required taxa. Accordingly, neither acute nor chronic criteria could be calculated using EPA methods.

RTR 1-17: Comment acknowledged.

Review 1-18: *Final criteria statement*

Derived using the best available data, the acute criterion of 1 ng/L and the chronic criterion of 0.003 ng/L should be protective of aquatic species in the Sacramento and San Joaquin River basins. The statement that the criteria were derived to be protective of aquatic life in the Sacramento and San Joaquin Rivers is a bit misleading, however, as the criteria were not derived exclusively using endemic species. The criteria were in fact derived for a generic freshwater North American ecosystem. The authors appropriately point out that the robustness of the derived criteria is limited by available data and should be updated as new information becomes available.

RTR 1-18: The statement regarding use of the criteria for freshwater ecosystems has been revised to the following:

While the aim of this criteria report was to derive criteria protective of aquatic life in the Sacramento and San Joaquin Rivers, these criteria would be appropriate for any freshwater ecosystem in North America, unless species more sensitive than are represented by the species examined in the development of these criteria are likely to occur in those ecosystems.

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

REVIEW 2-1: For cypermethrin, the proposed acute and chronic criteria are 1 ng/L and 0.003 ng/L, respectively.

The acute criterion was derived using acute toxicity data for eight organisms, the most sensitive of which was the amphipod *Hyalella azteca* with a mean EC50 value of 2.7 ng/L. This criterion appears sufficiently low to protect sensitive aquatic organisms.

RTR 2-1: Comment acknowledged.

REVIEW 2-2: The chronic criterion was calculated using available acute-to-chronic ratios (ACR) because there were chronic values available for relatively few families of organisms. The chronic value of 0.003 ng/L was based on the ACR for *Daphnia magna* of 949. As this ratio is relatively high, the resulting chronic criterion is fairly low. Although the proposed chronic criterion does appear conservative, it would be prudent to adopt this criterion until additional studies can be performed. If additional studies indicate that the ACR for *Daphnia magna* is atypically high, it may be warranted to raise the chronic criterion.

RTR 2-2: The chronic criterion has been recalculated in the final criteria report to be 0.2 ng/L as the *Daphnia magna* study was found to not be appropriate for use in criteria calculation.

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

REVIEW 3-1: The cypermethrin water quality criteria were derived by applying a methodology recently developed by the University of California, Davis (TenBrook et al. 2009). The authors evaluated 108 original studies on the effects of cypermethrin on aquatic organisms and identified 8 acute

and 2 chronic toxicity studies that were reliable and relevant for the water quality criteria derivation.

RTR 3-1: Comment acknowledged.

REVIEW 3-2: The acute water quality criterion was derived by using the species sensitivity distribution (SSD) procedure since data sets from more than five taxa were sufficient to conduct the procedure. A couple of adjustments were made according to the methodology due to the nature of the data sets. The log-logistic distribution was selected for the SSD procedure instead of the Burr III distribution due to the latter's lack of fit to the data sets. The median 1st percentile value was used for the final criterion calculation instead of the median 5th percentile value because the criterion calculated from the 5th percentile value was two times higher than the SMAV of the most sensitive species *Hyaella azteca*. The selection of a better distribution and the adjustment for the final criterion calculation appear to be necessary and appropriate. The adjusted SSD procedure resulted in a final acute water quality criterion of 1 ng/L. The report properly evaluated the existing toxicity data from sensitive, threatened, and endangered species and ecosystem studies. The evaluation suggested that the derived acute criterion is protective of aquatic organisms under the current knowledge of cypermethrin toxicity.

RTR 3-2: Comment acknowledged.

REVIEW 3-3: The chronic water quality criterion was calculated by using the acute-to-chronic ratio (ACR) method. For the same reasons discussed previously for acute criterion derivation, the median 1st percentile value from the log-logistic distribution of acute toxicity values was used to calculate the chronic criterion. However, the use of the ACR calculated from a *Daphnia magna* toxicity study (Kim et al. 2008) is arguable for the following reasons:

1. The report stated that “it is recommended that only the SMACRs for species with SMAVs within a factor of 10 of the acute 5th percentile value should be used for the final multi-species ACR (section 3-4.2.1, parts 1-2 TenBrook et al. 2009a), which for cypermethrin is only the SMACR for *Daphnia magna* of 949” (Page 7-8). The statement is inaccurate because the *Daphnia* SMAV is over a factor of 20 of the acute 5th percentile value (0.01269 µg/L/0.0006 µg/L SMAV = 21).

RTR 3-3: We agree that the *Daphnia magna* SMAV was not the SMAV nearest the acute value. The derivation of the chronic criterion has been revised, and the *D. magna* ACR from the Kim et al. (2008) study is no longer used in the calculation of the final ACR. Upon consultation with other co-authors of the UCD methodology, we agreed that only RR data should be used to calculate ACRs

(contrary to the ACRs proposed in the draft report). This interpretation excludes the Kim et al. (2008) study because the acute test was rated RL.

REVIEW 3-4: 2. From my understanding, the cypermethrin chronic toxicity data sets do not meet any of the three conditions for the ACR calculation recommended on Section 3-4.2.1 Single-chemical, multispecies ACR based on measured data, TenBrook et al. 2009. As described in the report, the SMACRs of the three species rated as RR for the chronic criterion derivation did not show a clear trend of increasing or decreasing as the SMAVs increased, the ACRs from all the species are not within a factor of ten, and none of the SMACRs are less than 2.0. Therefore, as recommended by TenBrook et al., the ACR should be derived by the procedure in Section 3-4.2.2, i.e., calculating the geometric mean of any available ACRs based on **measured** data, plus enough default ACRs of 12.4. In the case of cypermethrin, the ACR would be 3.9 that was used in the report as an example chronic criterion.

RTR 3-4: In the revision of the chronic criterion calculation, all ACRs proposed for use in the draft criteria report were excluded because each one was based on toxicity data that did not rate RR (or LR for saltwater species). Thus, in the final chronic criterion in the final criteria report was calculated with only the default ACR.

REVIEW 3-5: 3. The acute toxicity value by Kim et al. (2008) was rated as having low reliability and excluded from the acute criterion derivation. Therefore, using the acute data to calculate the ACR that is used for the chronic criterion calculation is inconsistent with the acute criterion calculation even though the data is the lowest and provides the most protective criterion.

RTR 3-5: We agree with this interpretation of the method and have revised the chronic criterion calculation to exclude ACRs based on data that were not rated RR (or LR for saltwater species).

REVIEW 3-6: 4. As reasoned in the report, toxicity values calculated with measured concentrations are typically lower than those calculated with nominal concentrations because pyrethroids tend to adsorb to glassware and solids resulting in less bioavailability in the dissolved phase (Page 8, this report). Therefore, the water quality criteria derived from toxicity of nominal concentrations tend to be less protective of aquatic life. The rationale is likely true for acute and chronic toxicity calculations but not necessarily true for ACR calculations. It is unknown whether the adsorption is proportional to chemical concentrations and exposure durations or whether a linear relationship between the adsorption and concentrations exists. Using nominal concentrations to calculate ACR values can add another tier of uncertainty to the final criterion calculation.

RTR 3-6: There is currently no specific guidance in the method stating that nominal concentrations cannot be used for ACR calculations, but the provision that only data rated RR will ensure that only high quality studies are used. If the UCD methodology is revised in the future we will consider this input.

REVIEW 3-7: The authors appropriately addressed the limitations and uncertainties involved in the criteria derivation. Because of the high hydrophobicity of pyrethroids that could lead to significant chemical loss in dissolved phase during toxicity tests, it is more appropriate to derive the criteria by using measured concentrations from flow-through tests. However, the majority of the toxicity data used for the criteria derivation are from static or static renewal tests and are calculated from nominal concentrations. This could underestimate the toxicity of cypermethrin resulting in an underestimated water quality criterion. For the chronic criterion, the limitations and uncertainties are primarily attributed to the limited number of data sets (only three reliable and relevant data sets available), the lack of paired data to calculate a multi-species ACR, and the absence of the chronic toxicity data on the most sensitive species *Hyalella azteca*. Other uncertainties are related to toxicity increases with lower temperatures and addition of PBO in pyrethroid formulations. Nevertheless, those limitations and uncertainties could not be corrected or quantified unless additional data are available in the future.

RTR 3-7: Comment acknowledged.

REVIEW 3-8: Editorial comment: spell out “SR” on the 2nd paragraph, page 12. “SR” stands for “Static renewal test” in this report but it is not the case here.

RTR 3-8: The acronym “SR” has been spelled out when referring to “synergistic ratio” in the final report.

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